

## MEDICOM GRANTS

7300.1

<u>Date of Agreement</u>	<u>Entiti(es) Receiving Grant</u>	<u>Title IEP</u>	<u>Total Grant Amount</u>	<u>Bates</u>	<u>Exhibit 7300</u>
4/16/2001	Medicom Worldwide, Inc.	"Effective Pain Management Techniques and the Changing Guidelines to hnprove Pain Managment".	\$691,200	TEVA_MDL_A_01850067 TEVA_MDL_A_01167083	7300R (Includes grant total) and S
12/21/2001	Medicom Worldwide, Inc.	Series of Medical Education Programs to be held throughout 2002	\$876,620	TEVA_MDL_A_01850173	7300T
<b>2001 TOTAL</b>			<b>\$1,567,820</b>		
3/12/2002	Medicom Worldwide, Inc.	A CME self-study monograph based on relevant lectures and poster presentations at APS meeting March 14-17, 2002.	\$35,000	TEVA_MDL_A_01850178	7300U
<b>2002 TOTAL</b>			<b>\$35,000</b>		
1/23/2003	Medicom Worldwide, Inc.	2003 Educational Activities for Pain Management	\$2,252,000	TEVA_MDL_A_01850606	7300V
1/27/2003	Medicom Worldwide, Inc.	Series of Medical Education Programs throughout 2003	\$368,558	TEVA_MDL_A_01850598	7300A
2/3/2003	Medicom Worldwide, Inc.	Educational Activities - AAPM 2003	\$134,375	TEVA_MDL_A_01850590	7300W
3/21/2003	Medicom Worldwide, Inc.	Educational Activities - AAPM&R 2003	\$125,468	TEVA_MDL_A_01850619	7300X
12/12/2003	Medicom Worldwide, Inc.	ESP Website and Newsletters	\$400,000	TEVA_AAMD_00861734	7300B
12/12/2003	Medicom Worldwide, Inc.	Series of 350 educational lectures and 30 symposia during 2004	\$4,368,980	TEVA_MDL_A_01167948	7300Y
12/12/2003	Medicom Worldwide, Inc.	CME satellite symposium at AAPM&R	\$135,000	TEVA_MDL_A_01167327	7300Z



**MEDICOM GRANTS**

**7300.2**

12/12/2003	Medicom Worldwide, Inc.	CME Teleconference Series effective pain management techniques and the changing guidelines to improve pain management	\$150,000	TEVA_MDL_A_01851421	7300AA
<b>2003 Total</b>			<b>\$7,934,381</b>		
7/2/2004	Medicom Worldwide, Inc.	"Treatment of Chronic Pain in the Primary Care Setting" Symposium t at PRI MED EAST in Boston, October 31, 2004	\$247,350	TEVA_MDL_A_01851444	7300BB
7/20/2004	Medicom Worldwide, Inc.	Amendment to 350 Live Event reduced to 214 events	\$2,476,472	TEVA_MDL_A_01851434	7300CC
8/3/2004	Medicom Worldwide, Inc.	"A Blueprint for Successful Opioid Management: Providing Care While Preventing Misuse and Diversion" symposium at the AAPM' s 21st Annual Meeting.	\$171,750	TEVA_MDL_A_01851208	7300DD
8/24/2004	Medicom Worldwide, Inc.	2004 Medical Education Forum: Development and Management of a Clinical Experts in Pain Faculty Meeting	\$300,000	TEVA_MDL_A_01851427	7300EE
8/26/2004	Medicom Worldwide, Inc.	Clinical Dialogues in Pain Management Program	\$2,921,000	TEVA_MDL_A_01851401	7300FF
11/15/2004	Medicom Worldwide, Inc.	"The Building Blocks of Breakthrough Pain Treatment" 2005 APS Satellite Symposium	\$191,725	TEVA_MDL_A_01851377	7300GG
12/6/2004	ROI Media Group, Inc.	"Emerging Solutions in Pain"	\$2,019,175	TEVA_MDL_A_01851621	7300C
<b>2004 Total</b>			<b>\$8,327,472</b>		

**MEDICOM GRANTS**

**7300.3**

6/27/2005	MediCom Worldwide, Inc.	Current Practices and Future Perspectives in the Management of Chronic Pain at 66th American Academy of Physical Medicine and Rehabilitation (AAPM&R) Annual Assembly, October 27-30, 2005, in Philadelphia, Pennsylvania.	\$154,750	TEVA_MDL_A_01852791	7300HH
12/1/2005	Medical Learning Solutions, Inc.	Emerging Solutions in Pain Part A	\$806,332	TEVA_MDL_A_01855368	7300D
12/1/2005	Medical Learning Solutions, Inc.	Emerging Solutions in Pain Grant Part B	\$964,006	TEVA_MDL_A_01855438	7300E
12/1/2005	Medical Learning Solutions, Inc.	Emerging Solutions in Pain Grant Part C	\$381,901	TEVA_MDL_A_01855509	7300F
<b>2005 Total</b>			<b>\$2,306,989</b>		
10/26/2006	Medicom Worldwide, Inc.	ASPMN symposium and enduring materials	\$366,610	TEVA_MDL_A_01855189	7300II
11/2/2006	Medicom Worldwide, Inc.	International Association of Pain and Chemical Dependency Satellite Symposium: Opioid Therapy in Chronic Pain with Breakthrough Episodes: Therapeutic Advances and their Impact on Risk	\$246,110	TEVA_MDL_A_01855263	7300JJ
11/20/2006	Medical Learning Solutions, Inc. (IEP Provider) MediCom Worldwide, Inc. (Educational Partner)	Emerging Solutions in Pain Toolkit and 2007 Initiatives	\$2,064,510	TEVA_AAMD_00861369	7300G
12/6/2006	Medical Solutions, Inc. (IEP Provider) MediCom Worldwide, Inc. (Educational Partner)	2007 Emerging Solutions in Pain Lecture Series	\$525,397	TEVA_MDL_A_03315345	7300H

**MEDICOM GRANTS**

**7300.4**

12/19/2006	Medicom Worldwide, Inc.	Signal Transduction of Pain: Implications for Opioid Therapy, at the 26th Annual Meeting American Pain Society May 3, 2007 in Washington, DC,	\$320,760.00	TEVA_MDL_A_06751788	7300KK
<b>2006 Total</b>			<b>\$1,458,877.00</b>		
7/27/2007	Medical Solutions, Inc. (IEP Provider) MediCom Worldwide, Inc. (Educational Partner)	Continued Support for the Emerging Solutions in Pain /initiative	\$1,829,504	TEVA_MDL_A_06763724	7300I
<b>2007 Total</b>			<b>\$1,829,504</b>		
1/25/2008	Medical Learning Solutions, Inc.	Emerging Solutions in Pain Meet the Experts Exhibit Booth at IASP 2008	\$182,506	TEVA_MDL_A_06760054	7300J
5/2/2008	MediCom Worldwide, Inc. ("Provider") Medical Learning Solutions ("Educational Partner")	2008 Emerging Solutions in Pain Lecture in Conjunction with AAPMgmt 2008	\$350,423	TEVA_MDL_A_06764039	7300K
5/28/2008	MediCom Worldwide, Inc. and American Society for Pain Management Nursing.	American Society for Pain Medicine Nursing Satellite Symposium" Refining the Art of Assessment in the Patient with Chronic Pain: The Key to Minimizing Risk and Improved Outcomes" and Enduring Materials	\$388,206	TEVA_AAMD_00861705	7300L
8/20/2008	Medicom Worldwide, Inc.	"Minimizing Risk and Improving Outcomes in Chronic Pain: A Focus on the Challenge of Communication and Interviewing Skills in Assessing Pain Patients "	\$252,121	TEVA_MDL_A_00502769	7300M
11/6/2008	Medicom Worldwide, Inc.	Emerging Solutions in Pain Meet the Experts Booth	\$150,635	TEVA_MDL_A_03315976	7300N
<b>2008 Total</b>			<b>\$1,323,891</b>		

**MEDICOM GRANTS**

**7300.5**

1/15/2009	Medicom Worldwide, Inc.	Emerging Solutions in Pain	\$1,617,114	TEVA_MDL_A_06766853	7300O
<b>2009 Total</b>			<b>\$1,617,114</b>		
12/15/2010	Medicom Worldwide, Inc.	ESP Live! At the American Academy of Pain Medicine	\$50,000.00	TEVA_MDL_A_01174644	7300MM
<b>2010 Total</b>			<b>\$50,000.00</b>		
10/18/2011	Medicom Worldwide, Inc.	"Effective Strategies in Managing Breakthrough Pain (008626),"	\$199,880	TEVA_MDL_A_01176418	7300P
12/5/2011	Medicom Worldwide, Inc.	"Conference Coverage, Live from APS 2012, 008896"	\$75,500	TEVA_MDL_A_01176720	7300Q
<b>2011 Total</b>			<b>\$275,380</b>		
<b>2001 - 2011 TOTAL</b>			<b>\$26,726,428.00</b>		



101 Washington Street  
Morrisville, PA 19067

Tel 215-337-9991  
800-408-4242  
Fax 215-337-0960

Website [www.MedicalEd.com](http://www.MedicalEd.com)

January 27, 2003

P. Andrew Pyfer  
Product Director  
Cephalon, Inc.  
145 Brandywine Parkway  
West Chester, PA 19380

Dear Mr. Pyfer:

MediCom Worldwide is accredited by the Accreditation council for continuing Medical Education to sponsor continuing medical education for physicians and is an ACPE-approved provider of pharmacy continuing education, as well as an approved provider of nursing continuing education through the California State Board of Registered Nursing.

A comprehensive needs assessment has identified interests of health care providers who manage patients suffering from pain. Based on this educational need, we are requesting an educational grant from Cephalon, Inc. to support the development and implementation of several continuing education activities on the subjects of effective pain management techniques and the changing guidelines to improve pain management. The budget to fund these activities is approximately \$368,558.00.

Proposed Educational Activities for Pain Management

Continuation of quarterly newsletter issued to health care professionals  
Development and production of CME self-study programs on CD to accompany newsletters  
Development of BRC-type announcements of self-study programs online  
Development, production, and certification of CME monographs  
Continuation of Internet presence, *Emerging Solutions in Pain.com*  
Adaptation of three to five CME events to online ESP self-study programs

These scientific activities, will be developed independently and then adapted to enduring CME material in various formats, and will comply with all ACCME, FDA, AMA, and ACPE regulations for industry-supported professional continuing education. The target audience for these activities are pain management specialists, oncologists and anesthesiologists.

As a supplement to our direct mail and web site announcement of these educational activities, we request Cephalon representatives to disseminate information regarding these programs to the medical community.

However, the content of such information is the responsibility of the accredited provider and any such distribution will be solely as a supplement to provider's primary method of announcement and promotion.

Thank you, in advance, for your consideration of this request. Should you agree to provide funding for this project, Letters of Agreement will be forwarded to you as soon as possible.

101 Washington St.  
Morrisville, PA 19067  
215-337-9991

1

Thank you, in advance, for your consideration of this request. Should you agree to provide funding for this project, Letters of Agreement will be forwarded to you as soon as possible.

Respectfully,

A handwritten signature in cursive script, appearing to read "Joan Meyer".

Joan Meyer RN, MA  
Executive Director, Continuing Education

101 Washington St.  
Morrisville, PA 19067  
215-337-9991

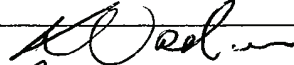

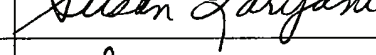
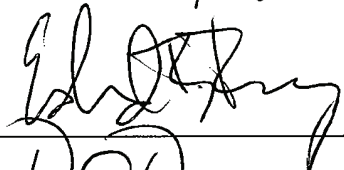

## Cephalon Review of Education Grant

The attached Grant amount has been reviewed by members of the MEP team.

**Program Name:** Unrestricted Educational Grant:

**Medicom Worldwide, Inc.**

**2003 Educational Activities for Pain Management**

<u>Department</u>	<u>Name</u>	<u>Signature</u>	<u>Date</u>
Medical Affairs	Kiumars Vadieli		4/7/03
	Jess Amchin		4/2/03
	Susan Larijani		4/2/03
Legal	Ed Berg		3/28/03
Marketing	Andy Pyfer		4/08/03
	Christine Wells		
	Paula Castagno		



101 Washington Street  
Morrisville, PA 19067

Tel 215-337-9991  
800-408-4242  
Fax 215-337-0960

Website [www.MedicalEd.com](http://www.MedicalEd.com)

## MEDICAL EDUCATION AGREEMENT

As a condition of Cephalon, Inc.'s contribution of funds to support a series of independent medical education programs (with CME credits), the Scientific and Educational Activity provider agrees to the following terms and conditions:

This Agreement ("Agreement") is entered into as of January 27, 2003 by and between Cephalon, Inc. ("Cephalon") and MediCom Worldwide, Inc. ("Provider") regarding a series of medical education programs supported by Cephalon to be held throughout 2003. The parties' mutual objectives are to provide a balanced, independent, scientifically rigorous program to promote the education of attendees. The amount of the educational grant requested is \$368,558.00.

1. Statement of Purpose. This program is for scientific and educational purposes only and not to promote any commercial drug products.
2. Control of Content and Selection of Presenters and Moderators. The provider is ultimately responsible for the control of content and selection of presenters and moderators. Cephalon or its agents may respond to requests initiated by the provider for suggestions of presenters or sources of possible presenters. Cephalon will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Cephalon and speaker; and will provide this information in writing. Provider will seek suggestions from other sources, and will, in its sole discretion, select presenters and moderators.
3. Disclosure of Financial Relationships. Provider will direct speakers and moderators to disclose to the audience commercial support or funding or other significant financial relationships between the speakers and moderators and Cephalon and/or any other commercial company whose products are pertinent to the content of the presentation. Provider will disclose Cephalon's support at this program.
4. Involvement in Content. There will be no "scripting," emphasis, or influence on content by Cephalon or its agents. However, Cephalon may provide technical support to speakers, e.g., furnishing slides or data, upon their request.
5. Ancillary Promotional Activities. No promotional activities will be permitted in the same room as, or in the obligatory path to, the educational activity. No product advertisements will be permitted within the program or handouts.



6. Objectivity and Balance. Provider will advise presenters that data regarding Cephalon products (or competing products) are to be objectively selected and presented. Provider will provide the opportunity for speakers and the audience to discuss information, both favorable and unfavorable, about the product(s) and/or alternative treatments.

7. Limitations of Data. Provider will request the speakers, to the extent possible, to disclose limits on the data, e.g., that it involves ongoing research, interim analyses, preliminary data, or unsupported opinion.

8. Discussion of Unapproved Uses. Provider will request that presenters disclose when a product is not approved in the United States for the use under discussion.

9. Actiq® Risk Management Program. Provider is aware that Actiq (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- Actiq is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- Actiq is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.

10. Opportunity for Debate. Provider will ensure opportunities for questioning by attendees and scientific debate with and between presenters.

11. Independence of Provider in the Use of Contributed Funds.

(a) funds should be in the form of an educational grant made payable to the provider organization.

(b) Provider must be advised of all other support by Cephalon of the CME activity (e.g., distributing brochures, preparing slides). If Provider disapproves of this activity, it shall promptly notify Cephalon.

(c) no other funds from Cephalon will be paid to the program director, faculty, or others involved with this CME activity, e.g., additional honoraria.

12. General.

(a) Cephalon agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.

(b) Provider agrees to: (1) abide by the ACCME Standards for Commercial Support of Continuing Medical Education; (2) acknowledge educational support from Cephalon in program brochures, syllabi, and other program materials; and (3) upon request, furnish Cephalon with a report concerning the expenditure of the funds provided by Cephalon.

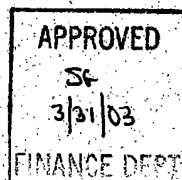
IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

MEDICOM WORLDWIDE, INC.

CEPHALON, INC.

By: *Joan Meyer*  
Name: Joan Meyer  
Title: Executive Director, Cont. Ed  
Date: January 27, 2003

By: *[Signature]*  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_



**First Union  
National Bank**

62-22681

DATE

CHECK NC

04/25/2003


00152751

Three hundred sixty eight thousand five hundred fifty eight and no/100

TO THE  
ORDER  
OF

**MediCom Worldwide Inc**  
101 Washington Ave  
Morrisville, PA 19067

\$368,558.00

  
 William A. Bennett  
 AUTHORIZED SIGNATURE

0001527510 00311002250 20799500640570

FACE OF DOCUMENT HAS A COLORED "VOID" BACKGROUND ON WHITE SECURITY PAPER

145 Brandywine Parkway  
West Chester, PA 19380

04/25/2003

00152751

INVOICE NO

DATE \_\_\_\_\_

## DESCRIPTION

PAID AMOUNT

## DISCOUNT

APPLIED AMOUNT

CME Website & News 04/22/2003 VCH00059464

04/22/200

VCH00059464

**\$368,558.00**

\$368,558.00

INTERNAL NO

VENDOR #

**VENDOR**

**TOTALS**

**TOTALS****TOTALS**

533 MEDCOM000000 med1com worldwide inc

\$368,958.00



# ACCOUNTS PAYABLE CHECK REQUEST



**PAYEE NAME:** Medicom Worldwide Inc.

**ADDRESS:** 101 Washington Street  
Morrisville, PA 19067

**INVOICE NUMBER:** n/a

**INVOICE DATE:** n/a

**DUE DATE:** n/a

**P.O. NUMBER (if applicable):** n/a

**DESCRIPTION:** CME Website and Newsletters

<u>G/L ACCOUNT NUMBER</u>	<u>DEPARTMENT</u>	<u>PROJECT</u>	<u>AMOUNT</u>
7640	63100	ACTQ	\$ 368,558.00

**TOTAL:** \$ 368,558.00

Prepared By: Suzanne Richards

Extension: 6532

Department Number: 63100

Approved By: \_\_\_\_\_

Print Approvers Name: \_\_\_\_\_

Approvers Title: SG

Charles A. Resnick III 4/17/03

\*\*\*\*\* Mark here if the check is to be picked up by the preparer: ☒ \*\*\*\*\*

**Please note:** If there is any documentation to be mailed along with the payment, please attach a copy in addition to the copy for Accounting's records

Accounting Use Only:

Batch Number: \_\_\_\_\_

Voucher Number: \_\_\_\_\_

Entry Date: \_\_\_\_\_

4/8/2003





### 2004 MEDICAL EDUCATION AGREEMENT III

As a condition of Cephalon, Inc's contribution of funds to support an Internet set for healthcare professionals offering a series of independent medical education programs (with CME, CPE, and CNE credits), the Scientific and Educational Activity provider agrees to the following terms and conditions:

This Agreement ("Agreement") is entered into as of December 12, 2003 by and between Cephalon, Inc. ("Cephalon") and MediCom Worldwide, Inc. ("Provider") regarding the customization, redesign, and relaunch of the Emerging Solutions in Pain ("Website") and the development and production of three ESP newsletters supported by Cephalon to be produced and implemented in 2004.

Cephalon wishes to obtain the programming and the Internet management services of MediCom to customize, program, and relaunch an existing MediCom-owned and -managed website, [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com), (including but not limited to the underlying programs and data) as described elsewhere within. Such Website will be available for use by healthcare professionals during the term of this funding agreement.

All elements of the Customization shall remain the exclusive property of MediCom. MediCom shall exclusively own all United States and International copyrights and all other intellectual property rights in the Website, Program content offered, and any associated Databases. The Services performed under this Agreement are considered a customization performed at the request of Cephalon to a pre-existing work owned and operated by MediCom under a previous educational grant from Cephalon in support of this activity during 2003. In the event such ongoing relationship should terminate, MediCom reserves the right to seek other client funding of this Internet endeavor under a separate client agreement.

The parties' mutual objectives are to provide a balanced, independent, scientifically rigorous interactive, educational Internet website to promote the education of attendees, as well as offer three self-study CME activities via direct mail. The amount of the educational grant requested is \$400,000

1. Statement of Purpose. This program is for scientific and educational purposes only and not to promote any commercial drug products.

2. Control of Content and Selection of Presenters and Moderators. The provider is ultimately responsible for the control of content and selection of presenters and

moderators. Cephalon or its agents may respond to requests initiated by the provider for suggestions of presenters or sources of possible presenters. Cephalon will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Cephalon and speaker; and will provide this information in writing. Provider will seek suggestions from other sources, and will, in its sole discretion, select presenters and moderators.

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4. Involvement in Content. There will be no "scripting," emphasis, or influence on content by Cephalon or its agents. However, Cephalon may provide technical support to speakers, e.g., furnishing slides or data, upon their request.

5. Ancillary Promotional Activities. No promotional activities will be permitted in the same room as, or in the obligatory path to, the educational activity. No product advertisements will be permitted within the program or handouts.

6. Objectivity and Balance. Provider will advise presenters that data regarding Cephalon products (or competing products) are to be objectively selected and presented. Provider will provide the opportunity for speakers and the audience to discuss information, both favorable and unfavorable, about the product(s) and/or alternative treatments.

7. Limitations of Data. Provider will request the speakers, to the extent possible, to disclose limits on the data, e.g., that it involves ongoing research, interim analyses, preliminary data, or unsupported opinion.

8. Discussion of Unapproved Uses. Provider will request that presenters disclose when a product is not approved in the United States for the use under discussion.

9. Actiq® Risk Management Program. Provider is aware that Actiq (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

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- This product must not be used in opioid nontolerant patients.

- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.

10. Opportunity for Debate. Provider will ensure opportunities for questioning by attendees and scientific debate with and between presenters.

11. Independence of Provider in the Use of Contributed Funds.

(a) funds should be in the form of an educational grant made payable to the provider organization.

(b) Provider must be advised of all other support by Cephalon of the CME activity (e.g., distributing brochures, preparing slides). If Provider disapproves of this activity, it shall promptly notify Cephalon.

(c) no other funds from Cephalon will be paid to the program director, faculty, or others involved with this CME activity, e.g., additional honoraria.

12. General.

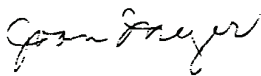
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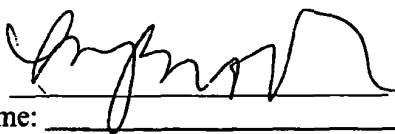
(b) Provider agrees to: (1) abide by the ACCME Standards for Commercial Support of Continuing Medical Education; (2) acknowledge educational support from Cephalon in program brochures, syllabi, and other program materials; and (3) upon request, furnish Cephalon with a report concerning the expenditure of the funds provided by Cephalon.

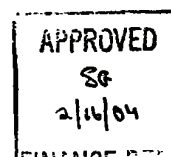
IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

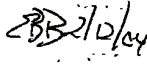
MEDICOM WORLDWIDE, INC.

CEPHALON, INC.

By:   
 Name: Joan Meyer  
 Title: Executive Director, Cont. Ed  
 Date: December 12, 2003

By:   
 Name: \_\_\_\_\_  
 Title: \_\_\_\_\_  
 Date: \_\_\_\_\_



  
 \_\_\_\_\_

ROI-Emerging Solutions in Pain 05



ROI Media Group, Inc.  
*Emerging Solutions in Pain*

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101 Washington Street  
Morrisville, PA 19067

Terrence Terifay  
Cephalon, Inc.  
145 Brandywine Parkway  
West Chester, PA 19380-4245

December 1, 2004

Dear Mr. Terifay:

ROI Media Group, Inc. has recently completed a comprehensive needs assessment to identify the educational needs of clinicians who provide care to patients with chronic pain. This needs assessment was compiled from the following sources:

- Clinical advisory review
- Survey of health care professionals
- Literature search

Based on the identified educational need, ROI Media Group is requesting an educational grant from Cephalon, Inc. to support the development and implementation of a diverse series of activities that shall comprise an initiative entitled Emerging Solutions in Pain, or ESP. The ESP initiative will focus on balancing the clinical need to provide adequate analgesia to patients with chronic pain with the legal and societal need to monitor for potential issues of abuse, addiction and diversion of controlled substances. These activities will be designed and planned as follows:

- Live, peer-to-peer activities; these will include the following:
  - The **RES**ponsible Pain Education Can be Therapeutic, or RESPECT, meeting series, as a series of regional meetings accredited for physicians, pharmacists and nurses
  - The Meet the Expert Booth, which will be presented at six national congresses in 2005, allowing clinicians to interact directly with clinical experts in the fields of pain management, abuse, addiction and diversion
- Print- and multimedia-based activities; these will include the following:
  - A multimedia CD-ROM-based Tool Kit for distribution of the ESP tools and resources
  - A website that will act as a repository and resource center for the ESP initiative
  - An educational slide kit series
  - Print and multimedia informational pieces highlighting the ESP initiative

December 1, 2004

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The total budget to fund these activities is approximately \$2,019,175. Please see the detailed budget section of this proposal for complete grant funding proposals.

These scientific events will comply with all ACCME, FDA, AMA, and ACPE regulations for industry-supported professional continuing education. ROI Media Group will work with a third party CE vendor of our choice in the planning, execution and development of the accredited activities associated with the ESP initiative.

Thank you in advance for your consideration of this request.

Respectfully,



Sheri L. Gavinski  
President,  
ROI Media Group, Inc.

December 1, 2004

ROI Media Group, Inc. • 101 Washington Street • Morrisville, PA 19067  
215-337-9991

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## *Needs Assessment*

More than 80 million Americans live with serious chronic pain that interferes with day-to-day functioning in their personal, social, and work lives. Followed by cancer and heart disease, chronic pain is the third leading cause of physical impairment in the United States.<sup>1</sup> While pain management may be viewed as pure science, there are obstacles to overcome in the effective treatment of pain. The Americans Living with Pain Survey (ALPS)<sup>2</sup> notes patients' concerns with potential side effects (56%), medication addiction (50%), the need for increased usage over time (50%), and the possibility of having to take these drugs for the remainder of their lives (49%). These sentiments are echoed by healthcare providers who acknowledge the need for the education of physicians and medical students as essential to the prevention and treatment of pain disorders, as well as to the recognition of addictive disorders with regard to opioid analgesics.<sup>3</sup>

The *Emerging Solutions in Pain* initiatives are educational awareness programs that will be developed to help clinicians address the most critical issues involving the use of opioid analgesics in pain management today. These issues include balancing the fundamental rights of patients with the challenge of identifying and treating those patients who are at risk for opioid misuse, abuse or diversion; as well as complying with the complex regulations involved in prescribing controlled substances. In March 2004, the Office of National Drug Control Policy stated, "6.2 million American's were current abusers of prescription drugs."<sup>4</sup> This information, while extremely important and relevant, has raised numerous questions regarding the treatment of pain patients, misuse, abuse, diversion of drugs and addiction. Of note, addiction rarely occurs among people who use a pain reliever; many studies have shown that properly managed medical use of opioid analgesic drugs is prudent and rarely causes clinical addiction, which is defined as compulsive, often uncontrollable use.<sup>5</sup> The critical aspect of this statement is "properly managed medical use"; these programs will define the body of knowledge necessary for health care providers to provide safe and effective therapy of pain, to identify and manage addictive disorders in patients with pain and to treat pain in individuals with addictive disorders. It will include essential knowledge in overlapping areas of interest in the fields of pain medicine and addiction medicine, and will also address guidelines and practice standards that medical professionals may assimilate into their treatment of chronic pain patients, to effectively balance the assessment for abuse, addiction and diversion potential with the delivery of adequate analgesia.

<sup>1</sup> American Academy of Physical Medicine and Rehabilitation. "Conditions That PM&R Physicians Treat," from the web at <http://www.aapmr.org/condtreat/pain/fibro.htm>, last accessed July 1, 2004.

<sup>2</sup> New Survey Reals Emerging "Lifestyle of Pain" in America. American Chronic Pain Association Website Press Release, May 6, 2004.

<sup>3</sup> American Medical Association, "About the AMA Position on Pain Management Using Opioid Analgesics," 2004, from the web at <http://www.ama-assn.org/ama/pub/category/11541.html>, last accessed March 1, 2004.

<sup>4</sup> Office of National Drug Control Policy, "News Release, March 1, 2004" from the web at <http://www.whitehousedrugpolicy.gov/news/press04/030104.html> last accessed May 27, 2004.

<sup>5</sup> National Institute on Drug Abuse, "NIDA InfoFacts," from the web at <http://www.nida.nih.gov/Infobox/painmed.html>, last accessed March 1, 2004.



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## *Program Summary*

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<b>Program Title</b>	Emerging Solutions in Pain
<b>Program Overview</b>	<p><b>Emerging Solutions in Pain (ESP)</b> is an ongoing initiative that is being developed by physicians for physicians, pharmacists and other healthcare professionals, to address some of the most critical issues in pain management today. These issues involve balancing the fundamental rights of patients and clinicians with the challenge of identifying patients who are at greater or lesser risk for opioid misuse and addiction, and with the challenges associated with the complex regulations involved in prescribing controlled substances. Through the expertise of a cadre of leading pain and addiction medicine experts, the <b>ESP</b> program will provide clinicians with guidance in the implementation of good practice management techniques, emphasizing favorable interaction with regulatory and law enforcement agencies, as well as, effective assessment, monitoring and documentation strategies, which will contribute to the overall goal of optimizing outcomes for their pain patients.</p> <p>The Emerging Solutions in Pain initiatives will be divided into four primary areas: in-person communications, print communications; computer-based communications and continuing education / distance learning initiatives. Each tactic will be specifically developed to highlight the critical messages contained in the Emerging Solutions in Pain initiative, and to effectively disseminate information regarding efficacious and safe treatment of chronic pain patients to health care professionals involved in the care of these patients.</p>
<b>Intended Audience</b>	The primary audience of the Emerging Solutions in Pain initiative will be physicians, pharmacists and other health care professionals who provide care to patients with chronic pain.
<b>Format</b>	The Emerging Solutions in Pain initiative is intended to be a multi-faceted program, with programs presented in a variety of formats and activity types. These programs include accredited programs and non-accredited programs; live, peer-to-peer activities; multimedia CD-ROMs, Internet-based activities and programs; journal articles; and interactive meeting booths at national association meeting and congresses.
<b>Distribution</b>	ROI Media will announce and promote Emerging Solutions in Pain initiatives and programs through a variety of tactics and methods, including journal advertisements; Internet banner advertisements; direct mail; and both multimedia and print publications.
<b>Request for Sponsor Support</b>	As a supplement to these primary methods, ROI Media Group may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of ROI Media Group, and any such distribution will solely be as a supplement to ROI's primary methods of announcement and promotion.
<b>Total Budget:</b>	\$2,019,175



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**Emerging Solutions in Pain  
Summary of Proposed Budget  
December 1, 2004**

<b>Cost Summary</b>	
Approximate Total, Direct Expenses	\$ 96,550
Total, Indirect Expenses	\$ 99,008
Cost of Programming and Duplication of the ESP Tool Kit CD-ROM	\$ 195,558
Approximate Total, Direct Expenses	\$ 41,850
Total, Indirect Expenses	\$ 215,929
Cost of Development and Maintenance of the Emerging Solutions in Pain Website	\$ 257,779
Approximate Total, Direct Expenses	\$ 71,730
Total, Indirect Expenses	\$ 54,189
Cost of Development and Production of the Emerging Solutions in Pain Mini-Disc Slim Jim	\$ 125,919
Approximate Total, Direct Expenses	\$ 362,900
Total, Indirect Expenses	\$ 290,751
Cost of Emerging Solutions in Pain RESPECT Meeting Series	\$ 653,651
Approximate Total, Direct Expenses	\$ 14,350
Total, Indirect Expenses	\$ 69,097
Cost of Development and Production of the Emerging Solutions in Pain Educational Slide Kit Series	\$ 83,447
Approximate Total, Direct Expenses	\$ 479,455
Total, Indirect Expenses	\$ 223,366
Cost of Development, Production and Management of the Emerging Solutions in Pain Meet the Experts Booth	\$ 702,821
<b>Total, 2005 Emerging Solutions in Pain Initiatives</b>	<b>\$ 2,019,175</b>

Approval Signature \_\_\_\_\_

Date \_\_\_\_\_

**Note: no work may begin until ROI Media receives, via email or fax, this approval with signature and date**

December 1, 2004

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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain Tool Kit CD-ROM
<b>Program Overview</b>	ROI Media Group is proposing to create a multi-media CD-ROM of the Emerging Solutions in Pain Tool Kit. This Tool Kit will provide health care professionals with an extensive array of tools for assessing the potential for abuse, addiction and diversion in their patients with chronic pain, for monitoring their pain patients, and for accessing information regarding "best practices" in the long-term management of these patients. The CD-ROM will feature electronic versions of all Tools, as well as multi-media case studies, printable documents, references and hyperlinks to relevant Web sites, including <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a> .
<b>Intended Audience</b>	The primary audience of the Emerging Solutions in Pain Tool Kit CD-ROM will be physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain.
<b>Program Objectives</b>	<p>The Emerging Solutions in Pain Tool Kit CD-ROM will have objectives that include providing health care professionals with:</p> <ol style="list-style-type: none"> <li>(1) Tools for assessing the potential of abuse, addiction and diversion in their chronic pain patients</li> <li>(2) Tools for monitoring their patients who are prescribed opioids for chronic pain</li> <li>(3) Resources for learning about state and federal guidelines for prescribing opioids, and for implementing these guidelines effectively in their practices</li> <li>(4) Tools and Resources in an easy-to-use multimedia CD-ROM</li> </ol>
<b>Format</b>	A multimedia CD-ROM
<b>Distribution</b>	<p>The Emerging Solutions in Pain Tool Kit CD-ROM will be available through the following avenues:</p> <ol style="list-style-type: none"> <li>(1) Through distribution at the Emerging Solutions in Pain Meet the Expert Booth</li> <li>(2) Through distribution at the RESPECT Meeting Series</li> <li>(3) Through BRC request cards</li> <li>(4) Through electronic requests at <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a></li> </ol>
<b>Request for Sponsor Support</b>	<p>ROI Media Group will announce and promote the Emerging Solution in Pain Tool Kit CD-ROM through the means of distribution outlined above. In addition, all Emerging Solutions in Pain initiatives will direct clinicians to <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a>, where the Tool Kit CD-ROM will be prominently featured. These will include journal advertisements, banner advertisements and brochures for the Emerging Solutions in Pain initiative.</p> <p>As a supplement to these primary methods, ROI Media Group may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of ROI Media Group, and any such distribution will solely be as a supplement to ROI's primary methods of announcement and promotion.</p>
<b>Total Budget:</b>	\$195,558





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Proposal Number: 05-027a  
Date: December 1, 2004

**Emerging Solutions in Pain: Multimedia CD-ROM Tool Kit**  
***Proposed Budget***  
December 1, 2004

***Program Description***

This proposed budget is for the programming and duplication of a multimedia CD-ROM that will house all Tools developed for the Emerging Solutions in Pain Tool Kit, Version 1.0

<b><i>Cost Summary</i></b>		
Approximate Total, Direct Expenses	\$	96,550
Total, Indirect Expenses	\$	99,008
<b>Cost of Programming and Duplication of the ESP Tool Kit CD-ROM</b>	<b>\$</b>	<b>195,558</b>





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Proposal Number: 05-027a

Date: December 1, 2004

**Emerging Solutions in Pain: Multimedia CD-ROM Tool Kit**  
**Proposed Budget**  
**December 1, 2004**

*Detailed Budget Itemization*

<b>Direct Expenses, Approximate</b>	
<b>Duplication: ESP Tool Kit CD-ROM, Quantity: 50,000</b>	\$ 43,450
Four color, two page CD mailer with two inside pockets to house four-color silk-screened CD-ROM plus 16-page four-color saddle-stitched booklet. 4/0 + varnish, score, fold, insertion of CD, shrinkwrapping.	
<b>Audio track recording</b>	\$ 6,500
Professional voice talent narration of Tool Kit instructions, KOL commentary, etc.	
<b>Clinical expert honoraria</b>	\$ 1,500
Preparation, review of audio commentary	
<b>Printing: Representative BRCs, Quantity: 43,500</b>	\$ 15,225
Four color, three panel BRC with perforation, bundled in 25s; each representative to receive four bundles of 25. 100# Opus Gloss Cover, 4/4 + varnish, score, fold, perforate, wafer seal.	
<b>Shipping of BRCs to fulfillment center</b>	\$ 500
<b>Postage for returned BRCs (estimated 20% return)</b>	\$ 6,525
<b>Postage to ship CDs for BRC requests</b>	\$ 12,000
<b>Journal advertisement</b>	\$ 10,500
Journal fees for placement of three advertisements in 2005	
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$ 350
<b>Approximate Total, Direct Expenses</b>	<b>\$ 96,550</b>

<b>Indirect Expenses</b>	
<b>IT / programming services</b>	\$ 30,000
Includes programming of multi-media CD-ROM, including user-friendly CD interface; programming of Tools, instructions and commentary; programming of user request databases; technical assistance	
<b>Graphic design / production services</b>	\$ 22,500
Includes production of multi-media animation and graphics for CD; adaptation of design for CD case, rep BRC, journal advertisements; typesetting, layout, proofing, coordination with print and duplication vendors	
<b>Medical / scientific services</b>	\$ 6,000
Includes content development for rep BRC, journal advertisement, CD booklet	
<b>Fulfillment of CDs in response to returned rep BRCs</b>	\$ 17,400
<b>Administrative and accounting fees</b>	\$ 8,623
<b>Project management</b>	\$ 14,486
<b>Total, Indirect Expenses</b>	<b>\$ 99,008</b>

December 1, 2004

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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain Web Site
<b>Program Overview</b>	ROI Media Group is proposing to create a multimedia Web Site to house and promote the Emerging Solutions in Pain initiative. This Web Site will provide health care professionals with an extensive array of tools for assessing the potential for abuse, addiction and diversion in their patients with chronic pain, for monitoring their pain patients, and for accessing information regarding "best practices" in the long-term management of these patients. Registered members of EmergingSolutionsinPain.com will be able to access and print available Tools and supporting references, view multi-media case studies, read relevant literature and journal articles, view schedules for upcoming events such as the Meet the Expert Booth, and register for live peer-to-peer meetings that are part of the Emerging Solutions in Pain initiative.
<b>Intended Audience</b>	The primary audience of the Emerging Solutions in Pain Web Site will be physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain.
<b>Program Objectives</b>	<p>The goal of the Emerging Solutions in Pain Web Site will be to educate clinicians on:</p> <ol style="list-style-type: none"> <li>(1) The need to identify patients who are at increased risk of diversion, addiction and/or abuse of pain medications</li> <li>(2) The critical importance of treating all pain patients, including those who may be at higher risk for abuse, addiction and/or diversion</li> <li>(3) The tools and tactics that will assist these clinicians in treating their pain patients while maintaining good practice management</li> </ol> <p>Secondary goals of the Emerging Solutions in Pain Web Site include:</p> <ol style="list-style-type: none"> <li>(1) To act as a cost-effective method of distribution of the tools in the ESP Tool Kit</li> <li>(2) To establish a resource for clinicians who are seeking information on pain practice management and assessment, documentation and monitoring tools</li> </ol>
<b>Format</b>	A multimedia Web Site, with separate links for assessing and monitoring patients whose chronic pain is being treated with opioids; for "best practice" information; for journal articles relevant to the Emerging Solutions in Pain initiative; for other Emerging Solutions in Pain information and programs
<b>Distribution</b>	The Emerging Solutions in Pain Web Site will be available to all individuals via the Internet at <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a> . Free registration will be required to access the majority of information on the Web Site, including all of the Emerging Solutions in Pain Tools and journal articles
<b>Request for Sponsor Support</b>	<p>ROI Media Group will announce and promote the Emerging Solution in Pain Web Site through journal advertisements, banner advertisements and announcement brochures for the Emerging Solutions in Pain initiative.</p> <p>As a supplement to these primary methods, ROI Media Group may request the assistance of Cephalon, Inc. in the dissemination of information regarding this</p>



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### *Program Summary*

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program to the medical community. The content of such information, however, is the responsibility of ROI Media Group, and any such distribution will solely be as a supplement to ROI's primary methods of announcement and promotion.

**Total Budget:** \$257,779



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Proposal Number: 05-028a  
Date: December 1, 2004

**Emerging Solutions in Pain: Website**  
***Proposed Budget***  
December 1, 2004

***Program Description***

This proposed budget is for the development, programming, and 12-month maintenance of the Emerging Solutions in Pain Website. Two versions will be launched in 2005: Version 1.0, housing all of the ESP Tools, a repository of journal articles, program links and membership; and Version 2.0, with expanded multimedia content and services.

<b><i>Cost Summary</i></b>	
Approximate Total, Direct Expenses	\$ 41,850
Total, Indirect Expenses	\$ 215,929
<b>Cost of Development and Maintenance of the Emerging Solutions in Pain Website</b>	<b>\$ 257,779</b>



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Proposal Number: 05-028a  
Date: December 1, 2004

**Emerging Solutions in Pain: Website**  
**Proposed Budget**  
December 1, 2004

*Detailed Budget Itemization*

<b>Direct Expenses, Approximate</b>	
<b>Clinical expert honoraria</b>	\$ 24,000
Three clinical experts, to review website content quarterly	
<b>Stock photography / illustrations</b>	\$ 4,000
<b>Licensing fees for journal article PDFs</b>	\$ 3,000
<b>Journal / banner advertisement</b>	\$ 10,500
Journal fees for placement of three advertisements in 2005 / advertisement fees for Internet banner advertising	
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$ 350
<b>Approximate Total, Direct Expenses</b>	<b>\$ 41,850</b>

<b>Indirect Expenses</b>	
<b>IT / programming services</b>	\$ 74,000
Includes programming of new ESP.com, Version 1.0 and 2.0; programming of new navigation and associated Website organization, new membership system/new benefits of membership; set-up of functionality associated with housing ESP Tools and journal articles; programming of meeting schedule functionality and adaptation of meeting registration functionality; posting new slides; removing unused functionality from previous ESP.com; programming of new graphics and content; coordination with Internet and database programming vendors	
<b>Graphic design / production services</b>	\$ 40,000
Includes production of new graphics for ESP.com, based upon Summer 2004 ESP Newsletter; adaptation of design for journal advertisements; typesetting, layout, proofing, coordination with journals and other vendors	
<b>Medical / scientific services</b>	\$ 30,000
Includes content development for ESP.com, development of copy for new Web pages, coordination with clinical reviewers, development of copy for journal advertisements	
<b>Website maintenance, 12 months total</b>	\$ 42,000
Includes all hosting and co-location fees; routine website maintenance; and technical support	
<b>Administrative and accounting fees</b>	\$ 11,168
<b>Project management</b>	\$ 18,761
<b>Total, Indirect Expenses</b>	<b>\$ 215,929</b>

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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain Mini-Disc Publication
<b>Program Overview</b>	ROI Media Group is proposing to develop, program and produce a multimedia, animated Mini-Disc that will highlight the Emerging Solutions in Pain initiative, focusing on the Emerging Solutions in Pain Web Site and Tool Kit. The Mini-Disc will be housed in a Slim Jim-style publication that will describe the Emerging Solutions in Pain initiative and the information contained in the attached Mini-Disc.
<b>Intended Audience</b>	The primary audience of the Emerging Solutions in Pain Mini-Disc will be physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain.
<b>Program Objectives</b>	<p>The objectives of the Emerging Solutions in Pain Mini-Disc Publication will include the following:</p> <ol style="list-style-type: none"> <li>(1) To increase awareness of the need for the Emerging Solution in Pain initiative in the medical community today</li> <li>(2) To provide top-line descriptions and examples of the assessment, monitoring and practice management tools available through the Emerging Solutions in Pain initiative, via the Web Site and Tool Kit</li> <li>(3) To advertise the Emerging Solutions in Pain Web Site as a continually evolving resource for clinicians involved in the field of pain management</li> </ol>
<b>Format</b>	A multimedia business card-sized (i.e., "Mini-Disc") CD-ROM, housed in a Slim-Jim style brochure-type publication
<b>Distribution</b>	The Emerging Solutions in Pain Mini-Disc Publication will be available to health care professionals who attend the RESPECT Meeting Series or who visit the Meet the Experts Booth.
<b>Request for Sponsor Support</b>	<p>ROI Media Group will utilize the Emerging Solutions in Pain Mini-Disc Publication to announce and promote the Emerging Solution in Pain initiatives through the RESPECT Meeting Series and the Meet the Experts Booth.</p> <p>As a supplement to these primary methods, ROI Media Group may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of ROI Media Group, and any such distribution will solely be as a supplement to ROI's primary methods of announcement and promotion.</p>
<b>Total Budget:</b>	\$125,919



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Proposal Number: 05-029a

Date: December 1, 2004

## Emerging Solutions in Pain: Mini-Disc Slim Jim

### *Proposed Budget*

December 1, 2004

#### *Program Description*

This proposed budget is for the development, programming, and production of a multimedia, animated Mini-Disc that will highlight the Emerging Solutions in Pain initiative, focusing on ESP.com and the Tool Kit. The Mini-Disc will be housed in a Slim Jim that promotes the ESP initiative and the information contained in the attached Mini-Disc.

<i>Cost Summary</i>	
Approximate Total, Direct Expenses	\$ 71,730
Total, Indirect Expenses	\$ 54,189
<b>Cost of Development and Production of the Emerging Solutions in Pain Mini-Disc Slim Jim</b>	<b>\$ 125,919</b>

December 1, 2004

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Proposal Number: 05-029a  
Date: December 1, 2004

**Emerging Solutions in Pain: Mini-Disc Slim Jim**  
**Proposed Budget**  
December 1, 2004

*Detailed Budget Itemization*

<b>Direct Expenses, Approximate</b>	
<b>Mini-Disc Slim Jim duplication and printing</b>	\$ 64,380
Includes duplication of business card-type mini CD-ROMs, with 4/0 silk screening; printing of slim jim: 9.25" x 10" flat size, folds to 3.75" x 9", 100# Opus Gloss Cover, 4/4 + varnish; insertion of mini-disc via glue dot; wafer-sealing. Quantity: 100,000	
<b>Audio track production</b>	\$ 3,000
Includes audio track recording of professional voice talent for use in mini-disc programming; based on clinical expert commentary	
<b>Clinical expert honorarium: review</b>	\$ 1,500
<b>Clinical expert honorarium: commentary production</b>	\$ 1,500
<b>Shipping to fulfillment center</b>	\$ 1,000
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$ 350
<b>Approximate Total; Direct Expenses</b>	<b>\$ 71,730</b>

<b>Indirect Expenses</b>	
<b>IT / programming services</b>	\$ 19,500
Includes in-studio production of audio track with professional narration; programming of mini-disc, including audio track commentary, multimedia graphics, demo versions of ESP Tools, user-friendly splash page and navigation menu, embedded hyperlink to ESP.com	
<b>Graphic design / production services</b>	\$ 12,500
Includes production of new graphics and animations for mini-disc, adaptation of design for slim jim and mini-disc silk screen; typesetting and layout of slim jim, proofing, coordination with vendors	
<b>Regulatory / review process services</b>	\$ 4,000
Includes preparation of submission copies plus reference support for one round of Cephalon PRC review; preparation of mock-ups for one mechanical review; preparation of all materials for one DDMAC submission	
<b>Medical / scientific services</b>	\$ 3,000
Includes development of content and copy for mini-disc and slim jim; coordination with clinical expert(s) for review and commentary; adaptation of expert commentary to audio script	
<b>Administrative and accounting fees</b>	\$ 5,668
<b>Project management</b>	\$ 9,521
<b>Total; Indirect Expenses</b>	<b>\$ 54,189</b>

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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain RESPECT Meeting Series
<b>Program Overview</b>	ROI Media Group is proposing to develop, produce and manage an accredited series of regional meetings, directed toward physicians, pharmacists, nurses and other health care professionals who are involved in the care of patients with chronic pain. These RESPECT, or <b>RES</b> ponsible <b>P</b> ain <b>E</b> ducation <b>C</b> an be <b>T</b> herapeutic, meetings will educate clinicians, not only on the role of opioid therapy in the chronic pain patient, but also on the critical need to balance analgesia with the potential of each patient for abuse, addiction or diversion.
<b>CE Provider</b>	<p>Based on the need to educate clinicians in the assessment and treatment of chronic pain patients who may be at risk for abuse, addiction and diversion, the RESPECT Meeting Series will be accredited by a third party CE vendor of our choice.</p> <p>The RESPECT meetings will be accredited for:</p> <ul style="list-style-type: none"> <li>• CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each activity will be approved for a maximum of three hours of category 1 credit toward the AMA Physician's Recognition Award.</li> <li>• CPE credit for pharmacists by the Accreditation Council for Pharmacy Education. Each activity will be approved for a maximum of 3.0 credit hours (0.3 CEU) for Continuing Pharmacy Education</li> <li>• CNE credit for nurses. Each activity will be approved for a maximum of 3.0 Contact Hours.</li> </ul>
<b>Intended Audience</b>	The primary audience of the RESPECT series includes clinicians who provide care to patients with pain. These clinicians will include physicians, pharmacists and nurses, but may be extended to other clinical and non-clinical members of a multi-disciplinary treatment team, such as social workers, case managers, etc.
<b>Program Objectives</b>	<p>The purpose of the RESPECT Meeting Series is to educate clinicians on the key tenets of the Emerging Solutions in Pain initiative, focusing on the role of appropriate assessment and monitoring techniques, and good practice management strategies, in achieving effective interactions between members of the treatment team.</p> <p>The primary emphasis of the meeting series will be the critical need to involve all members of the treatment team in achieving an appropriate balance between pain control and minimization of abuse, addiction and diversion. Thus, communication among team members will be one topic of discussion, as will the appropriate use of the Emerging Solutions in Pain tools and strategies in achieving effective interactions between mixed audiences of clinicians.</p> <p>The secondary goal of the RESPECT meeting series will be to determine the feasibility of establishing regular meetings of these multidisciplinary clinicians in their local areas. If interest exists among the clinicians in attendance, follow up</p>



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## *Program Summary*

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will be conducted to confirm that sufficient interest exists to merit a regular meeting schedule. If this follow-up indicates that sufficient interest exists among local clinicians to establish a regular RESPECT meeting series, ROI will coordinate between the local clinicians and appropriate RESPECT faculty to develop a meeting schedule, and to identify appropriate topics of discussion and coordinate meeting logistics for initial meetings. Dr. Joseph Shurman has been tentatively identified as the lead RESPECT faculty who will be instrumental in working with ROI and local clinicians during the establishment of regular local RESPECT meetings.

**Format** A series of live, peer-to-peer activities scheduled in 10 cities throughout the United States

**Post-Activity  
 Feedback**

Course evaluation forms will be required of all participants who seek to receive continuing education credit. ROI will work with the third party CE vendor to summarize the information collected from these forms in a formal report to evaluate program effectiveness.

Participants will evaluate the following as excellent, good, fair or poor:

- (1) Overall content
- (2) Faculty teaching effectiveness
- (3) Format
- (4) Audio / visual quality

Participants will also respond to the following questions:

- (1) How well did the program achieve its educational objectives?
- (2) Do you feel the program material was useful and practice-oriented?
- (3) Do you feel that the information provided in this educational activity will aid in improving patient care in your practice?
- (4) Do you feel that fair balance was maintained for all therapeutic options?
- (5) Would you participate in future educational activities?

**Distribution** ROI Media and the third party CE vendor will announce and promote the RESPECT Meetings primarily through direct mail and advertisement at the Emerging Solutions in Pain Web Site.

**Request for  
 Sponsor Support**

As a supplement to these primary methods, ROI Media Group and the third party CE vendor may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of ROI Media Group, and any such distribution will solely be as a supplement to ROI's primary methods of announcement and promotion.

**Total Budget:** \$653,651

December 1, 2004



101 Washington St, Suite 110  
Morrisville, PA 19067

Proposal Number: 05-030a

Date: December 1, 2004

## Emerging Solutions in Pain: RESPECT Meeting Series

### *Proposed Budget*

December 1, 2004

#### *Program Description*

This proposed budget is for the development, production and management of 10 accredited RESPECT Meetings in support of the Emerging Solutions in Pain initiatives.

<i>Program Parameters</i>	
Number of RESPECT meetings	10
Presenting faculty per activity	2
Non-presenting faculty panel members per activity	3
Health care professional attendees per meeting	50
Direct mail invitations to health care professionals per activity	2500

<i>Cost Summary</i>	
Approximate Total, Direct Expenses	\$ 362,900
Total, Indirect Expenses	\$ 290,751
<b>Cost of Emerging Solutions in Pain RESPECT Meeting Series</b>	<b>\$ 653,651</b>



101 Washington St, Suite 110  
Morrisville, PA 19067

Proposal Number: 05-030a  
Date: December 1, 2004

**Emerging Solutions in Pain: RESPECT Meeting Series**  
**Proposed Budget**  
December 1, 2004

*Detailed Budget Itemization*

<b>Direct Expenses, Approximate</b>	
<b>Direct mail invitations, mail services, postage</b>	\$ 20,700
Personalized invitations to be mailed to every potential participant; includes printing, assembly, mail services and postage. Postage estimated at \$0.37 per direct mail piece	
<b>Direct mail list purchase</b>	\$ 15,000
<b>Print materials</b>	\$ 15,000
Includes printing of shell materials for adaptation and use in individualized dinner meeting kits for every meeting; meeting kits to include accreditation information, speaker biographical and disclosure information, agenda, and handout materials	
<b>Speaker honoraria</b>	\$ 90,000
<b>Speaker travel (air, OOP, hotel)</b>	\$ 57,500
<b>Ground transportation</b>	\$ 8,000
<b>Catering</b>	\$ 79,200
<b>Audio/visual services</b>	\$ 50,000
<b>Onsite coordination</b>	\$ 23,500
<b>Shipping/Fed Ex</b>	\$ 4,000
<b>Approximate Total, Direct Expenses</b>	
	\$ 362,900

<b>Indirect Expenses</b>	
<b>Program development</b>	\$ 100,000
Includes all labor associated with initial program set-up and development, including creation of text for print support materials, graphic design, typesetting and layout of all support materials, and development and creation of final program appearance	
<b>Meeting management</b>	\$ 25,000
Includes coordination with faculty for content, dates, travel and all other program details	
<b>Recruitment</b>	\$ 35,000
<b>IT / programming services</b>	\$ 15,000
Includes programming of online registration capabilities at ESP.com, development and programming of registration and participant feedback databases	
<b>Accreditation of program for CME, CPE, CNE</b>	\$ 15,000
<b>Continuing Education participant certificates</b>	\$ 7,500
<b>Administrative and accounting fees</b>	\$ 44,832
<b>Project management</b>	\$ 48,419
<b>Total, Indirect Expenses</b>	
	\$ 290,751



101 Washington Street  
 Morrisville, Pennsylvania 19067  
 Phone 215.337.6100  
 Fax 215.337.0960

## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain Educational Slide Kit Series
<b>Program Overview</b>	ROI Media Group is proposing to develop and produce a series of three educational slide kits, of approximately 40-50 slides per kit, for use in the Emerging Solutions in Pain initiatives. The slide kit series will be based upon diverse topics relevant to the Emerging Solutions in Pain initiatives, and will be entirely derived from pre-existing sources of information. The first slide kit will be based upon Dr. Howard Heit's Universal Precautions, with subsequent slide kits based upon the Emerging Solutions in Pain Tool Kit, Consensus Paper and other pre-existing related sources of information. Slides will be distributed to Emerging Solutions in Pain faculty for use in the RESPECT meeting series via CD-ROM; a subset of slides (unalterable JPG format) will be available to registered members of the Emerging Solutions in Pain Web Site.
<b>Intended Audience</b>	The primary audience of the Emerging Solutions in Pain Educational Slide Kit Series will be Faculty Members who lecture in the RESPECT meeting series, to physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain. The secondary audience of the Emerging Solutions in Pain Educational Slide Kit Series will be registered users of the Emerging Solutions in Pain Web Site.
<b>Program Objectives</b>	<p>The objective of the Emerging Solutions in Pain Educational Slide Kit Series is to provide clinical expert faculty with a detailed set of annotated Power Point slides for use in peer-to-peer live programs. The topics of these slides may include:</p> <ol style="list-style-type: none"> <li>(1) Use of Dr. Howard Heit's "Universal Precautions" as a basis for development of good practice management techniques</li> <li>(2) The issues associated with balancing effective pain control and minimization of the risk of abuse, addiction and diversion in pain patients</li> <li>(3) The importance of identifying patients at risk for abuse, addiction and diversion, and tools and techniques for compassionately treating these patients, regardless of their identified risk level</li> <li>(4) Effective use of the assessment, monitoring and practice management tools in the Emerging Solutions in Pain Tool Kit</li> </ol>
<b>Format</b>	A series of three educational slide kits, composed of 40 – 50 annotated slides per kit
<b>Distribution</b>	The Emerging Solutions in Pain Educational Slide Kit Series will be available to all clinical expert faculty of the Emerging Solutions in Pain initiatives and the RESPECT meeting series. In addition, other health care professionals, who are registered members of the Emerging Solutions in Pain Web Site will be able to access a subset of each slide kit.
<b>Request for Sponsor Support</b>	<p>ROI Media Group is promoting the Emerging Solutions in Pain initiatives and the RESPECT Meeting Series through a variety of methods, including direct mail, publication of a multimedia Mini-Disc, journal and banner advertisements, and the Meet the Experts Booth.</p> <p>As a supplement to these primary methods, ROI Media Group may request the assistance of Cephalon, Inc. in the dissemination of information regarding this</p>



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### *Program Summary*

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program to the medical community. The content of such information, however, is the responsibility of ROI Media Group, and any such distribution will solely be as a supplement to ROI's primary methods of announcement and promotion.

**Total Budget:** \$83,447



101 Washington St, Suite 110  
Morrisville, PA 19067

Proposal Number: 05-031a

Date: December 1, 2004

## Emerging Solutions in Pain: Educational Slide Kit Series

### *Proposed Budget*

December 1, 2004

#### *Program Description*

This proposed budget is for the development and production of a series of three educational slide kits, of approximately 40-50 slides per kit, for use in the Emerging Solutions in Pain initiatives. These slide kits will be based upon existing sources of information, including the ESP Tool Kit, White Paper, Universal Precautions, and other pre-existing related sources of information. Slides will be distributed to ESP faculty via CD-ROM; subset of slides (unalterable JPG format) will be available to registered members of ESP.com

<i>Cost Summary</i>	
Approximate Total, Direct Expenses	\$ 14,350
Total, Indirect Expenses	\$ 69,097
<b>Cost of Development and Production of the Emerging Solutions in Pain Educational Slide Kit Series</b>	<b>\$ 83,447</b>



101 Washington St, Suite 110  
Morrisville, PA 19067

Proposal Number: 05-031a

Date: December 1, 2004

## Emerging Solutions in Pain: Educational Slide Kit Series

### *Proposed Budget*

December 1, 2004

#### *Detailed Budget Itemization*

<i>Direct Expenses, Approximate</i>	
Clinical expert honoraria, two KOLs	\$ 14,000
Miscellaneous (non-fulfillment shipping, faxes, etc.)	\$ 350
<b>Approximate Total, Direct Expenses</b>	<b>\$ 14,350</b>

<i>Indirect Expenses</i>	
<b>Medical / scientific services</b>	\$ 25,000
Includes coordination with clinical experts, medical writer for adaptation of ESP educational slides and annotations from existing sources; identification of key sources of information, including ESP Tool Kit, White Paper, Universal Precautions and other source material; identification of references; identification of subset of slides for use and distribution through ESP.com	
<b>Graphic design / production services</b>	\$ 20,000
Includes development of slide design based on other ESP initiatives; creation of graphs, charts and other images for slides; layout of annotations; proofreading; graphic design of splash screen, navigation functions for slide CD; graphic design and layout of CD label	
<b>IT / programming services</b>	\$ 7,500
Includes programming of one CD for the slide kit series, with interactive user interface and splash screen	
<b>CD duplication</b>	\$ 500
Includes duplication of slide kit series CD-ROM with 4/0 CD label; insertion into jewel case; quantity: 100	
<b>Administrative and accounting fees</b>	\$ 3,368
<b>Project management</b>	\$ 12,729
<b>Total, Indirect Expenses</b>	<b>\$ 69,097</b>





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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain Meet the Experts Booth
<b>Program Overview</b>	ROI Media Group is proposing to develop and produce the Meet the Experts Booth, an informational and interactive display booth for use at national congresses and association meetings. Booth functionality to include a seating area for meeting attendees to interact with Emerging Solutions in Pain clinical experts; computer terminals featuring interactive displays highlighting the Emerging Solutions in Pain initiatives, membership registration for the Emerging Solutions in Pain Web Site, and the Emerging Solutions in Pain Tool Kit.
<b>Intended Audience</b>	The primary audience of the Emerging Solutions in Pain Meet the Experts Booth will be physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain and who attend selected national association meetings and congresses. Currently suggested meetings include the 2005 meetings of the AAPM, APS, AANP, AAFP and ASAM.
<b>Program Objectives</b>	<p>The purpose of the Emerging Solutions in Pain Meet the Expert Booth is to disseminate information concerning the Emerging Solutions in Pain initiative to clinicians practicing in the field of pain management, and to educate those clinicians on the assessment and monitoring of pain patients, and on good practice management techniques. Clinicians visiting the booth will have opportunities to:</p> <ol style="list-style-type: none"> <li>(1) Interact with Emerging Solutions in Pain clinical experts in small discussion groups, focusing on tools and strategies that will contribute to a proper balance of pain control and abuse/diversion minimization</li> <li>(2) On computer terminals, view multi-media, interactive programs highlighting the issues associated with minimization of abuse, addiction and diversion, the Emerging Solutions in Pain Tool Kit and associated case studies</li> <li>(3) Receive copies of the Emerging Solutions in Pain Tool Kit CD-ROM, Consensus Paper and other support materials, such as the Mini-Disc Publication</li> <li>(4) Gain exposure to the resources available at the Emerging Solutions in Pain Web Site, and register as a "member", thereby expediting their ability to access online resources</li> </ol>
<b>Format</b>	An interactive meeting booth, to be presented at national association meetings and congresses and featuring live peer-to-peer interactions with Emerging Solutions in Pain clinical experts, as well as interactive, multimedia programs that highlight the Emerging Solutions in Pain initiatives.
<b>Distribution</b>	The Emerging Solutions in Pain Meet the Expert Booth will be available at selected national association meetings and congresses; meetings identified to date include the AAPM, APS, AANP, AAFP and ASAM. The announcement of the Booth will be made via direct mail to registered meeting attendees and members, and via journal and/or banner advertisements. Information at the Booth will be provided by Emerging Solutions in Pain clinical experts and by ROI Media staff members.



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### *Program Summary*

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**Request for  
Sponsor Support**

ROI Media Group is promoting the Emerging Solutions in Pain Meet the Experts Booth through a variety of methods, including direct mail, publication of a multimedia Mini-Disc, and journal and banner advertisements.

As a supplement to these primary methods, ROI Media Group may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of ROI Media Group, and any such distribution will solely as a supplement to ROI's primary methods of announcement and promotion.

**Total Budget:** \$702,821



101 Washington St, Suite 110  
Morrisville, PA 19067

Proposal Number: 05-032a  
Date: December 1, 2004

**Emerging Solutions in Pain: Meet the Experts Booth**  
***Proposed Budget***  
December 1, 2004

***Program Description***

This proposed budget is for the development and production of the Meet the Experts Booth, an informational and interactive display booth for use at national congresses and association meetings. Booth functionality to include a seating area for meeting attendees to interact with ESP KOLs; plasma screen for use in KOL presentations; two computer terminals featuring interactive displays highlighting ESP initiatives, ESP.com membership registration, and ESP Tool Kit. The ESP Meet the Experts Booth will be presented at four national meetings in 2005: AAPM (February 24-26, 2005: Palm Springs, CA); APS (March 30-April 2, 2005: Boston, MA); AANP (June 17-22, 2005: Fort Lauderdale, FL); and AAFP (September 28-October 2, 2005: San Francisco, CA). In addition, a modified booth will be presented at ASAM (April 14-17; Boston, MA), for purposes of distributing information regarding the ESP initiatives.

<b>Cost Summary</b>	
Approximate Total, Direct Expenses	\$ 479,455
Total, Indirect Expenses	\$ 223,367
<b>Cost of Development, Production, Presentation and Management of the Emerging Solutions in Pain Meet the Experts Booth</b>	<b>\$ 702,821</b>



101 Washington St, Suite 110  
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Proposal Number: 05-032a  
Date: December 1, 2004

**Emerging Solutions in Pain: Meet the Experts Booth**  
**Proposed Budget**  
December 1, 2004

*Detailed Budget Itemization*

<b>Direct Expenses, Approximate</b>		
Adaptation of existing booth (design panels, retro fit for multi-media capabilities, etc.)	\$	45,000
Booth staff & KOL uniform (shirt, ties)	\$	1,500
<b>AAPM Meeting (2/23-27/04 Palm Springs, CA)</b>		
Exhibit space (includes liability insurance)	\$	14,000
Booth set-up/tear-down (floor plan, shop prep, installation and dismantling including labor supervision, travel)	\$	23,380
Equipment rental (computer units, plasma screen, switcher unit, audio w/ lav mic, electrical, telecommunication links, chairs, carpeting, etc.)	\$	9,630
Shipping of booth to meeting site	\$	8,025
Shipping of supplies (mini-discs, Tool Kits, etc) to meeting site - delivery to booth charges	\$	2,000
Badge Reader System (3 units)	\$	700
<b>Booth advertisement</b>		
Direct mail booth advertisement (also used for attendee bag insert, door drop, Cephalon booth)		
Meeting attendee list purchase	\$	250
Printing	\$	3,150
Postage	\$	2,590
Advertisement in meeting catalog/publication (full page, 4/c)	\$	1,775
Attendee bag insert fee		
Door drop fee	\$	3,000
Booth posters, printing	\$	750
<b>KOL expenses: two KOL faculty</b>		
Honoraria	\$	10,000
Meeting registration	\$	2,400
Travel: air, hotel, ground, OOP	\$	4,300
<b>ROI expenses: three ROI staff</b>		
Travel: air, hotel, ground, OOP	\$	6,900
Exhibitor registration	\$	300

December 1, 2004

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Proposal Number: 05-032a  
Date: December 1, 2004

**Emerging Solutions in Pain: Meet the Experts Booth**  
**Proposed Budget**  
**December 1, 2004**

*Detailed Budget Itemization, Continued*

<b>Direct Expenses, Approximate, Continued</b>	
<b>APS Meeting (3/30/04 - 4/2/04 Boston, MA)</b>	
Exhibit space	\$ 14,000
Booth set-up/tear-down (floor plan, shop prep, installation and dismantling including labor supervision, travel)	\$ 20,919
Equipment rental (computer units, plasma screen, switcher unit, audio w/ lav mic, electrical, telecommunication links, chairs, carpeting, etc.)	\$ 11,770
Shipping of booth to meeting site	\$ 11,235
Shipping of supplies (mini-discs, Tool Kits, etc) to meeting site - delivery to booth charges	\$ 2,000
Badge Reader System (3 units)	\$ 700
Booth advertisement	
Direct mail booth advertisement	
Meeting attendee list purchase	\$ 500
Printing	\$ 3,150
Postage	\$ 2,590
Advertisement in meeting catalog/publication	\$ 1,200
Booth posters, printing	\$ 600
KOL expenses: two KOL faculty	
Honoraria	\$ 10,000
Meeting registration	\$ 1,200
Travel: air, hotel, ground, OOP	\$ 4,300
ROI expenses: three ROI staff	
Travel: air, hotel, ground, OOP	\$ 6,900
Exhibitor registration	\$ 300



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Proposal Number: 05-032a

Date: December 1, 2004

**Emerging Solutions in Pain: Meet the Experts Booth**  
**Proposed Budget**  
December 1, 2004

*Detailed Budget Itemization, Continued*

**Direct Expenses, Approximate, Continued**

<b>AANP Meeting (6/17-22/04 Ft. Lauderdale, FL)</b>	
Exhibit space	\$ 9,000
Booth set-up/tear-down (floor plan, shop prep, installation and dismantling including labor supervision, travel)	\$ 18,779
Equipment rental (computer units, plasma screen, switcher unit, audio w/ lav mic, electrical, telecommunication links, chairs, carpeting, etc.)	\$ 10,165
Shipping of booth to meeting site	\$ 8,025
Shipping of supplies (mini-discs, Tool Kits, etc) to meeting site - delivery to booth charges	\$ 2,000
Badge Reader System (3 units)	\$ 700
Booth advertisement	
Direct mail booth advertisement	
Meeting attendee list purchase	\$ 500
Printing	\$ 3,150
Postage	\$ 2,590
Advertisement in meeting catalog/publication	\$ 1,200
Booth posters, printing	\$ 600
KOL expenses: two KOL faculty	
Honoraria	\$ 10,000
Meeting registration	\$ 1,200
Travel: air, hotel, ground, OOP	\$ 4,300
ROI expenses: three ROI staff	
Travel: air, hotel, ground, OOP	\$ 6,900
Exhibitor registration	\$ 300

December 1, 2004

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Proposal Number: 05-032a

Date: December 1, 2004

## Emerging Solutions in Pain: Meet the Experts Booth

### *Proposed Budget*

December 1, 2004

#### *Detailed Budget Itemization, Continued*

#### ***Direct Expenses, Approximate, Continued***

<b>AAFP Meeting (9/28/04 - 10/2/04 San Francisco, CA)</b>	
Exhibit space	\$ 14,850
Booth set-up/tear-down (floor plan, shop prep, installation and dismantling including labor supervision, travel)	\$ 26,590
Equipment rental (computer units, plasma screen, switcher unit, audio w/ lav mic, electrical, telecommunication links, chairs, carpeting, etc.)	\$ 11,770
Shipping of booth to meeting site	\$ 11,235
Shipping of supplies (mini-discs, Tool Kits, etc) to meeting site - delivery to booth charges	\$ 2,000
Badge Reader System (3 units)	\$ 700
Booth advertisement	
Direct mail booth advertisement	
Meeting attendee list purchase	\$ 600
Printing	\$ 7,200
Postage	\$ 5,920
Advertisement in meeting catalog/publication	\$ 12,700
Doctor Bag insert	\$ 7,500
Booth posters, printing	\$ 600
KOL expenses: two KOL faculty	
Honoraria	\$ 10,000
Meeting registration	\$ 1,200
Travel: air, hotel, ground, OOP	\$ 4,300
ROI expenses: three ROI staff	
Travel: air, hotel, ground, OOP	\$ 6,900
Exhibitor registration	\$ 300

December 1, 2004

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Proposal Number: 05-032a

Date: December 1, 2004

**Emerging Solutions in Pain: Meet the Experts Booth**  
**Proposed Budget**  
December 1, 2004

*Detailed Budget Itemization, Continued*

<b>Direct Expenses, Approximate, Continued</b>	
<b>ASAM Meeting (4/14-17/04 Dallas, TX)</b>	
Exhibit space	\$ 1,300
Booth Rental for 8X10 Space	\$ 3,500
Booth set-up/tear-down (floor plan, shop prep, installation and dismantling including labor supervision, travel)	\$ 14,499
Equipment rental (computer units, plasma screen, switcher unit, audio w/ lav mic, electrical, telecommunication links, chairs, carpeting, etc.)	\$ 5,885
Shipping of booth to meeting site	\$ 5,885
Shipping of supplies (mini-discs, Tool Kits, etc) to meeting site - delivery to booth charges	\$ 2,000
Booth advertisement	
Direct mail booth advertisement	
Meeting attendee list purchase	\$ 750
Printing	\$ 1,125
Postage	\$ 925
Advertisement in meeting catalog/publication	\$ 1,800
Booth posters, printing	\$ 600
ROI expenses: three ROI staff	
Travel: air, hotel, ground, OOP	\$ 5,500
Exhibitor registration	\$ 200
Miscellaneous (non-fulfillment shipping, faxes, etc.)	\$ 700
<b>Approximate Total, Direct Expenses</b>	<b>\$ 479,455</b>

December 1, 2004

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101 Washington St, Suite 110  
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Proposal Number: 05-032a  
Date: December 1, 2004

**Emerging Solutions in Pain: Meet the Experts Booth**  
**Proposed Budget**  
**December 1, 2004**

*Detailed Budget Itemization, Continued*

<b>Indirect Expenses</b>	
<b>Medical / scientific services</b>	\$ 15,000
Includes development of content for interactive booth displays, direct mail and meeting advertisements; selection of demo clips from ESP.com and Tool Kit; coordination of presentation content with ESP KOLs	
<b>Graphic design / production services</b>	\$ 25,000
Includes development of display graphics for booth panels, graphics for interactive booth displays; graphic design, typesetting and layout of booth posters and advertisements (direct mail plus meeting catalog); proofreading; coordination with print vendors; etc.	
<b>IT / programming services</b>	\$ 22,000
Includes adaptation of ESP Tool Kit and Website demos for use in interactive booth displays; programming of interactive displays featuring interactive user-friendly navigation page; modules for ESP Tool Kit, Website, Website member registration and poll/evaluation functions; database programming to capture Website member registrations and user responses to poll/evaluation questions	
<b>Conference management services</b>	
Includes ROI labor to manage pre-meeting booth set-up, post-meeting booth tear-down; staffing booth during meeting; coordination with KOLs pre-meeting, post-meeting and during meeting; coordination with conference vendors, coordination of booth advertising; etc.	
Conference management services: AAPM	\$ 18,000
Conference management services: APS	\$ 14,400
Conference management services: AANP	\$ 21,600
Conference management services: AAFP	\$ 18,000
Conference management services: ASAM	\$ 14,400
<b>Administrative and accounting fees</b>	\$ 27,973
<b>Project management</b>	\$ 46,994
<b>Total, Indirect Expenses</b>	\$ 223,367

December 1, 2004

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## EDUCATIONAL GRANT DRAFT REQUEST

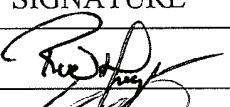
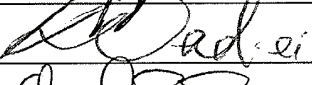

The attached material has been reviewed and is approved:

Payee: ROI Media Group, Inc.

Amount: \$2,019,175

Type of Program: Emerging Solutions in Pain

Submitted for Review: 12/14/2004

DEPARTMENT	NAME	SIGNATURE	DATE
Scientific Communications	Rod Hughes		12-16-04
Medical Affairs	Kiumars Vadiei		12/16/04
Legal & Government	Ed Berg		12/16/04

Return to: Suzanne Richards, ext. 86532

*UP @ meeting w Rod H., Michael R & me.*  
*before signing, please set*  
*Andy I. by me,*  
*Ed B*

## MEDICAL EDUCATION AGREEMENT

As a condition of Cephalon, Inc.'s contribution of funds to support an independent medical education program (with or without CME credits), the Scientific and Educational Activity provider agrees to the following terms and conditions:

This Agreement ("Agreement") is entered into as of December 6, 2004 by and between Cephalon, Inc. ("Cephalon") and ROI Media Group, Inc. ("Provider") regarding a medical education program sponsored by Cephalon entitled "Emerging Solutions in Pain". The parties' mutual objectives are to provide a balanced, independent, scientifically rigorous program to promote the education of attendees.

1. Statement of Purpose. This program is for scientific and educational purposes only and not to promote any commercial drug products.

2. Control of Content and Selection of Presenters and Moderators. The provider is ultimately responsible for the control of content and selection of presenters and moderators. Cephalon or its agents may respond to requests initiated by the provider for suggestions of presenters or sources of possible presenters. Cephalon will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Cephalon and speaker; and will provide this information in writing. Provider will seek suggestions from other sources, and will, in its sole discretion, select presenters and moderators.

3. Disclosure of Financial Relationships. Provider will direct speakers and moderators to disclose to the audience commercial support or funding or other significant financial relationships between the speakers and moderators and Cephalon and/or any other commercial company whose products are pertinent to the content of the presentation. Provider will disclose Cephalon's support at this program.

4. Involvement in Content. There will be no "scripting," emphasis, or influence on content by Cephalon or its agents. However, Cephalon may provide technical support to speakers, e.g., furnishing slides or data, upon their request.

5. Ancillary Promotional Activities. No promotional activities will be permitted in the same room as, or in the obligatory path to, the educational activity. No product advertisements will be permitted within the program or handouts.

6. Objectivity and Balance. Provider will advise presenters that data regarding Cephalon products (or competing products) are to be objectively selected and presented. Provider will provide the opportunity for speakers and the audience to discuss information, both favorable and unfavorable, about the product(s) and/or alternative treatments.

7. Limitations of Data. Provider will request the speakers, to the extent possible, to disclose limits on the data, e.g., that it involves ongoing research, interim analyses, preliminary data, or unsupported opinion.

8. Discussion of Unapproved Uses. Provider will request that presenters disclose when a product is not approved in the United States for the use under discussion.

9. ACTIQ Risk Management Program. Provider is aware that ACTIQ® (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- ACTIQ is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- ACTIQ is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.
- ACTIQ is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

10. Opportunity for Debate. Provider will ensure opportunities for questioning by attendees and scientific debate with and between presenters.

11. Independence of Provider in the Use of Contributed Funds.

(a) funds should be in the form of an educational grant made payable to the provider organization.

(b) Provider must be advised of all other support by Cephalon of the CME activity (e.g., distributing brochures, preparing slides). If Provider disapproves of this activity, it shall promptly notify Cephalon.

(c) no other funds from Cephalon will be paid to the program director, faculty, or others involved with this CME activity, e.g., additional honoraria.

12. General.

(a) Cephalon agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.

(b) Provider agrees to: (1) abide by the ACCME Standards for Commercial Support of Continuing Medical Education; (2) acknowledge educational support from Cephalon in program brochures, syllabi, and other program materials; and (3) upon request, furnish Cephalon with a report concerning the expenditure of the funds provided by Cephalon.

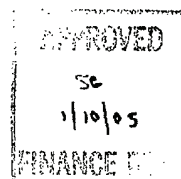
IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

ROI MEDIA GROUP, INC.

CEPHALON, INC.

By: *Shari L. Gaurinshi*  
 Name: Shari L. Gaurinshi  
 Title: President, ROI Media Group Inc.

By: *[Signature]*  
 Name: Lynne Brookes  
 Title: Vice President, Marketing



G:\Med Ed Agreements\ROI - ESP.doc

ROI Media Group, Inc.

101 Washington Street  
Morrisville, PA 19067**Invoice**

Date	Invoice #
10/27/2005	1313

Bill To
Cephalon, Inc. 41 Moores Road Frazer, PA 19355

P.O. No.	Terms	Project
013534	UPON RECEIPT	Cephalon

Quantity	Description	Rate	Amount
	Final Third Billing of Emerging Solutions in Pain Program (grant)	673,000.00	673,000.00
Federal Tax ID 90-0135153 Thank you!		<b>Total</b>	\$673,000.00

to AIP 11/10/05

COPY

Rod J. Hughes, PhD  
Vice President  
Scientific Communications





145 BRANDYWINE PARKWAY  
WEST CHESTER, PENNSYLVANIA 19380  
(610) 344-0200  
FAX (610) 738-6311

ACTIQ

07300C.40  
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No.

**013534**

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shipping papers and packages.

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TODAY'S DATE

DATE REQUIRED

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CEPHALON, INC.

145 BRANDYWINE PARKWAY

WEST CHESTER, PA 19380

ATTN: Suzanne Richards

X 86532

TO ROI Media Group

101 Washington Street, Suite 110  
Morrisville, PA 19067

FAX # 215-337-0960

QTY ORDERED	UNIT OF MEASURE	DEPT. CODE G/L ACCT.	PROJECT/ CAPITAL CODE	STOCK NO./DESCRIPTION	UNIT PRICE	TOTAL
EB		631 7640	ACTQ	Emerging Solutions in Pain Program		2,019,000 <sup>00</sup>
ORDER PROCESSOR		DATE ORDERED		BUYER	SHIP VIA	
		2-10-05		Donna Price	TOTAL EXTENDED PRICE 2,019,000 <sup>00</sup>	

- Please send one copy of your invoice.
- Order is to be entered in accordance with prices, delivery and specifications shown above.
- Notify us immediately if you are unable to ship as specified.

AUTHORIZED BY

Lynne Brookes  
PRINT NAME

V.P. Marketing



# Cephalon

145 BRANDYWINE PARKWAY  
WEST CHESTER, PENNSYLVANIA 19380  
(610) 344-0200  
FAX (610) 738-6311

## PURCHASE ORDER

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TODAY'S DATE

DATE REQUIRED

1/26/05  
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145 BRANDYWINE PARKWAY

WEST CHESTER, PA 19380

ATTN: Suzanne Richards  
X 86532

TO ROI Media Group  
101 Washington Street, Suite 110  
Morrisville, PA 19067  
FAX # 215-337-0960

QTY ORDERED	UNIT OF MEASURE	DEPT. CODE G/L ACCT.	PROJECT/ CAPITAL CODE	STOCK NO./DESCRIPTION	UNIT PRICE	TOTAL
EB		631 7640	ACTQ	Emerging Solutions in Pain Program		2,019,000 <sup>00</sup>
ORDER PROCESSOR		DATE ORDERED		BUYER	SHIP VIA	
						TOTAL EXTENDED PRICE 2,019,000 <sup>00</sup>

- Please send one copy of your invoice.
- Order is to be entered in accordance with prices, delivery and specifications shown above.
- Notify us immediately if you are unable to ship as specified.

AUTHORIZED BY

Confidential

TEVA\_MDL\_A\_01851661

P-29481 \_ 00057

From: Origin ID: (610)738-6532  
Suzanne Richards  
CEPHALON  
145 BRANDYWINE PARKWAY  
  
WEST CHESTER, PA 19380



C150914040505

Ship Date: 11JAN05  
Actual Wgt: 1 LB  
System#: 2402709/INET2000  
Account#: S \*\*\*\*\*

REF: 631

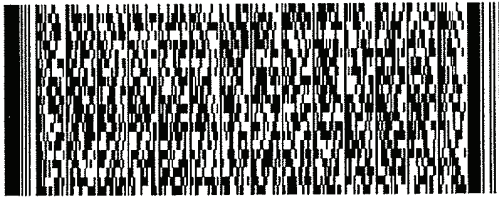


Delivery Address Bar Code

SHIP TO: (215)337-9991

BILL SENDER

**Sheri Gavinski**  
**ROI Media Group**  
**101 Washington Street**  
**Suite 110**  
**Morrisville, PA 19067**

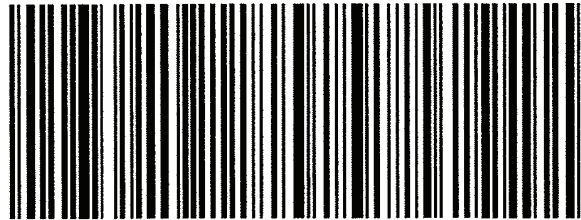
**STANDARD OVERNIGHT****WED**Deliver By:  
12JAN05

TRK# 7908 8411 2064

FORM  
0201

PHL A2

19067 -PA-US

**17 NXXA**

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# 2006 *Emerging Solutions in Pain* Grant Request

*Presented to:*

**Edward Hoey**  
Cephalon, Inc.

*By:*

Sheri Gavinski  
Medical Learning Solutions, Inc.

101 Washington Street, Suite 110  
Morrisville, PA 19067  
Tel 215-337-6100  
800-397-9774  
Fax 800-329-9755



Medical Learning Solutions, Inc.



101 Washington Street  
Morrisville, Pennsylvania 19067  
Phone 215.337.6100  
Fax 215.337.0960

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101 Washington Street  
Morrisville, PA 19067

Edward Hoey  
Cephalon, Inc.  
41 Moores Road  
Frazer, PA 19355

November 28, 2005

Dear Mr. Hoey:

Medical Learning Solutions, Inc. has recently completed a comprehensive needs assessment to identify the educational needs of clinicians who provide care to patients with chronic pain. This needs assessment was compiled from the following sources:

- Evaluation summaries of completed and ongoing 2005 Emerging Solutions in Pain programs and activities
- Clinical advisory review
- Survey of health care professionals, including participants in completed and ongoing 2005 Emerging Solutions in Pain programs
- Literature search

Based on the identified educational need, Medical Learning Solutions is requesting an educational grant from Cephalon, Inc. to support the continuation and further development of the **Emerging Solutions in Pain**, or **ESP**, initiatives. This will include the continuation of selected **ESP** programs instituted in 2005, as well as the development and implementation of a diverse series of new activities designed to further increase the knowledge and practice management skills of those clinicians who provide care to patients with chronic pain. The **ESP** initiatives will continue to focus on balancing the clinical need to provide adequate analgesia to patients with chronic pain with the legal and societal need to monitor for potential issues of abuse, addiction and diversion of controlled substances.

These activities will be designed and planned as follows:

- Fundamental Emerging Solutions in Pain Programs (*Grant Request Part A*); these will include the following:
  - Continuance of the Emerging Solutions in Pain web site
  - Convention of an expanded Emerging Solutions in Pain Faculty Advisory Board, to address development of new Tools and areas of focus
  - Enhancements to the Emerging Solutions in Pain content, in the form of new Tools and resources

- An expanded awareness campaign to include coordinated advertising in multiple media formats
- Continuing education initiatives associated with *Practical Pain Management*, featuring in-publication articles focusing on topics relevant to Emerging Solutions in Pain
- Live Emerging Solutions in Pain Educational Events and Activities (*Grant Request Part B*); these will include the following:
  - Continuance of the Meet the Expert exhibit booth at select, larger association meetings and expansion of the Meet the Expert mini-booth at smaller association meetings
  - Recreation of the RESPECT meeting series to focus on the provision of trained Emerging Solutions in Pain faculty to regional and local meetings of clinician associations, grand rounds programs and other similar venues
  - Adaptation of the current RESPECT meeting content to focus on the educational needs of single-clinician groups at regional and local meetings of clinician associations
- Programs to Further Expand the Reach of the Emerging Solutions in Pain Educational Events and Activities (*Grant Request Part C*); these will include the following:
  - Development and implementation of a full-day seminar program, to be held for clinical attendees of a national congress, focusing on the intersection of pain management and addiction medicine
  - Additional RESPECT meetings, held at regional and local meetings of clinician associations, grand rounds programs and other similar venues

The budget to fund these activities is approximately \$964,006 for Grant Request Part A; \$806,332 for Grant Request Part B and \$381,901 for Grant Request Part C. Please refer to the detailed budget section of this proposal for complete grant funding proposals.

These scientific events will comply with all ACCME, FDA, AMA, and ACPE regulations for industry-supported professional continuing education. MLS will be working with MediCom Worldwide, Inc. in the planning, execution and development of the accredited activities associated with the **ESP** initiatives. MediCom Worldwide is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians and is approved by the Accreditation Council for Pharmacy Education to provide pharmacy continuing education, as well as an approved provider of nursing continuing education through the California State Board of Registered Nursing.

Thank you in advance for your consideration of this request.

Respectfully,



Sheri L. Gavinski  
President,  
Medical Learning Solutions, Inc.





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## ***NEEDS ASSESSMENT***

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In the United States alone, an estimated 50 million people suffer from some form of chronic pain, and another 25 million people suffer acute pain resulting from surgery or an accident.<sup>1</sup> Significantly, approximately two thirds of patients have been living with their pain for more than five years,<sup>2</sup> resulting in an alarming decrease, not only in quality of life, but in productivity for these individuals, as well. A survey conducted in 2000 reported that 36 million Americans missed work the previous year due to pain, and 83 million indicated that pain had affected their participation in various activities.<sup>3</sup>

It is well-established that chronic pain is a multi-faceted problem requiring intervention from a range of specialists in different disciplines.<sup>4</sup> Over the last decade, governments, professional organizations and institutions across the country have taken positive steps to improve physician training in pain management and palliative care, in accordance with recommendations issued by the World Health Organization.<sup>5</sup> These changes are indicators of the increasing recognition of pain relief and palliative care as appropriate subjects for professional education.

The increased focus on appropriate pain management has also resulted in certain challenges that impact health care professionals and patients alike. Some of these challenges result from confusion on the part of either patients or health care professionals, or both, regarding the potential of narcotic pain medications for abuse, addiction, misuse and diversion. Other challenges result from increased media attention regarding the prevalence of abuse and diversion, or from a lack of education and understanding regarding regulations for appropriate prescription of Schedule II agents. Patients, for example, may hesitate to use narcotics over fears of addiction, while health care professionals may be reluctant to prescribe opioids over concerns of increased scrutiny or investigation by local, state or federal law enforcement officials. When these types of concerns are combined with controversies surrounding the lack of scientific data on addiction, complex regulatory policies, and vague practice guidelines, the barriers to successful pain management become significant; undertreatment of pain is an all-too-common result.

One often-cited barrier in prescribing opioid analgesics to patients with chronic pain is the perception that physicians who treat their patients with these medications will come under increased scrutiny from the DEA and other regulatory and/or law enforcement agencies. This perception is due, in part, to documented increases in the diversion and sale of oxycodone and hydrocodone products. The source for much of this information is a unique epidemiologic network, known as Community Epidemiology Work Groups, or CEWG, that is designed to inform drug abuse prevention and treatment agencies, public health officials, policymakers, and the general public about current and emerging drug abuse patterns. Of the approximately 7,300 narcotic analgesic/opiate items analyzed by forensic laboratories across 19 CEWG areas in 2004, nearly 91 percent represented four drug classes: hydrocodone (35.3 percent), oxycodone (23.1 percent), methadone (19.1 percent), and codeine (13.3 percent).<sup>9</sup>

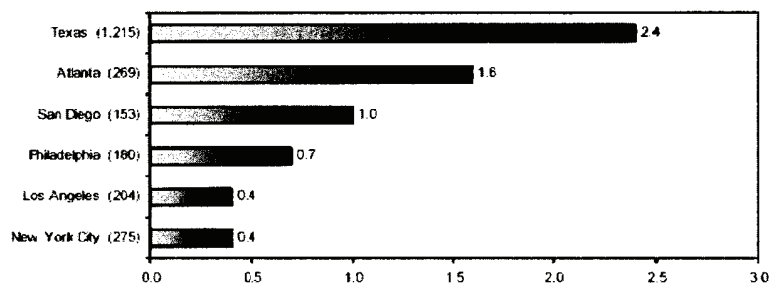


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## NEEDS ASSESSMENT

Exhibit 1 shows the number of hydrocodone items in 6 CEWG sites where more than 100 items were reported in 2004

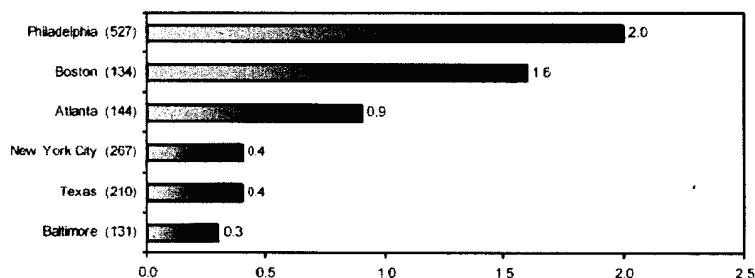
**Exhibit 1. Number of Hydrocodone Items Reported by Forensic Laboratories in 6 CEWG Areas, Ordered by Percentage of Total Items: FY 2004**



SOURCE: NFLIS, DEA

Exhibit 2 depicts the number of oxycodone items analyzed by forensic laboratories in 6 CEWG areas where more than 100 were reported.

**Exhibit 2. Number of Oxycodone Items Reported by Forensic Laboratories in 6 CEWG Areas, Ordered by Percentage of Total Items: FY 2004**



SOURCE: NFLIS, DEA

As can be seen in Exhibit 1 and Exhibit 2 above, there are clearly issues with abuse, misuse and diversion associated with some narcotic agents in certain geographic locations. Moreover, in March of 2004 the Office of National Drug Control Policy stated, "6.2 million Americans were current abusers of prescription drugs."<sup>6</sup> This information, while extremely important, is not, however, a justification for undertreatment of pain, even in those patients who may be identified at higher risk for abuse, misuse, addiction or diversion. Many studies have shown, in fact, that properly managed medical use of opioid analgesic drugs is effective and rarely causes clinical addiction, which is defined as compulsive, often uncontrollable use.<sup>7</sup> The key to this statement is "properly managed medical use", which consists of a



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## NEEDS ASSESSMENT

comprehensive pain management program of assessment, monitoring and documentation, consistently utilized for all patients with chronic pain.

If properly managed medical use of opioids is a cornerstone of effective pain management, however, even today, many health care professionals lack the understanding, knowledge and tools for appropriate use of narcotic medications. Critically, pain management is not a significant area of focus in many medical schools, and physicians often graduate with misconceptions regarding appropriate pain management practices and techniques. In a recent study of medical students' attitudes toward pain and the use of opioid analgesics, half of senior medical students surveyed believed addiction risks associated with opioids are substantial, and more than one third were concerned about drug regulatory agency investigations. Moreover, these seniors were more pessimistic than freshmen surveyed about relieving chronic pain, and they appeared to have less understanding about the sources of pain in cancer patients.<sup>8</sup>

### NEEDS ASSESSMENT SURVEYS

To further define the educational needs of clinicians active in the field of pain management, our group conducted a series of surveys in 2005, in which we asked physicians about their practices and the therapies that they utilize to provide analgesia. The first survey was conducted among participants in the 2005 RESPECT meeting series, with a selection of evaluation questions and responses from this survey summarized in Exhibit 3, below.

**Exhibit 3: Selections from the 2005 RESPECT Meeting Program Evaluation Form**

<b><i>Do you manage patients who are experiencing acute pain?</i></b>	
Many	44%
Few	30%
None	8%
<b><i>Do you manage patients who are experiencing chronic pain?</i></b>	
Many	50%
Few	24%
None	6%
<b><i>How do you currently manage pain patients?</i></b>	
Opioids	25%
Combination of all methods	16%
Non-opioids	14%
OTC medications	10%
Psychological/social therapy	3%
Physical therapy	3%



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## NEEDS ASSESSMENT

Other	3%
<b><i>If you don't utilize opioid analgesics, why?</i></b>	
Concerns over issues of abuse, misuse, addiction and diversion	39%
Concerns over federal and state regulations	12%
Don't feel opioids are necessary	8%
<b><i>Are pain management interdisciplinary teams a standard of practice in your geographic area?</i></b>	
No	57%
Yes	24%

This information collected from the RESPECT meeting participants has been separately validated through two needs assessment surveys that question health care professionals regarding their needs for pain-related information. The first of these two surveys provided data regarding clinicians' top interests, preferred method of education, and other details regarding continuing education, collected from almost 1300 clinicians specializing in the field of pain management. The following results demonstrate topics that the respondents view to be of high interest in pain management:

- |  |     |
|--|-----|
| 1. Pharmacologic Advances in Pain Management | 78% |
| 2. Chronic Nonmalignant Pain Management      | 75% |
| 3. Acute Pain Management                     | 57% |
| 4. Addiction, Substance Abuse                | 47% |
| 5. Cancer Pain Management                    | 41% |

The second of these two surveys was conducted among more than 900 clinicians who participated in pain management continuing education programs in 2003 – 2005, and focused specifically on suggested topics for future programs. While numerous, diverse program topics were suggested, several core topics were suggested repeatedly by more than 130 respondents. These topics included:

1. Drug abuse and addiction
2. Treating the chemically dependent with chronic pain
3. Opioids for the treatment of pain
4. Narcotics: dosages, indications and contraindications
5. Assessment guidelines and tools
6. Pain-related case studies



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## NEEDS ASSESSMENT

7. Legal issues, including regulations from the DEA, medical board issues and pharmacy law matters

When the results of these surveys are combined, it is clear that additional curriculum and training are required to help insure improvements in the delivery of pain relief, to include identifying the:

- Critical issues involving the use of opioid analgesics
- Fundamental rights of patients to pain treatment
- Patients at high risk for opioid misuse, abuse and/or diversion
- Legal ramifications when prescribing controlled substances

One of the ways this challenge can be met is through the continuance of continuing education programs that focus on pain management in general, and, specifically, the effective use of opioids in patients with chronic pain. The goal of such programs must be to support clinicians in improving patient care while reducing the potential for abuse, addiction, diversion, and medical regulatory/malpractice liability exposures arising from poor pain management practices.

### References

1. National Pain Survey, conducted for Ortho-McNeil Pharmaceutical, 1999.
2. Chronic Pain in America: Roadblocks to Relief, survey conducted for the American Pain Society, The American Academy of Pain Medicine and Janssen Pharmaceutica, 1999.
3. Pain in America: A Research Report, Survey conducted for Merck by the Gallup Organization, 2000.
4. Zarnegar R. Pain Management Programs. BJA - CEPD Reviews, Volume 5, Number 3, 15 June 2005, pp. 80-83(4).
5. World Health Organization. <http://www.who.int/en/>. Accessed September 16, 2005.
6. Office of National Drug Control Policy, "News Release, March 1, 2004" from the web at <http://www.whitehousedrugpolicy.gov/news/press04/030104.html> last accessed May 27, 2004.
7. National Institute on Drug Abuse, "NIDA InfoFacts," from the web at <http://www.nida.nih.gov/Infofax/painmed.html>, accessed March 1, 2004.
8. Weinstein SM, et al. Medical Students' Attitudes Toward Pain and the Use of Opioid Analgesics: Implications for Changing Medical School Curriculum. *South Med J.* 2000;93(5):472-478.
9. National Institute on Drug Abuse. Advance Report and Highlights/Executive Summary: Abuse of Stimulants and Other Drugs. Proceedings of the Community Epidemiology Work Group. January 2005. [http://www.drugabuse.gov/PDF/CEWG/AdvReport\\_Vol1\\_105.pdf](http://www.drugabuse.gov/PDF/CEWG/AdvReport_Vol1_105.pdf). Accessed September 22, 2005.



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## **NEEDS ASSESSMENT**

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### **PROGRAM OVERVIEW: THE 2005 EMERGING SOLUTIONS IN PAIN INITIATIVE**

**Emerging Solutions in Pain (ESP)** is an ongoing initiative that was developed by clinicians for physicians, pharmacists, nurses and other healthcare professionals who are active in the field of pain management. The **ESP** initiative, which was launched in February of 2005, was created specifically to address the issues and critical unmet needs in the field of pain management. These issues specifically involve balancing the fundamental rights of patients and clinicians with the challenge of identifying patients who are at greater or lesser risk for opioid misuse and addiction, and with the challenges associated with the complex regulations involved in prescribing controlled substances. In 2005, the **ESP** initiative included a diverse array of activities and programs, including the development of a multimedia CD-ROM-based clinician Tool Kit; a clinician-focused web site for the dissemination of pain management information; an exhibit booth that provided clinician attendees of national congresses with information regarding the Emerging Solutions in Pain tools and resources; and a series of ten accredited regional meetings that focused on the importance of establishing standards of care and the interdisciplinary team in proactive pain management. Each of these activities is summarized below.

The **ESP** initiative is based upon ongoing input and expertise from a renowned group of clinical experts with backgrounds in pain management, addiction medicine, anesthesiology and neurology. These experts include those individuals listed in Exhibit 4, below. Based on input from these experts, in 2005, the Emerging Solutions in Pain initiative was dedicated to the development, production and dissemination of information and tools focused on assessment, monitoring and best practices for treating patients with opioids. These experts also provided extensive guidance and input in terms of the most effective methods for delivering this information to practicing clinicians.

### **Exhibit Four-A: The Emerging Solutions in Pain Faculty Advisory Board**

*Gerald M. Aronoff, MD, DABPM, FAAEP*  
Chairman, Department of Pain Medicine  
Presbyterian Orthopaedic Hospital  
Charlotte, North Carolina

*Fernando T. Avila, MD*  
Private Practice,  
Pain Management and Anesthesiology  
San Antonio, TX

*David B. Brushwood, RPh, JD*  
Professor, Pharmacy Health Care Administration  
College of Pharmacy  
University of Florida  
Gainesville, FL

*Daniel M. Gruener, MD*  
President, Greater Philadelphia Pain Society  
Clinical Assistant Professor of Psychiatry  
Jefferson Medical College  
Philadelphia, Pennsylvania





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## **NEEDS ASSESSMENT**

---

***Jeffrey A. Gudin, MD***

Clinical Director  
Pain Management Center  
Englewood Hospital and Medical Center  
Englewood, New Jersey

***Mitchell Halter, MD***

Neurologist  
Integrative Pain Center of Arizona  
Tucson, AZ

***Howard A. Heit, MD, FACP, FASAM***

Assistant Clinical Professor of Medicine,  
Georgetown University School of Medicine  
Washington, DC

***Steven D. Passik, PhD***

Director, Symptom Management and Palliative Care  
Markey Cancer Center  
Associate Professor of Medicine and Behavioral Sciences  
University of Kentucky  
Lexington, Kentucky

***Joseph Shurman, MD***

Anesthesiologist and Pain Consultant  
Scripps Memorial Hospital  
La Jolla, California  
Clinical Assistant Professor and Pain Consultant  
University of California, San Diego  
San Diego, California

***Lynn R. Webster, MD, FACPM, FASAM***

Alpine Pain and Addiction Medicine  
Salt Lake City, UT

**Exhibit Four-B: Other Contributing Faculty to the Emerging Solutions in Pain Initiatives**

Daniel Bennett, MD  
Daniel Brookoff, MD  
Andrea Cheville, MD  
Doris Cope, MD  
Douglas Gourlay, MD, FRCPC, FASAM  
Jayson Hymes, MD, MPH, FACPM  
Benjamin Johnson, Jr, MD  
Bill McCarberg, MD  
Michael Moskowitz, MD, MPH  
Richard Payne, MD  
Steven Stanos, DO



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## **NEEDS ASSESSMENT**

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### **2006 Emerging Solutions in Pain Initiatives**

The information collected through the first 11 months of the Emerging Solutions in Pain initiative clearly indicates that a significant educational need exists for continuing education programs and resources devoted to the needs of clinicians who provide care to patients with chronic pain. Based on these educational needs, it is recommended that a series of initiatives be implemented in 2006 to continue and extend the 2005 Emerging Solutions in Pain programs. These initiatives include the following.

#### **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

1. Continuance of the Emerging Solutions in Pain web site at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com)
2. Recruitment and convention of an expanded Emerging Solutions in Pain Faculty Advisory Board, to address development of new Tools and areas of focus
3. Enhancements to the Emerging Solutions in Pain content, distributed via the web site and a new Tool Kit; enhancements to be based upon Faculty recommendations
4. Expanded awareness campaign to include coordinated advertising in multiple media formats
5. Continuing education initiatives associated with *Practical Pain Management*, featuring in-publication articles focusing on topics relevant to Emerging Solutions in Pain

#### **Grant Request Part B: Live Emerging Solutions in Pain Educational Events and Activities**

1. Continuance of the Meet the Expert exhibit booth at select, larger association meetings and expansion of the Meet the Expert mini-booth at smaller association meetings
2. Recreation of the RESPECT meeting series to focus on the provision of trained Emerging Solutions in Pain faculty to regional and local meetings of clinician associations, grand rounds programs and other similar venues
3. Adaptation of the current RESPECT meeting content to focus on the educational needs of single-clinician groups at regional and local meetings of clinician associations

#### **Grant Request Part C: Programs to Further Expand the Reach of the Emerging Solutions in Pain Educational Events and Activities**

1. Development and implementation of a full-day seminar program, to be held for clinical attendees of a national congress, focusing on the intersection of pain management and addiction medicine
2. Additional RESPECT meetings, held at regional and local meetings of clinician associations, grand rounds programs and other similar venues





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## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

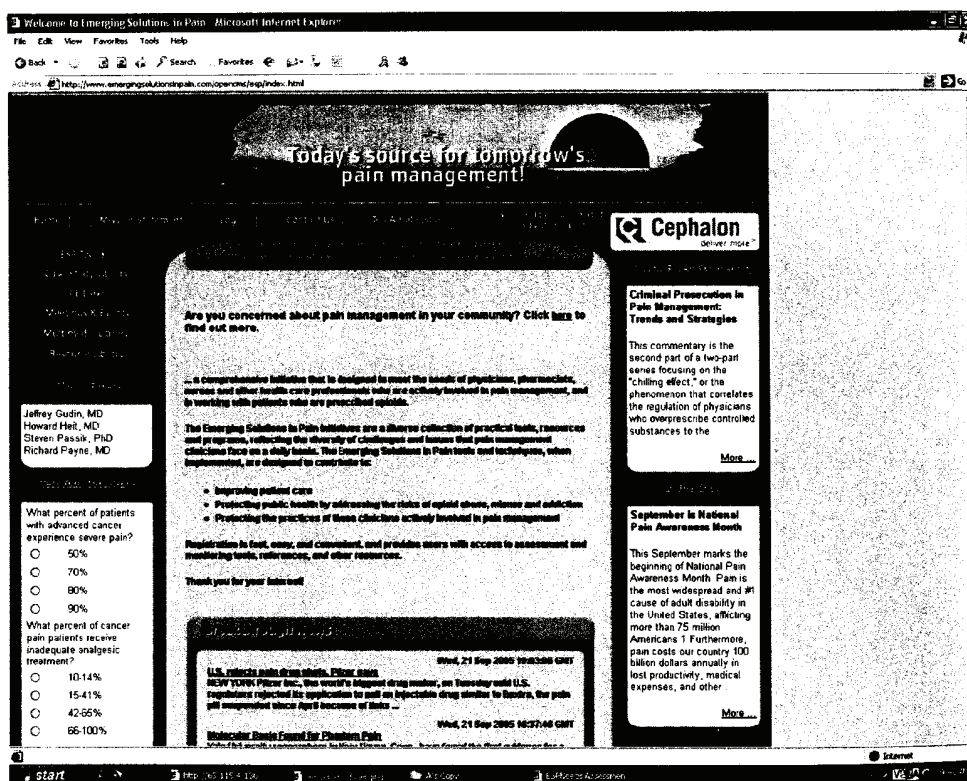
### **Program Overview: Summary of Work Completed in 2005**

#### **1. THE EMERGING SOLUTIONS IN PAIN (ESP) WEB SITE**

This web-based, comprehensive initiative is designed to meet the needs of physicians, pharmacists, nurses and other health care professionals who are actively involved in the management of patients who may be or are actively prescribed opioids. This easy-to-access web site is the repository of an invaluable and diverse collection of practical tools, resources, information, recent updates, and various other programs that reflect the diverse challenges and issues facing pain management clinicians today (Exhibit A-1).

In addition, members are required to register prior to accessing the fundamental Emerging Solutions in Pain resources and tools. This enables tracking of information pertaining to member specialty and Tool use, and provides a method for updating site users with information regarding new programs and tools as they become available.

#### **Exhibit A-1: The Emerging Solutions in Pain Home Page**

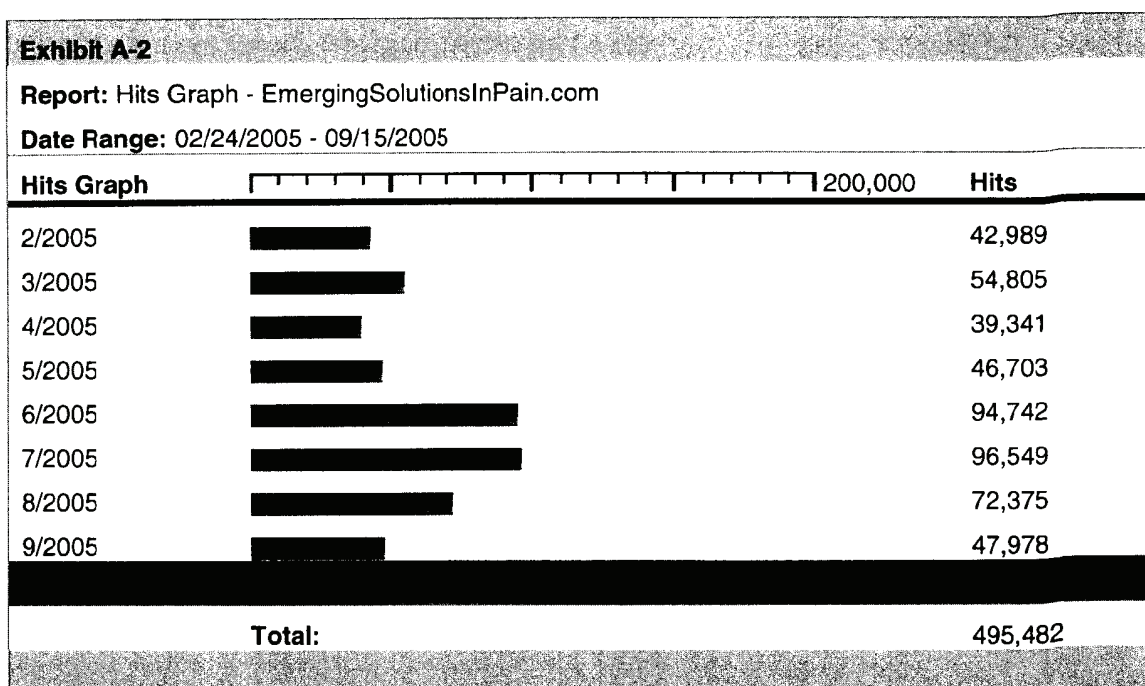




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## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

Since the launch of the Emerging Solutions in Pain website in February, 2005, almost 500,000 hits to the site has resulted in more than 17.33 Gigabytes of information being downloaded directly from the ESP site to practicing clinicians; more than 77.48 Megabytes of information is downloaded daily. Exhibit A-2 shows the trend of recent activity on ESP in terms of successful hits over time.

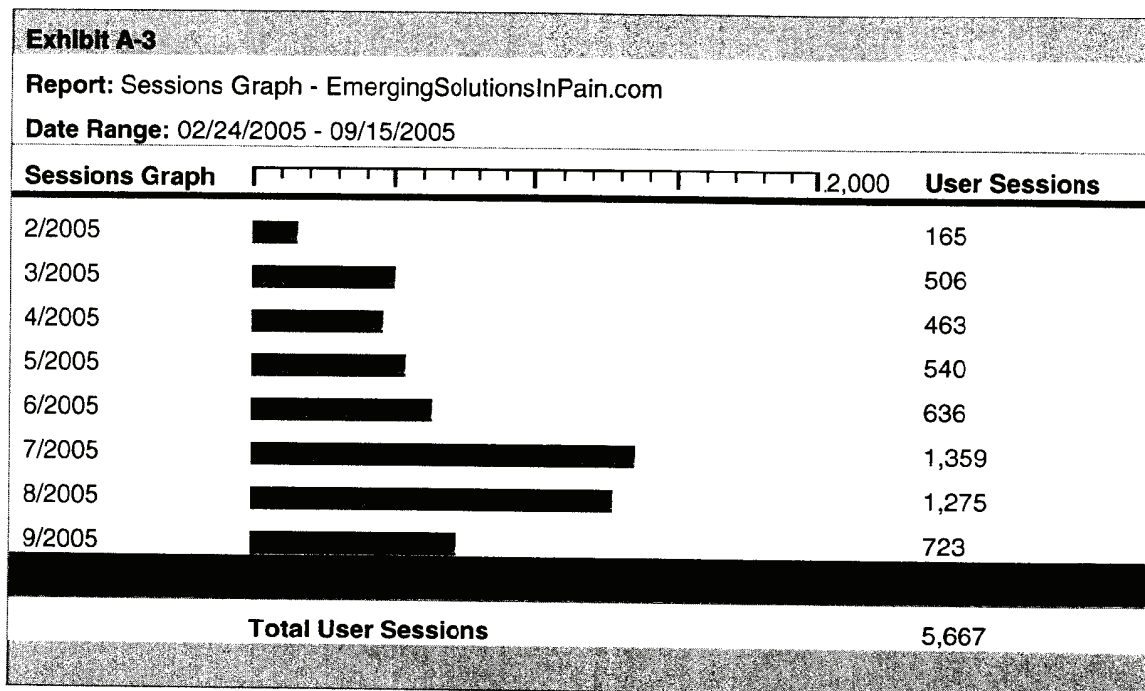




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## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

Exhibit A-3 demonstrates the trend of recent activity on the Emerging Solutions in Pain website, in terms of visitor sessions over time. An individual visitor defines a "session" as a series of clicks on ESP during a specific period of time. A session is initiated when the visitor arrives at ESP, and it ends when the browser is closed or after a period of inactivity. The significant number of monthly sessions is not surprising, given the many diverse tools available to practicing clinicians, both as printable documents and as electronic downloads.



A significant measure of website relevance is the number of credible, non-related web sites linked to the site. The number of sites hyperlinked to ESP or that mention the ESP site is a measure of the growing influence of the Emerging Solutions in Pain initiative in the pain management community (Exhibit A-4).

### **Exhibit A-4**

1. **American Physical Therapy Association**  
(<http://www.apta.org/AM/Template.cfm?Section=Archives2&Template=/Customsource/TaggedPage/PTIssue.cfm&Issue=09/02/2005#article24599>)
2. **American Chronic Pain Association** ([http://www.theacpa.org/pf\\_03\\_05.asp](http://www.theacpa.org/pf_03_05.asp))
3. **The Legal Side of Pain**  
(<http://www.legalsideofpain.com/index.cfm?fuseaction=page.display&pid=10>)



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## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

4. **Find That CE** ([http://www.findthatce.com/search\\_advanced/detail.php?ceid=844](http://www.findthatce.com/search_advanced/detail.php?ceid=844))
5. **Actiq® Educational Offerings** (<http://www.actiq.com/physicians/mededucation/>)
6. **Pain.com**  
([http://www.pain.com/sections/categories\\_of\\_pain/breakthrough/Resources/professional\\_resources/resource.cfm?id=1341](http://www.pain.com/sections/categories_of_pain/breakthrough/Resources/professional_resources/resource.cfm?id=1341))
7. **Painfoundation.org**  
([http://www.painfoundation.org/marylandpain/Downloads/ESP\\_Brief.pdf#search='emergingsolutionsinpain.com'](http://www.painfoundation.org/marylandpain/Downloads/ESP_Brief.pdf#search='emergingsolutionsinpain.com'))
8. **American Society for Pain Management Nursing** (<http://www.aspmnhouston.org/about.html>)
9. **Doctor's Guide**  
(<http://www.docguide.com/news/content.nsf/medicalresourcesweb?openform&id=e85e90285e487ca885256b1e00595908&cond=cme-related+sites>)
10. **American Alliance of Cancer Pain Initiatives**  
([http://www.aacpi.org/PCP\\_webpages/AnalgesicPharm.pdf#search='emergingsolutionsinpain.com'](http://www.aacpi.org/PCP_webpages/AnalgesicPharm.pdf#search='emergingsolutionsinpain.com'))

### **2. THE ESP TOOL KIT CD-ROM**

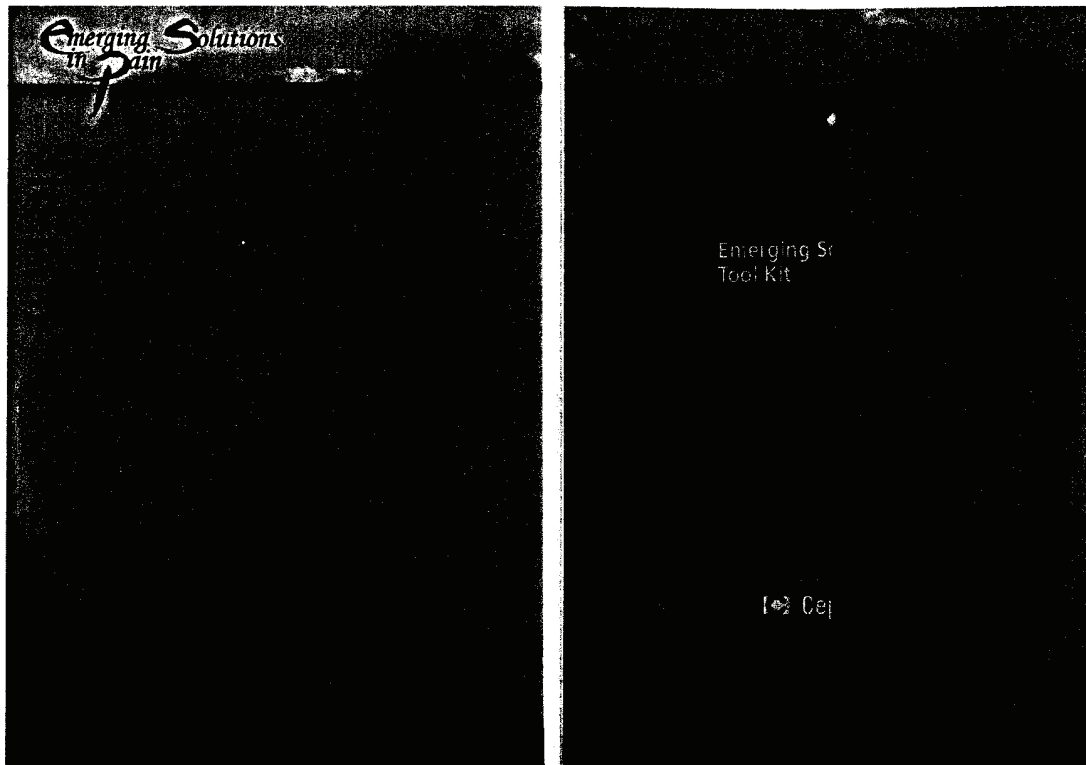
The Emerging Solutions in Pain Tool Kit CD-ROM (Exhibit A-5) provides health care professionals with an extensive array of electronic tools that may be used to effectively assess a patient's potential for opioid abuse, addiction, and diversion; to monitor the patient who is prescribed opioids; and to implement best practices in the management of patients with chronic pain. Every tool featured on this CD-ROM is available in electronic format, enabling instant and convenient access to clinicians who wish to view the informative multimedia slide-audio programs, the helpful printable documents, or the resourceful references and hyper links to access all content instantaneously.



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## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

**Exhibit A-5**



To date, 71,265 Emerging Solution in Pain Tool Kit CD-ROMs have been shipped and/or distributed to health care professionals who are involved in pain treatment and management.

### **3. THE ESP MINI-DISC PUBLICATION**

The Emerging Solutions in Pain Mini-Disc was created to focus health care professionals on the diverse resources and educational tools available to them via both the Emerging Solutions in Pain website and the ESP Tool Kit CD-ROM. The accompanying ESP Slim Jim Publication (Exhibit A-6) highlights and describes not only the contents of the attached Mini-Disc, but also the entire Emerging Solutions in Pain initiative, as well. In addition, the Publication also features a Business Reply Card (BRC), attached along the perforated edge, providing health care professionals with a convenient method for requesting the ESP Tool Kit CD-ROM; this BRC is a source of data for future mailings, as well.



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## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

The ESP Mini-Disc Publication is easily distributed at either a RESPECT Meeting Series or at one of the Meet the Experts booths. To date, almost 73,000 of the ESP Mini-Disc Publications have been shipped or distributed to health care professionals.

### **Exhibit A-6**

**Request Your Complimentary Copy Today!  
The Emerging Solutions in Pain Tool Kit**

First Name	Last Name		Appt/Suite	Zip Code
Mailing Address		City	State	Fax Number
Phone Number		E-Mail Address		

☐ I would like to receive other information from Emerging Solutions in Pain

**Please Order Your Copy in One of Four Ways...**

**By Phone** 800-337-9774  
**By Fax** 800-504-0960  
**By Web** [www.emergingsolutionsinpain.com](http://www.emergingsolutionsinpain.com)  
**By Mail** Please return this card





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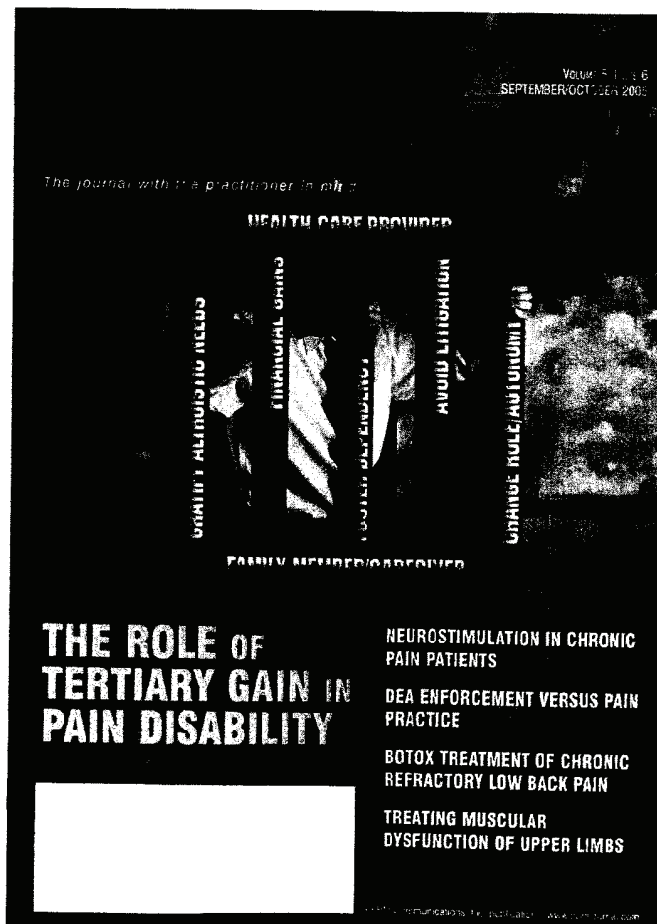
## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

### **4. AWARENESS CAMPAIGN**

In order to create awareness as well as increase the reach and frequency of the Emerging Solutions in Pain initiatives, a targeted campaign has been implemented in 2005, with the goal of disseminating key information to health care professionals who provide care to patients with chronic pain. This campaign has included journal and Internet advertisements, press releases and commentaries.

#### *Practical Pain Management*

This journal is published for the medical practitioner who is dedicated to helping patients experiencing chronic pain. Through a coordinated series of program informational announcements, including one press release, one clinical editorial and a series of three back cover or full-page advertisements, key Emerging Solutions in Pain messages have reached the 39,000-clinician subscriber list every month since May, 2005. As can be seen from the occupational breakout and percentage of total readership (Exhibit A-7, below), the top five occupations that clearly deal with the management of pain on a daily basis, are now much more familiar with Emerging Solutions in Pain and with the practical services and tools created by ESP to support their practice and patients.





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## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

### **Exhibit A-7: Practical Pain Management Demographics**

SPECIALTY	TOTAL QUALIFIED	PERCENT OF TOTAL
Anesthesiology/Pain Med _____	3,467	9.4
Dental Specialties _____	462	1.2
Emergency Medicine _____	474	1.3
Family Practice _____	6,571	17.6
General Practice _____	1,504	4.1
General Surgery _____	659	1.8
Internal Medicine _____	5,736	15.4
Neurology/Neurosurgery _____	4,287	11.6
Ob/Gyn _____	243	0.7
Occupational/Industrial Medicine _____	332	0.9
Oncology/Hematology _____	248	0.7
Orthopedic Medicine/Surgery _____	4,283	11.6
Pain Medicine/Management _____	1,606	4.3
Pediatrics _____	408	1.1
Physical Med & Rehab/Sports Med _____	2,642	7.1
Radiology: Oncology/Diagnostic/Interventional _____	413	1.1
Rheumatology _____	1,253	3.4
Other _____	2,488	6.7
<b>TOTAL QUALIFIED CIRCULATION</b>	<b>37,076</b>	<b>100.0</b>

*The American Academy of Physical Medicine and Rehabilitation (AAPM&R) Web site: [www.aapmr.org](http://www.aapmr.org)*

The American Academy of Physical Medicine and Rehabilitation is a national medical society representing more than 7,000 physicians who are specialists in the field of physical medicine and rehabilitation. The Emerging Solutions in Pain Meet the Expert Booth will be present at the 2005 AAPM&R National Meeting, to be held in Philadelphia, PA in October. In conjunction with this opportunity, ESP has placed a banner advertisement on the AAPM&R web site that will be viewable and will include a click-through link to [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com) until January, 2006. This banner is located at:

<http://www.aapmr.org/assembly/prelim/aa05l.htm>

The AAPM&R web site reported almost 32,000 user sessions in June, 2005; each of these users will thus be potentially exposed to key Emerging Solutions in Pain messages.





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## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

### ***Program Overview: Proposed 2006 Activities***

The following activities are recommended as the Fundamental Emerging Solutions in Pain Programs in 2006.

1. Continuance of the Emerging Solutions in Pain web site at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com)
2. Recruitment and convention of an expanded Emerging Solutions in Pain Faculty Advisory Board, to address development of new Tools and areas of focus
3. Enhancements to the Emerging Solutions in Pain content, distributed via the web site and a new Tool Kit; enhancements to be based upon Faculty recommendations
4. Expanded awareness campaign to include coordinated advertising in multiple media formats
5. Continuing education initiatives associated with *Practical Pain Management*, featuring in-publication articles focusing on topics relevant to Emerging Solutions in Pain



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Proposal Number: 06-003

Date: November 28, 2005

**Emerging Solutions in Pain**  
**Summary of Proposed Budget, Grant Request Part A**  
*Fundamental Emerging Solutions in Pain Programs*  
November 28, 2005

<b>Cost Summary</b>	
<b>ESP Website</b>	
Approximate Total, Direct Expenses	\$ 22,350
Indirect Expenses	\$ 129,229
Cost of Expansion and Maintenance of the Emerging Solutions in Pain Website	\$ 151,579
<b>ESP Faculty Advisory Committee Meeting</b>	
Approximate Total, Direct Expenses	\$ 71,062
Indirect Expenses	\$ 66,500
Cost of 2006 Emerging Solutions in Pain Faculty Advisory Committee Meeting	\$ 137,562
<b>ESP Tool Kit</b>	
Approximate Total, Direct Expenses	\$ 45,000
Indirect Expenses	\$ 105,850
Cost of Development and Production of Emerging Solutions in Pain Tool Kit, Volume Two	\$ 150,850
<b>ESP Awareness Campaign</b>	
Approximate Total, Direct Expenses	\$ 45,000
Indirect Expenses	\$ 16,500
Cost of 2006 ESP Awareness Campaign	\$ 61,500
<b>Accredited Journal Article Series</b>	
Approximate Total, Direct Expenses	\$ 216,000
Indirect Expenses	\$ 88,841
Cost of PPMJ Accredited Journal Article Series	\$ 304,841
<b>Total Budget, 2006 Fundamental Emerging Solutions in Pain Programs</b>	<b>\$ 806,332</b>

Approval Signature \_\_\_\_\_

Date \_\_\_\_\_

Note: no work may begin until Medical Learning Solutions receives, via email or fax, this approval with signature and date



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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain Web Site
<b>Program Overview</b>	Medical Learning Solutions is proposing to continue and expand the multimedia Web Site that currently houses and promotes the Emerging Solutions in Pain initiative. This Web Site provides health care professionals with an extensive array of tools for assessing the potential for abuse, addiction and diversion in their patients with chronic pain, for monitoring their pain patients, and for accessing information regarding "best practices" in the long-term management of these patients. Registered members of EmergingSolutionsinPain.com can access and print available Tools and supporting references, view video-slide/audio-based case studies, read relevant literature and journal articles, view schedules for upcoming events such as the Meet the Expert Booth, and register for live peer-to-peer meetings that are part of the Emerging Solutions in Pain initiative.
<b>Intended Audience</b>	The primary audience of the Emerging Solutions in Pain Web Site are physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain.
<b>Program Objectives</b>	<p>in 2006, one goal of the Emerging Solutions in Pain Web Site will be to continue to provide clinicians with tools and resources for assessing and monitoring the risk potential of their patients for opioid misuse, abuse and addiction. New goals for the Emerging Solutions in Pain web site include the following:</p> <ol style="list-style-type: none"> <li>(1) Expand the reach of this web site and the important information it contains to the following groups: <ol style="list-style-type: none"> <li>a. Non-physician members of the pain management community, e.g., nurses, physician assistants, pharmacists</li> <li>b. Pain specialists and addictionologists who have not yet registered at the web site</li> <li>c. Medical students who have an interest in treating pain as part of their studies</li> <li>d. Physicians who treat pain as part of their practice and who have not yet registered at the web site</li> </ol> </li> <li>(2) Provide new resources and tools for clinicians who are involved in pain management. These tools and resources will be identified, in part, at the 2006 Faculty Advisory Committee Meeting, but may include one or more of the following: <ol style="list-style-type: none"> <li>a. Online versions of any new tools developed through the 2006 Emerging Solutions in Pain initiatives</li> <li>b. A searchable database of FAQs, answering the most common questions clinicians have pertaining to opioid misuse, abuse and addiction</li> <li>c. A dynamic online forum in which clinicians may post questions or comments for other registered users to respond to, or for one of the Emerging Solutions in Pain faculty to answer</li> <li>d. An expanded listing of links to other pain management resources</li> </ol> </li> </ol>
<b>Format</b>	A multimedia Web Site, with separate links for assessing and monitoring patients whose chronic pain is being treated with opioids; for "best practice" information;



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### *Program Summary*

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	for journal articles relevant to the Emerging Solutions in Pain initiative; for other Emerging Solutions in Pain information and programs
<b>Distribution</b>	The Emerging Solutions in Pain Web Site will be available to all individuals via the Internet at <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a> . Free registration will be required to access the majority of information on the Web Site, including all of the Emerging Solutions in Pain Tools and journal articles
<b>Request for Sponsor Support</b>	<p>Medical Learning Solutions will announce and promote the Emerging Solution in Pain Web Site through journal advertisements, banner advertisements and announcement brochures for the Emerging Solutions in Pain initiative.</p> <p>As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.</p>
<b>Total Budget:</b>	\$151,579



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Proposal Number: 06-003  
Date: November 28, 2005

**Expansion and Maintenance of the Emerging Solutions in Pain Website**  
**Projected Budget Estimate**  
November 28, 2005

<b>Cost Summary</b>	
<b>Approximate Total, Direct Expenses</b>	\$ 22,350
<b>Total, Indirect Expenses</b>	\$ 129,229
<b>Expansion and Maintenance of the Emerging Solutions in Pain Website</b>	<b>\$ 151,579</b>

<b>Direct Expenses, Approximate</b>	
<b>Clinical expert honoraria</b> Honoraria for authorship of monthly column, <i>Clinical Expert Commentary</i> ; selected <i>In the Know</i> columns	\$ 17,000
<b>Topix.net feed</b>	\$ 3,000
<b>Stock photography / Illustrations</b>	\$ 2,000
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$ 350
<b>Approximate Total, Direct Expenses</b>	<b>\$ 22,350</b>

<b>Indirect Expenses</b>	
<b>IT / programming services</b> Includes programming of new tools, resources and content, to be determined by consultation with Faculty Advisory Committee; coordination with Internet and database programming vendors	\$ 26,800
<b>Graphic design / production services</b> Includes production of new graphics associated with new tools and resources	\$ 10,500
<b>Medical / scientific services</b> Includes all content development for ESP.com, development of copy for new Web pages as needed, coordination with clinical reviewers, ongoing development of clinical expert commentary, In the News summaries and Topix.net feed; maintenance of links and other information	\$ 33,000
<b>Website maintenance, 12 months total</b> Includes all hosting and co-location fees; routine website maintenance; and technical support	\$ 42,000
<b>Administrative and accounting fees</b>	\$ 3,168
<b>Project management</b>	\$ 13,761
<b>Total, Indirect Expenses</b>	<b>\$ 129,229</b>



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## *Program Summary*

- Program Title** The Emerging Solutions in Pain 2006 Faculty Advisory Board Meeting
- Program Overview** The Emerging Solutions in Pain initiative was developed by clinicians for physicians, pharmacists, nurses and other health care professionals involved in the field of pain management. The input and guidance of these clinicians was instrumental in determining the original parameters and scope of the initiative, and remains critical for the ongoing success of future Emerging Solutions in Pain initiatives. Medical Learning Solutions is therefore recommending that the Emerging Solutions in Pain Faculty Advisory Committee reconvene for a one-day meeting in February 2006. At this meeting, the Faculty will address the current needs of clinicians involved in the field of pain management, and identify potential areas for the development of future Emerging Solutions in Pain tools and resources.
- Medical Learning Solutions is recommending that the 2006 Emerging Solutions in Pain Faculty Advisory Committee include all currently active Emerging Solutions in Pain faculty members, as well as a select group of clinicians that have made some contribution to the 2005 Emerging Solutions in Pain initiatives. The members of the Faculty Advisory Committee have therefore been tentatively identified to include those individuals listed below; final Committee selection will be based upon faculty availability; additional names will be added, as needed.
- Daniel Bennett, MD  
Daniel Brookoff, MD  
David B. Brushwood, RPh, JD  
Douglas Gourlay, MD, FRCPC, FASAM  
Jeffrey A. Gudin, MD  
Howard A. Heit, MD, FACP, FASAM  
Benjamin Johnson, Jr., MD  
Christine Miaskowski, RN, PhD, FAAN  
Steven D. Passik, PhD  
Joseph Shurman, MD  
Steven Stanos, DO  
Lynn R. Webster, MD, FACPM, FASAM
- Int nded Audience** The primary audience who will benefit from a reconvention of an expanded Emerging Solutions in Pain Faculty Advisory Committee will be physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain, and who utilize opioids in their pain practices. The needs of these clinicians will be specifically addressed at the Advisory Board Meeting, and new Emerging Solutions in Pain tools and resources will be recommended by the Faculty for their use in 2006.
- Pr gram Objectives** The purpose of the Emerging Solutions in Pain Faculty Advisory Committee is to provide guidance for future direction of the Emerging Solutions in Pain initiatives. This will require the accomplishment of the following objectives at the Advisory Committee Meeting:



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## *Program Summary*

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- (1) Summarize the activities and programs that comprised the 2005 Emerging Solutions in Pain initiatives
- (2) Outline current trends in the use of opioids for the treatment of chronic pain, focusing on any new developments in laws or regulations pertaining to the prescription of controlled substances; new products and therapies that will be available for the treatment of chronic pain; and new reports pertaining to the assessment, monitoring or documentation of patients who are prescribed opioids
- (3) Based on the above, recommend:
  - a. New tools and resources that would meet the unmet needs of clinicians who provide care to patients with chronic pain
  - b. Changes and updates to the current RESPECT slide modules

<b>Format</b>	A one-day meeting, to be tentatively held in February 2006. The exact date and location of this meeting will be based on the schedules of the attending faculty; it is anticipated that this meeting will be held immediately before or after a national congress or association meeting which the majority of faculty will attend. Options for this meeting include the International Conference on Pain & Chemical Dependency in Brooklyn, New York and the American Academy of Pain Medicine Meeting in San Diego, California.
<b>Distribution</b>	Attendance at the 2006 Emerging Solutions in Pain Faculty Advisory Committee Meeting will be determined by past participation in the Emerging Solutions in Pain initiatives. Invitations will be issued to currently active faculty members and to select faculty who made some contribution to the initiatives in 2005.
<b>Total Budget:</b>	\$137,562



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Proposal Number: 06-003  
Date: November 28, 2005

**2006 Emerging Solutions in Pain Faculty Advisory Committee Meeting**  
***Proposed Budget***  
November 28, 2005

<b><i>Program Parameters</i></b>	
Attending faculty	11
Clinical expert moderator	1
Length of meeting	1 day

<b><i>Cost Summary</i></b>	
Approximate Total, Direct Expenses	\$ 71,062
Total, Indirect Expenses	\$ 66,500
<b>Cost of 2006 Emerging Solutions in Pain Faculty Advisory Committee Meeting</b>	<b>\$ 137,562</b>





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Proposal Number: 06-003  
Date: November 28, 2005

**2006 Emerging Solutions in Pain Faculty Advisory Committee Meeting**  
***Proposed Budget***  
November 28, 2005

*Detailed Budget Itemization*

***Direct Expenses, Approximate***

<b>Print materials</b>	
Meeting kits to include agenda, handout materials, current RESPECT meeting slides and 4/c binder	\$ 2,000
<b>Speaker honoraria (11 faculty member + 1 moderator)</b>	\$ 32,500
<b>Speaker travel (air, OOP, hotel)</b>	\$ 13,600
<b>ROI staff travel (air, OOP, hotel)</b>	\$ 5,000
<b>Ground transportation</b>	\$ 2,400
<b>Venue rental fee</b>	\$ 1,000
<b>Food &amp; Beverage (Dinner, Buffet Breakfast, Buffet Lunch, Two Breaks)</b>	\$ 6,062
<b>Audio/visual services</b>	\$ 6,000
<b>Transcription</b>	\$ 1,500
<b>Miscellaneous (non-fulfillment shipping, faxes, FedEx, etc.)</b>	\$ 1,000
<b><i>Approximate Total, Direct Expenses</i></b>	<b>\$ 71,062</b>

***Indirect Expenses***

<b>Program development</b>	\$ 12,500
<b>Graphic design</b>	\$ 17,000
Includes all labor associated with initial program set-up and development, including development and production of meeting slides, coordination of print support materials, graphic design, typesetting and layout of all support materials, and development and creation of final program appearance	
<b>Meeting management</b>	\$ 13,000
Includes faculty management, venue coordination, meeting logistics, travel and all other program details	
<b>Site inspection</b>	\$ 3,000
<b>Onsite management (four staff members)</b>	\$ 6,000
<b>Administrative and accounting fees</b>	\$ 2,585
<b>Project management</b>	\$ 12,415
<b><i>Total, Indirect Expenses</i></b>	<b>\$ 66,500</b>



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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain Tool Kit, Volume Two
<b>Program Overview</b>	<p>Medical Learning Solutions is proposing to develop new tools and content for the Emerging Solutions in Pain Tool Kit, Volume Two. Volume One of the Tool Kit provided clinicians with specific tools for assessing the potential for abuse, addiction and diversion in their patients with chronic pain, for monitoring their pain patients, and for accessing information regarding "best practices" in the long-term management of these patients. Volume Two will expand upon the tools and resources presented in Volume One, as directed by the Emerging Solutions in Pain faculty attending the 2006 Faculty Advisory Committee Meeting.</p> <p>The new tools and resources that will be included in Volume Two of the Tool Kit will be available via a new multi-media CD-ROM, as well as via a downloadable series at the Emerging Solutions in Pain web site.</p>
<b>Intended Audience</b>	The primary audience of the Emerging Solutions in Pain Tool Kit Volume Two will be physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain.
<b>Program Objectives</b>	<p>The specific tools and resources that will make up the Emerging Solutions in Pain Tool Kit Volume Two will be taken from recommendations made by the Emerging Solutions in Pain Faculty. These tools and resources may include the following:</p> <ol style="list-style-type: none"> <li>(1) Tools for assessing functionality in patients who are prescribed opioids, such as a driving impairment test</li> <li>(2) Tools to assist in appropriate documentation of those patients who are prescribed opioids, such as chart stickers or downloadable return visit forms</li> <li>(3) Resources outlining specific legal issues associated with prescribing opioids</li> <li>(4) Case studies of patients who have had issues with misuse, abuse or addiction to opioids</li> </ol>
<b>Format</b>	A multimedia CD-ROM and online at <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a>
<b>Distribution</b>	<p>The Emerging Solutions in Pain Tool Kit Volume Two will be available through the following avenues:</p> <ol style="list-style-type: none"> <li>(1) Through BRC request cards</li> <li>(2) Through electronic download at <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a></li> <li>(3) Through distribution at the Emerging Solutions in Pain Meet the Expert Booth</li> <li>(4) Through distribution at the RESPECT Meeting Series</li> </ol>
<b>Request for Sponsor Support</b>	<p>Medical Learning Solutions will announce and promote the Emerging Solution in Pain Tool Kit Volume Two through the means of distribution outlined above. In addition, all Emerging Solutions in Pain initiatives will direct clinicians to <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a>, where Volume Two will be prominently featured. These will include journal advertisements, banner advertisements and brochures for the Emerging Solutions in Pain initiative.</p> <p>As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. in the dissemination of information</p>



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### *Program Summary*

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regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.

**Total Budget:** \$150,850



101 Washington St, Suite 110  
Morrisville, PA 19067

Proposal Number: 06-003  
Date: November 28, 2005

**2006 Emerging Solutions in Pain Tool Kit, Volume Two**  
**Proposed Budget**  
November 28, 2005

<b>Cost Summary</b>	
<b>Approximate Total, Direct Expenses</b>	\$ 45,000
<b>Total, Indirect Expenses</b>	\$ 105,850
<b>Development and Production of the Emerging Solutions in Pain Tool Kit, Volume Two</b>	<b>\$ 150,850</b>

<b>Detailed Budget Itemization</b>	
<b>Direct Expenses, Approximate</b>	
<b>Duplication: ESP Tool Kit CD-ROM, Quantity: 10,000</b>	
Four color, two page CD mailer with two inside pockets to house four-color silk-screened CD-ROM plus 16-page four-color saddle-stitched booklet. 4/0 + varnish, score, fold, insertion of CD, shrinkwrapping.	\$ 24,500
<b>Audio track recording</b>	
Professional voice talent narration of Tool Kit instructions, KOL commentary, etc.	\$ 3,500
<b>Clinical expert honoraria</b>	
Preparation, review of audio commentary	\$ 9,000
<b>Postage for returned BRCs*</b>	
<b>Postage to ship CDs for BRC requests*</b>	\$ 2,500
<b>Miscellaneous (non-fulfillment shipping, taxes, etc.)</b>	\$ 5,000
	\$ 500
<b>Approximate Total, Direct Expenses</b>	<b>\$ 45,000</b>

<b>Indirect Expenses</b>	
<b>IT / programming services</b>	
Includes programming of multi-media CD-ROM, including user-friendly CD interface; programming of Tools and resources, instructions and commentary; adaptation of all Tools and resources to formats appropriate for online posting and use	\$ 33,465
<b>Graphic design / production services</b>	
Includes production of multi-media animation and graphics for CD; adaptation of design for CD case, rep BRC, journal advertisements; typesetting, layout, proofing, coordination with print and duplication vendors	\$ 13,500
<b>Medical / scientific services</b>	
Includes content development for rep BRC, journal advertisement, CD booklet	\$ 37,630
<b>Fulfillment of CDs in response to returned rep BRCs</b>	\$ 5,000
<b>Administrative and accounting fees</b>	\$ 2,543
<b>Project management</b>	\$ 13,712
<b>Total, Indirect Expenses</b>	<b>\$ 105,850</b>

\*Note that "BRCs" refers to excess Business Reply Cards printed in 2005 in association with the ESP Slim Jim. BRCs will not be re-printed in 2006.



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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain Awareness Campaign
<b>Program Overview</b>	Medical Learning Solutions is proposing to increase the number of health care professionals who are aware of the Emerging Solutions in Pain initiative through the development and implementation of a coordinated series of advertising campaigns in 2006. The goal of this awareness campaign is to expand the reach of the Emerging Solutions in Pain initiatives to health care professionals who will benefit from the educational information presented at the web site, on the Tool Kit CD-ROM, at the Meet the Experts Booth and at the RESPECT meeting series.
<b>Intend d Audience</b>	The primary audience of the Emerging Solutions in Pain Tool Kit Volume Two will include physicians, pharmacists, nurses, physician assistants, and other health care professionals who provide care to patients with chronic pain.
<b>Program Objectives</b>	<p>The overall objective of the 2006 Awareness Campaign is to increase the number of health care professionals who are active in the Emerging Solutions in Pain community. The specific objectives will include, but are not limited to:</p> <ol style="list-style-type: none"> <li>(1) Increase the number of registered users at <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a></li> <li>(2) Increase the number of user sessions at <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a></li> <li>(3) Increase the total amount of information downloaded at <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a></li> </ol>
<b>Format</b>	Journal and banner advertisements
<b>Distribution</b>	<p>The 2006 Emerging Solutions in Pain Awareness Campaign will include, but is not limited to:</p> <ol style="list-style-type: none"> <li>(1) Journal advertisements in <i>Practical Pain Management Journal</i></li> <li>(2) Banner advertisements at select professional pain management organization web sites</li> </ol>
<b>R qu st for Sponsor Support</b>	<p>Medical Learning Solutions will coordinate the Emerging Solution in Pain Awareness Campaign through the means of distribution outlined above.</p> <p>As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.</p>
<b>Total Budget:</b>	\$61,500



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Proposal Number: 06-003  
Date: November 28, 2005

**2006 Emerging Solutions in Pain Awareness Campaign**  
**Proposed Budget**  
November 28, 2005

<b>Cost Summary</b>	
Approximate Total, Direct Expenses	\$ 45,000
Total, Indirect Expenses	\$ 16,500
<b>Development and Implementation of the 2006 Emerging Solutions in Pain Awareness Campaign</b>	<b>\$ 61,500</b>

<b>Detailed Budget Itemization</b>	
<b>Direct Expenses, Approximate</b>	
<b>Journal advertisements, 12 months</b> Four-color, full-page advertising series in selected pain management journals	\$ 40,200
<b>Banner advertisements, 6 months</b> Advertising campaign at select professional organization web sites, to occur in conjunction with annual congresses and association meetings	\$ 4,200
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$ 600
<b>Approximate Total, Direct Expenses</b>	<b>\$ 45,000</b>

<b>Indirect Expenses</b>	
<b>Graphic design / production services</b>	\$ 8,750
<b>Medical / scientific services</b>	\$ 2,000
<b>Administrative and accounting fees</b>	\$ 750
<b>Project management</b>	\$ 5,000
<b>Total, Indirect Expenses</b>	<b>\$ 16,500</b>



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## *Program Summary*

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- Program Title** The Emerging Solutions in Pain Accredited Article Series
- Program Overview** Medical Learning Solutions is proposing to develop and produce an accredited series of eight journal articles, directed toward physicians, pharmacists, nurses and other health care professionals who are involved in the care of patients with chronic pain. This series of accredited articles will be initially published in the *Practical Pain Management Journal*; all articles will be available for credit online at the Emerging Solutions in Pain web site, as well.
- CE Provider** Based on the need to educate clinicians in the assessment and treatment of chronic pain patients who may be at risk for abuse, addiction and diversion, the The Emerging Solutions in Pain Accredited Article Series will be accredited by a third party CE vendor of our choice.
- All articles in the Accredited Article Series will be accredited for:
- CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each activity will be approved for a maximum of one hour of category 1 credit toward the AMA Physician's Recognition Award.
  - CPE credit for pharmacists by the Accreditation Council for Pharmacy Education. Each activity will be approved for a maximum of 1.0 credit hour (0.1 CEU) for Continuing Pharmacy Education
  - CNE credit for nurses. Each activity will be approved for a maximum of 1.0 Contact Hours.
- Int nded Audience** The primary audience of The Emerging Solutions in Pain Accredited Article Series includes physicians, pharmacists, nurses and other health care professionals who provide care to patients with pain.
- Program Objectives** The purpose of The Emerging Solutions in Pain Accredited Article Series is to educate clinicians on key topics relating to the Emerging Solutions in Pain initiatives. These topics may include, but are not limited to, the following:
- (1) Assessing functionality in patients prescribed opioids for chronic pain
  - (2) Urine drug testing and other methods for monitoring patients who are prescribed opioids
  - (3) Determining relative risk of opioid abuse
  - (4) Issues relating to drug testing in patients who are prescribed opioids
  - (5) Standards of care in pain management
  - (6) The importance of interdisciplinary teams in effective pain management
  - (7) Neurobiology of addiction
  - (8) Legal issues associated with the prescription of opioids





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## *Program Summary*

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<b>Format</b>	A series of eight four-page accredited articles in the <i>Practical Pain Management Journal</i>
<b>Post-Activity Feedback</b>	<p>Course evaluation forms will be required of all participants who seek to receive continuing education credit. Medical Learning Solutions will work with the third party CE vendor to summarize the information collected from these forms in a formal report to evaluate program effectiveness.</p> <p>Participants will evaluate the following as excellent, good, fair or poor:</p> <ol style="list-style-type: none"> <li>(1) Overall content</li> <li>(2) Faculty teaching effectiveness</li> <li>(3) Format</li> </ol> <p>Participants will also respond to the following questions:</p> <ol style="list-style-type: none"> <li>(1) How well did the program achieve its educational objectives?</li> <li>(2) Do you feel the program material was useful and practice-oriented?</li> <li>(3) Do you feel that the information provided in this educational activity will aid in improving patient care in your practice?</li> <li>(4) Do you feel that fair balance was maintained for all therapeutic options?</li> <li>(5) Would you participate in future educational activities?</li> </ol>
<b>Distribution</b>	Medical Learning Solutions and the third party CE vendor will announce and promote The Emerging Solutions in Pain Accredited Article Series primarily through advertisement at the Emerging Solutions in Pain web site.
<b>Request for Sponsor Support</b>	As a supplement to these primary methods, Medical Learning Solutions and the third party CE vendor may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.
<b>Total Budget:</b>	\$304,841





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Proposal Number: 06-003

Date: November 28, 2005

### Emerging Solutions in Pain Accredited Journal Article Series

A Series of 4-Page Articles Inserted in *Practical Pain Management Journal* and Posted  
Online at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com)

November 28, 2005

<b>Program Parameters</b>	
Number of 2006 issues	8
Total 2006 articles	8
Pages per article	4
Circulation per article	39,000

<b>Cost Summary</b>			
	One-Time Charges	Per Article Costs	Total, Eight Article Series
Approximate Total, Direct Expenses; Development and Production	\$ -	\$ 27,000	\$ 216,000
Total, Indirect Expenses; Development and Production	\$ 2,000	\$ 10,855	\$ 86,841
Subtotal	\$ 2,000	\$ 37,855	\$ 302,841
<b>Cost of Eight Emerging Solutions in Pain Accredited Journal Article Series</b>			<b>\$ 304,841</b>

<b>Per Issue Cost</b>	<b>\$ 0.98</b>
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Proposal Number: 06-003

Date: November 28, 2005

## Emerging Solutions in Pain Accredited Journal Article Series

A Series of 4-Page Articles Inserted in *Practical Pain Management Journal* and Posted  
Online at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com)

November 28, 2005

### Detailed Budget Itemization

<b>Approximate Direct Expenses, Development and Production</b>			
	One-Time Charges	Per Article Costs	Total, Eight Article Series
Clinical expert honoraria		\$ 3,000	\$ 24,000
Insert page charges, <i>PPMJ</i> Four-page article printed on matte cover stock as journal insert		\$ 10,000	\$ 80,000
Accreditation of program for CME, CPE, CNE		\$ 8,000	\$ 64,000
Continuing Education participant certificates (estimate 750 certificates per program)		\$ 6,000	\$ 48,000
<b>Approximate Total, Direct Expenses, Development and Production</b>	\$ -	\$ 27,000	\$ 216,000

<b>Indirect Expenses, Development and Production</b>			
	One-Time Charges	Per Article Costs	Total, Eight Article Series
<b>Program development</b> Includes coordination with clinical expert for receipt of article; coordination with accreditor, internal teams, <i>PPMJ</i> staff		\$ 1,200	\$ 9,600
<b>Medical services</b> Includes development of supporting verbiage (needs assessment, objectives, etc.) and self-assessment; editorial services; fact-checking services; proofreading		\$ 2,400	\$ 19,200
<b>Production services</b> Includes layout and typesetting of articles, supporting web pages for online posting		\$ 275	\$ 2,200
<b>Programming of finished monograph for Web-posting, archiving</b>		\$ 950	\$ 7,600
<b>Database creation, management</b>	\$ 2,000	\$ -	\$ -
<b>Administrative and accounting fees</b>		\$ 2,566	\$ 20,528
<b>Project management</b>		\$ 3,464	\$ 27,713
<b>Total, Indirect Expenses, Development and Production</b>	\$ 2,000	\$ 10,855	\$ 86,841



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## **Grant Request Part B: Live Emerging Solutions in Pain Educational Events and Activities**

### **Program Overview: Summary of Work Completed in 2005**

#### **1. ESP MEET THE EXPERTS BOOTH**

Another key Emerging Solutions in Pain initiative for 2005 is the ESP Meet the Experts exhibit booth, which is an informational and interactive exhibit booth that features mini-presentations by leading experts in pain and addiction medicine at select national healthcare association conferences. The goals of the Meet the Expert booth are several-fold:

1. Introduce the Emerging Solutions in Pain initiative to clinicians attending the meeting
2. Distribute ESP resources to clinicians, including the Emerging Solutions in Pain Tool Kit CD-ROM and Mini-Disc Publication
3. Provide clinicians with an opportunity to meet with national leaders in the field of pain management, in an intimate setting designed to foster interaction and discussion
4. Capture clinical expert presentations for video replay at the Emerging Solutions in Pain web site
5. Allow clinicians to explore the Emerging Solutions in Pain web site and the Tool Kit CD-ROM through interactive kiosks
6. Make clinicians aware that new and innovative resources are being added to the ESP web site on a continuing basis

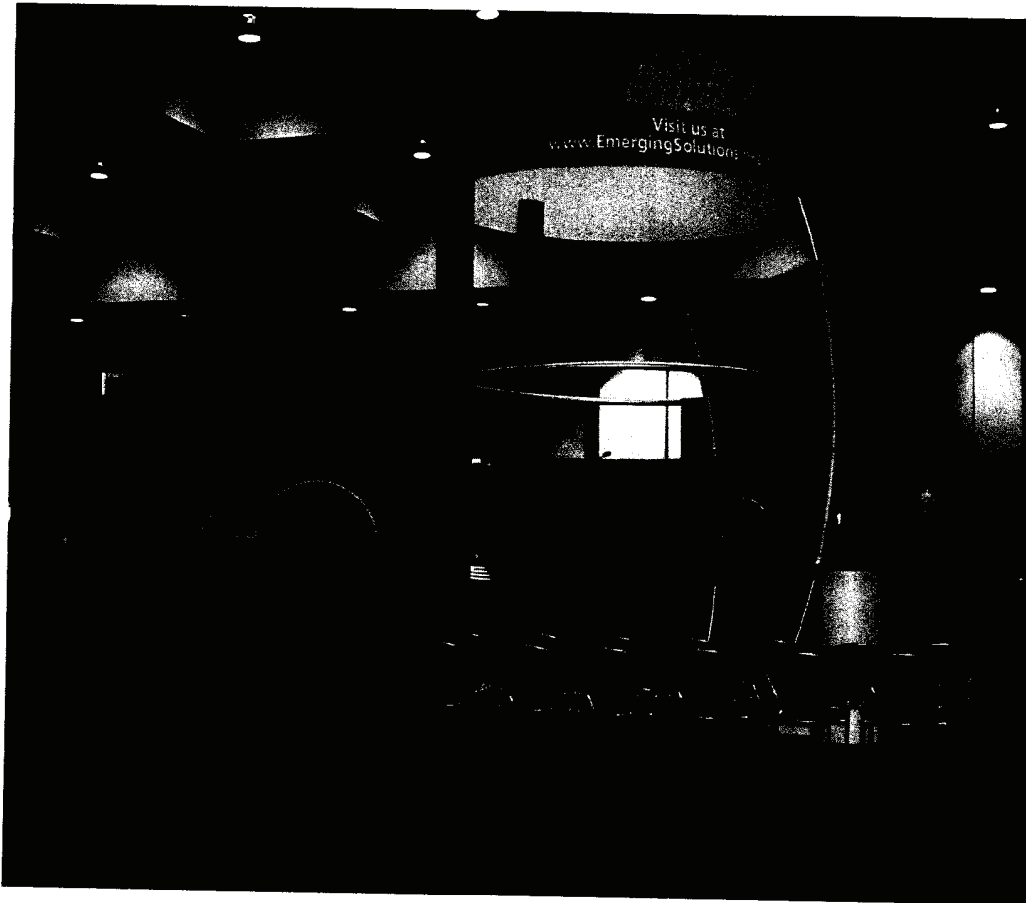
Through 2005, the Meet the Expert Booth has disseminated Emerging Solutions in Pain information and resources to clinicians at multiple meetings:

<b>Meeting</b>	<b>Date</b>	<b>Location</b>
AAPM	February, 2005	Palm Springs, CA
APS	March, 2005	Boston, MA
ASAM	April, 2005	Dallas, TX
AAFP	September, 2005	San Francisco, CA
AAPM&R	October, 2005	Philadelphia, PA



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## **Grant Request Part B: Live Emerging Solutions in Pain Educational Events and Activities**



### **2. THE ESP RESPECT (RESPONSIBLE PAIN EDUCATION CAN BE THERAPEUTIC) MEETING SERIES**

This accredited series of regional meetings is directed toward physicians, pharmacists, nurses, and other allied health care professionals who provide care to patients with chronic pain. The RESPECT meetings focus on the role of opioids in pain management, concerns over addiction, and the potential for diversion. One of the goals of this series is to educate clinicians on resources that are available within their own community for building interdisciplinary teams and networks to improve the quality of care for patients with chronic pain. As such, these programs are accredited for physicians, pharmacists and nurses; topics addressed include:

1. Standards of care for determining a patient's treatment plan
2. Interdisciplinary team approaches to pain management



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## ***Grant Request Part B: Live Emerging Solutions in Pain Educational Events and Activities***

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### 3. Two – three case studies of patients in the actual community

Each meeting participant receives a RESPECT binder with all slides presented in the program, as well as tools and information specific to the treatment of patients with pain in the local community. Resources in this binder include:

1. The Emerging Solutions in Pain Tool Kit CD-ROM
2. The American Pain Foundation TARGET Chronic Pain Card
3. Opioid Risk Tool (both clinician and patient forms)
4. The Hamilton Rating Scale for Depression
5. Return Visit Clinician Checklist and Patient Questionnaire
6. Internet resources, organized by:
  - a. Federal government resources
  - b. State government resources
  - c. Legal resources
  - d. Pain management resources
  - e. Professional Associations
  - f. Online Continuing Education (CE) resources
7. State-specific information from the state medical board(s)

The faculty for each RESPECT meeting is composed of two nationally-known faculty and two to three regional speakers, thus creating a dynamic presentation that addresses challenges associated with pain management on both a national and regional level.

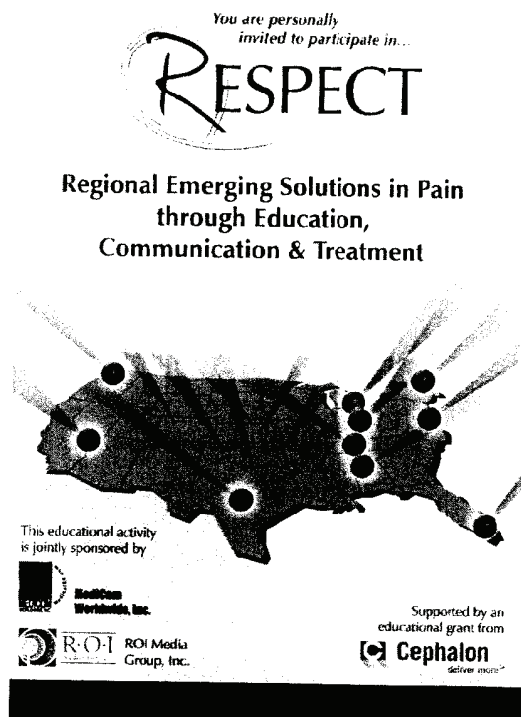
To date, there have been seven RESPECT meetings involving 47 physicians, 113 pharmacists, 72 nurses and 38 other allied health care specialists.



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## **Grant Request Part B: Live Emerging Solutions in Pain Educational Events and Activities**

### **Exhibit B-1**



### **Program Overview: Proposed 2006 Activities**

The following activities are recommended as the Live Emerging Solutions in Pain Educational Events and Activities in 2006.

1. Continuance of the Meet the Expert exhibit booth at select, larger association meetings and expansion of the Meet the Expert mini-booth at smaller association meetings
2. Recreation of the RESPECT meeting series to focus on the provision of trained Emerging Solutions in Pain faculty to regional and local meetings of clinician associations, grand rounds programs and other similar venues
3. Adaptation of the current RESPECT meeting content to focus on the educational needs of single-clinician groups at regional and local meetings of clinician associations



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Proposal Number: 06-003  
Date: November 28, 2005

**Emerging Solutions in Pain**  
**Summary of Proposed Budget, Grant Request Part B**  
*Live Emerging Solutions in Pain Educational Events and Activities*  
November 28, 2005

<b>Cost Summary</b>	
<b>Meet the Experts Booth</b>	
Approximate Total, Direct Costs	\$ 380,150
Indirect Costs	\$ 208,290
Cost of the 2006 Meet the Expert Booth Series	\$ 588,440
<b>RESPECT Meetings</b>	
Approximate Total, Direct Costs	\$ 170,950
Indirect Costs	\$ 204,616
Cost of a 20-Activity RESPECT Meeting Series	\$ 375,566
<b>Total Budget, 2006 Live Emerging Solutions in Pain Educational Events and Activities</b>	<b>\$ 964,006</b>

Approval Signature \_\_\_\_\_

Date \_\_\_\_\_

**Note: no work may begin until Medical Learning Solutions receives, via email or fax, this approval with signature and date**





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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain Meet the Experts Booth
<b>Program Overview</b>	<p>Medical Learning Solutions is proposing to continue utilizing the Meet the Experts Booth as an informational and interactive display for educating clinicians in the Emerging Solutions in Pain initiatives at national congresses and association meetings. In 2006, Medical Learning Solutions is proposing to tailor Booth activities to the size and specific purpose of the congress or association. Thus, at larger meetings, the full Meet the Expert Booth will be utilized, while a smaller Emerging Solutions in Pain Booth will be displayed at smaller congress and association meetings.</p> <p>Functionality for the full-size Meet the Expert Booth will include a seating area for meeting attendees to interact with Emerging Solutions in Pain clinical experts; computer terminals featuring interactive displays highlighting the Emerging Solutions in Pain initiatives, membership registration for the Emerging Solutions in Pain Web Site, and the Emerging Solutions in Pain Tool Kit. The smaller Emerging Solutions in Pain Booth will focus on interactive displays of the Tool Kit and video highlights of previous Meet the Expert presentations; membership registration; and distribution of the Emerging Solutions in Pain Tool Kit.</p>
<b>Intended Audience</b>	The primary audience of the Emerging Solutions in Pain Meet the Experts Booth will be physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain and who attend selected national association meetings and congresses. Currently suggested meetings include the 2006 meetings of the AAPM, AAPM&R, AANP, AMCP and ASAM.
<b>Program Objectives</b>	<p>The purpose of the Emerging Solutions in Pain Meet the Expert Booth is to disseminate information concerning the Emerging Solutions in Pain initiative to clinicians practicing in the field of pain management, and to educate those clinicians on the assessment and monitoring of pain patients, and on good practice management techniques. Clinicians visiting the booth will have opportunities to:</p> <ol style="list-style-type: none"> <li>(1) Interact with Emerging Solutions in Pain clinical experts in small discussion groups, focusing on tools and strategies that will contribute to a proper balance of pain control and abuse/diversion minimization (full-size Meet the Expert Booth only)</li> <li>(2) On computer terminals, view multi-media, interactive programs highlighting the issues associated with minimization of abuse, addiction and diversion, the Emerging Solutions in Pain Tool Kit and associated case studies</li> <li>(3) Receive copies of the Emerging Solutions in Pain Tool Kit CD-ROM and other support materials, such as the Mini-Disc Publication</li> <li>(4) Gain exposure to the resources available at the Emerging Solutions in Pain Web Site, and register as a "member", thereby expediting their ability to access online resources</li> </ol>
<b>Format</b>	An interactive meeting booth, to be presented at national association meetings and congresses. The full-size Meet the Expert Booth will feature live peer-to-peer interactions with Emerging Solutions in Pain clinical experts, as well as interactive, multimedia programs that highlight the Emerging Solutions in Pain initiatives. The smaller Emerging Solutions in Pain Booth will focus on educating clinicians in the availability of the Emerging Solutions in Pain initiatives.



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## *Program Summary*

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### **Distribution**

The Emerging Solutions in Pain Meet the Expert Booth will be available at selected national association meetings and congresses; meetings identified to date include the AAPM, AAPM&R, AANP, AMCP and ASAM. The announcement of the Booth will be made via direct mail to registered meeting attendees and members, and via journal and/or banner advertisements. Information at the Booth will be provided by Emerging Solutions in Pain clinical experts and by Medical Learning Solutions staff members.

### **Request for Sponsor Support**

Medical Learning Solutions is promoting the Emerging Solutions in Pain Meet the Experts Booth through a variety of methods, including direct mail, publication of a multimedia Mini-Disc, and journal and banner advertisements.

As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely as a supplement to MLS' primary methods of announcement and promotion.

**Total Budget:** \$588,440



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Proposal Number: 06-003

Date: November 28, 2005

**2006 Emerging Solutions in Pain Exhibition Booth Series**  
***Proposed Budget***  
November 28, 2005

<b><i>Program Parameters</i></b>	
Number of Exhibitions of the Full-Size Meet the Expert Booth	2
Number of Exhibitions of the Smaller Emerging Solutions in Pain Booth	3

<b><i>Cost Summary</i></b>		
	Per Meeting	Total
One-Time Approximate Direct Expenses	\$ -	\$ 47,000
Approximate Total, Direct Expenses: Full-Size Booth (AAPM, AAPM&R)	\$ 111,570	\$ 193,500
Approximate Total, Direct Expenses: Mini ESP Booth (ASAM, AANP, AMCP)	\$ 46,550	\$ 139,650
Total, Indirect Expenses	\$ 64,598	\$ 208,290
<b>Total Cost of the 2006 Emerging Solutions in Pain Exhibition Booth Series</b>		<b>\$ 588,440</b>



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Proposal Number: 06-003

Date: November 28, 2005

## 2006 Emerging Solutions in Pain Exhibition Booth Series

### *Proposed Budget*

November 28, 2005

#### *Detailed Budget Itemization*

<b>Approximate Total, Direct Expenses</b>		
<b>One-Tim Approximate Direct Expenses</b>		
	Per Meeting	Total
Update of existing mini-booth; new graphic panels for full-size booth		\$ 15,000
Booth give-aways		\$ 30,000
Miscellaneous (non-fulfillment shipping, faxes, etc.)		\$ 2,000
<i>Subtotal, One-Time Approximate Direct Expenses</i>		<i>\$ 47,000</i>
<b>Full-Size Booth (AAPM, AAPM&amp;R)</b>		
		<i>2 meetings total</i>
Exhibit space (includes liability insurance)	\$ 15,400	\$ 30,800
Booth set-up/tear-down (floor plan, shop prep, installation and dismantling including labor supervision, travel)	\$ 25,720	\$ 51,440
Equipment rental (computer units, plasma screen, switcher unit, audio w/ lav mic, electrical, telecommunication links, chairs, carpeting, etc.)	\$ 10,590	\$ 21,180
Shipping of booth to AAPM meeting site only	\$ 8,820	\$ 8,820
Shipping of booth to AAPM&R meeting site only (note additional shipping charges for Hawaii location of AAPM&R)	\$ 20,820	\$ 20,820
Shipping of supplies (mini-discs, Tool Kits, etc) to meeting site - delivery to booth charges	\$ 2,200	\$ 4,400
Badge Reader System (3 units)	\$ 770	\$ 1,540
Booth advertisement		
Advertisement in meeting catalog/publication (full page, 4/c)	\$ 2,925	\$ 5,850
Booth posters, printing	\$ 825	\$ 1,650
KOL expenses: two KOL faculty		
Honoraria	\$ 12,000	\$ 24,000
Travel: air, hotel, ground, OOP	\$ 4,300	\$ 8,600
ROI expenses: three ROI staff		
Travel: air, hotel, ground, OOP	\$ 6,900	\$ 13,800
Exhibitor registration	\$ 300	\$ 600
<i>Subtotal, Approximate Direct Expenses for Full-Size Booth</i>		<i>\$ 111,570</i>
		<i>\$ 193,500</i>



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Proposal Number: 06-003

Date: November 28, 2005

**2006 Emerging Solutions in Pain Exhibition Booth Series**  
***Proposed Budget***  
November 28, 2005

*Detailed Budget Itemization*

<b><i>Approximate Total, Direct Expenses (continued)</i></b>		
	Per Meeting	Total
<b>Mini Booth (AANP, AMCP, ASAM)</b>		<i>3 meetings total</i>
Exhibit space (includes liability insurance)	\$ 1,430	\$ 4,290
Booth Rental for 8X10 Space	\$ 3,850	\$ 11,550
Booth set-up/tear-down (floor plan, shop prep, installation and dismantling including labor supervision, travel)	\$ 15,950	\$ 47,850
Equipment rental (computer units, plasma screen, switcher unit, audio w/ lav mic, electrical, telecommunication links, chairs, carpeting, etc.)	\$ 6,475	\$ 19,425
Shipping of booth to meeting site	\$ 7,975	\$ 23,925
Shipping of supplies (mini-discs, Tool Kits, etc) to meeting site - delivery to booth charges	\$ 2,200	\$ 6,600
Booth advertisement		
Advertisement in meeting catalog/publication	\$ 2,310	\$ 6,930
Booth posters, printing	\$ 660	\$ 1,980
ROI expenses: three ROI staff		
Travel: air, hotel, ground, OOP	\$ 5,500	\$ 16,500
Exhibitor registration	\$ 200	\$ 600
<b><i>Subtotal, Approximate Direct Expenses for Mini Booth</i></b>	<b>\$ 46,550</b>	<b>\$ 139,650</b>



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Proposal Number: 06-003

Date: November 28, 2005

**2006 Emerging Solutions in Pain Exhibition Booth Series**  
***Proposed Budget***  
November 28, 2005

***Detailed Budget Itemization***

<b><i>Total, Indirect Expenses</i></b>		
	Per Meeting	Total
<b>Medical / scientific services</b> Includes development of content for meeting advertisements; ; coordination of presentation content with ESP KOLs	\$ 4,000	\$ 20,000
<b>Graphic design / production services</b> Includes development of display graphics for booth panels, graphics for interactive booth displays; graphic design, typesetting and layout of booth posters and advertisements (direct mail plus meeting catalog); proofreading; coordination with print vendors; etc.	\$ 2,000	\$ 10,000
<b>Conference management services</b> staffing booth during meeting; coordination with KOLs pre-meeting, post-meeting and during meeting; coordination with conference vendors, coordination of booth advertising; etc.		
<b>Conference management services: Full-Size Booth (2 total)</b>	\$ 26,700	\$ 53,400
<b>Conference management services: Mini Booth (3 total)</b>	\$ 17,300	\$ 51,900
<b>Administrative and accounting fees</b>	\$ 5,460	\$ 27,301
<b>Project management</b>	\$ 9,138	\$ 45,689
<b><i>Total, Indirect Expenses</i></b>	<b>\$ 64,598</b>	<b>\$ 208,290</b>



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## *Program Summary*

<b>Program Title</b>	The Emerging Solutions in Pain RESPECT Meeting Series
<b>Program Overview</b>	<p>Medical Learning Solutions is proposing to adapt the 2005 RESPECT meetings into a new series that focuses on the provision of trained Emerging Solutions in Pain faculty to regional and local meetings of clinician associations, grand rounds programs and other similar venues. The 2006 RESPECT Meeting Series will therefore focus on providing practical clinical information via an accredited lecture series to health care professionals practicing in local clinics, hospitals and office settings.</p> <p>In this series, Medical Learning Solutions is proposing to update the 2005 RESPECT Meeting slide modules with information that will be appropriate for smaller groups of clinicians, such as will attend local and regional association meetings and grand rounds presentations. Select Emerging Solutions in Pain faculty who express interest and availability will then be trained remotely via teleconference in the new data; these individuals will form a RESPECT Meeting Speakers' Bureau. Medical Learning Solutions will work with local and regional association meetings and hospitals hosting grand rounds presentations to identify meetings of clinicians which will benefit from an accredited presentation focusing on Emerging Solutions in Pain/RESPECT Meeting topics. After a need has been identified, Medical Learning Solutions will coordinate all logistical arrangements for the presentation with a trained, available Faculty member.</p>
<b>CE Provider</b>	<p>Based on the need to educate clinicians in the assessment and treatment of chronic pain patients who may be at risk for abuse, addiction and diversion, The Emerging Solutions in Pain RESPECT Meeting Series will be accredited by a third party CE vendor of our choice.</p> <p>The Meeting Series will be accredited for:</p> <ul style="list-style-type: none"> <li>• CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each activity will be approved for a maximum of one hour of category 1 credit toward the AMA Physician's Recognition Award.</li> <li>• CPE credit for pharmacists by the Accreditation Council for Pharmacy Education. Each activity will be approved for a maximum of 1.0 credit hour (0.1 CEU) for Continuing Pharmacy Education</li> <li>• CNE credit for nurses. Each activity will be approved for a maximum of 1.0 Contact Hours.</li> </ul>
<b>Intend d Audience</b>	The primary audience of The Emerging Solutions in Pain RESPECT Meeting Series includes clinicians who provide care to patients with pain. These clinicians will include physicians, pharmacists and nurses, but may be extended to other clinical and non-clinical members of a multi-disciplinary treatment team, such as social workers, case managers, etc.





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## *Program Summary*

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- Program Objectives** The purpose of the RESPECT Meeting Series is to educate clinicians on the key tenets of the Emerging Solutions in Pain initiative, focusing on the role of appropriate assessment and monitoring techniques, and good practice management strategies, in achieving effective interactions between members of the treatment team. In addition, other topics may be included, based upon recommendations made by the Emerging Solutions in Pain Faculty Advisory Committee.
- Format** A series of live, peer-to-peer activities scheduled in conjunction with local and regional association meetings and at hospital or clinic-based grand rounds programs throughout the United States. This proposal is for 20 RESPECT meetings.
- Post-Activity Feedback** Course evaluation forms will be required of all participants who seek to receive continuing education credit. Medical Learning Solutions will work with the third party CE vendor to summarize the information collected from these forms in a formal report to evaluate program effectiveness.
- Participants will evaluate the following as excellent, good, fair or poor:
- (1) Overall content
  - (2) Faculty teaching effectiveness
  - (3) Format
  - (4) Audio/visual
- Participants will also respond to the following questions:
- (1) How well did the program achieve its educational objectives?
  - (2) Do you feel the program material was useful and practice-oriented?
  - (3) Do you feel that the information provided in this educational activity will aid in improving patient care in your practice?
  - (4) Do you feel that fair balance was maintained for all therapeutic options?
  - (5) Would you participate in future educational activities?
- Distribution** Medical Learning Solutions and the third party CE vendor will announce and promote The Emerging Solutions in Pain RESPECT Meeting Series primarily through arrangement with the local/regional association hosting the meeting; or the hospital sponsoring the grand rounds presentation. Medical Learning Solutions will also advertise availability of these meetings via advertisement on the Emerging Solutions in Pain web site.
- Request for Sponsor Support** As a supplement to these primary methods, Medical Learning Solutions and the third party CE vendor may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.
- Total Budget:** \$375,566



101 Washington St, Suite 110  
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Proposal Number: 06-003  
Date: November 28, 2005

**Emerging Solutions in Pain 2006 RESPECT Meeting Series**  
***Projected Budget Estimate***

November 28, 2005

<b><i>Program Parameters</i></b>	
Number of regional association symposia	10
Faculty presenter per activity	1
Approximate number, health care professional attendees per meeting	30
Direct mail invitations to health care professionals	150

<b><i>Cost Summary</i></b>		
	One-time only costs	Each group of 10 meetings
Approximate Total, Direct Meeting Series Expenses	\$ -	\$ 75,725
Total, Indirect Meeting Series Expenses	\$ 47,663	\$ 64,726
Approximate Total, Direct Meeting Support Expenses	\$ 19,500	\$ -
Total, Indirect Meeting Support Expenses	\$ 27,500	\$ -
Subtotal, one-time only costs	\$ 94,663	\$ -
Subtotal, 20-meeting RESPECT series	\$ -	\$ 280,903
<b>Cost of 2006 Emerging Solutions in Pain 20-Meeting RESPECT Series</b>	<b>\$</b>	<b>375,566</b>



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Proposal Number: 06-003  
Date: November 28, 2005

**Emerging Solutions in Pain 2006 RESPECT Meeting Series**  
**Projected Budget Estimate**  
November 28, 2005

*Detailed Budget Itemization*

<b>Direct Meeting Expenses, Approximate</b>		
	One-time only costs	Each group of 10 meetings
<b>Direct mail invitations, mail services, postage</b>	\$ -	\$ 4,725
Personalized invitations to be mailed to every potential participant; includes printing, assembly, mail services and postage. Postage estimated at \$0.37 per direct mail piece		
<b>Direct mail list purchase</b>	\$ -	\$ -
<b>Print materials</b>	\$ -	\$ 3,500
Includes printing of shell materials for adaptation and use in individualized symposia kits for every symposium; kits to include accreditation information, speaker biographical and disclosure information, agenda, reference materials and handout materials, where appropriate		
<b>Speaker honoraria</b>	\$ -	\$ 25,000
<b>Speaker travel (air, OOP, hotel)</b>	\$ -	\$ 12,000
<b>Ground transportation</b>	\$ -	\$ 2,000
<b>Catering</b>	\$ -	\$ 15,000
<b>Audio/visual services</b>	\$ -	\$ 5,000
<b>Onsite CME coordination</b>	\$ -	\$ 7,500
<b>Shipping/Fed Ex</b>	\$ -	\$ 1,000
<b>Approximate Total, Direct Meeting Expenses</b>	\$ -	\$ 75,725

<b>Indirect Meeting Expenses</b>		
	One-time only costs	Each group of 10 meetings
<b>Program development</b>	\$ 45,000	\$ -
Includes all labor associated with initial program set-up and development, including creation of text for print support materials, graphic design, typesetting and layout of all support materials, and development and creation of final program appearance		
<b>Medical Services</b>	\$ 18,000	\$ 20,000
Includes all labor associated with content of each symposium, including identification and production of resources specific for each region and clinicians in each association; review and coordination of content with faculty		
<b>Meeting management</b>		\$ 18,000
Includes coordination with association for date of symposium and all meeting-related logistical details; coordination with faculty for dates, travel and all other program details		
<b>Accreditation of program for CME, CPE, CNE</b>	\$ 15,000	\$ -
<b>Continuing Education participant certificates</b>		\$ 4,500
<b>Administrative and accounting fees</b>	\$ 6,240	\$ 9,458
<b>Project management</b>	\$ 8,423	\$ 12,768
<b>Total, Indirect Meeting Expenses</b>	\$ 47,663	\$ 64,726



101 Washington St, Suite 110  
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Proposal Number: 06-003

Date: November 28, 2005

# **Emerging Solutions in Pain 2006 RESPECT Meeting Series** **Projected Budget Estimate**

November 28, 2005

## *Detailed Budget Itemization*

<b>Direct Meeting Support Expenses, Approximate</b>		
	One-time only costs	Each group of 10 meetings
<b>Slide module updates</b>		
Medical writing	\$ 8,500	\$ -
Speaker honoraria	\$ 3,500	\$ -
<b>Production of non-accredited video from one RESPECT meeting</b>		
Equipment rental	\$ 3,000	\$ -
Travel	\$ 4,500	\$ -
<b>Approximate Total, Direct Meeting Support Expenses</b>	<b>\$ 19,500</b>	<b>\$ -</b>

<b>Indirect Meeting Support Expenses</b>		
	One-time only costs	Each group of 10 meetings
<b>Slide module updates</b>		
Program development	\$ 2,300	\$ -
Medical services	\$ 7,950	\$ -
<b>Production of non-accredited video from one RESPECT meeting</b>		
Program development	\$ 1,775	\$ -
Editing, post production	\$ 9,975	\$ -
<b>Administrative and accounting fees</b>	<b>\$ 3,320</b>	<b>\$ -</b>
<b>Project management</b>	<b>\$ 4,480</b>	<b>\$ -</b>
<b>Total, Indirect Meeting Support Expenses</b>	<b>\$ 27,500</b>	<b>\$ -</b>



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## ***Grant Request Part C: Programs to Further Expand the Reach of the Emerging Solutions in Pain Educational Events and Activities***

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### ***Program Overview: Proposed 2006 Activities***

The following activities are recommended as a series of programs that will further expand the reach of the Emerging Solutions in Pain Educational Events and Activities in 2006.

1. Development and implementation of a full-day seminar program, to be held for clinical attendees of a national congress, focusing on the intersection of pain management and addiction medicine
2. Additional RESPECT meetings, held at regional and local meetings of clinician associations, grand rounds programs and other similar venues

### **1. The Emerging Solutions in Pain Full-Day Lecture Program**

The American Society for Addiction Medicine (ASAM) has historically held an accredited, full-day lecture one day prior to the convening of its annual meeting for those ASAM members attending the meeting. This lecture, known as the Common Threads program, has focused on topical issues relating to the convergence of pain and addiction medicine. For logistical reasons, this meeting will not be offered by ASAM to its members at the 2006 meeting. However, the educational need of these clinicians, to increase their knowledge and understanding of the pain management and the impact of addiction on effective pain therapy, continues to exist.

Medical Learning Solutions is therefore proposing to create an accredited full-day lecture program that will educate ASAM members on topics relevant to the Emerging Solutions in Pain initiatives. Through a series of presentations by Emerging Solutions in Pain faculty, this program will focus on a scientific and clinical evaluation of the fields of pain management and addiction, and will include relevant case studies for discussion and presentation.

### **2. The ESP RESPECT (RESponsible Pain Education Can be Therapeutic) Meeting Series**

The RESPECT Meeting Series has been described previously in the Grant Request Part B, in which a series of 20 RESEPT Meetings were proposed, to be held in conjunction with local and regional association meetings and grand rounds presentations. The recommendation for this portion of the Grant Request is for an additional 10 RESPECT meetings in this series. The additional 10 meetings will utilize the same program infrastructure, content and trained faculty as the first 20 meetings, thereby cost-effectively extending the reach of this portion of the 2006 Emerging Solutions in Pain initiative.



101 Washington St, Suite 110  
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Proposal Number: 06-003  
Date: November 28, 2005

**Emerging Solutions in Pain  
Summary of Proposed Budget, Grant Request Part C**

*Programs to Further Expand the Reach of the Emerging Solutions in Pain Educational  
Events and Activities*  
November 28, 2005

<b>Cost Summary</b>	
<b>Full-day ESP Symposium</b>	
Approximate Total, Direct Expenses	\$ 132,850
Indirect Expenses	\$ 108,600
Cost of One Full-Day ESP Symposium Held at the 2006 ASAM Meeting	\$ 241,450
<b>RESPECT Meeting Series Extension</b>	
Approximate Total, Direct Expenses	\$ 75,725
Indirect Expenses	\$ 64,726
Cost of 10-Program Extension of the 2006 RESPECT Meeting Series	\$ 140,451
<b>Total Budget, 2006 Programs to Further Expand the Reach of the Emerging Solutions in Pain Educational Events and Activities</b>	<b>\$ 381,901</b>

Approval Signature \_\_\_\_\_

Date \_\_\_\_\_

**Note: no work may begin until Medical Learning Solutions receives, via email or fax, this approval with signature and date**



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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain Accredited Full-Day Lecture Program
<b>Program Overview</b>	<p>Medical Learning Solutions is proposing to create an accredited full-day lecture program that will educate ASAM members on topics relevant to the Emerging Solutions in Pain initiatives. Through a series of presentations by Emerging Solutions in Pain faculty, this program will focus on a scientific and clinical evaluation of the fields of pain management and addiction, and will include relevant case studies for presentation and discussion.</p> <p>The core group of proposed faculty includes:</p> <ol style="list-style-type: none"> <li>(1) Howard Heit, MD, FACP, FASAM</li> <li>(2) Douglas Gourlay, MD, MSc, FRCPC</li> <li>(3) Seddon Savage, MD, FASAM</li> <li>(4) Steven Passik, PhD</li> </ol> <p>Other faculty will be recruited based upon recommendations by the core faculty. Specific lecture topics will be identified based upon a consensus of the core faculty, but may include topics such as:</p> <ol style="list-style-type: none"> <li>(1) Evaluating the risk of opioid abuse in the chronic pain patient</li> <li>(2) Pharmacologic therapies for the chronic pain patient with a history of drug abuse or addiction</li> <li>(3) Legal issues in prescribing opioids to the chronic pain patient</li> <li>(4) New pharmacologic agents for treating chronic pain patients</li> </ol>
<b>Intended Audience</b>	The primary audience of The Emerging Solutions in Pain Accredited Full-Day Lecture Program includes clinicians who provide care to patients with pain and who specialize in addiction medicine.
<b>Program Objectives</b>	The purpose of the Emerging Solutions in Pain Accredited Full-Day Lecture Program is to educate clinicians on topical issues relating to the convergence of pain and addiction medicine. In addition, other topics may be included, based upon recommendations made by the core faculty identified above and by the Emerging Solutions in Pain Faculty Advisory Committee.
<b>Format</b>	One full-day seminar program held one day prior to the Annual ASAM Conference, held in San Diego, California. This program will be comprised primarily as didactic lecture. An audience response system will also be utilized throughout the program to enhance audience participation and a more interactive experience.
<b>Activity Feedback</b>	<p>To help establish a return on education metric for this program, Medical Learning Solutions will develop with the moderator a series of opening questions that will utilize the audience response keypad system. These questions will gather basic audience demographics, educational understanding of content prior to the educational activity, ratings scales on specific clinical techniques, etc. This would occur during the introduction of the program, similar to a pre-test. Data received from this activity would be correlated to information gathered during the post-test, thereby establishing prior- vs post-program educational metrics.</p> <p>Course evaluation forms and a written post-test will be required of all participants who seek to receive continuing education credit. Medical Learning Solutions will</p>





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## *Program Summary*

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work with the third party CE vendor to summarize the information collected from these forms in a formal report to evaluate program effectiveness.

- (A) Participants will evaluate the following as excellent, good, fair or poor:
  - (1) Overall content
  - (2) Faculty teaching effectiveness
  - (3) Format
  - (4) Audio/visual
- (B) Participants will also respond to the following questions:
  - (1) How well did the program achieve its educational objectives?
  - (2) Do you feel the program material was useful and practice-oriented?
  - (3) Do you feel that the information provided in this educational activity will aid in improving patient care in your practice?
  - (4) Do you feel that fair balance was maintained for all therapeutic options?
  - (5) Would you participate in future educational activities?
- (C) Participants will also complete a post-test specific to the content topics, ACPE accreditation required.

### **CE Provider**

Based on the need to educate clinicians in the issues associated with treating chronic pain patients who may be at high risk for abuse, addiction or diversion of controlled substances, The Emerging Solutions in Pain Accredited Full-Day Lecture Program will be accredited by a third party CE vendor of our choice.

The Lecture Program will be accredited for:

- CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each activity will be approved for a maximum of seven hours of category 1 credit toward the AMA Physician's Recognition Award.
- CPE credit for pharmacists by the Accreditation Council for Pharmacy Education. Each activity will be approved for a maximum of 7.0 credit hours (0.7 CEU) for Continuing Pharmacy Education
- CNE credit for nurses. Each activity will be approved for a maximum of 7.0 Contact Hours.

### **Distribution**

Medical Learning Solutions and the third party CE vendor will announce and promote The Emerging Solutions in Pain Accredited Full-Day Lecture Program primarily through direct mail to ASAM members. Medical Learning Solutions will also advertise availability of this meeting via advertisement on the Emerging Solutions in Pain website.

### **Request for Sponsor Support**

As a supplement to these primary methods, Medical Learning Solutions and the third party CE vendor may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.

**Total Budget:** \$241,450



101 Washington St, Suite 110  
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Proposal Number: 06-003  
Date: November 28, 2005

**Emerging Solutions in Pain Full-Day Accredited Symposium**  
***Proposed Budget***  
November 28, 2005

***Program Description***

This proposed budget is for the development, production and management of a full-day CME-accredited stand-alone live event to coincide with the ASAM Annual Conference in San Diego on May 4, 2006. This program would support the Emerging Solutions in Pain mission of providing medical education in the area of pain management and the issues of misuse, abuse, and addiction.

<b><i>Program Parameters</i></b>	
Presenting faculty @ activity	6
Health care professional attendees @ meeting	250
Direct mail invitations to health care professionals per activity	5000

<b><i>Cost Summary</i></b>	
Approximate Total, Direct Expenses	\$ 132,850
Total, Indirect Expenses	\$ 108,600
<b>Cost of Emerging Solutions in Pain Full-Day Accredited Symposium</b>	<b>\$ 241,450</b>



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Morrisville, PA 19067

Proposal Number: 06-003  
Date: November 28, 2005

**Emerging Solutions in Pain Full-Day Accredited Symposium**  
**Proposed Budget**  
November 28, 2005

**Detailed Budget Itemization**

<b>Direct Expenses, Approximate</b>	
<b>Direct mail invitations, mail services, postage</b>	
Printing	\$ 2,700
Postage	\$ 1,950
Fax Blast	\$ 750
Email Blast	\$ 250
<b>Direct mail list purchase</b>	\$ 2,000
<b>Print materials</b>	
Printing meeting kits to include accreditation information, speaker biographical and disclosure information, agenda, handout materials, current journal articles by faculty, etc. and 4/c binder	\$ 4,500
Set design pieces (banners, podium signs, gobo, directional signage, etc.)	\$ 2,500
<b>Speaker honoraria (6 faculty members)</b>	\$ 20,000
<b>Speaker travel (air, OOP, hotel)</b>	\$ 11,550
<b>ROI staff travel</b>	\$ 5,600
<b>Ground transportation</b>	\$ 1,750
<b>Venue rental fee, service fees, etc.</b>	\$ 6,100
<b>Travel, site visit</b>	\$ 2,000
<b>Food &amp; Beverage (Continental Breakfast, Buffet Lunch, Afternoon Break for 250)</b>	\$ 24,000
<b>Audio/visual services</b>	\$ 14,000
<b>Audience response system</b>	\$ 10,000
<b>Accreditation of program for CME, CPE, CNE</b>	\$ 15,000
<b>Continuing Education participant certificates</b>	\$ 4,500
<b>Onsite CME coordination</b>	\$ 1,500
<b>Miscellaneous (non-fulfillment shipping, faxes, FedEx, etc.)</b>	\$ 2,200
<b>Approximate Total, Direct Expenses</b>	
	\$ 132,850

<b>Indirect Expenses</b>	
<b>Program development</b>	\$ 37,700
Includes all labor associated with initial program set-up and development, including creation of program content, text for print support materials, graphic design, typesetting and layout of all support materials, and development and creation of final program appearance	
<b>Medical and scientific writing</b>	\$ 12,100
<b>Site visit</b>	\$ 2,500
<b>Meeting coordination</b>	\$ 18,500
Includes faculty management, meeting logistics, travel and all other program details	
<b>Telephone recruitment</b>	\$ 8,500
<b>Onsite meeting management</b>	\$ 3,200
<b>Registration database development and management (includes online registration)</b>	\$ 1,500
<b>Administrative and accounting fees</b>	\$ 4,268
<b>Project management</b>	\$ 20,332
<b>Total, Indirect Expenses</b>	
	\$ 108,600

\* Tax and gratuity figures have not been included in this estimated budget



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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain RESPECT Meeting Series
<b>Program Overview</b>	<p>Medical Learning Solutions is proposing to adapt the 2005 RESPECT meetings into a new series that focuses on the provision of trained Emerging Solutions in Pain faculty to regional and local meetings of clinician associations, grand rounds programs and other similar venues. The 2006 RESPECT Meeting Series will therefore focus on providing practical clinical information via an accredited lecture series to health care professionals practicing in local clinics, hospitals and office settings.</p> <p>Medical Learning Solutions will work with local and regional association meetings and hospitals hosting grand rounds presentations to identify meetings of clinicians which will benefit from an accredited presentation focusing on Emerging Solutions in Pain/RESPECT Meeting topics. After a need has been identified, Medical Learning Solutions will coordinate all logistical arrangements for the presentation with a trained, available Faculty member.</p>
<b>CE Provider</b>	<p>Based on the need to educate clinicians in the assessment and treatment of chronic pain patients who may be at risk for abuse, addiction and diversion, The Emerging Solutions in Pain RESPECT Meeting Series will be accredited by a third party CE vendor of our choice.</p> <p>The Meeting Series will be accredited for:</p> <ul style="list-style-type: none"> <li>• CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each activity will be approved for a maximum of one hour of category 1 credit toward the AMA Physician's Recognition Award.</li> <li>• CPE credit for pharmacists by the Accreditation Council for Pharmacy Education. Each activity will be approved for a maximum of 1.0 credit hour (0.1 CEU) for Continuing Pharmacy Education</li> <li>• CNE credit for nurses. Each activity will be approved for a maximum of 1.0 Contact Hours.</li> </ul>
<b>Intended Audience</b>	The primary audience of The Emerging Solutions in Pain RESPECT Meeting Series includes clinicians who provide care to patients with pain. These clinicians will include physicians, pharmacists and nurses, but may be extended to other clinical and non-clinical members of a multi-disciplinary treatment team, such as social workers, case managers, etc.
<b>Program Objectives</b>	The purpose of the RESPECT Meeting Series is to educate clinicians on the key tenets of the Emerging Solutions in Pain initiative, focusing on the role of appropriate assessment and monitoring techniques, and good practice management strategies, in achieving effective interactions between members of the treatment team. In addition, other topics may be included, based upon



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## *Program Summary*

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recommendations made by the Emerging Solutions in Pain Faculty Advisory Committee.

### **Format**

A series of live, peer-to-peer activities scheduled in conjunction with local and regional association meetings and at hospital or clinic-based grand rounds programs throughout the United States. This proposal is for 10 RESPECT meetings.

### **Post-Activity Feedback**

Course evaluation forms will be required of all participants who seek to receive continuing education credit. Medical Learning Solutions will work with the third party CE vendor to summarize the information collected from these forms in a formal report to evaluate program effectiveness.

Participants will evaluate the following as excellent, good, fair or poor:

- (1) Overall content
- (2) Faculty teaching effectiveness
- (3) Format
- (4) Audio/visual

Participants will also respond to the following questions:

- (1) How well did the program achieve its educational objectives?
- (2) Do you feel the program material was useful and practice-oriented?
- (3) Do you feel that the information provided in this educational activity will aid in improving patient care in your practice?
- (4) Do you feel that fair balance was maintained for all therapeutic options?
- (5) Would you participate in future educational activities?

### **Distribution**

Medical Learning Solutions and the third party CE vendor will announce and promote The Emerging Solutions in Pain RESPECT Meeting Series primarily through arrangement with the local/regional association hosting the meeting; or the hospital sponsoring the grand rounds presentation. Medical Learning Solutions will also advertise availability of these meetings via advertisement on the Emerging Solutions in Pain web site.

### **Request for Sponsor Support**

As a supplement to these primary methods, Medical Learning Solutions and the third party CE vendor may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.

**Total Budget:** \$140,451



Proposal Number: 06-003

Date: November 28, 2005

101 Washington St, Suite 110  
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**Extension of 2006 Emerging Solutions in Pain RESPECT Meeting Series**  
**Projected Budget Estimate**

November 28, 2005

<b>Program Parameters</b>	
Number of regional association symposia	10
Faculty presenter per activity	1
Approximate number, health care professional attendees per meeting	30
Direct mail invitations to health care professionals	150

<b>Cost Summary</b>		
	One-time only costs	Each group of 10 meetings
Approximate Total, Direct Meeting Series Expenses	\$ -	\$ 75,725
Total, Indirect Meeting Series Expenses	\$ -	\$ 64,726
<b>Cost of 10-Meeting Extension of 2006 Emerging Solutions in Pain RESPECT Series</b>	<b>\$</b>	<b>140,451</b>



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Proposal Number: 06-003  
Date: November 28, 2005

**Extension of 2006 Emerging Solutions in Pain RESPECT Meeting Series**  
**Projected Budget Estimate**  
November 28, 2005

**Detailed Budget Itemization**

<b>Direct Meeting Expenses, Approximate</b>		
	One-time only costs	Each group of 10 meetings
<b>Direct mail invitations, mail services, postage</b>	\$ -	\$ 4,725
Personalized invitations to be mailed to every potential participant; includes printing, assembly, mail services and postage. Postage estimated at \$0.37 per direct mail piece		
<b>Direct mail list purchase</b>	\$ -	\$ -
<b>Print materials</b>	\$ -	\$ 3,500
Includes printing of shell materials for adaptation and use in individualized symposia kits for every symposium; kits to include accreditation information, speaker biographical and disclosure information, agenda, reference materials and handout materials, where appropriate		
<b>Speaker honoraria</b>	\$ -	\$ 25,000
<b>Speaker travel (air, OOP, hotel)</b>	\$ -	\$ 12,000
<b>Ground transportation</b>	\$ -	\$ 2,000
<b>Catering</b>	\$ -	\$ 15,000
<b>Audio/visual services</b>	\$ -	\$ 5,000
<b>Onsite CME coordination</b>	\$ -	\$ 7,500
<b>Shipping/Fed Ex</b>	\$ -	\$ 1,000
<b>Approximate Total, Direct Meeting Expenses</b>	\$ -	\$ 75,725

<b>Indirect Meeting Expenses</b>		
	One-time only costs	Each group of 10 meetings
<b>Program development</b>	\$ -	\$ -
Includes all labor associated with initial program set-up and development, including creation of text for print support materials, graphic design, typesetting and layout of all support materials, and development and creation of final program appearance		
<b>Medical Services</b>	\$ -	\$ 20,000
Includes all labor associated with content of each symposium, including identification and production of resources specific for each region and clinicians in each association; review and coordination of content with faculty		
<b>Meeting management</b>		\$ 18,000
Includes coordination with association for date of symposium and all meeting-related logistical details; coordination with faculty for dates, travel and all other program details		
<b>Accreditation of program for CME, CPE, CNE</b>	\$ -	\$ -
<b>Continuing Education participant certificates</b>		\$ 4,500
<b>Administrative and accounting fees</b>	\$ -	\$ 9,458
<b>Project management</b>	\$ -	\$ 12,768
<b>Total, Indirect Meeting Expenses</b>	\$ -	\$ 64,726



**EDUCATIONAL GRANT DRAFT REQUEST**



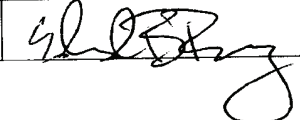
The attached material has been reviewed and is approved:

Payee: Medical Learning Solutions, Inc.

Amount: \$964,006

Type of Program: *Emerging Solutions in Pain* Grant Request part A

Submitted for Review: November 30, 2005

DEPARTMENT	NAME	SIGNATURE	DATE
Scientific Communications	Rod Hughes		11-30-05
Medical Affairs	Kiumars Vadieli		11/30/05
Legal & Government	Ed Berg		11/30/05

Return to: Candice McCarthy 35663 – Scientific Communications



## MEDICAL EDUCATION AGREEMENT

Cephalon, Inc.  
41 Moores Road  
PO. Box 4011  
Frazer, PA 19355

As a condition of Cephalon, Inc.'s contribution of funds to support an independent medical education program (with or without CME credits), the Scientific and Educational Activity provider agrees to the following terms and conditions:

This Agreement ("Agreement") is entered into as of December 1, 2005 by and between Cephalon, Inc. ("Cephalon") and Medical Learning Solutions ("Provider") regarding a medical education program sponsored by Cephalon entitled "Emerging Solutions in Pain" Part A with ongoing activities and development throughout calendar year 2006. The parties' mutual objectives are to provide a balanced, independent, scientifically rigorous program to promote the education of attendees.

1. Statement of Purpose. This program is for scientific and educational purposes only and not to promote any commercial drug products.

2. Control of Content and Selection of Presenters and Moderators. The provider is ultimately responsible for the control of content and selection of presenters and moderators. Cephalon or its agents may respond to requests initiated by the provider for suggestions of presenters or sources of possible presenters. Cephalon will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Cephalon and speaker; and will provide this information in writing. Provider will seek suggestions from other sources, and will, in its sole discretion, select presenters and moderators.

3. Disclosure of Financial Relationships. Provider will direct speakers and moderators to disclose to the audience commercial support or funding or other significant financial relationships between the speakers and moderators and Cephalon and/or any other commercial company whose products are pertinent to the content of the presentation. Provider will disclose Cephalon's support at this program.

4. Involvement in Content. There will be no "scripting," emphasis, or influence on content by Cephalon or its agents. However, Cephalon may provide technical support to speakers, e.g., furnishing slides or data, upon their request.

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7. Limitations of Data. Provider will request the speakers, to the extent possible, to disclose limits on the data, e.g., that it involves ongoing research, interim analyses, preliminary data, or unsupported opinion.

8. Discussion of Unapproved Uses. Provider will request that presenters disclose when a product is not approved in the United States for the use under discussion.

9. ACTIQ Risk Management Program. Provider is aware that ACTIQ® (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- ACTIQ is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- ACTIQ is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.
- ACTIQ is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

10. Opportunity for Debate. Provider will ensure opportunities for questioning by attendees and scientific debate with and between presenters.

#### 11. Independence of Provider in the Use of Contributed Funds.

(a) funds should be in the form of an educational grant made payable to the provider organization.

(b) Provider must be advised of all other support by Cephalon of the CME activity (e.g., distributing brochures, preparing slides). If Provider disapproves of this activity, it shall promptly notify Cephalon.

(c) no other funds from Cephalon will be paid to the program director, faculty, or others involved with this CME activity, e.g., additional honoraria.

#### 12. General.

(a) Cephalon agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.

(b) Provider agrees to: (1) abide by the ACCME Standards for Commercial Support of Continuing Medical Education; (2) acknowledge educational support from Cephalon in program brochures, syllabi, and other program materials; and (3) upon request, furnish Cephalon with a report concerning the expenditure of the funds provided by Cephalon.

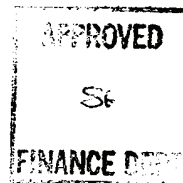
IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

Medical Learning Solutions, Inc.

CEPHALON, INC.

By: *Shari E. Gavinski*  
 Name: Shari E. Gavinski  
 Title: President, Medical Learning Solutions, Inc.

By: *R. Hughes*  
 Name: Rod Hughes, PhD  
 Title: Vice President Scientific Communications



# Cephalon

# PURCHASE ORDER

No. **017637**

NOT VALID UNTIL A NUMBER IS ASSIGNED!

41 Moores Road  
Frazer, PA 19355-3021  
FAX (610) 738-6311

DIRECT ALL INVOICES TO ACCOUNTS PAYABLE DEPARTMENT

DATE: Dec. 9, 2005

**DUE DATE: Dec. 9, 2005**

TO: Medical Learning Solutions, Inc.  
101 Washington Street  
Suite 110  
Morrisville, PA 19067  
Attn: Sheri Gavinski, President

**SHIP TO:** Cephalon, Inc.  
145 Brandywine Parkway  
West Chester, PA 19380

**FAX** 800-329-9755

ORIGINATOR  
OF P.O. Mary Ann Berlin

QTY ORDERED	UNIT OF MEASURE	DEPT CODE G/L ACCT	PROJECT/ CAPITAL CODE	STOCK NO./DESCRIPTION	UNIT PRICE	TOTAL
SS 12/15/05		440-7640	PAIN ACTA	CME Grant - Emerging Solutions in Pain - Part A		\$806,332.00
				3 installment payments of	268,777	
				R/jk		
				Charles A. Neelant III 12/15/05		
ORDER PROCESSOR	DATE ORDERED	BUYER	SHIP VIA	TOTAL EXTENDED PRICE		\$806,332.00
	12-16-05	Diana Price				

1. Please send one copy of your invoice.
2. Order is to be entered in accordance with prices, delivery and specifications shown above.
3. Notify us immediately if you are unable to ship as specified.

AUTHORIZED BY

Rod Hughes, VP - Sci. Communications

PRINT NAME

Lesley Russell, Sr. VP - Clin. Research



Medical Learning Solutions  
101 Washington Street  
Morrisville, PA 19067

# Invoice

Date	Invoice #
2/10/2006	1316A

Submitted  
A/P

3/17/06

Bill To
Cephalon, Inc. 41 Moores Road Frazer, PA 19355 Attn: Ed Hoey

P.O. No.	Terms	Project
017637	UPON RECEIPT	Cephalon

Quantity	Description	Rate	Amount
	FirstThird Billing of Emerging Solutions in Pain Program 2006 (grant) Part A	268,777.00	268,777.00
Federal Tax ID 90-0135153 Thank you!		<b>Total</b>	\$268,777.00

*Rod J. Hughes*  
Rod J. Hughes, PhD  
Vice President  
Scientific Communications

*Henry*

**EDUCATIONAL GRANT DRAFT REQUEST**

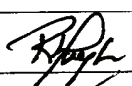
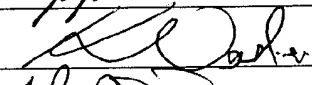
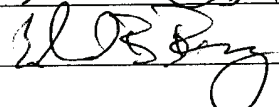
The attached material has been reviewed and is approved:

Payee: Medical Learning Solutions, Inc.

Amount: \$806,332

Type of Program: *Emerging Solutions in Pain* Grant Request part B

Submitted for Review: November 30, 2005

DEPARTMENT	NAME	SIGNATURE	DATE
Scientific Communications	Rod Hughes		12-1-05
Medical Affairs	Kiumars Vadie		12-1-05
Legal & Government	Ed Berg		12/1/05

Return to: Candice McCarthy 35663 – Scientific Communications





## MEDICAL EDUCATION AGREEMENT

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41 Moores Road  
P.O. Box 4011  
Frazer, PA 19355

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IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

Medical Learning Solutions, Inc.

CEPHALON, INC.

By: *Stewart L. Gavinski*  
 Name: Sheri L. Gavinski  
 Title: President, Medical Learning Solutions, Inc.

By: *Rod Hughes*  
 Name: Rod Hughes, PhD  
 Title: Vice President Scientific Communications





NOT VALID UNTIL A NUMBER IS ASSIGNED!

P-29481 00133



Medical Learning Solutions  
101 Washington Street  
Morrisville, PA 19067

# Invoice

Date	Invoice #
2/10/2006	1317A

<b>Bill To</b>
Cephalon, Inc. 41 Moores Road Frazer, PA 19355 Attn: Ed Hoey

P.O. No.	Terms	Project
017638	UPON RECEIPT	Cephalon

Quantity	Description	Rate	Amount
	FirstThird Billing of Emerging Solutions in Pain Program 2006 (grant) Part B	321,335.00	321,335.00
		<p><b>Submitted</b> <b>A/P</b> 3/3/04 cm</p>	
		<p><i>Henry Hughes</i> 2/11/06</p> <p><b>Red J. Hughes PhD</b> <b>Vice Pres. Sci Com</b> <b>Scientific Communications</b></p>	
Federal Tax ID 90-0135153 Thank you!		<b>Total</b>	\$321,335.00

# 2006 *Emerging Solutions in Pain* Grant Request

*Presented to:*

Edward Hoey  
Cephalon, Inc.

*By:*

Sheri Gavinski  
Medical Learning Solutions, Inc.

101 Washington Street, Suite 110  
Morrisville, PA 19067  
Tel 215-337-6100  
800-397-9774  
Fax 800-329-9755



**MLS**  
Medical Learning Solutions, Inc.

Medical Learning Solutions, Inc.



101 Washington Street  
Morrisville, Pennsylvania 19067  
Phone 215.337.6100  
Fax 215.337.0960

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101 Washington Street  
Morrisville, PA 19067

Edward Hoey  
Cephalon, Inc.  
41 Moores Road  
Frazer, PA 19355

November 28, 2005

Dear Mr. Hoey:

Medical Learning Solutions, Inc. has recently completed a comprehensive needs assessment to identify the educational needs of clinicians who provide care to patients with chronic pain. This needs assessment was compiled from the following sources:

- Evaluation summaries of completed and ongoing 2005 Emerging Solutions in Pain programs and activities
- Clinical advisory review
- Survey of health care professionals, including participants in completed and ongoing 2005 Emerging Solutions in Pain programs
- Literature search

Based on the identified educational need, Medical Learning Solutions is requesting an educational grant from Cephalon, Inc. to support the continuation and further development of the **Emerging Solutions in Pain**, or **ESP**, initiatives. This will include the continuation of selected **ESP** programs instituted in 2005, as well as the development and implementation of a diverse series of new activities designed to further increase the knowledge and practice management skills of those clinicians who provide care to patients with chronic pain. The **ESP** initiatives will continue to focus on balancing the clinical need to provide adequate analgesia to patients with chronic pain with the legal and societal need to monitor for potential issues of abuse, addiction and diversion of controlled substances.

These activities will be designed and planned as follows:

- Fundamental Emerging Solutions in Pain Programs (*Grant Request Part A*); these will include the following:
  - Continuance of the Emerging Solutions in Pain web site
  - Convention of an expanded Emerging Solutions in Pain Faculty Advisory Board, to address development of new Tools and areas of focus
  - Enhancements to the Emerging Solutions in Pain content, in the form of new Tools and resources

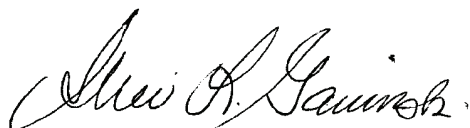
- An expanded awareness campaign to include coordinated advertising in multiple media formats
  - Continuing education initiatives associated with *Practical Pain Management*, featuring in-publication articles focusing on topics relevant to Emerging Solutions in Pain
- Live Emerging Solutions in Pain Educational Events and Activities (*Grant Request Part B*); these will include the following:
  - Continuance of the Meet the Expert exhibit booth at select, larger association meetings and expansion of the Meet the Expert mini-booth at smaller association meetings
  - Recreation of the RESPECT meeting series to focus on the provision of trained Emerging Solutions in Pain faculty to regional and local meetings of clinician associations, grand rounds programs and other similar venues
  - Adaptation of the current RESPECT meeting content to focus on the educational needs of single-clinician groups at regional and local meetings of clinician associations
- Programs to Further Expand the Reach of the Emerging Solutions in Pain Educational Events and Activities (*Grant Request Part C*); these will include the following:
  - Development and implementation of a full-day seminar program, to be held for clinical attendees of a national congress, focusing on the intersection of pain management and addiction medicine
  - Additional RESPECT meetings, held at regional and local meetings of clinician associations, grand rounds programs and other similar venues

The budget to fund these activities is approximately \$964,006 for Grant Request Part A; \$806,332 for Grant Request Part B and \$381,901 for Grant Request Part C. Please refer to the detailed budget section of this proposal for complete grant funding proposals.

These scientific events will comply with all ACCME, FDA, AMA, and ACPE regulations for industry-supported professional continuing education. MLS will be working with MediCom Worldwide, Inc. in the planning, execution and development of the accredited activities associated with the **ESP** initiatives. MediCom Worldwide is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians and is approved by the Accreditation Council for Pharmacy Education to provide pharmacy continuing education, as well as an approved provider of nursing continuing education through the California State Board of Registered Nursing.

Thank you in advance for your consideration of this request.

Respectfully,



Sheri L. Gavinski  
President,  
Medical Learning Solutions, Inc.



101 Washington Street  
 Morrisville, Pennsylvania 19067  
 Phone 215.337.6100  
 Fax 215.337.0960

## ***NEEDS ASSESSMENT***

---

In the United States alone, an estimated 50 million people suffer from some form of chronic pain, and another 25 million people suffer acute pain resulting from surgery or an accident.<sup>1</sup> Significantly, approximately two thirds of patients have been living with their pain for more than five years,<sup>2</sup> resulting in an alarming decrease, not only in quality of life, but in productivity for these individuals, as well. A survey conducted in 2000 reported that 36 million Americans missed work the previous year due to pain, and 83 million indicated that pain had affected their participation in various activities.<sup>3</sup>

It is well-established that chronic pain is a multi-faceted problem requiring intervention from a range of specialists in different disciplines.<sup>4</sup> Over the last decade, governments, professional organizations and institutions across the country have taken positive steps to improve physician training in pain management and palliative care, in accordance with recommendations issued by the World Health Organization.<sup>5</sup> These changes are indicators of the increasing recognition of pain relief and palliative care as appropriate subjects for professional education.

The increased focus on appropriate pain management has also resulted in certain challenges that impact health care professionals and patients alike. Some of these challenges result from confusion on the part of either patients or health care professionals, or both, regarding the potential of narcotic pain medications for abuse, addiction, misuse and diversion. Other challenges result from increased media attention regarding the prevalence of abuse and diversion, or from a lack of education and understanding regarding regulations for appropriate prescription of Schedule II agents. Patients, for example, may hesitate to use narcotics over fears of addiction, while health care professionals may be reluctant to prescribe opioids over concerns of increased scrutiny or investigation by local, state or federal law enforcement officials. When these types of concerns are combined with controversies surrounding the lack of scientific data on addiction, complex regulatory policies, and vague practice guidelines, the barriers to successful pain management become significant; undertreatment of pain is an all-too-common result.

One often-cited barrier in prescribing opioid analgesics to patients with chronic pain is the perception that physicians who treat their patients with these medications will come under increased scrutiny from the DEA and other regulatory and/or law enforcement agencies. This perception is due, in part, to documented increases in the diversion and sale of oxycodone and hydrocodone products. The source for much of this information is a unique epidemiologic network, known as Community Epidemiology Work Groups, or CEWG, that is designed to inform drug abuse prevention and treatment agencies, public health officials, policymakers, and the general public about current and emerging drug abuse patterns. Of the approximately 7,300 narcotic analgesic/opiate items analyzed by forensic laboratories across 19 CEWG areas in 2004, nearly 91 percent represented four drug classes: hydrocodone (35.3 percent), oxycodone (23.1 percent), methadone (19.1 percent), and codeine (13.3 percent).<sup>9</sup>

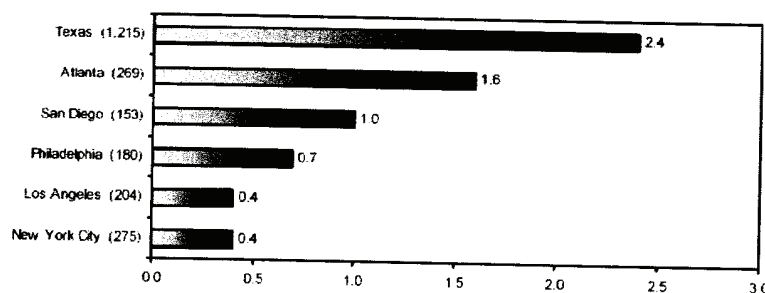


101 Washington Street  
Morrisville, Pennsylvania 19067  
Phone 215.337.6100  
Fax 215.337.0960

## NEEDS ASSESSMENT

Exhibit 1 shows the number of hydrocodone items in 6 CEWG sites where more than 100 items were reported in 2004

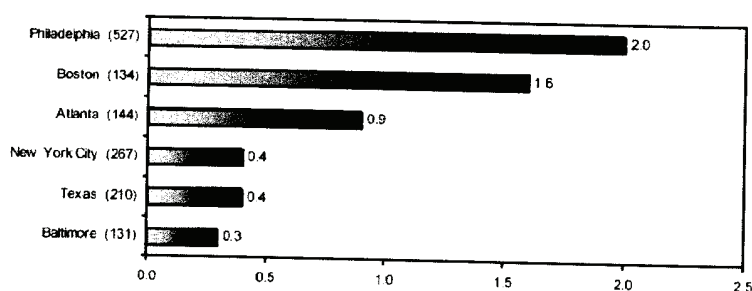
**Exhibit 1. Number of Hydrocodone Items Reported by Forensic Laboratories in 6 CEWG Areas, Ordered by Percentage of Total Items: FY 2004**



SOURCE: NFLIS, DEA

Exhibit 2 depicts the number of oxycodone items analyzed by forensic laboratories in 6 CEWG areas where more than 100 were reported.

**Exhibit 2. Number of Oxycodone Items Reported by Forensic Laboratories in 6 CEWG Areas, Ordered by Percentage of Total Items: FY 2004**



SOURCE: NFLIS, DEA

As can be seen in Exhibit 1 and Exhibit 2 above, there are clearly issues with abuse, misuse and diversion associated with some narcotic agents in certain geographic locations. Moreover, in March of 2004 the Office of National Drug Control Policy stated, "6.2 million Americans were current abusers of prescription drugs."<sup>6</sup> This information, while extremely important, is not, however, a justification for undertreatment of pain, even in those patients who may be identified at higher risk for abuse, misuse, addiction or diversion. Many studies have shown, in fact, that properly managed medical use of opioid analgesic drugs is effective and rarely causes clinical addiction, which is defined as compulsive, often uncontrollable use.<sup>7</sup> The key to this statement is "properly managed medical use", which consists of a



101 Washington Street  
Morrisville, Pennsylvania 19067  
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## NEEDS ASSESSMENT

comprehensive pain management program of assessment, monitoring and documentation, consistently utilized for all patients with chronic pain.

If properly managed medical use of opioids is a cornerstone of effective pain management, however, even today, many health care professionals lack the understanding, knowledge and tools for appropriate use of narcotic medications. Critically, pain management is not a significant area of focus in many medical schools, and physicians often graduate with misconceptions regarding appropriate pain management practices and techniques. In a recent study of medical students' attitudes toward pain and the use of opioid analgesics, half of senior medical students surveyed believed addiction risks associated with opioids are substantial, and more than one third were concerned about drug regulatory agency investigations. Moreover, these seniors were more pessimistic than freshmen surveyed about relieving chronic pain, and they appeared to have less understanding about the sources of pain in cancer patients.<sup>8</sup>

### NEEDS ASSESSMENT SURVEYS

To further define the educational needs of clinicians active in the field of pain management, our group conducted a series of surveys in 2005, in which we asked physicians about their practices and the therapies that they utilize to provide analgesia. The first survey was conducted among participants in the 2005 RESPECT meeting series, with a selection of evaluation questions and responses from this survey summarized in Exhibit 3, below.

**Exhibit 3: Selections from the 2005 RESPECT Meeting Program Evaluation Form**

<b><i>Do you manage patients who are experiencing acute pain?</i></b>	
Many	44%
Few	30%
None	8%
<b><i>Do you manage patients who are experiencing chronic pain?</i></b>	
Many	50%
Few	24%
None	6%
<b><i>How do you currently manage pain patients?</i></b>	
Opioids	25%
Combination of all methods	16%
Non-opioids	14%
OTC medications	10%
Psychological/social therapy	3%
Physical therapy	3%



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## NEEDS ASSESSMENT

Other	3%
<b><i>If you don't utilize opioid analgesics, why?</i></b>	
Concerns over issues of abuse, misuse, addiction and diversion	39%
Concerns over federal and state regulations	12%
Don't feel opioids are necessary	8%
<b><i>Are pain management interdisciplinary teams a standard of practice in your geographic area?</i></b>	
No	57%
Yes	24%

This information collected from the RESPECT meeting participants has been separately validated through two needs assessment surveys that question health care professionals regarding their needs for pain-related information. The first of these two surveys provided data regarding clinicians' top interests, preferred method of education, and other details regarding continuing education, collected from almost 1300 clinicians specializing in the field of pain management. The following results demonstrate topics that the respondents view to be of high interest in pain management:

1. Pharmacologic Advances in Pain Management	78%
2. Chronic Nonmalignant Pain Management	75%
3. Acute Pain Management	57%
4. Addiction, Substance Abuse	47%
5. Cancer Pain Management	41%

The second of these two surveys was conducted among more than 900 clinicians who participated in pain management continuing education programs in 2003 – 2005, and focused specifically on suggested topics for future programs. While numerous, diverse program topics were suggested, several core topics were suggested repeatedly by more than 130 respondents. These topics included:

1. Drug abuse and addiction
2. Treating the chemically dependent with chronic pain
3. Opioids for the treatment of pain
4. Narcotics: dosages, indications and contraindications
5. Assessment guidelines and tools
6. Pain-related case studies





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## NEEDS ASSESSMENT

7. Legal issues, including regulations from the DEA, medical board issues and pharmacy law matters

When the results of these surveys are combined, it is clear that additional curriculum and training are required to help insure improvements in the delivery of pain relief, to include identifying the:

- Critical issues involving the use of opioid analgesics
- Fundamental rights of patients to pain treatment
- Patients at high risk for opioid misuse, abuse and/or diversion
- Legal ramifications when prescribing controlled substances

One of the ways this challenge can be met is through the continuance of continuing education programs that focus on pain management in general, and, specifically, the effective use of opioids in patients with chronic pain. The goal of such programs must be to support clinicians in improving patient care while reducing the potential for abuse, addiction, diversion, and medical regulatory/malpractice liability exposures arising from poor pain management practices.

### References

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2. Chronic Pain in America: Roadblocks to Relief, survey conducted for the American Pain Society, The American Academy of Pain Medicine and Janssen Pharmaceutica, 1999.
3. Pain in America: A Research Report, Survey conducted for Merck by the Gallup Organization, 2000.
4. Zarnegar R. Pain Management Programs. BJA - CEPD Reviews, Volume 5, Number 3, 15 June 2005, pp. 80-83(4).
5. World Health Organization. <http://www.who.int/en/>. Accessed September 16, 2005.
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9. National Institute on Drug Abuse. Advance Report and Highlights/Executive Summary: Abuse of Stimulants and Other Drugs. Proceedings of the Community Epidemiology Work Group. January 2005. [http://www.drugabuse.gov/PDF/CEWG/AdvReport\\_Vol1\\_105.pdf](http://www.drugabuse.gov/PDF/CEWG/AdvReport_Vol1_105.pdf). Accessed September 22, 2005.





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### PROGRAM OVERVIEW: THE 2005 EMERGING SOLUTIONS IN PAIN INITIATIVE

**Emerging Solutions in Pain (ESP)** is an ongoing initiative that was developed by clinicians for physicians, pharmacists, nurses and other healthcare professionals who are active in the field of pain management. The **ESP** initiative, which was launched in February of 2005, was created specifically to address the issues and critical unmet needs in the field of pain management. These issues specifically involve balancing the fundamental rights of patients and clinicians with the challenge of identifying patients who are at greater or lesser risk for opioid misuse and addiction, and with the challenges associated with the complex regulations involved in prescribing controlled substances. In 2005, the **ESP** initiative included a diverse array of activities and programs, including the development of a multimedia CD-ROM-based clinician Tool Kit; a clinician-focused web site for the dissemination of pain management information; an exhibit booth that provided clinician attendees of national congresses with information regarding the Emerging Solutions in Pain tools and resources; and a series of ten accredited regional meetings that focused on the importance of establishing standards of care and the interdisciplinary team in proactive pain management. Each of these activities is summarized below.

The **ESP** initiative is based upon ongoing input and expertise from a renowned group of clinical experts with backgrounds in pain management, addiction medicine, anesthesiology and neurology. These experts include those individuals listed in Exhibit 4, below. Based on input from these experts, in 2005, the Emerging Solutions in Pain initiative was dedicated to the development, production and dissemination of information and tools focused on assessment, monitoring and best practices for treating patients with opioids. These experts also provided extensive guidance and input in terms of the most effective methods for delivering this information to practicing clinicians.

#### Exhibit Four-A: The Emerging Solutions in Pain Faculty Advisory Board

*Gerald M. Aronoff, MD, DABPM, FAAEP*  
Chairman, Department of Pain Medicine  
Presbyterian Orthopaedic Hospital  
Charlotte, North Carolina

*Fernando T. Avila, MD*  
Private Practice,  
Pain Management and Anesthesiology  
San Antonio, TX

*David B. Brushwood, RPh, JD*  
Professor, Pharmacy Health Care Administration  
College of Pharmacy  
University of Florida  
Gainesville, FL

*Daniel M. Gruener, MD*  
President, Greater Philadelphia Pain Society  
Clinical Assistant Professor of Psychiatry  
Jefferson Medical College  
Philadelphia, Pennsylvania



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## NEEDS ASSESSMENT

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*Jeffrey A. Gudin, MD*

Clinical Director  
Pain Management Center  
Englewood Hospital and Medical Center  
Englewood, New Jersey

*Mitchell Halter, MD*

Neurologist  
Integrative Pain Center of Arizona  
Tucson, AZ

*Howard A. Heit, MD, FACP, FASAM*

Assistant Clinical Professor of Medicine,  
Georgetown University School of Medicine  
Washington, DC

*Steven D. Passik, PhD*

Director, Symptom Management and Palliative Care  
Markey Cancer Center  
Associate Professor of Medicine and Behavioral Sciences  
University of Kentucky  
Lexington, Kentucky

*Joseph Shurman, MD*

Anesthesiologist and Pain Consultant  
Scripps Memorial Hospital  
La Jolla, California  
Clinical Assistant Professor and Pain Consultant  
University of California, San Diego  
San Diego, California

*Lynn R. Webster, MD, FACPM, FASAM*

Alpine Pain and Addiction Medicine  
Salt Lake City, UT

### **Exhibit Four-B: Other Contributing Faculty to the Emerging Solutions in Pain Initiatives**

Daniel Bennett, MD  
Daniel Brookoff, MD  
Andrea Cheville, MD  
Doris Cope, MD  
Douglas Gourlay, MD, FRCPC, FASAM  
Jayson Hymes, MD, MPH, FACPM  
Benjamin Johnson, Jr, MD  
Bill McCarberg, MD  
Michael Moskowitz, MD, MPH  
Richard Payne, MD  
Steven Stanos, DO



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## **NEEDS ASSESSMENT**

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### **2006 Emerging Solutions in Pain Initiatives**

The information collected through the first 11 months of the Emerging Solutions in Pain initiative clearly indicates that a significant educational need exists for continuing education programs and resources devoted to the needs of clinicians who provide care to patients with chronic pain. Based on these educational needs, it is recommended that a series of initiatives be implemented in 2006 to continue and extend the 2005 Emerging Solutions in Pain programs. These initiatives include the following.

#### **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

1. Continuance of the Emerging Solutions in Pain web site at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com)
2. Recruitment and convention of an expanded Emerging Solutions in Pain Faculty Advisory Board, to address development of new Tools and areas of focus
3. Enhancements to the Emerging Solutions in Pain content, distributed via the web site and a new Tool Kit; enhancements to be based upon Faculty recommendations
4. Expanded awareness campaign to include coordinated advertising in multiple media formats
5. Continuing education initiatives associated with *Practical Pain Management*, featuring in-publication articles focusing on topics relevant to Emerging Solutions in Pain

#### **Grant Request Part B: Live Emerging Solutions in Pain Educational Events and Activities**

1. Continuance of the Meet the Expert exhibit booth at select, larger association meetings and expansion of the Meet the Expert mini-booth at smaller association meetings
2. Recreation of the RESPECT meeting series to focus on the provision of trained Emerging Solutions in Pain faculty to regional and local meetings of clinician associations, grand rounds programs and other similar venues
3. Adaptation of the current RESPECT meeting content to focus on the educational needs of single-clinician groups at regional and local meetings of clinician associations

#### **Grant Request Part C: Programs to Further Expand the Reach of the Emerging Solutions in Pain Educational Events and Activities**

1. Development and implementation of a full-day seminar program, to be held for clinical attendees of a national congress, focusing on the intersection of pain management and addiction medicine
2. Additional RESPECT meetings, held at regional and local meetings of clinician associations, grand rounds programs and other similar venues



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## Grant Request Part A: Fundamental Emerging Solutions in Pain Programs

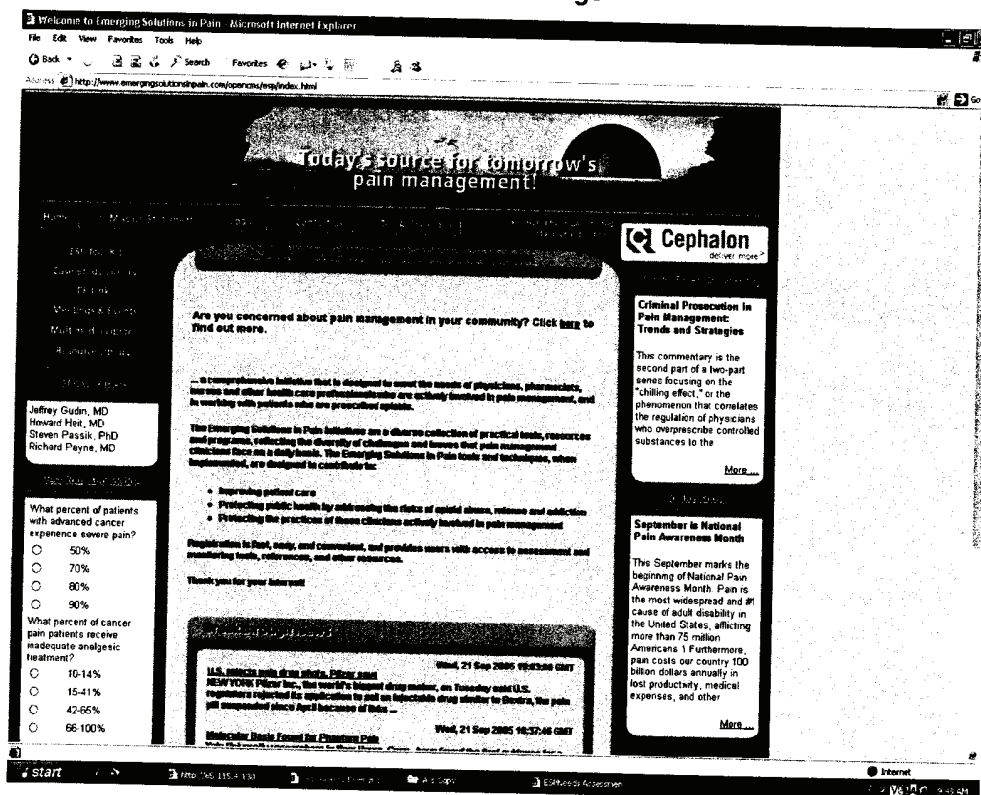
### **Program Overview: Summary of Work Completed in 2005**

#### **1. THE EMERGING SOLUTIONS IN PAIN (ESP) WEB SITE**

This web-based, comprehensive initiative is designed to meet the needs of physicians, pharmacists, nurses and other health care professionals who are actively involved in the management of patients who may be or are actively prescribed opioids. This easy-to-access web site is the repository of an invaluable and diverse collection of practical tools, resources, information, recent updates, and various other programs that reflect the diverse challenges and issues facing pain management clinicians today (Exhibit A-1).

In addition, members are required to register prior to accessing the fundamental Emerging Solutions in Pain resources and tools. This enables tracking of information pertaining to member specialty and Tool use, and provides a method for updating site users with information regarding new programs and tools as they become available.

#### **Exhibit A-1: The Emerging Solutions in Pain Home Page**



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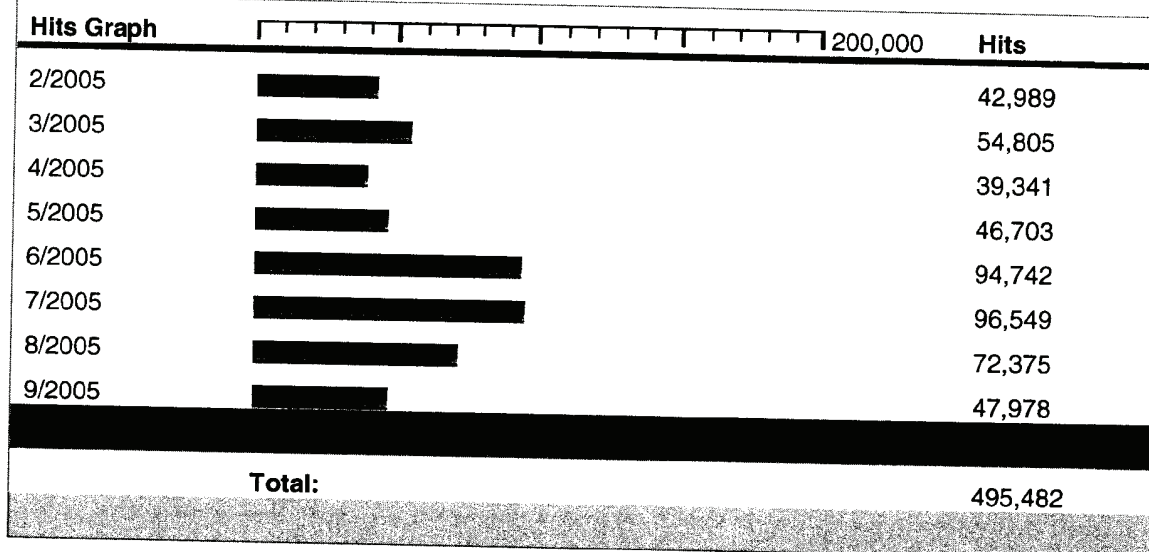
## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

Since the launch of the Emerging Solutions in Pain website in February, 2005, almost 500,000 hits to the site has resulted in more than 17.33 Gigabytes of information being downloaded directly from the ESP site to practicing clinicians; more than 77.48 Megabytes of information is downloaded daily. Exhibit A-2 shows the trend of recent activity on ESP in terms of successful hits over time.

### **Exhibit A-2**

**R port:** Hits Graph - EmergingSolutionsInPain.com

**Date Range:** 02/24/2005 - 09/15/2005

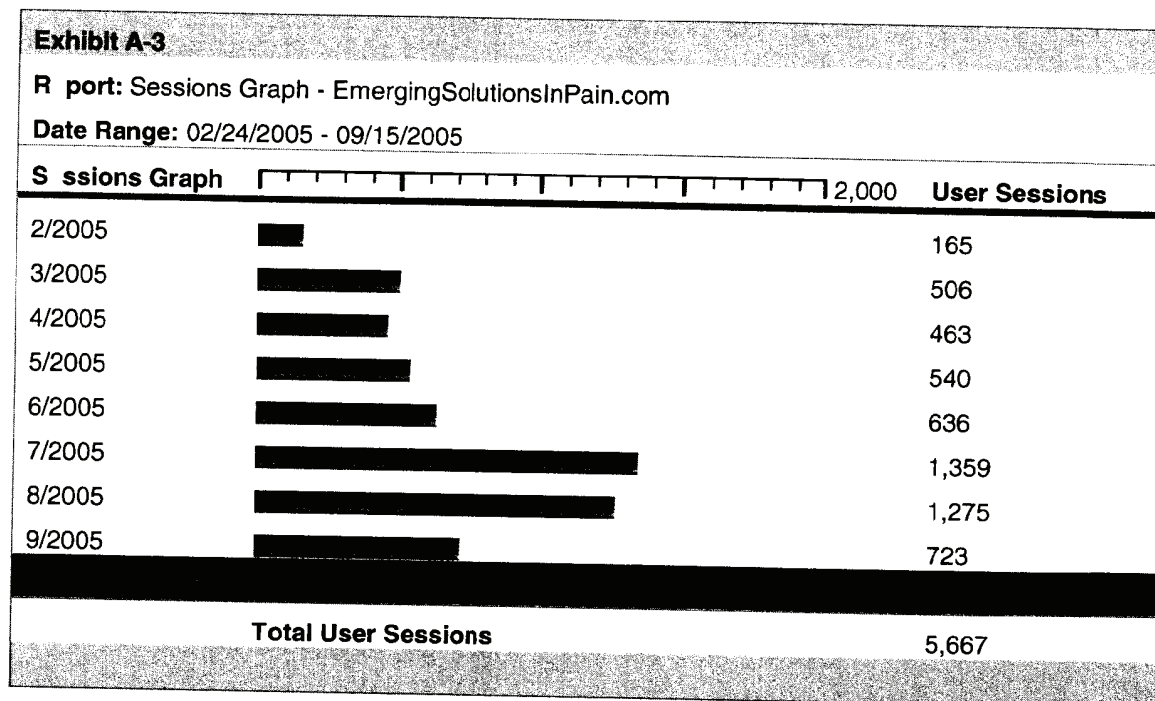




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## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

Exhibit A-3 demonstrates the trend of recent activity on the Emerging Solutions in Pain website, in terms of visitor sessions over time. An individual visitor defines a "session" as a series of clicks on ESP during a specific period of time. A session is initiated when the visitor arrives at ESP, and it ends when the browser is closed or after a period of inactivity. The significant number of monthly sessions is not surprising, given the many diverse tools available to practicing clinicians, both as printable documents and as electronic downloads.



A significant measure of website relevance is the number of credible, non-related web sites linked to the site. The number of sites hyperlinked to ESP or that mention the ESP site is a measure of the growing influence of the Emerging Solutions in Pain initiative in the pain management community (Exhibit A-4).

### **Exhibit A-4**

1. **American Physical Therapy Association**  
(<http://www.apta.org/AM/Template.cfm?Section=Archives2&Template=/Customsource/TaggedPage/PTIssue.cfm&Issue=09/02/2005#article24599>)
2. **American Chronic Pain Association** ([http://www.theacpa.org/pf\\_03\\_05.asp](http://www.theacpa.org/pf_03_05.asp))
3. **The Legal Side of Pain**  
(<http://www.legalsideofpain.com/index.cfm?fuseaction=page.display&pid=10>)





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## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

4. **Find That CE** ([http://www.findthatce.com/search\\_advanced/detail.php?ceid=844](http://www.findthatce.com/search_advanced/detail.php?ceid=844))
5. **Actiq® Educational Offerings** (<http://www.actiq.com/physicians/mededucation/>)
6. **Pain.com**  
([http://www.pain.com/sections/categories\\_of\\_pain/breakthrough/Resources/professional\\_resources/resource.cfm?id=1341](http://www.pain.com/sections/categories_of_pain/breakthrough/Resources/professional_resources/resource.cfm?id=1341))
7. **Painfoundation.org**  
([http://www.painfoundation.org/marylandpain/Downloads/ESP\\_Brief.pdf#search='emergingsolutionsinpain.com'](http://www.painfoundation.org/marylandpain/Downloads/ESP_Brief.pdf#search='emergingsolutionsinpain.com'))
8. **American Society for Pain Management Nursing** (<http://www.aspmnhouston.org/about.html>)
9. **Doctor's Guide**  
(<http://www.docguide.com/news/content.nsf/medicalresourcesweb?openform&id=e85e90285e487ca885256b1e00595908&cond=cme-related+sites>)
10. **American Alliance of Cancer Pain Initiatives**  
([http://www.aacpi.org/PCP\\_webpages/AnalgesicPharm.pdf#search='emergingsolutionsinpain.com'](http://www.aacpi.org/PCP_webpages/AnalgesicPharm.pdf#search='emergingsolutionsinpain.com'))

### **2. THE ESP TOOL KIT CD-ROM**

The Emerging Solutions in Pain Tool Kit CD-ROM (Exhibit A-5) provides health care professionals with an extensive array of electronic tools that may be used to effectively assess a patient's potential for opioid abuse, addiction, and diversion; to monitor the patient who is prescribed opioids; and to implement best practices in the management of patients with chronic pain. Every tool featured on this CD-ROM is available in electronic format, enabling instant and convenient access to clinicians who wish to view the informative multimedia slide-audio programs, the helpful printable documents, or the resourceful references and hyper links to access all content instantaneously.

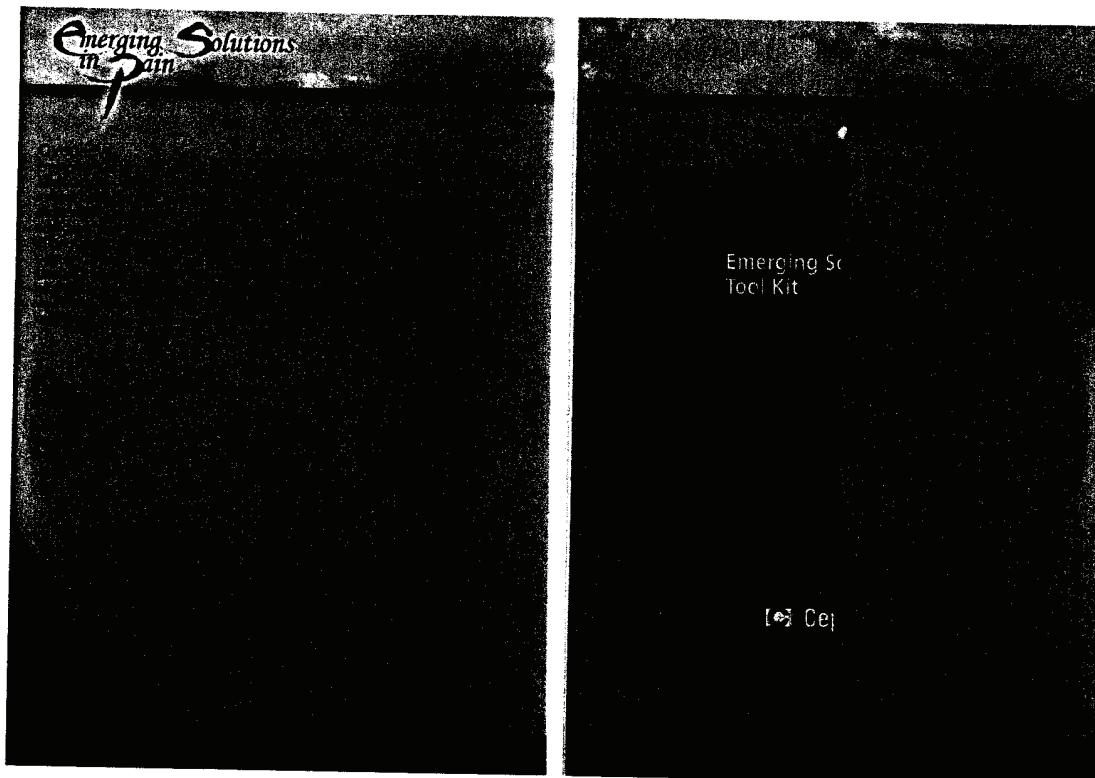




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## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

**Exhibit A-5**



To date, 71,265 Emerging Solution in Pain Tool Kit CD-ROMs have been shipped and/or distributed to health care professionals who are involved in pain treatment and management.

### **3. THE ESP MINI-DISC PUBLICATION**

The Emerging Solutions in Pain Mini-Disc was created to focus health care professionals on the diverse resources and educational tools available to them via both the Emerging Solutions in Pain website and the ESP Tool Kit CD-ROM. The accompanying ESP Slim Jim Publication (Exhibit A-6) highlights and describes not only the contents of the attached Mini-Disc, but also the entire Emerging Solutions in Pain initiative, as well. In addition, the Publication also features a Business Reply Card (BRC), attached along the perforated edge, providing health care professionals with a convenient method for requesting the ESP Tool Kit CD-ROM; this BRC is a source of data for future mailings, as well.

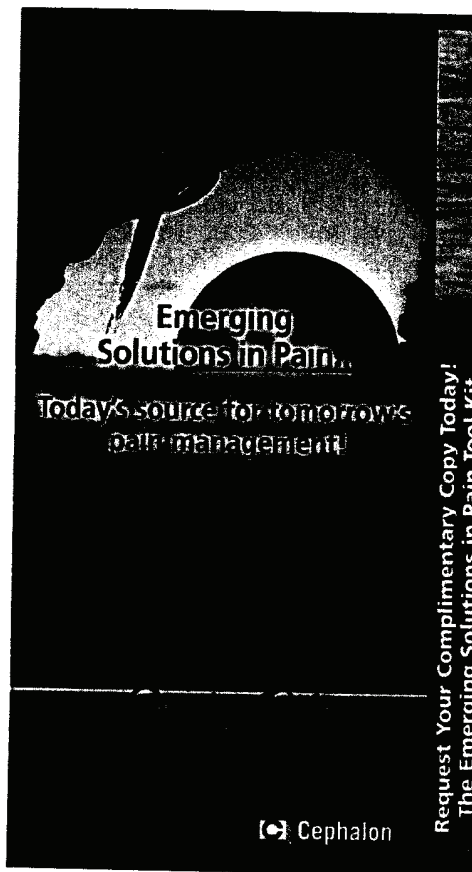


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## Grant Request Part A: Fundamental Emerging Solutions in Pain Programs

The ESP Mini-Disc Publication is easily distributed at either a RESPECT Meeting Series or at one of the Meet the Experts booths. To date, almost 73,000 of the ESP Mini-Disc Publications have been shipped or distributed to health care professionals.

### Exhibit A-6



**Emerging Solutions in Pain**  
Today's source for tomorrow's pain management

**Request Your Complimentary Copy Today!  
The Emerging Solutions in Pain Tool Kit**

**Cephalon**

**First Name**  **Last Name**

**Mailing Address**

**City**  **State**  **Zip Code**

**Phone Number**  **Fax Number**

**E-Mail Address**

☐ I would like to receive other information from Emerging Solutions in Pain

**Please Order Your Copy in One of Four Ways...**

**By Mail** Please return this card **By Web** [www.emergingsolutionsinpain.com](http://www.emergingsolutionsinpain.com)

**By Phone** 800-397-9774 **By Fax** 800-504-0960



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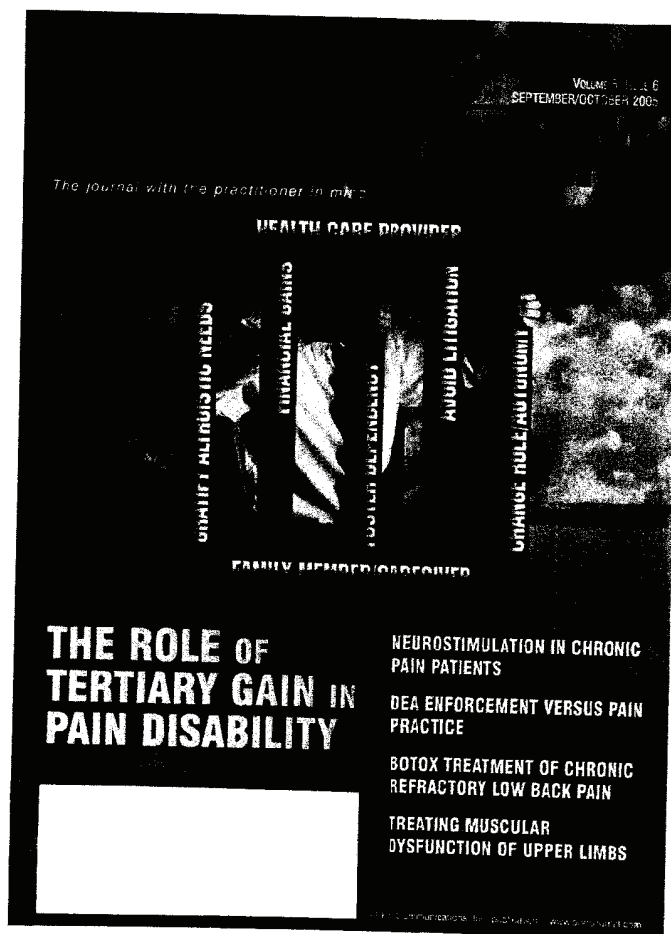
## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

### **4. AWARENESS CAMPAIGN**

In order to create awareness as well as increase the reach and frequency of the Emerging Solutions in Pain initiatives, a targeted campaign has been implemented in 2005, with the goal of disseminating key information to health care professionals who provide care to patients with chronic pain. This campaign has included journal and Internet advertisements, press releases and commentaries.

#### *Practical Pain Management*

This journal is published for the medical practitioner who is dedicated to helping patients experiencing chronic pain. Through a coordinated series of program informational announcements, including one press release, one clinical editorial and a series of three back cover or full-page advertisements, key Emerging Solutions in Pain messages have reached the 39,000-clinician subscriber list every month since May, 2005. As can be seen from the occupational breakout and percentage of total readership (Exhibit A-7, below), the top five occupations that clearly deal with the management of pain on a daily basis, are now much more familiar with Emerging Solutions in Pain and with the practical services and tools created by ESP to support their practice and patients.



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## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

### **Exhibit A-7: Practical Pain Management Demographics**

SPECIALTY	TOTAL QUALIFIED	PERCENT OF TOTAL
Anesthesiology/Pain Med	3,467	9.4
Dental Specialties	462	1.2
Emergency Medicine	474	1.3
Family Practice	6,571	17.6
General Practice	1,504	4.1
General Surgery	659	1.8
Internal Medicine	5,736	15.4
Neurology/Neurosurgery	4,287	11.6
Ob/Gyn	243	0.7
Occupational/Industrial Medicine	332	0.9
Oncology/Hematology	248	0.7
Orthopedic Medicine/Surgery	4,283	11.6
Pain Medicine/Management	1,606	4.3
Pediatrics	408	1.1
Physical Med & Rehab/Sports Med	2,642	7.1
Radiology: Oncology/Diagnostic/Interventional	413	1.1
Rheumatology	1,253	3.4
Other	2,488	6.7
<b>TOTAL QUALIFIED CIRCULATION</b>	<b>37,076</b>	<b>100.0</b>

*The American Academy of Physical Medicine and Rehabilitation (AAPM&R) Web site: [www.aapmr.org](http://www.aapmr.org)*

The American Academy of Physical Medicine and Rehabilitation is a national medical society representing more than 7,000 physicians who are specialists in the field of physical medicine and rehabilitation. The Emerging Solutions in Pain Meet the Expert Booth will be present at the 2005 AAPM&R National Meeting, to be held in Philadelphia, PA in October. In conjunction with this opportunity, ESP has placed a banner advertisement on the AAPM&R web site that will be viewable and will include a click-through link to [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com) until January, 2006. This banner is located at:

<http://www.aapmr.org/assembly/prelim/aa05l.htm>

The AAPM&R web site reported almost 32,000 user sessions in June, 2005; each of these users will thus be potentially exposed to key Emerging Solutions in Pain messages.



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## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

### ***Program Overview: Proposed 2006 Activities***

The following activities are recommended as the Fundamental Emerging Solutions in Pain Programs in 2006.

1. Continuance of the Emerging Solutions in Pain web site at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com)
2. Recruitment and convention of an expanded Emerging Solutions in Pain Faculty Advisory Board, to address development of new Tools and areas of focus
3. Enhancements to the Emerging Solutions in Pain content, distributed via the web site and a new Tool Kit; enhancements to be based upon Faculty recommendations
4. Expanded awareness campaign to include coordinated advertising in multiple media formats
5. Continuing education initiatives associated with *Practical Pain Management*, featuring in-publication articles focusing on topics relevant to Emerging Solutions in Pain



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Proposal Number: 06-003  
Date: November 28, 2005

**Emerging Solutions in Pain**  
**Summary of Proposed Budget, Grant Request Part A**  
*Fundamental Emerging Solutions in Pain Programs*  
November 28, 2005

<b>Cost Summary</b>	
<b>ESP Website</b>	
Approximate Total, Direct Expenses	\$ 22,350
Indirect Expenses	\$ 129,229
Cost of Expansion and Maintenance of the Emerging Solutions in Pain Website	\$ 151,579
<b>ESP Faculty Advisory Committee Meeting</b>	
Approximate Total, Direct Expenses	\$ 71,062
Indirect Expenses	\$ 66,500
Cost of 2006 Emerging Solutions in Pain Faculty Advisory Committee Meeting	\$ 137,562
<b>ESP Tool Kit</b>	
Approximate Total, Direct Expenses	\$ 45,000
Indirect Expenses	\$ 105,850
Cost of Development and Production of Emerging Solutions in Pain Tool Kit, Volume Two	\$ 150,850
<b>ESP Awareness Campaign</b>	
Approximate Total, Direct Expenses	\$ 45,000
Indirect Expenses	\$ 16,500
Cost of 2006 ESP Awareness Campaign	\$ 61,500
<b>Accredited Journal Article Series</b>	
Approximate Total, Direct Expenses	\$ 216,000
Indirect Expenses	\$ 88,841
Cost of PPMJ Accredited Journal Article Series	\$ 304,841
<b>Total Budget, 2006 Fundamental Emerging Solutions in Pain Programs</b>	<b>\$ 806,332</b>

Approval Signature \_\_\_\_\_

Date \_\_\_\_\_

**Not : no work may begin until Medical Learning Solutions receives, via email or fax, this approval with  
signatur and dat**



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## *Program Summary*

<b>Program Title</b>	The Emerging Solutions in Pain Web Site
<b>Program Overview</b>	Medical Learning Solutions is proposing to continue and expand the multimedia Web Site that currently houses and promotes the Emerging Solutions in Pain initiative. This Web Site provides health care professionals with an extensive array of tools for assessing the potential for abuse, addiction and diversion in their patients with chronic pain, for monitoring their pain patients, and for accessing information regarding "best practices" in the long-term management of these patients. Registered members of EmergingSolutionsinPain.com can access and print available Tools and supporting references, view video-slide/audio-based case studies, read relevant literature and journal articles, view schedules for upcoming events such as the Meet the Expert Booth, and register for live peer-to-peer meetings that are part of the Emerging Solutions in Pain initiative.
<b>Intended Audience</b>	The primary audience of the Emerging Solutions in Pain Web Site are physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain.
<b>Program Objectives</b>	<p>in 2006, one goal of the Emerging Solutions in Pain Web Site will be to continue to provide clinicians with tools and resources for assessing and monitoring the risk potential of their patients for opioid misuse, abuse and addiction. New goals for the Emerging Solutions in Pain web site include the following:</p> <ol style="list-style-type: none"> <li>(1) Expand the reach of this web site and the important information it contains to the following groups:               <ol style="list-style-type: none"> <li>a. Non-physician members of the pain management community, e.g., nurses, physician assistants, pharmacists</li> <li>b. Pain specialists and addictionologists who have not yet registered at the web site</li> <li>c. Medical students who have an interest in treating pain as part of their studies</li> <li>d. Physicians who treat pain as part of their practice and who have not yet registered at the web site</li> </ol> </li> <li>(2) Provide new resources and tools for clinicians who are involved in pain management. These tools and resources will be identified, in part, at the 2006 Faculty Advisory Committee Meeting, but may include one or more of the following:               <ol style="list-style-type: none"> <li>a. Online versions of any new tools developed through the 2006 Emerging Solutions in Pain initiatives</li> <li>b. A searchable database of FAQs, answering the most common questions clinicians have pertaining to opioid misuse, abuse and addiction</li> <li>c. A dynamic online forum in which clinicians may post questions or comments for other registered users to respond to, or for one of the Emerging Solutions in Pain faculty to answer</li> <li>d. An expanded listing of links to other pain management resources</li> </ol> </li> </ol>
<b>Format</b>	A multimedia Web Site, with separate links for assessing and monitoring patients whose chronic pain is being treated with opioids; for "best practice" information;





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### *Program Summary*

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for journal articles relevant to the Emerging Solutions in Pain initiative; for other Emerging Solutions in Pain information and programs

**Distribution**

The Emerging Solutions in Pain Web Site will be available to all individuals via the Internet at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com). Free registration will be required to access the majority of information on the Web Site, including all of the Emerging Solutions in Pain Tools and journal articles

**Request for  
Sponsor Support**

Medical Learning Solutions will announce and promote the Emerging Solution in Pain Web Site through journal advertisements, banner advertisements and announcement brochures for the Emerging Solutions in Pain initiative.

As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.

**Total Budget:**

\$151,579



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Proposal Number: 06-003  
Date: November 28, 2005

**Expansion and Maintenance of the Emerging Solutions in Pain Website**  
**Projected Budget Estimate**  
November 28, 2005

<b>Cost Summary</b>	
<b>Approximate Total, Direct Expenses</b>	\$ 22,350
<b>Total, Indirect Expenses</b>	\$ 129,229
<b>Expansion and Maintenance of the Emerging Solutions in Pain Website</b>	<b>\$ 151,579</b>

<b>Direct Expenses, Approximate</b>	
<b>Clinical expert honoraria</b> Honoraria for authorship of monthly column, <i>Clinical Expert Commentary</i> ; selected <i>In the Know</i> columns	\$ 17,000
<b>Topix.net feed</b>	\$ 3,000
<b>Stock photography / illustrations</b>	\$ 2,000
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$ 350
<b>Approximate Total, Direct Expenses</b>	<b>\$ 22,350</b>

<b>Indirect Expenses</b>	
<b>IT / programming services</b> Includes programming of new tools, resources and content, to be determined by consultation with Faculty Advisory Committee; coordination with Internet and database programming vendors	\$ 26,800
<b>Graphic design / production services</b> Includes production of new graphics associated with new tools and resources	\$ 10,500
<b>Medical / scientific services</b> Includes all content development for ESP.com, development of copy for new Web pages as needed, coordination with clinical reviewers, ongoing development of clinical expert commentary, In the News summaries and Topix.net feed; maintenance of links and other information	\$ 33,000
<b>Website maintenance, 12 months total</b> Includes all hosting and co-location fees; routine website maintenance; and technical support	\$ 42,000
<b>Administrative and accounting fees</b>	\$ 3,168
<b>Project management</b>	\$ 13,761
<b>Total, Indirect Expenses</b>	<b>\$ 129,229</b>



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## *Program Summary*

<b>Program Title</b>	The Emerging Solutions in Pain 2006 Faculty Advisory Board Meeting
<b>Program Overview</b>	<p>The Emerging Solutions in Pain initiative was developed by clinicians for physicians, pharmacists, nurses and other health care professionals involved in the field of pain management. The input and guidance of these clinicians was instrumental in determining the original parameters and scope of the initiative, and remains critical for the ongoing success of future Emerging Solutions in Pain initiatives. Medical Learning Solutions is therefore recommending that the Emerging Solutions in Pain Faculty Advisory Committee reconvene for a one-day meeting in February 2006. At this meeting, the Faculty will address the current needs of clinicians involved in the field of pain management, and identify potential areas for the development of future Emerging Solutions in Pain tools and resources.</p> <p>Medical Learning Solutions is recommending that the 2006 Emerging Solutions in Pain Faculty Advisory Committee include all currently active Emerging Solutions in Pain faculty members, as well as a select group of clinicians that have made some contribution to the 2005 Emerging Solutions in Pain initiatives. The members of the Faculty Advisory Committee have therefore been tentatively identified to include those individuals listed below; final Committee selection will be based upon faculty availability; additional names will be added, as needed.</p> <p>Daniel Bennett, MD Daniel Brookoff, MD David B. Brushwood, RPh, JD Douglas Gourlay, MD, FRCPC, FASAM Jeffrey A. Gudin, MD Howard A. Heit, MD, FACP, FASAM Benjamin Johnson, Jr., MD Christine Miaskowski, RN, PhD, FAAN Steven D. Passik, PhD Joseph Shurman, MD Steven Stanos, DO Lynn R. Webster, MD, FACPM, FASAM</p>
<b>Intend d Audience</b>	The primary audience who will benefit from a reconvention of an expanded Emerging Solutions in Pain Faculty Advisory Committee will be physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain, and who utilize opioids in their pain practices. The needs of these clinicians will be specifically addressed at the Advisory Board Meeting, and new Emerging Solutions in Pain tools and resources will be recommended by the Faculty for their use in 2006.
<b>Program Objectives</b>	The purpose of the Emerging Solutions in Pain Faculty Advisory Committee is to provide guidance for future direction of the Emerging Solutions in Pain initiatives. This will require the accomplishment of the following objectives at the Advisory Committee Meeting:



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## *Program Summary*

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- (1) Summarize the activities and programs that comprised the 2005 Emerging Solutions in Pain initiatives
- (2) Outline current trends in the use of opioids for the treatment of chronic pain, focusing on any new developments in laws or regulations pertaining to the prescription of controlled substances; new products and therapies that will be available for the treatment of chronic pain; and new reports pertaining to the assessment, monitoring or documentation of patients who are prescribed opioids
- (3) Based on the above, recommend:
  - a. New tools and resources that would meet the unmet needs of clinicians who provide care to patients with chronic pain
  - b. Changes and updates to the current RESPECT slide modules

### **Format**

A one-day meeting, to be tentatively held in February 2006. The exact date and location of this meeting will be based on the schedules of the attending faculty; it is anticipated that this meeting will be held immediately before or after a national congress or association meeting which the majority of faculty will attend. Options for this meeting include the International Conference on Pain & Chemical Dependency in Brooklyn, New York and the American Academy of Pain Medicine Meeting in San Diego, California.

### **Distribution**

Attendance at the 2006 Emerging Solutions in Pain Faculty Advisory Committee Meeting will be determined by past participation in the Emerging Solutions in Pain initiatives. Invitations will be issued to currently active faculty members and to select faculty who made some contribution to the initiatives in 2005.

### **Total Budget:**

\$137,562



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Proposal Number: 06-003  
Date: November 28, 2005

**2006 Emerging Solutions in Pain Faculty Advisory Committee Meeting**  
***Proposed Budget***  
November 28, 2005

<b><i>Program Parameters</i></b>	
Attending faculty	11
Clinical expert moderator	1
Length of meeting	1 day

<b><i>Cost Summary</i></b>	
Approximate Total, Direct Expenses	\$ 71,062
Total, Indirect Expenses	\$ 66,500
<b>Cost of 2006 Emerging Solutions in Pain Faculty Advisory Committee Meeting</b>	<b>\$ 137,562</b>



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Proposal Number: 06-003  
Date: November 28, 2005

**2006 Emerging Solutions in Pain Faculty Advisory Committee Meeting**  
***Proposed Budget***  
**November 28, 2005**

*Detailed Budget Itemization*

***Direct Expenses, Approximate***

<b>Print materials</b>	
Meeting kits to include agenda, handout materials, current RESPECT meeting slides and 4/c binder	\$ 2,000
<b>Speaker honoraria (11 faculty member + 1 moderator)</b>	\$ 32,500
<b>Speaker travel (air, OOP, hotel)</b>	\$ 13,600
<b>ROI staff travel (air, OOP, hotel)</b>	\$ 5,000
<b>Ground transportation</b>	\$ 2,400
<b>Venue rental fee</b>	\$ 1,000
<b>Food &amp; Beverage (Dinner, Buffet Breakfast, Buffet Lunch, Two Breaks)</b>	\$ 6,062
<b>Audio/visual services</b>	\$ 6,000
<b>Transcription</b>	\$ 1,500
<b>Miscellaneous (non-fulfillment shipping, faxes, FedEx, etc.)</b>	\$ 1,000
<b><i>Approximate Total, Direct Expenses</i></b>	<b>\$ 71,062</b>

***Indirect Expenses***

<b>Program development</b>	\$ 12,500
<b>Graphic design</b>	\$ 17,000
Includes all labor associated with initial program set-up and development, including development and production of meeting slides, coordination of print support materials, graphic design, typesetting and layout of all support materials, and development and creation of final program appearance	
<b>Meeting management</b>	\$ 13,000
Includes faculty management, venue coordination, meeting logistics, travel and all other program details	
<b>Site inspection</b>	\$ 3,000
<b>Onsite management (four staff members)</b>	\$ 6,000
<b>Administrative and accounting fees</b>	\$ 2,585
<b>Project management</b>	\$ 12,415
<b><i>Total, Indirect Expenses</i></b>	<b>\$ 66,500</b>



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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain Tool Kit, Volume Two
<b>Program Overview</b>	<p>Medical Learning Solutions is proposing to develop new tools and content for the Emerging Solutions in Pain Tool Kit, Volume Two. Volume One of the Tool Kit provided clinicians with specific tools for assessing the potential for abuse, addiction and diversion in their patients with chronic pain, for monitoring their pain patients, and for accessing information regarding "best practices" in the long-term management of these patients. Volume Two will expand upon the tools and resources presented in Volume One, as directed by the Emerging Solutions in Pain faculty attending the 2006 Faculty Advisory Committee Meeting.</p> <p>The new tools and resources that will be included in Volume Two of the Tool Kit will be available via a new multi-media CD-ROM, as well as via a downloadable series at the Emerging Solutions in Pain web site.</p>
<b>Intended Audience</b>	The primary audience of the Emerging Solutions in Pain Tool Kit Volume Two will be physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain.
<b>Program Objectives</b>	<p>The specific tools and resources that will make up the Emerging Solutions in Pain Tool Kit Volume Two will be taken from recommendations made by the Emerging Solutions in Pain Faculty. These tools and resources may include the following:</p> <ol style="list-style-type: none"> <li>(1) Tools for assessing functionality in patients who are prescribed opioids, such as a driving impairment test</li> <li>(2) Tools to assist in appropriate documentation of those patients who are prescribed opioids, such as chart stickers or downloadable return visit forms</li> <li>(3) Resources outlining specific legal issues associated with prescribing opioids</li> <li>(4) Case studies of patients who have had issues with misuse, abuse or addiction to opioids</li> </ol>
<b>Format</b>	A multimedia CD-ROM and online at <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a>
<b>Distribution</b>	<p>The Emerging Solutions in Pain Tool Kit Volume Two will be available through the following avenues:</p> <ol style="list-style-type: none"> <li>(1) Through BRC request cards</li> <li>(2) Through electronic download at <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a></li> <li>(3) Through distribution at the Emerging Solutions in Pain Meet the Expert Booth</li> <li>(4) Through distribution at the RESPECT Meeting Series</li> </ol>
<b>Request for Sponsor Support</b>	<p>Medical Learning Solutions will announce and promote the Emerging Solution in Pain Tool Kit Volume Two through the means of distribution outlined above. In addition, all Emerging Solutions in Pain initiatives will direct clinicians to <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a>, where Volume Two will be prominently featured. These will include journal advertisements, banner advertisements and brochures for the Emerging Solutions in Pain initiative.</p> <p>As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. in the dissemination of information</p>





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### *Program Summary*

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regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.

**Total Budget:** \$150,850



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Proposal Number: 06-003

Date: November 28, 2005

**2006 Emerging Solutions in Pain Tool Kit, Volume Two**  
**Proposed Budget**  
November 28, 2005

<b>Cost Summary</b>	
<b>Approximate Total, Direct Expenses</b>	\$ 45,000
<b>Total, Indirect Expenses</b>	\$ 105,850
<b>Development and Production of the Emerging Solutions in Pain Tool Kit, Volume Two</b>	<b>\$ 150,850</b>

<b>Detailed Budget Itemization</b>	
<b>Direct Expenses, Approximate</b>	
<b>Duplication: ESP Tool Kit CD-ROM, Quantity: 10,000</b>	\$ 24,500
Four color, two page CD mailer with two inside pockets to house four-color silk-screened CD-ROM plus 16-page four-color saddle-stitched booklet. 4/0 + varnish, score, fold, insertion of CD, shrinkwrapping.	
<b>Audio track recording</b>	\$ 3,500
Professional voice talent narration of Tool Kit instructions, KOL commentary, etc.	
<b>Clinical expert honoraria</b>	\$ 9,000
Preparation, review of audio commentary	
<b>Postage for returned BRCs*</b>	\$ 2,500
<b>Postage to ship CDs for BRC requests*</b>	\$ 5,000
<b>Miscellaneous (non-fulfillment shipping, taxes, etc.)</b>	\$ 500
<b>Approximate Total, Direct Expenses</b>	<b>\$ 45,000</b>

<b>Indirect Expenses</b>	
<b>IT / programming services</b>	\$ 33,465
Includes programming of multi-media CD-ROM, including user-friendly CD interface; programming of Tools and resources, instructions and commentary; adaptation of all Tools and resources to formats appropriate for online posting and use	
<b>Graphic design / production services</b>	\$ 13,500
Includes production of multi-media animation and graphics for CD; adaptation of design for CD case, rep BRC, journal advertisements; typesetting, layout, proofing, coordination with print and duplication vendors	
<b>Medical / scientific services</b>	\$ 37,630
Includes content development for rep BRC, journal advertisement, CD booklet	
<b>Fulfillment of CDs in response to returned rep BRCs</b>	\$ 5,000
<b>Administrative and accounting fees</b>	\$ 2,543
<b>Project management</b>	\$ 13,712
<b>Total, Indirect Expenses</b>	<b>\$ 105,850</b>

\*Note that "BRCs" refers to excess Business Reply Cards printed in 2005 in association with the ESP Slim Jim. BRCs will not be re-printed in 2006.



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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain Awareness Campaign
<b>Program Overview</b>	Medical Learning Solutions is proposing to increase the number of health care professionals who are aware of the Emerging Solutions in Pain initiative through the development and implementation of a coordinated series of advertising campaigns in 2006. The goal of this awareness campaign is to expand the reach of the Emerging Solutions in Pain initiatives to health care professionals who will benefit from the educational information presented at the web site, on the Tool Kit CD-ROM, at the Meet the Experts Booth and at the RESPECT meeting series.
<b>Int nded Audience</b>	The primary audience of the Emerging Solutions in Pain Tool Kit Volume Two will include physicians, pharmacists, nurses, physician assistants, and other health care professionals who provide care to patients with chronic pain.
<b>Program Objectives</b>	<p>The overall objective of the 2006 Awareness Campaign is to increase the number of health care professionals who are active in the Emerging Solutions in Pain community. The specific objectives will include, but are not limited to:</p> <ol style="list-style-type: none"> <li>(1) Increase the number of registered users at <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a></li> <li>(2) Increase the number of user sessions at <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a></li> <li>(3) Increase the total amount of information downloaded at <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a></li> </ol>
<b>Format</b>	Journal and banner advertisements
<b>Distribution</b>	<p>The 2006 Emerging Solutions in Pain Awareness Campaign will include, but is not limited to:</p> <ol style="list-style-type: none"> <li>(1) Journal advertisements in <i>Practical Pain Management Journal</i></li> <li>(2) Banner advertisements at select professional pain management organization web sites</li> </ol>
<b>Request for Spons r Support</b>	<p>Medical Learning Solutions will coordinate the Emerging Solution in Pain Awareness Campaign through the means of distribution outlined above.</p> <p>As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.</p>
<b>Total Budget:</b>	\$61,500



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Proposal Number: 06-003  
Date: November 28, 2005

**2006 Emerging Solutions in Pain Awareness Campaign**  
***Proposed Budget***  
November 28, 2005

<b>Cost Summary</b>	
<b>Approximate Total, Direct Expenses</b>	\$ 45,000
<b>Total, Indirect Expenses</b>	\$ 16,500
<b>D v lopment and Implementation of the 2006 Emerging Solutions in Pain Awareness Campaign</b>	<b>\$ 61,500</b>

<b>Detailed Budget Itemization</b>	
<b>Direct Expenses, Approximate</b>	
<b>Journal advertisements, 12 months</b> Four-color, full-page advertising series in selected pain management journals	\$ 40,200
<b>Banner advertisements, 6 months</b> Advertising campaign at select professional organization web sites, to occur in conjunction with annual congresses and association meetings	\$ 4,200
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$ 600
<b>Approximate Total, Direct Expenses</b>	<b>\$ 45,000</b>

<b>Indirect Expenses</b>	
<b>Graphic design / production services</b>	\$ 8,750
<b>Medical / scientific services</b>	\$ 2,000
<b>Administrative and accounting fees</b>	\$ 750
<b>Project management</b>	\$ 5,000
<b>Total, Indirect Expenses</b>	<b>\$ 16,500</b>



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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain Accredited Article Series
<b>Program Overview</b>	Medical Learning Solutions is proposing to develop and produce an accredited series of eight journal articles, directed toward physicians, pharmacists, nurses and other health care professionals who are involved in the care of patients with chronic pain. This series of accredited articles will be initially published in the <i>Practical Pain Management Journal</i> ; all articles will be available for credit online at the Emerging Solutions in Pain web site, as well.
<b>CE Provider</b>	<p>Based on the need to educate clinicians in the assessment and treatment of chronic pain patients who may be at risk for abuse, addiction and diversion, the The Emerging Solutions in Pain Accredited Article Series will be accredited by a third party CE vendor of our choice.</p> <p>All articles in the Accredited Article Series will be accredited for:</p> <ul style="list-style-type: none"> <li>• CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each activity will be approved for a maximum of one hour of category 1 credit toward the AMA Physician's Recognition Award.</li> <li>• CPE credit for pharmacists by the Accreditation Council for Pharmacy Education. Each activity will be approved for a maximum of 1.0 credit hour (0.1 CEU) for Continuing Pharmacy Education</li> <li>• CNE credit for nurses. Each activity will be approved for a maximum of 1.0 Contact Hours.</li> </ul>
<b>Intended Audience</b>	The primary audience of The Emerging Solutions in Pain Accredited Article Series includes physicians, pharmacists, nurses and other health care professionals who provide care to patients with pain.
<b>Program Objectives</b>	<p>The purpose of The Emerging Solutions in Pain Accredited Article Series is to educate clinicians on key topics relating to the Emerging Solutions in Pain initiatives. These topics may include, but are not limited to, the following:</p> <ol style="list-style-type: none"> <li>(1) Assessing functionality in patients prescribed opioids for chronic pain</li> <li>(2) Urine drug testing and other methods for monitoring patients who are prescribed opioids</li> <li>(3) Determining relative risk of opioid abuse</li> <li>(4) Issues relating to drug testing in patients who are prescribed opioids</li> <li>(5) Standards of care in pain management</li> <li>(6) The importance of interdisciplinary teams in effective pain management</li> <li>(7) Neurobiology of addiction</li> <li>(8) Legal issues associated with the prescription of opioids</li> </ol>



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### *Program Summary*

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<b>Format</b>	A series of eight four-page accredited articles in the <i>Practical Pain Management Journal</i>
<b>Post-Activity Feedback</b>	<p>Course evaluation forms will be required of all participants who seek to receive continuing education credit. Medical Learning Solutions will work with the third party CE vendor to summarize the information collected from these forms in a formal report to evaluate program effectiveness.</p> <p>Participants will evaluate the following as excellent, good, fair or poor:</p> <ol style="list-style-type: none"> <li>(1) Overall content</li> <li>(2) Faculty teaching effectiveness</li> <li>(3) Format</li> </ol> <p>Participants will also respond to the following questions:</p> <ol style="list-style-type: none"> <li>(1) How well did the program achieve its educational objectives?</li> <li>(2) Do you feel the program material was useful and practice-oriented?</li> <li>(3) Do you feel that the information provided in this educational activity will aid in improving patient care in your practice?</li> <li>(4) Do you feel that fair balance was maintained for all therapeutic options?</li> <li>(5) Would you participate in future educational activities?</li> </ol>
<b>Distribution</b>	Medical Learning Solutions and the third party CE vendor will announce and promote The Emerging Solutions in Pain Accredited Article Series primarily through advertisement at the Emerging Solutions in Pain web site.
<b>Request for Sponsor Support</b>	As a supplement to these primary methods, Medical Learning Solutions and the third party CE vendor may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.
<b>Total Budget:</b>	\$304,841



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Proposal Number: 06-003

Date: November 28, 2005

### Emerging Solutions in Pain Accredited Journal Article Series

A Series of 4-Page Articles Inserted in *Practical Pain Management Journal* and Posted  
Online at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com)

November 28, 2005

<b>Program Parameters</b>	
Number of 2006 issues	8
Total 2006 articles	8
Pages per article	4
Circulation per article	39,000

<b>Cost Summary</b>			
	One-Time Charges	Per Article Costs	Total, Eight Article Series
Approximate Total, Direct Expenses; Development and Production	\$ -	\$ 27,000	\$ 216,000
Total, Indirect Expenses; Development and Production	\$ 2,000	\$ 10,855	\$ 86,841
Subtotal	\$ 2,000	\$ 37,855	\$ 302,841
<b>Cost of Eight Emerging Solutions in Pain Accredited Journal Article Series</b>			<b>\$ 304,841</b>

<b>Per Issue Cost</b>	<b>\$ 0.98</b>
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Proposal Number: 06-003

Date: November 28, 2005

## Emerging Solutions in Pain Accredited Journal Article Series

A Series of 4-Page Articles Inserted in *Practical Pain Management Journal* and Posted  
Online at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com)

November 28, 2005

### Detailed Budget Itemization

<b>Approximate Direct Expenses, Development and Production</b>			
	One-Time Charges	Per Article Costs	Total, Eight Article Series
<b>Clinical expert honoraria</b>		\$ 3,000	\$ 24,000
<b>Insert page charges, PPMJ</b>		\$ 10,000	\$ 80,000
Four-page article printed on matte cover stock as journal insert			
<b>Accreditation of program for CME, CPE, CNE</b>		\$ 8,000	\$ 64,000
<b>Continuing Education participant certificates (estimate 750 certificates per program)</b>		\$ 6,000	\$ 48,000
<b>Approximate Total, Direct Expenses, Development and Production</b>	\$ -	\$ 27,000	\$ 216,000

<b>Indirect Expenses, Development and Production</b>			
	One-Time Charges	Per Article Costs	Total, Eight Article Series
<b>Program development</b>		\$ 1,200	\$ 9,600
Includes coordination with clinical expert for receipt of article; coordination with accreditor, internal teams, PPMJ staff			
<b>Medical services</b>		\$ 2,400	\$ 19,200
Includes development of supporting verbiage (needs assessment, objectives, etc.) and self-assessment; editorial services; fact-checking services; proofreading			
<b>Production services</b>		\$ 275	\$ 2,200
Includes layout and typesetting of articles, supporting web pages for online posting			
<b>Programming of finished monograph for Web-posting, archiving</b>		\$ 950	\$ 7,600
<b>Database creation, management</b>	\$ 2,000	\$ -	\$ -
<b>Administrative and accounting fees</b>		\$ 2,566	\$ 20,528
<b>Project management</b>		\$ 3,464	\$ 27,713
<b>Total, Indirect Expenses, Development and Production</b>	\$ 2,000	\$ 10,855	\$ 86,841



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## **Grant Request Part B: Live Emerging Solutions in Pain Educational Events and Activities**

### **Program Overview: Summary of Work Completed in 2005**

#### **1. ESP MEET THE EXPERTS BOOTH**

Another key Emerging Solutions in Pain initiative for 2005 is the ESP Meet the Experts exhibit booth, which is an informational and interactive exhibit booth that features mini-presentations by leading experts in pain and addiction medicine at select national healthcare association conferences. The goals of the Meet the Expert booth are several-fold:

1. Introduce the Emerging Solutions in Pain initiative to clinicians attending the meeting
2. Distribute ESP resources to clinicians, including the Emerging Solutions in Pain Tool Kit CD-ROM and Mini-Disc Publication
3. Provide clinicians with an opportunity to meet with national leaders in the field of pain management, in an intimate setting designed to foster interaction and discussion
4. Capture clinical expert presentations for video replay at the Emerging Solutions in Pain web site
5. Allow clinicians to explore the Emerging Solutions in Pain web site and the Tool Kit CD-ROM through interactive kiosks
6. Make clinicians aware that new and innovative resources are being added to the ESP web site on a continuing basis

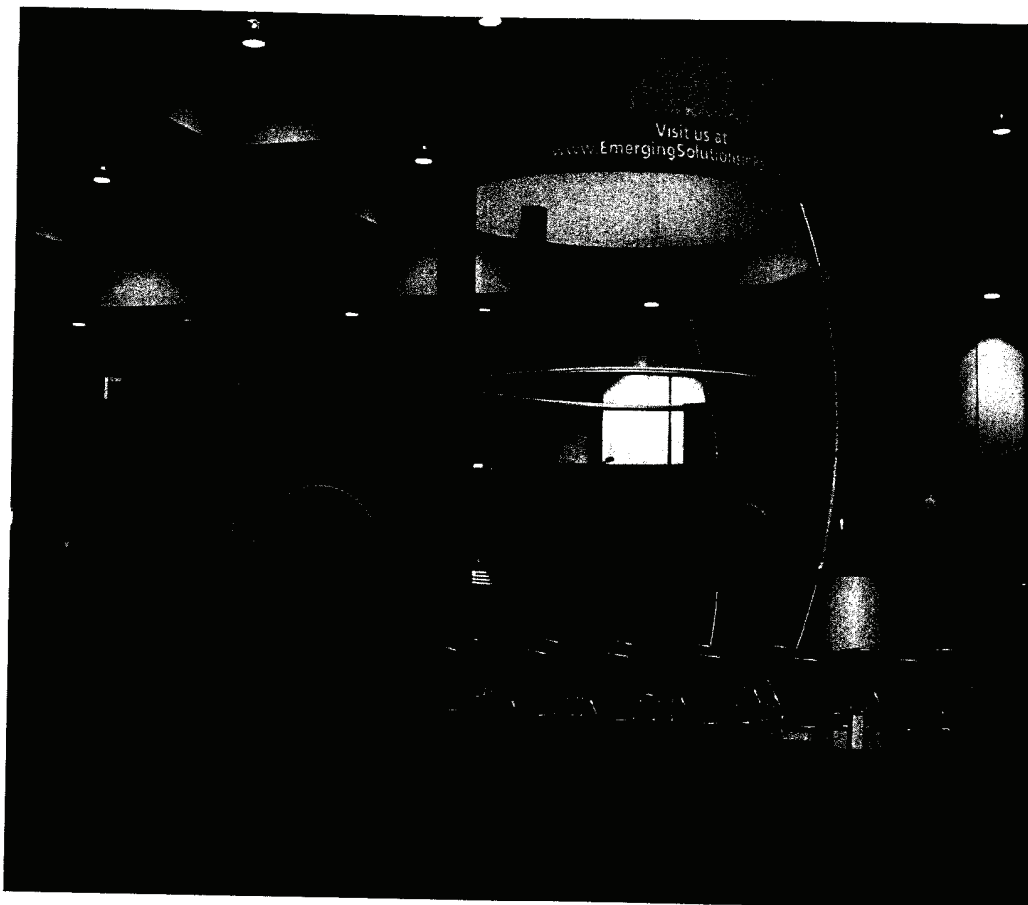
Through 2005, the Meet the Expert Booth has disseminated Emerging Solutions in Pain information and resources to clinicians at multiple meetings:

<b>Meeting</b>	<b>Date</b>	<b>Location</b>
AAPM	February, 2005	Palm Springs, CA
APS	March, 2005	Boston, MA
ASAM	April, 2005	Dallas, TX
AAFP	September, 2005	San Francisco, CA
AAPM&R	October, 2005	Philadelphia, PA



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## **Grant Request Part B: Live Emerging Solutions in Pain Educational Events and Activities**



### **2. THE ESP RESPECT (RESPONSIBLE PAIN EDUCATION CAN BE THERAPEUTIC) MEETING SERIES**

This accredited series of regional meetings is directed toward physicians, pharmacists, nurses, and other allied health care professionals who provide care to patients with chronic pain. The RESPECT meetings focus on the role of opioids in pain management, concerns over addiction, and the potential for diversion. One of the goals of this series is to educate clinicians on resources that are available within their own community for building interdisciplinary teams and networks to improve the quality of care for patients with chronic pain. As such, these programs are accredited for physicians, pharmacists and nurses; topics addressed include:

1. Standards of care for determining a patient's treatment plan
2. Interdisciplinary team approaches to pain management



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## ***Grant Request Part B: Live Emerging Solutions in Pain Educational Events and Activities***

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3. Two – three case studies of patients in the actual community

Each meeting participant receives a RESPECT binder with all slides presented in the program, as well as tools and information specific to the treatment of patients with pain in the local community. Resources in this binder include:

1. The Emerging Solutions in Pain Tool Kit CD-ROM
2. The American Pain Foundation TARGET Chronic Pain Card
3. Opioid Risk Tool (both clinician and patient forms)
4. The Hamilton Rating Scale for Depression
5. Return Visit Clinician Checklist and Patient Questionnaire
6. Internet resources, organized by:
  - a. Federal government resources
  - b. State government resources
  - c. Legal resources
  - d. Pain management resources
  - e. Professional Associations
  - f. Online Continuing Education (CE) resources
7. State-specific information from the state medical board(s)

The faculty for each RESPECT meeting is composed of two nationally-known faculty and two to three regional speakers, thus creating a dynamic presentation that addresses challenges associated with pain management on both a national and regional level.

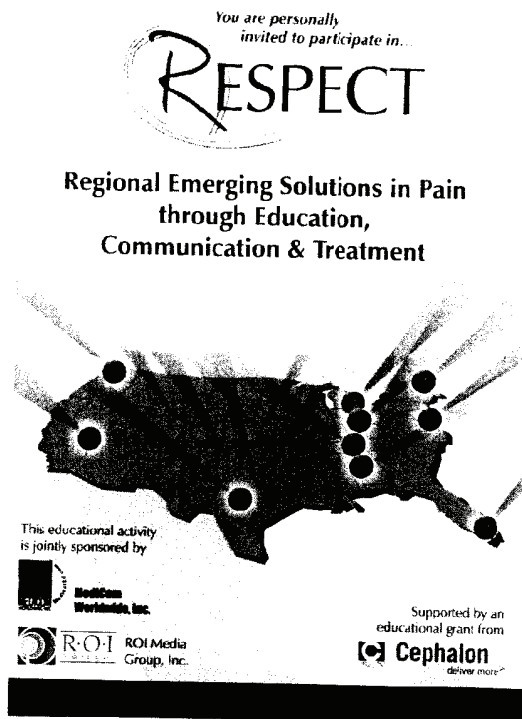
To date, there have been seven RESPECT meetings involving 47 physicians, 113 pharmacists, 72 nurses and 38 other allied health care specialists.



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## **Grant Request Part B: Live Emerging Solutions in Pain Educational Events and Activities**

### **Exhibit B-1**



### **Program Overview: Proposed 2006 Activities**

The following activities are recommended as the Live Emerging Solutions in Pain Educational Events and Activities in 2006.

1. Continuance of the Meet the Expert exhibit booth at select, larger association meetings and expansion of the Meet the Expert mini-booth at smaller association meetings
2. Recreation of the RESPECT meeting series to focus on the provision of trained Emerging Solutions in Pain faculty to regional and local meetings of clinician associations, grand rounds programs and other similar venues
3. Adaptation of the current RESPECT meeting content to focus on the educational needs of single-clinician groups at regional and local meetings of clinician associations



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Proposal Number: 06-003  
Date: November 28, 2005

**Emerging Solutions in Pain**  
**Summary of Proposed Budget, Grant Request Part B**  
*Live Emerging Solutions in Pain Educational Events and Activities*  
 November 28, 2005

<b>Cost Summary</b>	
<b>Meet the Experts Booth</b>	
Approximate Total, Direct Costs	\$ 380,150
Indirect Costs	\$ 208,290
Cost of the 2006 Meet the Expert Booth Series	\$ 588,440
<b>RESPECT Meetings</b>	
Approximate Total, Direct Costs	\$ 170,950
Indirect Costs	\$ 204,616
Cost of a 20-Activity RESPECT Meeting Series	\$ 375,566
<b>Total Budget, 2006 Live Emerging Solutions in Pain Educational Events and Activities</b>	<b>\$ 964,006</b>

Approval Signature \_\_\_\_\_

Date \_\_\_\_\_

**Note: no work may begin until Medical Learning Solutions receives, via email or fax, this approval with signature and date**



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## *Program Summary*

<b>Program Title</b>	The Emerging Solutions in Pain Meet the Experts Booth
<b>Program Overview</b>	<p>Medical Learning Solutions is proposing to continue utilizing the Meet the Experts Booth as an informational and interactive display for educating clinicians in the Emerging Solutions in Pain initiatives at national congresses and association meetings. In 2006, Medical Learning Solutions is proposing to tailor Booth activities to the size and specific purpose of the congress or association. Thus, at larger meetings, the full Meet the Expert Booth will be utilized, while a smaller Emerging Solutions in Pain Booth will be displayed at smaller congress and association meetings.</p> <p>Functionality for the full-size Meet the Expert Booth will include a seating area for meeting attendees to interact with Emerging Solutions in Pain clinical experts; computer terminals featuring interactive displays highlighting the Emerging Solutions in Pain initiatives, membership registration for the Emerging Solutions in Pain Web Site, and the Emerging Solutions in Pain Tool Kit. The smaller Emerging Solutions in Pain Booth will focus on interactive displays of the Tool Kit and video highlights of previous Meet the Expert presentations; membership registration; and distribution of the Emerging Solutions in Pain Tool Kit.</p>
<b>Intended Audience</b>	The primary audience of the Emerging Solutions in Pain Meet the Experts Booth will be physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain and who attend selected national association meetings and congresses. Currently suggested meetings include the 2006 meetings of the AAPM, AAPM&R, AANP, AMCP and ASAM.
<b>Program Objectives</b>	<p>The purpose of the Emerging Solutions in Pain Meet the Expert Booth is to disseminate information concerning the Emerging Solutions in Pain initiative to clinicians practicing in the field of pain management, and to educate those clinicians on the assessment and monitoring of pain patients, and on good practice management techniques. Clinicians visiting the booth will have opportunities to:</p> <ol style="list-style-type: none"> <li>(1) Interact with Emerging Solutions in Pain clinical experts in small discussion groups, focusing on tools and strategies that will contribute to a proper balance of pain control and abuse/diversion minimization (full-size Meet the Expert Booth only)</li> <li>(2) On computer terminals, view multi-media, interactive programs highlighting the issues associated with minimization of abuse, addiction and diversion, the Emerging Solutions in Pain Tool Kit and associated case studies</li> <li>(3) Receive copies of the Emerging Solutions in Pain Tool Kit CD-ROM and other support materials, such as the Mini-Disc Publication</li> <li>(4) Gain exposure to the resources available at the Emerging Solutions in Pain Web Site, and register as a "member", thereby expediting their ability to access online resources</li> </ol>
<b>Format</b>	An interactive meeting booth, to be presented at national association meetings and congresses. The full-size Meet the Expert Booth will feature live peer-to-peer interactions with Emerging Solutions in Pain clinical experts, as well as interactive, multimedia programs that highlight the Emerging Solutions in Pain initiatives. The smaller Emerging Solutions in Pain Booth will focus on educating clinicians in the availability of the Emerging Solutions in Pain initiatives.





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## *Program Summary*

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### **Distribution**

The Emerging Solutions in Pain Meet the Expert Booth will be available at selected national association meetings and congresses; meetings identified to date include the AAPM, AAPM&R, AANP, AMCP and ASAM. The announcement of the Booth will be made via direct mail to registered meeting attendees and members, and via journal and/or banner advertisements. Information at the Booth will be provided by Emerging Solutions in Pain clinical experts and by Medical Learning Solutions staff members.

### **Request for Sponsor Support**

Medical Learning Solutions is promoting the Emerging Solutions in Pain Meet the Experts Booth through a variety of methods, including direct mail, publication of a multimedia Mini-Disc, and journal and banner advertisements.

As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely as a supplement to MLS' primary methods of announcement and promotion.

**Total Budget:** \$588,440



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Proposal Number: 06-003

Date: November 28, 2005

**2006 Emerging Solutions in Pain Exhibition Booth Series**  
***Proposed Budget***  
November 28, 2005

<b><i>Program Parameters</i></b>	
Number of Exhibitions of the Full-Size Meet the Expert Booth	2
Number of Exhibitions of the Smaller Emerging Solutions in Pain Booth	3

<b><i>Cost Summary</i></b>		
	Per Meeting	Total
One-Time Approximate Direct Expenses	\$ -	\$ 47,000
Approximate Total, Direct Expenses: Full-Size Booth (AAPM, AAPM&R)	\$ 111,570	\$ 193,500
Approximate Total, Direct Expenses: Mini ESP Booth (ASAM, AANP, AMCP)	\$ 46,550	\$ 139,650
Total, Indirect Expenses	\$ 64,598	\$ 208,290
<b>Total Cost of the 2006 Emerging Solutions in Pain Exhibition Booth Series</b>		<b>\$ 588,440</b>



Proposal Number: 06-003

Date: November 28, 2005

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**2006 Emerging Solutions in Pain Exhibition Booth Series**  
**Proposed Budget**  
November 28, 2005

*Detailed Budget Itemization*

<b>Approximate Total, Direct Expenses</b>		
<b>One-Time Approximate Direct Expenses</b>		
	Per Meeting	Total
Update of existing mini-booth; new graphic panels for full-size booth		\$ 15,000
Booth give-aways		\$ 30,000
Miscellaneous (non-fulfillment shipping, faxes, etc.)		\$ 2,000
<i>Subtotal, One-Time Approximate Direct Expenses</i>		\$ 47,000
<b>Full-Size Booth (AAPM, AAPM&amp;R)</b>		<i>2 meetings total</i>
Exhibit space (includes liability insurance)	\$ 15,400	\$ 30,800
Booth set-up/tear-down (floor plan, shop prep, installation and dismantling including labor supervision, travel)	\$ 25,720	\$ 51,440
Equipment rental (computer units, plasma screen, switcher unit, audio w/ lav mic, electrical, telecommunication links, chairs, carpeting, etc.)	\$ 10,590	\$ 21,180
Shipping of booth to AAPM meeting site only	\$ 8,820	\$ 8,820
Shipping of booth to AAPM&R meeting site only (note additional shipping charges for Hawaii location of AAPM&R)	\$ 20,820	\$ 20,820
Shipping of supplies (mini-discs, Tool Kits, etc) to meeting site - delivery to booth charges	\$ 2,200	\$ 4,400
Badge Reader System (3 units)	\$ 770	\$ 1,540
Booth advertisement		
Advertisement in meeting catalog/publication (full page, 4/c)	\$ 2,925	\$ 5,850
Booth posters, printing	\$ 825	\$ 1,650
KOL expenses: two KOL faculty		
Honoraria	\$ 12,000	\$ 24,000
Travel: air, hotel, ground, OOP	\$ 4,300	\$ 8,600
ROI expenses: three ROI staff		
Travel: air, hotel, ground, OOP	\$ 6,900	\$ 13,800
Exhibitor registration	\$ 300	\$ 600
<i>Subtotal, Approximate Direct Expenses for Full-Size Booth</i>		\$ 111,570
		\$ 193,500



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Proposal Number: 06-003

Date: November 28, 2005

**2006 Emerging Solutions in Pain Exhibition Booth Series**  
**Proposed Budget**  
November 28, 2005

*Detailed Budget Itemization*

<b>Approximate Total, Direct Expenses (continued)</b>		
	Per Meeting	Total
<b>Mini Booth (AANP, AMCP, ASAM)</b>		<i>3 meetings total</i>
Exhibit space (includes liability insurance)	\$ 1,430	\$ 4,290
Booth Rental for 8X10 Space	\$ 3,850	\$ 11,550
Booth set-up/tear-down (floor plan, shop prep, installation and dismantling including labor supervision, travel)	\$ 15,950	\$ 47,850
Equipment rental (computer units, plasma screen, switcher unit, audio w/ lav mic, electrical, telecommunication links, chairs, carpeting, etc.)	\$ 6,475	\$ 19,425
Shipping of booth to meeting site	\$ 7,975	\$ 23,925
Shipping of supplies (mini-discs, Tool Kits, etc) to meeting site - delivery to booth charges	\$ 2,200	\$ 6,600
Booth advertisement		
Advertisement in meeting catalog/publication	\$ 2,310	\$ 6,930
Booth posters, printing	\$ 660	\$ 1,980
ROI expenses: three ROI staff		
Travel: air, hotel, ground, OOP	\$ 5,500	\$ 16,500
Exhibitor registration	\$ 200	\$ 600
<b>Subtotal, Approximate Direct Expenses for Mini Booth</b>	<b>\$ 46,550</b>	<b>\$ 139,650</b>



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**2006 Emerging Solutions in Pain Exhibition Booth Series**  
***Proposed Budget***  
November 28, 2005

***Detailed Budget Itemization***

***Total, Indirect Expenses***

	Per Meeting	Total
<b>Medical / scientific services</b> Includes development of content for meeting advertisements; ; coordination of presentation content with ESP KOLs	\$ 4,000	\$ 20,000
<b>Graphic design / production services</b> Includes development of display graphics for booth panels, graphics for interactive booth displays; graphic design, typesetting and layout of booth posters and advertisements (direct mail plus meeting catalog); proofreading; coordination with print vendors; etc.	\$ 2,000	\$ 10,000
<b>Conference management services</b> staffing booth during meeting; coordination with KOLs pre-meeting, post-meeting and during meeting; coordination with conference vendors, coordination of booth advertising; etc.		
<b>Conference management services: Full-Size Booth (2 total)</b>	\$ 26,700	\$ 53,400
<b>Conference management services: Mini Booth (3 total)</b>	\$ 17,300	\$ 51,900
<b>Administrative and accounting fees</b>	\$ 5,460	\$ 27,301
<b>Project management</b>	\$ 9,138	\$ 45,689
<b><i>Total, Indirect Expenses</i></b>	<b>\$ 64,598</b>	<b>\$ 208,290</b>



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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain RESPECT Meeting Series
<b>Program Overview</b>	<p>Medical Learning Solutions is proposing to adapt the 2005 RESPECT meetings into a new series that focuses on the provision of trained Emerging Solutions in Pain faculty to regional and local meetings of clinician associations, grand rounds programs and other similar venues. The 2006 RESPECT Meeting Series will therefore focus on providing practical clinical information via an accredited lecture series to health care professionals practicing in local clinics, hospitals and office settings.</p> <p>In this series, Medical Learning Solutions is proposing to update the 2005 RESPECT Meeting slide modules with information that will be appropriate for smaller groups of clinicians, such as will attend local and regional association meetings and grand rounds presentations. Select Emerging Solutions in Pain faculty who express interest and availability will then be trained remotely via teleconference in the new data; these individuals will form a RESPECT Meeting Speakers' Bureau. Medical Learning Solutions will work with local and regional association meetings and hospitals hosting grand rounds presentations to identify meetings of clinicians which will benefit from an accredited presentation focusing on Emerging Solutions in Pain/RESPECT Meeting topics. After a need has been identified, Medical Learning Solutions will coordinate all logistical arrangements for the presentation with a trained, available Faculty member.</p>
<b>CE Provider</b>	<p>Based on the need to educate clinicians in the assessment and treatment of chronic pain patients who may be at risk for abuse, addiction and diversion, The Emerging Solutions in Pain RESPECT Meeting Series will be accredited by a third party CE vendor of our choice.</p> <p>The Meeting Series will be accredited for:</p> <ul style="list-style-type: none"> <li>• CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each activity will be approved for a maximum of one hour of category 1 credit toward the AMA Physician's Recognition Award.</li> <li>• CPE credit for pharmacists by the Accreditation Council for Pharmacy Education. Each activity will be approved for a maximum of 1.0 credit hour (0.1 CEU) for Continuing Pharmacy Education</li> <li>• CNE credit for nurses. Each activity will be approved for a maximum of 1.0 Contact Hours.</li> </ul>
<b>Intended Audience</b>	The primary audience of The Emerging Solutions in Pain RESPECT Meeting Series includes clinicians who provide care to patients with pain. These clinicians will include physicians, pharmacists and nurses, but may be extended to other clinical and non-clinical members of a multi-disciplinary treatment team, such as social workers, case managers, etc.



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## *Program Summary*

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**Program Objectives** The purpose of the RESPECT Meeting Series is to educate clinicians on the key tenets of the Emerging Solutions in Pain initiative, focusing on the role of appropriate assessment and monitoring techniques, and good practice management strategies, in achieving effective interactions between members of the treatment team. In addition, other topics may be included, based upon recommendations made by the Emerging Solutions in Pain Faculty Advisory Committee.

**Format** A series of live, peer-to-peer activities scheduled in conjunction with local and regional association meetings and at hospital or clinic-based grand rounds programs throughout the United States. This proposal is for 20 RESPECT meetings.

**Post-Activity Feedback** Course evaluation forms will be required of all participants who seek to receive continuing education credit. Medical Learning Solutions will work with the third party CE vendor to summarize the information collected from these forms in a formal report to evaluate program effectiveness.

Participants will evaluate the following as excellent, good, fair or poor:

- (1) Overall content
- (2) Faculty teaching effectiveness
- (3) Format
- (4) Audio/visual

Participants will also respond to the following questions:

- (1) How well did the program achieve its educational objectives?
- (2) Do you feel the program material was useful and practice-oriented?
- (3) Do you feel that the information provided in this educational activity will aid in improving patient care in your practice?
- (4) Do you feel that fair balance was maintained for all therapeutic options?
- (5) Would you participate in future educational activities?

**Distribution** Medical Learning Solutions and the third party CE vendor will announce and promote The Emerging Solutions in Pain RESPECT Meeting Series primarily through arrangement with the local/regional association hosting the meeting; or the hospital sponsoring the grand rounds presentation. Medical Learning Solutions will also advertise availability of these meetings via advertisement on the Emerging Solutions in Pain web site.

**Request for Sponsor Support** As a supplement to these primary methods, Medical Learning Solutions and the third party CE vendor may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.

**Total Budget:** \$375,566





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Proposal Number: 06-003

Date: November 28, 2005

**Emerging Solutions in Pain 2006 RESPECT Meeting Series**  
**Projected Budget Estimate**  
November 28, 2005

<b>Program Parameters</b>	
Number of regional association symposia	10
Faculty presenter per activity	1
Approximate number, health care professional attendees per meeting	30
Direct mail invitations to health care professionals	150

<b>Cost Summary</b>		
	One-time only costs	Each group of 10 meetings
Approximate Total, Direct Meeting Series Expenses	\$ -	\$ 75,725
Total, Indirect Meeting Series Expenses	\$ 47,663	\$ 64,726
Approximate Total, Direct Meeting Support Expenses	\$ 19,500	\$ -
Total, Indirect Meeting Support Expenses	\$ 27,500	\$ -
Subtotal, one-time only costs	\$ 94,663	\$ -
Subtotal, 20-meeting RESPECT series	\$ -	\$ 280,903
<b>Cost of 2006 Emerging Solutions in Pain 20-Meeting RESPECT Series</b>		<b>\$ 375,566</b>



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Date: November 28, 2005

**Emerging Solutions in Pain 2006 RESPECT Meeting Series**  
**Projected Budget Estimate**  
November 28, 2005

**Detailed Budget Itemization**

<b>Direct Meeting Expenses, Approximate</b>		
	One-time only costs	Each group of 10 meetings
<b>Direct mail invitations, mail services, postage</b>	\$ -	\$ 4,725
Personalized invitations to be mailed to every potential participant; includes printing, assembly, mail services and postage. Postage estimated at \$0.37 per direct mail piece		
<b>Direct mail list purchase</b>	\$ -	\$ -
<b>Print materials</b>	\$ -	\$ 3,500
Includes printing of shell materials for adaptation and use in individualized symposia kits for every symposium; kits to include accreditation information, speaker biographical and disclosure information, agenda, reference materials and handout materials, where appropriate		
<b>Speaker honoraria</b>	\$ -	\$ 25,000
<b>Speaker travel (air, OOP, hotel)</b>	\$ -	\$ 12,000
<b>Ground transportation</b>	\$ -	\$ 2,000
<b>Catering</b>	\$ -	\$ 15,000
<b>Audio/visual services</b>	\$ -	\$ 5,000
<b>Onsite CME coordination</b>	\$ -	\$ 7,500
<b>Shipping/Fed Ex</b>	\$ -	\$ 1,000
<b>Approximate Total, Direct Meeting Expenses</b>	\$ -	\$ 75,725

<b>Indirect Meeting Expenses</b>		
	One-time only costs	Each group of 10 meetings
<b>Program development</b>	\$ 45,000	\$ -
Includes all labor associated with initial program set-up and development, including creation of text for print support materials, graphic design, typesetting and layout of all support materials, and development and creation of final program appearance		
<b>Medical Services</b>	\$ 18,000	\$ 20,000
Includes all labor associated with content of each symposium, including identification and production of resources specific for each region and clinicians in each association; review and coordination of content with faculty		
<b>Meeting management</b>		\$ 18,000
Includes coordination with association for date of symposium and all meeting-related logistical details; coordination with faculty for dates, travel and all other program details		
<b>Accreditation of program for CME, CPE, CNE</b>	\$ 15,000	\$ -
<b>Continuing Education participant certificates</b>		\$ 4,500
<b>Administrative and accounting fees</b>	\$ 6,240	\$ 9,458
<b>Project management</b>	\$ 8,423	\$ 12,768
<b>Total, Indirect Meeting Expenses</b>	\$ 47,663	\$ 64,726



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Date: November 28, 2005

**Emerging Solutions in Pain 2006 RESPECT Meeting Series**  
**Projected Budget Estimate**  
November 28, 2005

**Detailed Budget Itemization**

<b>Direct Meeting Support Expenses, Approximate</b>		
	One-time only costs	Each group of 10 meetings
<b>Slide module updates</b>		
Medical writing	\$ 8,500	\$ -
Speaker honoraria	\$ 3,500	\$ -
<b>Production of non-accredited video from one RESPECT meeting</b>		
Equipment rental	\$ 3,000	\$ -
Travel	\$ 4,500	\$ -
<b>Approximate Total, Direct Meeting Support Expenses</b>	<b>\$ 19,500</b>	<b>\$ -</b>

<b>Indirect Meeting Support Expenses</b>		
	One-time only costs	Each group of 10 meetings
<b>Slide module updates</b>		
Program development	\$ 2,300	\$ -
Medical services	\$ 7,950	\$ -
<b>Production of non-accredited video from one RESPECT meeting</b>		
Program development	\$ 1,775	\$ -
Editing, post production	\$ 9,975	\$ -
<b>Administrative and accounting fees</b>	<b>\$ 3,320</b>	<b>\$ -</b>
<b>Project management</b>	<b>\$ 4,480</b>	<b>\$ -</b>
<b>Total, Indirect Meeting Support Expenses</b>	<b>\$ 27,500</b>	<b>\$ -</b>



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## ***Grant Request Part C: Programs to Further Expand the Reach of the Emerging Solutions in Pain Educational Events and Activities***

### ***Program Overview: Proposed 2006 Activities***

The following activities are recommended as a series of programs that will further expand the reach of the Emerging Solutions in Pain Educational Events and Activities in 2006.

1. Development and implementation of a full-day seminar program, to be held for clinical attendees of a national congress, focusing on the intersection of pain management and addiction medicine
2. Additional RESPECT meetings, held at regional and local meetings of clinician associations, grand rounds programs and other similar venues

#### **1. The Emerging Solutions in Pain Full-Day Lecture Program**

The American Society for Addiction Medicine (ASAM) has historically held an accredited, full-day lecture one day prior to the convening of its annual meeting for those ASAM members attending the meeting. This lecture, known as the Common Threads program, has focused on topical issues relating to the convergence of pain and addiction medicine. For logistical reasons, this meeting will not be offered by ASAM to its members at the 2006 meeting. However, the educational need of these clinicians, to increase their knowledge and understanding of the pain management and the impact of addiction on effective pain therapy, continues to exist.

Medical Learning Solutions is therefore proposing to create an accredited full-day lecture program that will educate ASAM members on topics relevant to the Emerging Solutions in Pain initiatives. Through a series of presentations by Emerging Solutions in Pain faculty, this program will focus on a scientific and clinical evaluation of the fields of pain management and addiction, and will include relevant case studies for discussion and presentation.

#### **2. The ESP RESPECT (RESponsible Pain Education Can be Therapeutic) Meeting Series**

The RESPECT Meeting Series has been described previously in the Grant Request Part B, in which a series of 20 RESEPECT Meetings were proposed, to be held in conjunction with local and regional association meetings and grand rounds presentations. The recommendation for this portion of the Grant Request is for an additional 10 RESPECT meetings in this series. The additional 10 meetings will utilize the same program infrastructure, content and trained faculty as the first 20 meetings, thereby cost-effectively extending the reach of this portion of the 2006 Emerging Solutions in Pain initiative.



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Proposal Number: 06-003  
Date: November 28, 2005

**Emerging Solutions in Pain  
Summary of Proposed Budget, Grant Request Part C**

*Programs to Further Expand the Reach of the Emerging Solutions in Pain Educational  
Events and Activities*  
November 28, 2005

<b>Cost Summary</b>	
<b>Full-day ESP Symposium</b>	
Approximate Total, Direct Expenses	\$ 132,850
Indirect Expenses	\$ 108,600
Cost of One Full-Day ESP Symposium Held at the 2006 ASAM Meeting	\$ 241,450
<b>RESPECT Meeting Series Extension</b>	
Approximate Total, Direct Expenses	\$ 75,725
Indirect Expenses	\$ 64,726
Cost of 10-Program Extension of the 2006 RESPECT Meeting Series	\$ 140,451
<b>Total Budget, 2006 Programs to Further Expand the Reach of the Emerging Solutions in Pain Educational Events and Activities</b>	<b>\$ 381,901</b>

Approval Signature \_\_\_\_\_

Date \_\_\_\_\_

**Not : no work may begin until Medical Learning Solutions receives, via email or fax, this approval with  
signature and date**



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## *Program Summary*

<b>Program Title</b>	The Emerging Solutions in Pain Accredited Full-Day Lecture Program
<b>Program Overview</b>	<p>Medical Learning Solutions is proposing to create an accredited full-day lecture program that will educate ASAM members on topics relevant to the Emerging Solutions in Pain initiatives. Through a series of presentations by Emerging Solutions in Pain faculty, this program will focus on a scientific and clinical evaluation of the fields of pain management and addiction, and will include relevant case studies for presentation and discussion.</p> <p>The core group of proposed faculty includes:</p> <ol style="list-style-type: none"> <li>(1) Howard Heit, MD, FACP, FASAM</li> <li>(2) Douglas Gourlay, MD, MSc, FRCPC</li> <li>(3) Seddon Savage, MD, FASAM</li> <li>(4) Steven Passik, PhD</li> </ol> <p>Other faculty will be recruited based upon recommendations by the core faculty. Specific lecture topics will be identified based upon a consensus of the core faculty, but may include topics such as:</p> <ol style="list-style-type: none"> <li>(1) Evaluating the risk of opioid abuse in the chronic pain patient</li> <li>(2) Pharmacologic therapies for the chronic pain patient with a history of drug abuse or addiction</li> <li>(3) Legal issues in prescribing opioids to the chronic pain patient</li> <li>(4) New pharmacologic agents for treating chronic pain patients</li> </ol>
<b>Intended Audience</b>	The primary audience of The Emerging Solutions in Pain Accredited Full-Day Lecture Program includes clinicians who provide care to patients with pain and who specialize in addiction medicine.
<b>Program Objectives</b>	The purpose of the Emerging Solutions in Pain Accredited Full-Day Lecture Program is to educate clinicians on topical issues relating to the convergence of pain and addiction medicine. In addition, other topics may be included, based upon recommendations made by the core faculty identified above and by the Emerging Solutions in Pain Faculty Advisory Committee.
<b>Format</b>	One full-day seminar program held one day prior to the Annual ASAM Conference, held in San Diego, California. This program will be comprised primarily as didactic lecture. An audience response system will also be utilized throughout the program to enhance audience participation and a more interactive experience.
<b>Activity Feedback</b>	<p>To help establish a return on education metric for this program, Medical Learning Solutions will develop with the moderator a series of opening questions that will utilize the audience response keypad system. These questions will gather basic audience demographics, educational understanding of content prior to the educational activity, ratings scales on specific clinical techniques, etc. This would occur during the introduction of the program, similar to a pre-test. Data received from this activity would be correlated to information gathered during the post-test, thereby establishing prior- vs post-program educational metrics.</p> <p>Course evaluation forms and a written post-test will be required of all participants who seek to receive continuing education credit. Medical Learning Solutions will</p>



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## *Program Summary*

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work with the third party CE vendor to summarize the information collected from these forms in a formal report to evaluate program effectiveness.

- (A) Participants will evaluate the following as excellent, good, fair or poor:
  - (1) Overall content
  - (2) Faculty teaching effectiveness
  - (3) Format
  - (4) Audio/visual
- (B) Participants will also respond to the following questions:
  - (1) How well did the program achieve its educational objectives?
  - (2) Do you feel the program material was useful and practice-oriented?
  - (3) Do you feel that the information provided in this educational activity will aid in improving patient care in your practice?
  - (4) Do you feel that fair balance was maintained for all therapeutic options?
  - (5) Would you participate in future educational activities?
- (C) Participants will also complete a post-test specific to the content topics, ACPE accreditation required.

### **CE Provider**

Based on the need to educate clinicians in the issues associated with treating chronic pain patients who may be at high risk for abuse, addiction or diversion of controlled substances, The Emerging Solutions in Pain Accredited Full-Day Lecture Program will be accredited by a third party CE vendor of our choice.

The Lecture Program will be accredited for:

- CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each activity will be approved for a maximum of seven hours of category 1 credit toward the AMA Physician's Recognition Award.
- CPE credit for pharmacists by the Accreditation Council for Pharmacy Education. Each activity will be approved for a maximum of 7.0 credit hours (0.7 CEU) for Continuing Pharmacy Education
- CNE credit for nurses. Each activity will be approved for a maximum of 7.0 Contact Hours.

### **Distribution**

Medical Learning Solutions and the third party CE vendor will announce and promote The Emerging Solutions in Pain Accredited Full-Day Lecture Program primarily through direct mail to ASAM members. Medical Learning Solutions will also advertise availability of this meeting via advertisement on the Emerging Solutions in Pain website.

### **Request for Sponsor Support**

As a supplement to these primary methods, Medical Learning Solutions and the third party CE vendor may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.

**Total Budget:** \$241,450





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Proposal Number: 06-003  
Date: November 28, 2005

**Emerging Solutions in Pain Full-Day Accredited Symposium**  
***Proposed Budget***  
November 28, 2005

***Program Description***

This proposed budget is for the development, production and management of a full-day CME-accredited stand-alone live event to coincide with the ASAM Annual Conference in San Diego on May 4, 2006. This program would support the Emerging Solutions in Pain mission of providing medical education in the area of pain management and the issues of misuse, abuse, and addiction.

<b><i>Program Parameters</i></b>	
Presenting faculty @ activity	5
Health care professional attendees @ meeting	250
Direct mail invitations to health care professionals per activity	5000

<b><i>Cost Summary</i></b>	
Approximate Total, Direct Expenses	\$ 132,850
Total, Indirect Expenses	\$ 108,600
<b>Cost of Emerging Solutions in Pain Full-Day Accredited Symposium</b>	<b>\$ 241,450</b>



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Proposal Number: 06-003  
Date: November 28, 2005

**Emerging Solutions in Pain Full-Day Accredited Symposium**  
**Proposed Budget**  
November 28, 2005

**Detailed Budget Itemization**

<b>Direct Expenses, Approximate</b>	
<b>Direct mail invitations, mail services, postage</b>	
Printing	\$ 2,700
Postage	\$ 1,950
Fax Blast	\$ 750
Email Blast	\$ 250
<b>Direct mail list purchase</b>	\$ 2,000
<b>Print materials</b>	
Printing meeting kits to include accreditation information, speaker biographical and disclosure information, agenda, handout materials, current journal articles by faculty, etc. and 4/c binder	\$ 4,500
Set design pieces (banners, podium signs, gobo, directional signage, etc.)	\$ 2,500
<b>Speaker honoraria (6 faculty members)</b>	\$ 20,000
<b>Speaker travel (air, OOP, hotel)</b>	\$ 11,550
<b>ROI staff travel</b>	\$ 5,600
<b>Ground transportation</b>	\$ 1,750
<b>Venue rental fee, service fees, etc.</b>	\$ 6,100
<b>Travel, site visit</b>	\$ 2,000
<b>Food &amp; Beverage (Continental Breakfast, Buffet Lunch, Afternoon Break for 250)</b>	\$ 24,000
<b>Audio/visual services</b>	\$ 14,000
<b>Audience response system</b>	\$ 10,000
<b>Accreditation of program for CME, CPE, CNE</b>	\$ 15,000
<b>Continuing Education participant certificates</b>	\$ 4,500
<b>Onsite CME coordination</b>	\$ 1,500
<b>Miscellaneous (non-fulfillment shipping, taxes, FedEx, etc.)</b>	\$ 2,200
<b>Approximate Total, Direct Expenses</b>	
	\$ 132,850

<b>Indirect Expenses</b>	
<b>Program development</b>	\$ 37,700
Includes all labor associated with initial program set-up and development, including creation of program content, text for print support materials, graphic design, typesetting and layout of all support materials, and development and creation of final program appearance	
<b>Medical and scientific writing</b>	\$ 12,100
<b>Site visit</b>	\$ 2,500
<b>Meeting coordination</b>	\$ 18,500
Includes faculty management, meeting logistics, travel and all other program details	
<b>Telephone recruitment</b>	\$ 8,500
<b>Onsite meeting management</b>	\$ 3,200
<b>Registration database development and management (includes online registration)</b>	\$ 1,500
<b>Administrative and accounting fees</b>	\$ 4,268
<b>Project management</b>	\$ 20,332
<b>Total, Indirect Expenses</b>	
	\$ 108,600

\* Tax and gratuity figures have not been included in this estimated budget



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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain RESPECT Meeting Series
<b>Program Overview</b>	<p>Medical Learning Solutions is proposing to adapt the 2005 RESPECT meetings into a new series that focuses on the provision of trained Emerging Solutions in Pain faculty to regional and local meetings of clinician associations, grand rounds programs and other similar venues. The 2006 RESPECT Meeting Series will therefore focus on providing practical clinical information via an accredited lecture series to health care professionals practicing in local clinics, hospitals and office settings.</p> <p>Medical Learning Solutions will work with local and regional association meetings and hospitals hosting grand rounds presentations to identify meetings of clinicians which will benefit from an accredited presentation focusing on Emerging Solutions in Pain/RESPECT Meeting topics. After a need has been identified, Medical Learning Solutions will coordinate all logistical arrangements for the presentation with a trained, available Faculty member.</p>
<b>CE Provider</b>	<p>Based on the need to educate clinicians in the assessment and treatment of chronic pain patients who may be at risk for abuse, addiction and diversion, The Emerging Solutions in Pain RESPECT Meeting Series will be accredited by a third party CE vendor of our choice.</p> <p>The Meeting Series will be accredited for:</p> <ul style="list-style-type: none"> <li>• CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each activity will be approved for a maximum of one hour of category 1 credit toward the AMA Physician's Recognition Award.</li> <li>• CPE credit for pharmacists by the Accreditation Council for Pharmacy Education. Each activity will be approved for a maximum of 1.0 credit hour (0.1 CEU) for Continuing Pharmacy Education</li> <li>• CNE credit for nurses. Each activity will be approved for a maximum of 1.0 Contact Hours.</li> </ul>
<b>Int ended Audience</b>	The primary audience of The Emerging Solutions in Pain RESPECT Meeting Series includes clinicians who provide care to patients with pain. These clinicians will include physicians, pharmacists and nurses, but may be extended to other clinical and non-clinical members of a multi-disciplinary treatment team, such as social workers, case managers, etc.
<b>Pr gram Objectives</b>	The purpose of the RESPECT Meeting Series is to educate clinicians on the key tenets of the Emerging Solutions in Pain initiative, focusing on the role of appropriate assessment and monitoring techniques, and good practice management strategies, in achieving effective interactions between members of the treatment team. In addition, other topics may be included, based upon



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## *Program Summary*

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recommendations made by the Emerging Solutions in Pain Faculty Advisory Committee.

### **Format**

A series of live, peer-to-peer activities scheduled in conjunction with local and regional association meetings and at hospital or clinic-based grand rounds programs throughout the United States. This proposal is for 10 RESPECT meetings.

### **Post-Activity Feedback**

Course evaluation forms will be required of all participants who seek to receive continuing education credit. Medical Learning Solutions will work with the third party CE vendor to summarize the information collected from these forms in a formal report to evaluate program effectiveness.

Participants will evaluate the following as excellent, good, fair or poor:

- (1) Overall content
- (2) Faculty teaching effectiveness
- (3) Format
- (4) Audio/visual

Participants will also respond to the following questions:

- (1) How well did the program achieve its educational objectives?
- (2) Do you feel the program material was useful and practice-oriented?
- (3) Do you feel that the information provided in this educational activity will aid in improving patient care in your practice?
- (4) Do you feel that fair balance was maintained for all therapeutic options?
- (5) Would you participate in future educational activities?

### **Distribution**

Medical Learning Solutions and the third party CE vendor will announce and promote The Emerging Solutions in Pain RESPECT Meeting Series primarily through arrangement with the local/regional association hosting the meeting; or the hospital sponsoring the grand rounds presentation. Medical Learning Solutions will also advertise availability of these meetings via advertisement on the Emerging Solutions in Pain web site.

### **Request for Sponsor Support**

As a supplement to these primary methods, Medical Learning Solutions and the third party CE vendor may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.

**Total Budget:** \$140,451



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Morrisville, PA 19067

Proposal Number: 06-003  
Date: November 28, 2005

**Extension of 2006 Emerging Solutions in Pain RESPECT Meeting Series**  
***Projected Budget Estimate***  
November 28, 2005

<b><i>Program Parameters</i></b>	
Number of regional association symposia	10
Faculty presenter per activity	1
Approximate number, health care professional attendees per meeting	30
Direct mail invitations to health care professionals	150

<b><i>Cost Summary</i></b>		
	One-time only costs	Each group of 10 meetings
Approximate Total, Direct Meeting Series Expenses	\$ -	\$ 75,725
Total, Indirect Meeting Series Expenses	\$ -	\$ 64,726
<b>Cost of 10-Meeting Extension of 2006 Emerging Solutions in Pain RESPECT Series</b>	<b>\$</b>	<b>140,451</b>



Proposal Number: 06-003  
Date: November 28, 2005

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**Extension of 2006 Emerging Solutions in Pain RESPECT Meeting Series**  
**Projected Budget Estimate**  
November 28, 2005

**Detailed Budget Itemization**

<b>Direct Meeting Expenses, Approximate</b>		
	One-time only costs	Each group of 10 meetings
<b>Direct mail invitations, mail services, postage</b>	\$ -	\$ 4,725
Personalized invitations to be mailed to every potential participant; includes printing, assembly, mail services and postage. Postage estimated at \$0.37 per direct mail piece		
<b>Direct mail list purchase</b>	\$ -	\$ -
<b>Print materials</b>	\$ -	\$ 3,500
Includes printing of shell materials for adaptation and use in individualized symposia kits for every symposium; kits to include accreditation information, speaker biographical and disclosure information, agenda, reference materials and handout materials, where appropriate		
<b>Speaker honoraria</b>	\$ -	\$ 25,000
<b>Speaker travel (air, OOP, hotel)</b>	\$ -	\$ 12,000
<b>Ground transportation</b>	\$ -	\$ 2,000
<b>Catering</b>	\$ -	\$ 15,000
<b>Audio/visual services</b>	\$ -	\$ 5,000
<b>Onsite CME coordination</b>	\$ -	\$ 7,500
<b>Shipping/Fed Ex</b>	\$ -	\$ 1,000
<b>Approximate Total, Direct Meeting Expenses</b>	\$ -	\$ 75,725

<b>Indirect Meeting Expenses</b>		
	One-time only costs	Each group of 10 meetings
<b>Program development</b>	\$ -	\$ -
Includes all labor associated with initial program set-up and development, including creation of text for print support materials, graphic design, typesetting and layout of all support materials, and development and creation of final program appearance		
<b>Medical Services</b>	\$ -	\$ 20,000
Includes all labor associated with content of each symposium, including identification and production of resources specific for each region and clinicians in each association; review and coordination of content with faculty		
<b>Meeting management</b>		\$ 18,000
Includes coordination with association for date of symposium and all meeting-related logistical details; coordination with faculty for dates, travel and all other program details		
<b>Accreditation of program for CME, CPE, CNE</b>	\$ -	\$ -
<b>Continuing Education participant certificates</b>		\$ 4,500
<b>Administrative and accounting fees</b>	\$ -	\$ 9,458
<b>Project management</b>	\$ -	\$ 12,768
<b>Total, Indirect Meeting Expenses</b>	\$ -	\$ 64,726

2/16/06 ESP Part II

## Grant Folder Checklist

1. Grant proposal ✓
2. Grant Sign off sheet ✓
3. Signed Letter of agreement ✓
4. Signed invoice - ~~Leslie has / Rod signed~~ ✓
5. Metrics Letter
6. PO or check check request - ~~placed Leslie to sign~~ ✓
7. Copy of check and fed ex receipt - ~~OK have signed PO~~ ✓



# 2006 *Emerging Solutions in Pain* Grant Request

*Presented to:*

**Edward Hoey**  
Cephalon, Inc.

*By:*

Sheri Gavinski  
Medical Learning Solutions, Inc.

101 Washington Street, Suite 110  
Morrisville, PA 19067  
Tel 215-337-6100  
800-397-9774  
Fax 800-329-9755



**MLS**  
Medical Learning Solutions, Inc.

Medical Learning Solutions, Inc.



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101 Washington Street  
Morrisville, PA 19067

Edward Hoey  
Cephalon, Inc.  
41 Moores Road  
Frazer, PA 19355

November 28, 2005

Dear Mr. Hoey:

Medical Learning Solutions, Inc. has recently completed a comprehensive needs assessment to identify the educational needs of clinicians who provide care to patients with chronic pain. This needs assessment was compiled from the following sources:

- Evaluation summaries of completed and ongoing 2005 Emerging Solutions in Pain programs and activities
- Clinical advisory review
- Survey of health care professionals, including participants in completed and ongoing 2005 Emerging Solutions in Pain programs
- Literature search

Based on the identified educational need, Medical Learning Solutions is requesting an educational grant from Cephalon, Inc. to support the continuation and further development of the **Emerging Solutions in Pain**, or **ESP**, initiatives. This will include the continuation of selected **ESP** programs instituted in 2005, as well as the development and implementation of a diverse series of new activities designed to further increase the knowledge and practice management skills of those clinicians who provide care to patients with chronic pain. The **ESP** initiatives will continue to focus on balancing the clinical need to provide adequate analgesia to patients with chronic pain with the legal and societal need to monitor for potential issues of abuse, addiction and diversion of controlled substances.

These activities will be designed and planned as follows:

- Fundamental Emerging Solutions in Pain Programs (*Grant Request Part A*); these will include the following:
  - Continuance of the Emerging Solutions in Pain web site
  - Convention of an expanded Emerging Solutions in Pain Faculty Advisory Board, to address development of new Tools and areas of focus
  - Enhancements to the Emerging Solutions in Pain content, in the form of new Tools and resources

- An expanded awareness campaign to include coordinated advertising in multiple media formats
- Continuing education initiatives associated with *Practical Pain Management*, featuring in-publication articles focusing on topics relevant to Emerging Solutions in Pain
- Live Emerging Solutions in Pain Educational Events and Activities (*Grant Request Part B*); these will include the following:
  - Continuance of the Meet the Expert exhibit booth at select, larger association meetings and expansion of the Meet the Expert mini-booth at smaller association meetings
  - Recreation of the RESPECT meeting series to focus on the provision of trained Emerging Solutions in Pain faculty to regional and local meetings of clinician associations, grand rounds programs and other similar venues
  - Adaptation of the current RESPECT meeting content to focus on the educational needs of single-clinician groups at regional and local meetings of clinician associations
- Programs to Further Expand the Reach of the Emerging Solutions in Pain Educational Events and Activities (*Grant Request Part C*); these will include the following:
  - Development and implementation of a full-day seminar program, to be held for clinical attendees of a national congress, focusing on the intersection of pain management and addiction medicine
  - Additional RESPECT meetings, held at regional and local meetings of clinician associations, grand rounds programs and other similar venues

The budget to fund these activities is approximately \$964,006 for Grant Request Part A; \$806,332 for Grant Request Part B and \$381,901 for Grant Request Part C. Please refer to the detailed budget section of this proposal for complete grant funding proposals.

These scientific events will comply with all ACCME, FDA, AMA, and ACPE regulations for industry-supported professional continuing education. MLS will be working with MediCom Worldwide, Inc. in the planning, execution and development of the accredited activities associated with the ESP initiatives. MediCom Worldwide is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians and is approved by the Accreditation Council for Pharmacy Education to provide pharmacy continuing education, as well as an approved provider of nursing continuing education through the California State Board of Registered Nursing.

Thank you in advance for your consideration of this request.

Respectfully,



Sheri L. Gavinski  
President,  
Medical Learning Solutions, Inc.



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## NEEDS ASSESSMENT

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In the United States alone, an estimated 50 million people suffer from some form of chronic pain, and another 25 million people suffer acute pain resulting from surgery or an accident.<sup>1</sup> Significantly, approximately two thirds of patients have been living with their pain for more than five years,<sup>2</sup> resulting in an alarming decrease, not only in quality of life, but in productivity for these individuals, as well. A survey conducted in 2000 reported that 36 million Americans missed work the previous year due to pain, and 83 million indicated that pain had affected their participation in various activities.<sup>3</sup>

It is well-established that chronic pain is a multi-faceted problem requiring intervention from a range of specialists in different disciplines.<sup>4</sup> Over the last decade, governments, professional organizations and institutions across the country have taken positive steps to improve physician training in pain management and palliative care, in accordance with recommendations issued by the World Health Organization.<sup>5</sup> These changes are indicators of the increasing recognition of pain relief and palliative care as appropriate subjects for professional education.

The increased focus on appropriate pain management has also resulted in certain challenges that impact health care professionals and patients alike. Some of these challenges result from confusion on the part of either patients or health care professionals, or both, regarding the potential of narcotic pain medications for abuse, addiction, misuse and diversion. Other challenges result from increased media attention regarding the prevalence of abuse and diversion, or from a lack of education and understanding regarding regulations for appropriate prescription of Schedule II agents. Patients, for example, may hesitate to use narcotics over fears of addiction, while health care professionals may be reluctant to prescribe opioids over concerns of increased scrutiny or investigation by local, state or federal law enforcement officials. When these types of concerns are combined with controversies surrounding the lack of scientific data on addiction, complex regulatory policies, and vague practice guidelines, the barriers to successful pain management become significant; undertreatment of pain is an all-too-common result.

One often-cited barrier in prescribing opioid analgesics to patients with chronic pain is the perception that physicians who treat their patients with these medications will come under increased scrutiny from the DEA and other regulatory and/or law enforcement agencies. This perception is due, in part, to documented increases in the diversion and sale of oxycodone and hydrocodone products. The source for much of this information is a unique epidemiologic network, known as Community Epidemiology Work Groups, or CEWG, that is designed to inform drug abuse prevention and treatment agencies, public health officials, policymakers, and the general public about current and emerging drug abuse patterns. Of the approximately 7,300 narcotic analgesic/opiate items analyzed by forensic laboratories across 19 CEWG areas in 2004, nearly 91 percent represented four drug classes: hydrocodone (35.3 percent), oxycodone (23.1 percent), methadone (19.1 percent), and codeine (13.3 percent).<sup>9</sup>

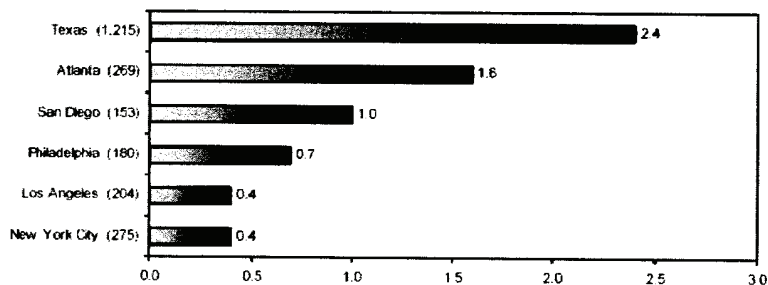


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## NEEDS ASSESSMENT

Exhibit 1 shows the number of hydrocodone items in 6 CEWG sites where more than 100 items were reported in 2004

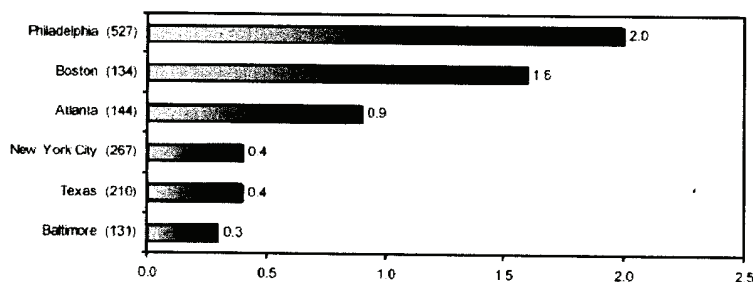
**Exhibit 1. Number of Hydrocodone Items Reported by Forensic Laboratories in 6 CEWG Areas, Ordered by Percentage of Total Items: FY 2004**



SOURCE: NFLIS, DEA

Exhibit 2 depicts the number of oxycodone items analyzed by forensic laboratories in 6 CEWG areas where more than 100 were reported.

**Exhibit 2. Number of Oxycodone Items Reported by Forensic Laboratories in 6 CEWG Areas, Ordered by Percentage of Total Items: FY 2004**



SOURCE: NFLIS, DEA

As can be seen in Exhibit 1 and Exhibit 2 above, there are clearly issues with abuse, misuse and diversion associated with some narcotic agents in certain geographic locations. Moreover, in March of 2004 the Office of National Drug Control Policy stated, "6.2 million Americans were current abusers of prescription drugs."<sup>6</sup> This information, while extremely important, is not, however, a justification for undertreatment of pain, even in those patients who may be identified at higher risk for abuse, misuse, addiction or diversion. Many studies have shown, in fact, that properly managed medical use of opioid analgesic drugs is effective and rarely causes clinical addiction, which is defined as compulsive, often uncontrollable use.<sup>7</sup> The key to this statement is "properly managed medical use", which consists of a



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## NEEDS ASSESSMENT

comprehensive pain management program of assessment, monitoring and documentation, consistently utilized for all patients with chronic pain.

If properly managed medical use of opioids is a cornerstone of effective pain management, however, even today, many health care professionals lack the understanding, knowledge and tools for appropriate use of narcotic medications. Critically, pain management is not a significant area of focus in many medical schools, and physicians often graduate with misconceptions regarding appropriate pain management practices and techniques. In a recent study of medical students' attitudes toward pain and the use of opioid analgesics, half of senior medical students surveyed believed addiction risks associated with opioids are substantial, and more than one third were concerned about drug regulatory agency investigations. Moreover, these seniors were more pessimistic than freshmen surveyed about relieving chronic pain, and they appeared to have less understanding about the sources of pain in cancer patients.<sup>8</sup>

### NEEDS ASSESSMENT SURVEYS

To further define the educational needs of clinicians active in the field of pain management, our group conducted a series of surveys in 2005, in which we asked physicians about their practices and the therapies that they utilize to provide analgesia. The first survey was conducted among participants in the 2005 RESPECT meeting series, with a selection of evaluation questions and responses from this survey summarized in Exhibit 3, below.

**Exhibit 3: Selections from the 2005 RESPECT Meeting Program Evaluation Form**

<b><i>Do you manage patients who are experiencing acute pain?</i></b>	
Many	44%
Few	30%
None	8%
<b><i>Do you manage patients who are experiencing chronic pain?</i></b>	
Many	50%
Few	24%
None	6%
<b><i>How do you currently manage pain patients?</i></b>	
Opioids	25%
Combination of all methods	16%
Non-opioids	14%
OTC medications	10%
Psychological/social therapy	3%
Physical therapy	3%





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## **NEEDS ASSESSMENT**

Other	3%
<b><i>If you don't utilize opioid analgesics, why?</i></b>	
Concerns over issues of abuse, misuse, addiction and diversion	39%
Concerns over federal and state regulations	12%
Don't feel opioids are necessary	8%
<b><i>Are pain management interdisciplinary teams a standard of practice in your geographic area?</i></b>	
No	57%
Yes	24%

This information collected from the RESPECT meeting participants has been separately validated through two needs assessment surveys that question health care professionals regarding their needs for pain-related information. The first of these two surveys provided data regarding clinicians' top interests, preferred method of education, and other details regarding continuing education, collected from almost 1300 clinicians specializing in the field of pain management. The following results demonstrate topics that the respondents view to be of high interest in pain management:

- |  |     |
|--|-----|
| 1. Pharmacologic Advances in Pain Management | 78% |
| 2. Chronic Nonmalignant Pain Management      | 75% |
| 3. Acute Pain Management                     | 57% |
| 4. Addiction, Substance Abuse                | 47% |
| 5. Cancer Pain Management                    | 41% |

The second of these two surveys was conducted among more than 900 clinicians who participated in pain management continuing education programs in 2003 – 2005, and focused specifically on suggested topics for future programs. While numerous, diverse program topics were suggested, several core topics were suggested repeatedly by more than 130 respondents. These topics included:

1. Drug abuse and addiction
2. Treating the chemically dependent with chronic pain
3. Opioids for the treatment of pain
4. Narcotics: dosages, indications and contraindications
5. Assessment guidelines and tools
6. Pain-related case studies



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## **NEEDS ASSESSMENT**

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7. Legal issues, including regulations from the DEA, medical board issues and pharmacy law matters

When the results of these surveys are combined, it is clear that additional curriculum and training are required to help insure improvements in the delivery of pain relief, to include identifying the:

- Critical issues involving the use of opioid analgesics
- Fundamental rights of patients to pain treatment
- Patients at high risk for opioid misuse, abuse and/or diversion
- Legal ramifications when prescribing controlled substances

One of the ways this challenge can be met is through the continuance of continuing education programs that focus on pain management in general, and, specifically, the effective use of opioids in patients with chronic pain. The goal of such programs must be to support clinicians in improving patient care while reducing the potential for abuse, addiction, diversion, and medical regulatory/malpractice liability exposures arising from poor pain management practices.

### **References**

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9. National Institute on Drug Abuse. Advance Report and Highlights/Executive Summary: Abuse of Stimulants and Other Drugs. Proceedings of the Community Epidemiology Work Group. January 2005. [http://www.drugabuse.gov/PDF/CEWG/AdvReport\\_Vol1\\_105.pdf](http://www.drugabuse.gov/PDF/CEWG/AdvReport_Vol1_105.pdf). Accessed September 22, 2005.



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## NEEDS ASSESSMENT

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### PROGRAM OVERVIEW: THE 2005 EMERGING SOLUTIONS IN PAIN INITIATIVE

**Emerging Solutions in Pain (ESP)** is an ongoing initiative that was developed by clinicians for physicians, pharmacists, nurses and other healthcare professionals who are active in the field of pain management. The **ESP** initiative, which was launched in February of 2005, was created specifically to address the issues and critical unmet needs in the field of pain management. These issues specifically involve balancing the fundamental rights of patients and clinicians with the challenge of identifying patients who are at greater or lesser risk for opioid misuse and addiction, and with the challenges associated with the complex regulations involved in prescribing controlled substances. In 2005, the **ESP** initiative included a diverse array of activities and programs, including the development of a multimedia CD-ROM-based clinician Tool Kit; a clinician-focused web site for the dissemination of pain management information; an exhibit booth that provided clinician attendees of national congresses with information regarding the Emerging Solutions in Pain tools and resources; and a series of ten accredited regional meetings that focused on the importance of establishing standards of care and the interdisciplinary team in proactive pain management. Each of these activities is summarized below.

The **ESP** initiative is based upon ongoing input and expertise from a renowned group of clinical experts with backgrounds in pain management, addiction medicine, anesthesiology and neurology. These experts include those individuals listed in Exhibit 4, below. Based on input from these experts, in 2005, the Emerging Solutions in Pain initiative was dedicated to the development, production and dissemination of information and tools focused on assessment, monitoring and best practices for treating patients with opioids. These experts also provided extensive guidance and input in terms of the most effective methods for delivering this information to practicing clinicians.

### Exhibit Four-A: The Emerging Solutions in Pain Faculty Advisory Board

**Gerald M. Aronoff, MD, DABPM, FAAEP**  
Chairman, Department of Pain Medicine  
Presbyterian Orthopaedic Hospital  
Charlotte, North Carolina

**Fernando T. Avila, MD**  
Private Practice,  
Pain Management and Anesthesiology  
San Antonio, TX

**David B. Brushwood, RPh, JD**  
Professor, Pharmacy Health Care Administration  
College of Pharmacy  
University of Florida  
Gainesville, FL

**Daniel M. Gruener, MD**  
President, Greater Philadelphia Pain Society  
Clinical Assistant Professor of Psychiatry  
Jefferson Medical College  
Philadelphia, Pennsylvania



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## **NEEDS ASSESSMENT**

---

***Jeffrey A. Gudin, MD***

Clinical Director  
Pain Management Center  
Englewood Hospital and Medical Center  
Englewood, New Jersey

***Mitchell Halter, MD***

Neurologist  
Integrative Pain Center of Arizona  
Tucson, AZ

***Howard A. Heit, MD, FACP, FASAM***

Assistant Clinical Professor of Medicine,  
Georgetown University School of Medicine  
Washington, DC

***Steven D. Passik, PhD***

Director, Symptom Management and Palliative Care  
Markey Cancer Center  
Associate Professor of Medicine and Behavioral Sciences  
University of Kentucky  
Lexington, Kentucky

***Joseph Shurman, MD***

Anesthesiologist and Pain Consultant  
Scripps Memorial Hospital  
La Jolla, California  
Clinical Assistant Professor and Pain Consultant  
University of California, San Diego  
San Diego, California

***Lynn R. Webster, MD, FACPM, FASAM***

Alpine Pain and Addiction Medicine  
Salt Lake City, UT

**Exhibit Four-B: Other Contributing Faculty to the Emerging Solutions in Pain Initiatives**

Daniel Bennett, MD  
Daniel Brookoff, MD  
Andrea Cheville, MD  
Doris Cope, MD  
Douglas Gourlay, MD, FRCPC, FASAM  
Jayson Hymes, MD, MPH, FACPM  
Benjamin Johnson, Jr, MD  
Bill McCarberg, MD  
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## **NEEDS ASSESSMENT**

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### **2006 Emerging Solutions in Pain Initiatives**

The information collected through the first 11 months of the Emerging Solutions in Pain initiative clearly indicates that a significant educational need exists for continuing education programs and resources devoted to the needs of clinicians who provide care to patients with chronic pain. Based on these educational needs, it is recommended that a series of initiatives be implemented in 2006 to continue and extend the 2005 Emerging Solutions in Pain programs. These initiatives include the following.

#### **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

1. Continuance of the Emerging Solutions in Pain web site at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com)
2. Recruitment and convention of an expanded Emerging Solutions in Pain Faculty Advisory Board, to address development of new Tools and areas of focus
3. Enhancements to the Emerging Solutions in Pain content, distributed via the web site and a new Tool Kit; enhancements to be based upon Faculty recommendations
4. Expanded awareness campaign to include coordinated advertising in multiple media formats
5. Continuing education initiatives associated with *Practical Pain Management*, featuring in-publication articles focusing on topics relevant to Emerging Solutions in Pain

#### **Grant Request Part B: Live Emerging Solutions in Pain Educational Events and Activities**

1. Continuance of the Meet the Expert exhibit booth at select, larger association meetings and expansion of the Meet the Expert mini-booth at smaller association meetings
2. Recreation of the RESPECT meeting series to focus on the provision of trained Emerging Solutions in Pain faculty to regional and local meetings of clinician associations, grand rounds programs and other similar venues
3. Adaptation of the current RESPECT meeting content to focus on the educational needs of single-clinician groups at regional and local meetings of clinician associations

#### **Grant Request Part C: Programs to Further Expand the Reach of the Emerging Solutions in Pain Educational Events and Activities**

1. Development and implementation of a full-day seminar program, to be held for clinical attendees of a national congress, focusing on the intersection of pain management and addiction medicine
2. Additional RESPECT meetings, held at regional and local meetings of clinician associations, grand rounds programs and other similar venues



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## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

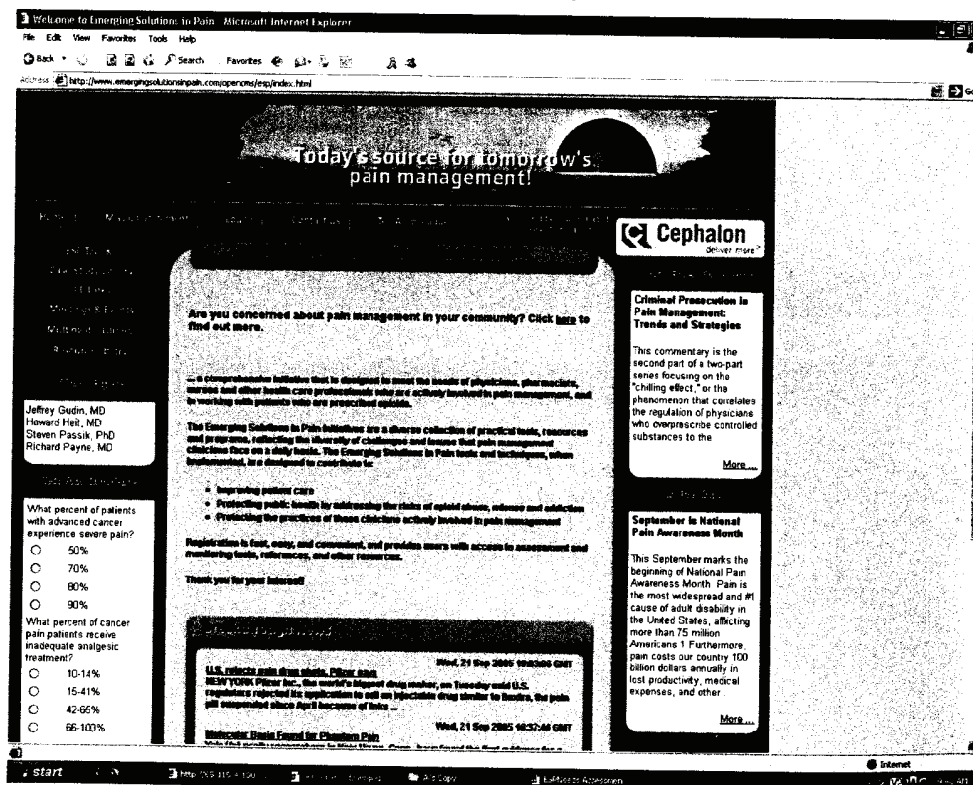
### **Program Overview: Summary of Work Completed in 2005**

#### **1. THE EMERGING SOLUTIONS IN PAIN (ESP) WEB SITE**

This web-based, comprehensive initiative is designed to meet the needs of physicians, pharmacists, nurses and other health care professionals who are actively involved in the management of patients who may be or are actively prescribed opioids. This easy-to-access web site is the repository of an invaluable and diverse collection of practical tools, resources, information, recent updates, and various other programs that reflect the diverse challenges and issues facing pain management clinicians today (Exhibit A-1).

In addition, members are required to register prior to accessing the fundamental Emerging Solutions in Pain resources and tools. This enables tracking of information pertaining to member specialty and Tool use, and provides a method for updating site users with information regarding new programs and tools as they become available.

#### **Exhibit A-1: The Emerging Solutions in Pain Home Page**



November 28, 2005

Page 12

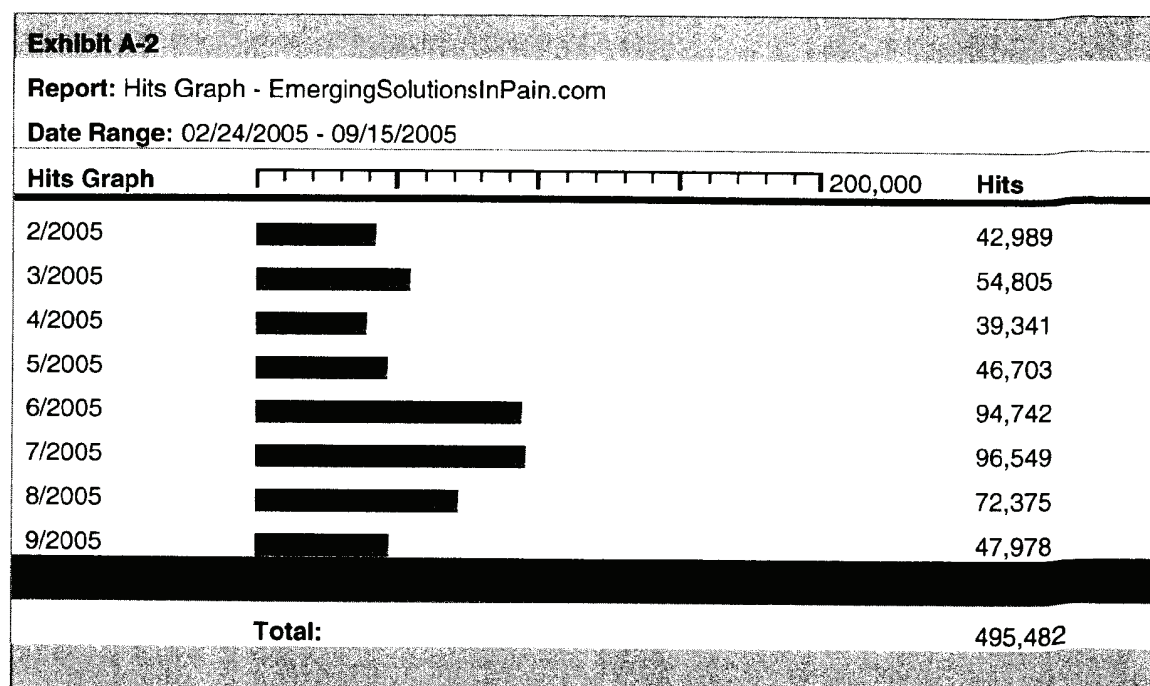




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## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

Since the launch of the Emerging Solutions in Pain website in February, 2005, almost 500,000 hits to the site has resulted in more than 17.33 Gigabytes of information being downloaded directly from the ESP site to practicing clinicians; more than 77.48 Megabytes of information is downloaded daily. Exhibit A-2 shows the trend of recent activity on ESP in terms of successful hits over time.



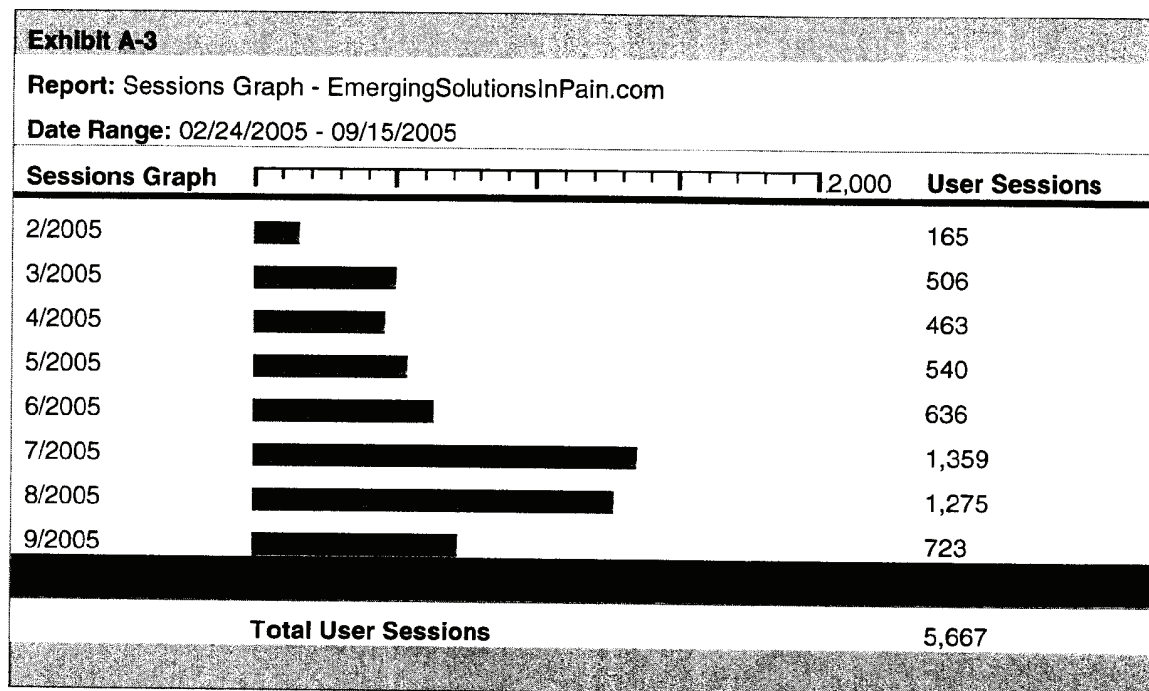




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## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

Exhibit A-3 demonstrates the trend of recent activity on the Emerging Solutions in Pain website, in terms of visitor sessions over time. An individual visitor defines a "session" as a series of clicks on ESP during a specific period of time. A session is initiated when the visitor arrives at ESP, and it ends when the browser is closed or after a period of inactivity. The significant number of monthly sessions is not surprising, given the many diverse tools available to practicing clinicians, both as printable documents and as electronic downloads.



A significant measure of website relevance is the number of credible, non-related web sites linked to the site. The number of sites hyperlinked to ESP or that mention the ESP site is a measure of the growing influence of the Emerging Solutions in Pain initiative in the pain management community (Exhibit A-4).

### **Exhibit A-4**

1. **American Physical Therapy Association**  
(<http://www.apta.org/AM/Template.cfm?Section=Archives2&Template=/Customsource/TaggedPage/PTIssue.cfm&Issue=09/02/2005#article24599>)
2. **American Chronic Pain Association** ([http://www.theacpa.org/pf\\_03\\_05.asp](http://www.theacpa.org/pf_03_05.asp))
3. **The Legal Side of Pain**  
(<http://www.legalsideofpain.com/index.cfm?fuseaction=page.display&pid=10>)



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## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

4. **Find That CE** ([http://www.findthatce.com/search\\_advanced/detail.php?ceid=844](http://www.findthatce.com/search_advanced/detail.php?ceid=844))
5. **Actiq® Educational Offerings** (<http://www.actiq.com/physicians/mededucation/>)
6. **Pain.com**  
([http://www.pain.com/sections/categories\\_of\\_pain/breakthrough/Resources/professional\\_resources/resource.cfm?id=1341](http://www.pain.com/sections/categories_of_pain/breakthrough/Resources/professional_resources/resource.cfm?id=1341))
7. **Painfoundation.org**  
([http://www.painfoundation.org/marylandpain/Downloads/ESP\\_Brief.pdf#search='emergingsolutionsinpain.com'](http://www.painfoundation.org/marylandpain/Downloads/ESP_Brief.pdf#search='emergingsolutionsinpain.com'))
8. **American Society for Pain Management Nursing** (<http://www.aspmnhouston.org/about.html>)
9. **Doctor's Guide**  
(<http://www.docguide.com/news/content.nsf/medicalresourcesweb?openform&id=e85e90285e487ca885256b1e00595908&cond=cme-related+sites>)
10. **American Alliance of Cancer Pain Initiatives**  
([http://www.aacpi.org/PCP\\_webpages/AnalgesicPharm.pdf#search='emergingsolutionsinpain.com'](http://www.aacpi.org/PCP_webpages/AnalgesicPharm.pdf#search='emergingsolutionsinpain.com'))

### **2. THE ESP TOOL KIT CD-ROM**

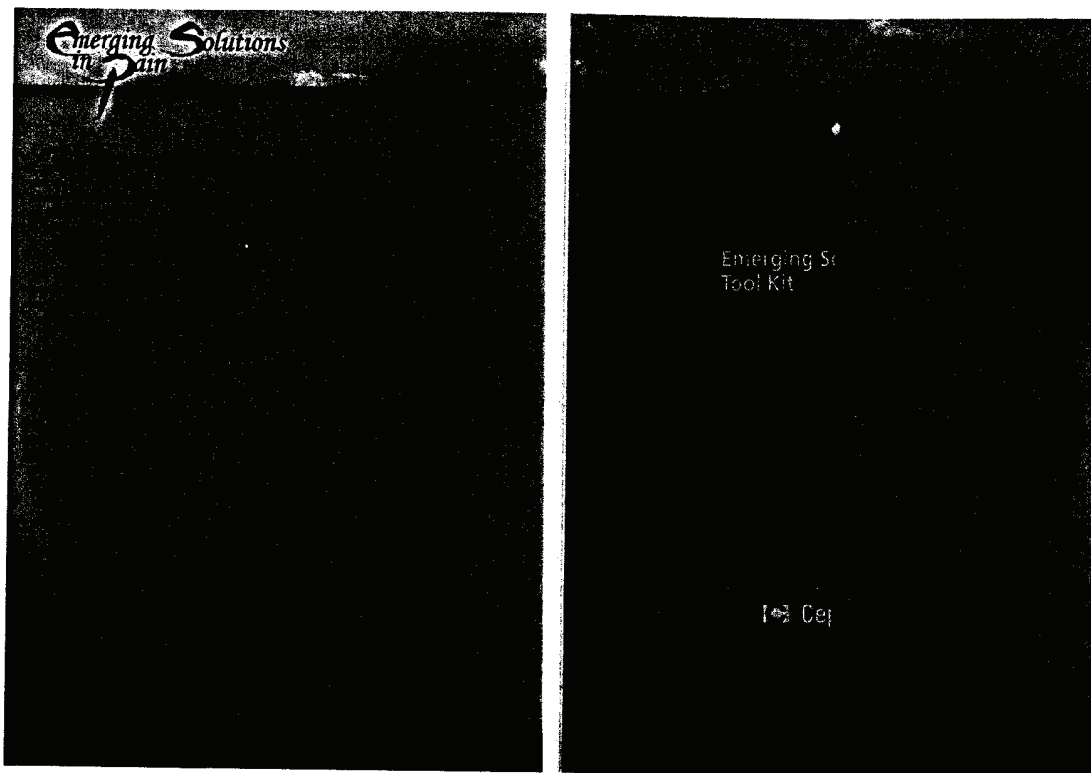
The Emerging Solutions in Pain Tool Kit CD-ROM (Exhibit A-5) provides health care professionals with an extensive array of electronic tools that may be used to effectively assess a patient's potential for opioid abuse, addiction, and diversion; to monitor the patient who is prescribed opioids; and to implement best practices in the management of patients with chronic pain. Every tool featured on this CD-ROM is available in electronic format, enabling instant and convenient access to clinicians who wish to view the informative multimedia slide-audio programs, the helpful printable documents, or the resourceful references and hyper links to access all content instantaneously.



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## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

**Exhibit A-5**



To date, 71,265 Emerging Solution in Pain Tool Kit CD-ROMs have been shipped and/or distributed to health care professionals who are involved in pain treatment and management.

### **3. THE ESP MINI-DISC PUBLICATION**

The Emerging Solutions in Pain Mini-Disc was created to focus health care professionals on the diverse resources and educational tools available to them via both the Emerging Solutions in Pain website and the ESP Tool Kit CD-ROM. The accompanying ESP Slim Jim Publication (Exhibit A-6) highlights and describes not only the contents of the attached Mini-Disc, but also the entire Emerging Solutions in Pain initiative, as well. In addition, the Publication also features a Business Reply Card (BRC), attached along the perforated edge, providing health care professionals with a convenient method for requesting the ESP Tool Kit CD-ROM; this BRC is a source of data for future mailings, as well.




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## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

The ESP Mini-Disc Publication is easily distributed at either a RESPECT Meeting Series or at one of the Meet the Experts booths. To date, almost 73,000 of the ESP Mini-Disc Publications have been shipped or distributed to health care professionals.

### **Exhibit A-6**



**Request Your Complimentary Copy Today!  
The Emerging Solutions in Pain Tool Kit**

First Name	Last Name		Appt/Suite
Mailing Address		City	State
City	Phone Number	Zip Code	Fax Number
E-Mail Address		Fax Number	

☐ I would like to receive other information from Emerging Solutions in Pain

**Please Order Your Copy in One of Four Ways...**

**By Phone** 800-397-9774  
**By Fax** 800-504-0560

**By Web** [www.emergingsolutionsinpain.com](http://www.emergingsolutionsinpain.com)

**By Mail** Please return this card



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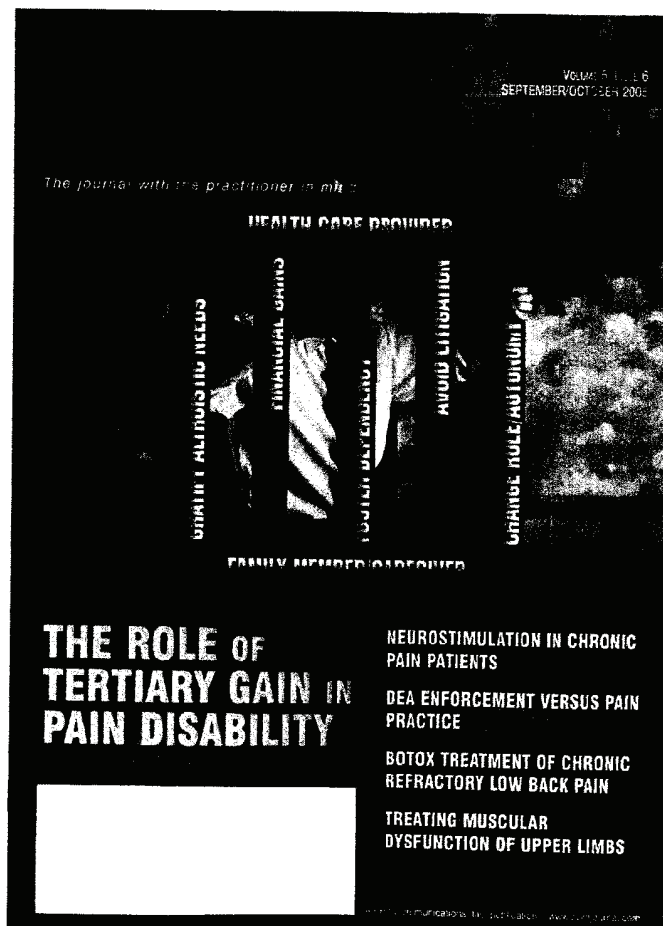
## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

### **4. AWARENESS CAMPAIGN**

In order to create awareness as well as increase the reach and frequency of the Emerging Solutions in Pain initiatives, a targeted campaign has been implemented in 2005, with the goal of disseminating key information to health care professionals who provide care to patients with chronic pain. This campaign has included journal and Internet advertisements, press releases and commentaries.

#### *Practical Pain Management*

This journal is published for the medical practitioner who is dedicated to helping patients experiencing chronic pain. Through a coordinated series of program informational announcements, including one press release, one clinical editorial and a series of three back cover or full-page advertisements, key Emerging Solutions in Pain messages have reached the 39,000-clinician subscriber list every month since May, 2005. As can be seen from the occupational breakout and percentage of total readership (Exhibit A-7, below), the top five occupations that clearly deal with the management of pain on a daily basis, are now much more familiar with Emerging Solutions in Pain and with the practical services and tools created by ESP to support their practice and patients.





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## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

### **Exhibit A-7: Practical Pain Management Demographics**

SPECIALTY	TOTAL QUALIFIED	PERCENT OF TOTAL
Anesthesiology/Pain Med _____	3,467	9.4
Dental Specialties _____	462	1.2
Emergency Medicine _____	474	1.3
Family Practice _____	6,571	17.6
General Practice _____	1,504	4.1
General Surgery _____	659	1.8
Internal Medicine _____	5,736	15.4
Neurology/Neurosurgery _____	4,287	11.6
Ob/Gyn _____	243	0.7
Occupational/Industrial Medicine _____	332	0.9
Oncology/Hematology _____	248	0.7
Orthopedic Medicine/Surgery _____	4,283	11.6
Pain Medicine/Management _____	1,606	4.3
Pediatrics _____	408	1.1
Physical Med & Rehab/Sports Med _____	2,642	7.1
Radiology: Oncology/Diagnostic/Interventional _____	413	1.1
Rheumatology _____	1,253	3.4
Other _____	2,488	6.7
<b>TOTAL QUALIFIED CIRCULATION</b>	<b>37,076</b>	<b>100.0</b>

*The American Academy of Physical Medicine and Rehabilitation (AAPM&R) Web site: [www.aapmr.org](http://www.aapmr.org)*

The American Academy of Physical Medicine and Rehabilitation is a national medical society representing more than 7,000 physicians who are specialists in the field of physical medicine and rehabilitation. The Emerging Solutions in Pain Meet the Expert Booth will be present at the 2005 AAPM&R National Meeting, to be held in Philadelphia, PA in October. In conjunction with this opportunity, ESP has placed a banner advertisement on the AAPM&R web site that will be viewable and will include a click-through link to [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com) until January, 2006. This banner is located at:

<http://www.aapmr.org/assembly/prelim/aa05l.htm>

The AAPM&R web site reported almost 32,000 user sessions in June, 2005; each of these users will thus be potentially exposed to key Emerging Solutions in Pain messages.



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## **Grant Request Part A: Fundamental Emerging Solutions in Pain Programs**

### ***Program Overview: Proposed 2006 Activities***

The following activities are recommended as the Fundamental Emerging Solutions in Pain Programs in 2006.

1. Continuance of the Emerging Solutions in Pain web site at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com)
2. Recruitment and convention of an expanded Emerging Solutions in Pain Faculty Advisory Board, to address development of new Tools and areas of focus
3. Enhancements to the Emerging Solutions in Pain content, distributed via the web site and a new Tool Kit; enhancements to be based upon Faculty recommendations
4. Expanded awareness campaign to include coordinated advertising in multiple media formats
5. Continuing education initiatives associated with *Practical Pain Management*, featuring in-publication articles focusing on topics relevant to Emerging Solutions in Pain





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Proposal Number: 06-003  
Date: November 28, 2005

**Emerging Solutions in Pain**  
**Summary of Proposed Budget, Grant Request Part A**  
*Fundamental Emerging Solutions in Pain Programs*  
November 28, 2005

<b>Cost Summary</b>	
<b>ESP Website</b>	
Approximate Total, Direct Expenses	\$ 22,350
Indirect Expenses	\$ 129,229
Cost of Expansion and Maintenance of the Emerging Solutions in Pain Website	\$ 151,579
<b>ESP Faculty Advisory Committee Meeting</b>	
Approximate Total, Direct Expenses	\$ 71,062
Indirect Expenses	\$ 66,500
Cost of 2006 Emerging Solutions in Pain Faculty Advisory Committee Meeting	\$ 137,562
<b>ESP Tool Kit</b>	
Approximate Total, Direct Expenses	\$ 45,000
Indirect Expenses	\$ 105,850
Cost of Development and Production of Emerging Solutions in Pain Tool Kit, Volume Two	\$ 150,850
<b>ESP Awareness Campaign</b>	
Approximate Total, Direct Expenses	\$ 45,000
Indirect Expenses	\$ 16,500
Cost of 2006 ESP Awareness Campaign	\$ 61,500
<b>Accredited Journal Article Series</b>	
Approximate Total, Direct Expenses	\$ 216,000
Indirect Expenses	\$ 88,841
Cost of PPMJ Accredited Journal Article Series	\$ 304,841
<b>Total Budget, 2006 Fundamental Emerging Solutions in Pain Programs</b>	<b>\$ 806,332</b>

Approval Signature \_\_\_\_\_

Date \_\_\_\_\_

**Note: no work may begin until Medical Learning Solutions receives, via email or fax, this approval with signature and date**



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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain Web Site
<b>Program Overview</b>	Medical Learning Solutions is proposing to continue and expand the multimedia Web Site that currently houses and promotes the Emerging Solutions in Pain initiative. This Web Site provides health care professionals with an extensive array of tools for assessing the potential for abuse, addiction and diversion in their patients with chronic pain, for monitoring their pain patients, and for accessing information regarding "best practices" in the long-term management of these patients. Registered members of EmergingSolutionsinPain.com can access and print available Tools and supporting references, view video-slide/audio-based case studies, read relevant literature and journal articles, view schedules for upcoming events such as the Meet the Expert Booth, and register for live peer-to-peer meetings that are part of the Emerging Solutions in Pain initiative.
<b>Intended Audience</b>	The primary audience of the Emerging Solutions in Pain Web Site are physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain.
<b>Program Objectives</b>	<p>in 2006, one goal of the Emerging Solutions in Pain Web Site will be to continue to provide clinicians with tools and resources for assessing and monitoring the risk potential of their patients for opioid misuse, abuse and addiction. New goals for the Emerging Solutions in Pain web site include the following:</p> <ol style="list-style-type: none"> <li>(1) Expand the reach of this web site and the important information it contains to the following groups: <ol style="list-style-type: none"> <li>a. Non-physician members of the pain management community, e.g., nurses, physician assistants, pharmacists</li> <li>b. Pain specialists and addictionologists who have not yet registered at the web site</li> <li>c. Medical students who have an interest in treating pain as part of their studies</li> <li>d. Physicians who treat pain as part of their practice and who have not yet registered at the web site</li> </ol> </li> <li>(2) Provide new resources and tools for clinicians who are involved in pain management. These tools and resources will be identified, in part, at the 2006 Faculty Advisory Committee Meeting, but may include one or more of the following: <ol style="list-style-type: none"> <li>a. Online versions of any new tools developed through the 2006 Emerging Solutions in Pain initiatives</li> <li>b. A searchable database of FAQs, answering the most common questions clinicians have pertaining to opioid misuse, abuse and addiction</li> <li>c. A dynamic online forum in which clinicians may post questions or comments for other registered users to respond to, or for one of the Emerging Solutions in Pain faculty to answer</li> <li>d. An expanded listing of links to other pain management resources</li> </ol> </li> </ol>
<b>Format</b>	A multimedia Web Site, with separate links for assessing and monitoring patients whose chronic pain is being treated with opioids; for "best practice" information;



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### *Program Summary*

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	for journal articles relevant to the Emerging Solutions in Pain initiative; for other Emerging Solutions in Pain information and programs
<b>Distribution</b>	The Emerging Solutions in Pain Web Site will be available to all individuals via the Internet at <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a> . Free registration will be required to access the majority of information on the Web Site, including all of the Emerging Solutions in Pain Tools and journal articles
<b>Request for Sponsor Support</b>	<p>Medical Learning Solutions will announce and promote the Emerging Solution in Pain Web Site through journal advertisements, banner advertisements and announcement brochures for the Emerging Solutions in Pain initiative.</p> <p>As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.</p>
<b>Total Budget:</b>	\$151,579



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Proposal Number: 06-003  
Date: November 28, 2005

**Expansion and Maintenance of the Emerging Solutions in Pain Website**  
**Projected Budget Estimate**  
November 28, 2005

<b>Cost Summary</b>	
<b>Approximate Total, Direct Expenses</b>	\$ 22,350
<b>Total, Indirect Expenses</b>	\$ 129,229
<b>Expansion and Maintenance of the Emerging Solutions in Pain Website</b>	<b>\$ 151,579</b>

<b>Direct Expenses, Approximate</b>	
<b>Clinical expert honoraria</b> Honoraria for authorship of monthly column, <i>Clinical Expert Commentary</i> ; selected <i>In the Know</i> columns	\$ 17,000
<b>Topix.net feed</b>	\$ 3,000
<b>Stock photography / illustrations</b>	\$ 2,000
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$ 350
<b>Approximate Total, Direct Expenses</b>	<b>\$ 22,350</b>

<b>Indirect Expenses</b>	
<b>IT / programming services</b> Includes programming of new tools, resources and content, to be determined by consultation with Faculty Advisory Committee; coordination with Internet and database programming vendors	\$ 26,800
<b>Graphic design / production services</b> Includes production of new graphics associated with new tools and resources	\$ 10,500
<b>Medical / scientific services</b> Includes all content development for ESP.com, development of copy for new Web pages as needed, coordination with clinical reviewers, ongoing development of clinical expert commentary, In the News summaries and Topix.net feed; maintenance of links and other information	\$ 33,000
<b>Website maintenance, 12 months total</b> Includes all hosting and co-location fees; routine website maintenance; and technical support	\$ 42,000
<b>Administrative and accounting fees</b>	\$ 3,168
<b>Project management</b>	\$ 13,761
<b>Total, Indirect Expenses</b>	<b>\$ 129,229</b>



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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain 2006 Faculty Advisory Board Meeting
<b>Program Overview</b>	<p>The Emerging Solutions in Pain initiative was developed by clinicians for physicians, pharmacists, nurses and other health care professionals involved in the field of pain management. The input and guidance of these clinicians was instrumental in determining the original parameters and scope of the initiative, and remains critical for the ongoing success of future Emerging Solutions in Pain initiatives. Medical Learning Solutions is therefore recommending that the Emerging Solutions in Pain Faculty Advisory Committee reconvene for a one-day meeting in February 2006. At this meeting, the Faculty will address the current needs of clinicians involved in the field of pain management, and identify potential areas for the development of future Emerging Solutions in Pain tools and resources.</p> <p>Medical Learning Solutions is recommending that the 2006 Emerging Solutions in Pain Faculty Advisory Committee include all currently active Emerging Solutions in Pain faculty members, as well as a select group of clinicians that have made some contribution to the 2005 Emerging Solutions in Pain initiatives. The members of the Faculty Advisory Committee have therefore been tentatively identified to include those individuals listed below; final Committee selection will be based upon faculty availability; additional names will be added, as needed.</p> <p>Daniel Bennett, MD Daniel Brookoff, MD David B. Brushwood, RPh, JD Douglas Gourlay, MD, FRCPC, FASAM Jeffrey A. Gudin, MD Howard A. Heit, MD, FACP, FASAM Benjamin Johnson, Jr., MD Christine Miaskowski, RN, PhD, FAAN Steven D. Passik, PhD Joseph Shurman, MD Steven Stanos, DO Lynn R. Webster, MD, FACPM, FASAM</p>
<b>Int nded Audience</b>	The primary audience who will benefit from a reconvention of an expanded Emerging Solutions in Pain Faculty Advisory Committee will be physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain, and who utilize opioids in their pain practices. The needs of these clinicians will be specifically addressed at the Advisory Board Meeting, and new Emerging Solutions in Pain tools and resources will be recommended by the Faculty for their use in 2006.
<b>Pr gram Objectives</b>	The purpose of the Emerging Solutions in Pain Faculty Advisory Committee is to provide guidance for future direction of the Emerging Solutions in Pain initiatives. This will require the accomplishment of the following objectives at the Advisory Committee Meeting:



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## *Program Summary*

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- (1) Summarize the activities and programs that comprised the 2005 Emerging Solutions in Pain initiatives
- (2) Outline current trends in the use of opioids for the treatment of chronic pain, focusing on any new developments in laws or regulations pertaining to the prescription of controlled substances; new products and therapies that will be available for the treatment of chronic pain; and new reports pertaining to the assessment, monitoring or documentation of patients who are prescribed opioids
- (3) Based on the above, recommend:
  - a. New tools and resources that would meet the unmet needs of clinicians who provide care to patients with chronic pain
  - b. Changes and updates to the current RESPECT slide modules

<b>Format</b>	A one-day meeting, to be tentatively held in February 2006. The exact date and location of this meeting will be based on the schedules of the attending faculty; it is anticipated that this meeting will be held immediately before or after a national congress or association meeting which the majority of faculty will attend. Options for this meeting include the International Conference on Pain & Chemical Dependency in Brooklyn, New York and the American Academy of Pain Medicine Meeting in San Diego, California.
<b>Distribution</b>	Attendance at the 2006 Emerging Solutions in Pain Faculty Advisory Committee Meeting will be determined by past participation in the Emerging Solutions in Pain initiatives. Invitations will be issued to currently active faculty members and to select faculty who made some contribution to the initiatives in 2005.
<b>Total Budget:</b>	\$137,562



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Morrisville, PA 19067

Proposal Number: 06-003  
Date: November 28, 2005

**2006 Emerging Solutions in Pain Faculty Advisory Committee Meeting**  
***Proposed Budget***  
November 28, 2005

<b><i>Program Parameters</i></b>	
Attending faculty	11
Clinical expert moderator	1
Length of meeting	1 day

<b><i>Cost Summary</i></b>	
Approximate Total, Direct Expenses	\$ 71,062
Total, Indirect Expenses	\$ 66,500
<b>Cost of 2006 Emerging Solutions in Pain Faculty Advisory Committee Meeting</b>	<b>\$ 137,562</b>





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Proposal Number: 06-003  
Date: November 28, 2005

**2006 Emerging Solutions in Pain Faculty Advisory Committee Meeting**  
***Proposed Budget***  
**November 28, 2005**

*Detailed Budget Itemization*

<b><i>Direct Expenses, Approximate</i></b>	
<b>Print materials</b>	
Meeting kits to include agenda, handout materials, current RESPECT meeting slides and 4/c binder	\$ 2,000
<b>Speaker honoraria (11 faculty member + 1 moderator)</b>	\$ 32,500
<b>Speaker travel (air, OOP, hotel)</b>	\$ 13,600
<b>ROI staff travel (air, OOP, hotel)</b>	\$ 5,000
<b>Ground transportation</b>	\$ 2,400
<b>Venue rental fee</b>	\$ 1,000
<b>Food &amp; Beverage (Dinner, Buffet Breakfast, Buffet Lunch, Two Breaks)</b>	\$ 6,062
<b>Audio/visual services</b>	\$ 6,000
<b>Transcription</b>	\$ 1,500
<b>Miscellaneous (non-fulfillment shipping, faxes, FedEx, etc.)</b>	\$ 1,000
<b><i>Approximate Total, Direct Expenses</i></b>	<b>\$ 71,062</b>

<b><i>Indirect Expenses</i></b>	
<b>Program development</b>	\$ 12,500
<b>Graphic design</b>	\$ 17,000
Includes all labor associated with initial program set-up and development, including development and production of meeting slides, coordination of print support materials, graphic design, typesetting and layout of all support materials, and development and creation of final program appearance	
<b>Meeting management</b>	\$ 13,000
Includes faculty management, venue coordination, meeting logistics, travel and all other program details	
<b>Site inspection</b>	\$ 3,000
<b>Onsite management (four staff members)</b>	\$ 6,000
<b>Administrative and accounting fees</b>	\$ 2,585
<b>Project management</b>	\$ 12,415
<b><i>Total, Indirect Expenses</i></b>	<b>\$ 66,500</b>



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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain Tool Kit, Volume Two
<b>Program Overview</b>	<p>Medical Learning Solutions is proposing to develop new tools and content for the Emerging Solutions in Pain Tool Kit, Volume Two. Volume One of the Tool Kit provided clinicians with specific tools for assessing the potential for abuse, addiction and diversion in their patients with chronic pain, for monitoring their pain patients, and for accessing information regarding "best practices" in the long-term management of these patients. Volume Two will expand upon the tools and resources presented in Volume One, as directed by the Emerging Solutions in Pain faculty attending the 2006 Faculty Advisory Committee Meeting.</p> <p>The new tools and resources that will be included in Volume Two of the Tool Kit will be available via a new multi-media CD-ROM, as well as via a downloadable series at the Emerging Solutions in Pain web site.</p>
<b>Intended Audience</b>	The primary audience of the Emerging Solutions in Pain Tool Kit Volume Two will be physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain.
<b>Program Objectives</b>	<p>The specific tools and resources that will make up the Emerging Solutions in Pain Tool Kit Volume Two will be taken from recommendations made by the Emerging Solutions in Pain Faculty. These tools and resources may include the following:</p> <ol style="list-style-type: none"> <li>(1) Tools for assessing functionality in patients who are prescribed opioids, such as a driving impairment test</li> <li>(2) Tools to assist in appropriate documentation of those patients who are prescribed opioids, such as chart stickers or downloadable return visit forms</li> <li>(3) Resources outlining specific legal issues associated with prescribing opioids</li> <li>(4) Case studies of patients who have had issues with misuse, abuse or addiction to opioids</li> </ol>
<b>Format</b>	A multimedia CD-ROM and online at <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a>
<b>Distribution</b>	<p>The Emerging Solutions in Pain Tool Kit Volume Two will be available through the following avenues:</p> <ol style="list-style-type: none"> <li>(1) Through BRC request cards</li> <li>(2) Through electronic download at <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a></li> <li>(3) Through distribution at the Emerging Solutions in Pain Meet the Expert Booth</li> <li>(4) Through distribution at the RESPECT Meeting Series</li> </ol>
<b>Request for Sponsor Support</b>	<p>Medical Learning Solutions will announce and promote the Emerging Solution in Pain Tool Kit Volume Two through the means of distribution outlined above. In addition, all Emerging Solutions in Pain initiatives will direct clinicians to <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a>, where Volume Two will be prominently featured. These will include journal advertisements, banner advertisements and brochures for the Emerging Solutions in Pain initiative.</p> <p>As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. in the dissemination of information</p>



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### *Program Summary*

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regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.

**Total Budget:** \$150,850



101 Washington St, Suite 110  
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Proposal Number: 06-003

Date: November 28, 2005

**2006 Emerging Solutions in Pain Tool Kit, Volume Two**  
**Proposed Budget**  
November 28, 2005

<b>Cost Summary</b>	
<b>Approximate Total, Direct Expenses</b>	\$ 45,000
<b>Total, Indirect Expenses</b>	\$ 105,850
<b>Development and Production of the Emerging Solutions in Pain Tool Kit, Volume Two</b>	<b>\$ 150,850</b>

<b>Detailed Budget Itemization</b>	
<b>Direct Expenses, Approximate</b>	
<b>Duplication: ESP Tool Kit CD-ROM, Quantity: 10,000</b> Four color, two page CD mailer with two inside pockets to house four-color silk-screened CD-ROM plus 16-page four-color saddle-stitched booklet. 4/0 + varnish, score, fold, insertion of CD, shrinkwrapping.	\$ 24,500
<b>Audio track recording</b> Professional voice talent narration of Tool Kit instructions, KOL commentary, etc.	\$ 3,500
<b>Clinical expert honoraria</b> Preparation, review of audio commentary	\$ 9,000
<b>Postage for returned BRCs*</b>	\$ 2,500
<b>Postage to ship CDs for BRC requests*</b>	\$ 5,000
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$ 500
<b>Approximate Total, Direct Expenses</b>	<b>\$ 45,000</b>

<b>Indirect Expenses</b>	
<b>IT / programming services</b> Includes programming of multi-media CD-ROM, including user-friendly CD interface; programming of Tools and resources, instructions and commentary; adaptation of all Tools and resources to formats appropriate for online posting and use	\$ 33,465
<b>Graphic design / production services</b> Includes production of multi-media animation and graphics for CD; adaptation of design for CD case, rep BRC, journal advertisements; typesetting, layout, proofing, coordination with print and duplication vendors	\$ 13,500
<b>Medical / scientific services</b> Includes content development for rep BRC, journal advertisement, CD booklet	\$ 37,630
<b>Fulfillment of CDs in response to returned rep BRCs</b>	\$ 5,000
<b>Administrative and accounting fees</b>	\$ 2,543
<b>Project management</b>	\$ 13,712
<b>Total, Indirect Expenses</b>	<b>\$ 105,850</b>

\*Note that "BRCs" refers to excess Business Reply Cards printed in 2005 in association with the ESP Slim Jim. BRCs will not be re-printed in 2006.



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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain Awareness Campaign
<b>Program Overview</b>	Medical Learning Solutions is proposing to increase the number of health care professionals who are aware of the Emerging Solutions in Pain initiative through the development and implementation of a coordinated series of advertising campaigns in 2006. The goal of this awareness campaign is to expand the reach of the Emerging Solutions in Pain initiatives to health care professionals who will benefit from the educational information presented at the web site, on the Tool Kit CD-ROM, at the Meet the Experts Booth and at the RESPECT meeting series.
<b>Intended Audience</b>	The primary audience of the Emerging Solutions in Pain Tool Kit Volume Two will include physicians, pharmacists, nurses, physician assistants, and other health care professionals who provide care to patients with chronic pain.
<b>Program Objectives</b>	<p>The overall objective of the 2006 Awareness Campaign is to increase the number of health care professionals who are active in the Emerging Solutions in Pain community. The specific objectives will include, but are not limited to:</p> <ol style="list-style-type: none"> <li>(1) Increase the number of registered users at <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a></li> <li>(2) Increase the number of user sessions at <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a></li> <li>(3) Increase the total amount of information downloaded at <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a></li> </ol>
<b>Format</b>	Journal and banner advertisements
<b>Distribution</b>	<p>The 2006 Emerging Solutions in Pain Awareness Campaign will include, but is not limited to:</p> <ol style="list-style-type: none"> <li>(1) Journal advertisements in <i>Practical Pain Management Journal</i></li> <li>(2) Banner advertisements at select professional pain management organization web sites</li> </ol>
<b>Request for Sponsor Support</b>	<p>Medical Learning Solutions will coordinate the Emerging Solution in Pain Awareness Campaign through the means of distribution outlined above.</p> <p>As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.</p>
<b>Total Budget:</b>	\$61,500



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Proposal Number: 06-003  
Date: November 28, 2005

**2006 Emerging Solutions in Pain Awareness Campaign**  
**Proposed Budget**  
November 28, 2005

<b>Cost Summary</b>	
<b>Approximate Total, Direct Expenses</b>	\$ 45,000
<b>Total, Indirect Expenses</b>	\$ 16,500
<b>Development and Implementation of the 2006 Emerging Solutions in Pain Awareness Campaign</b>	<b>\$ 61,500</b>

*Detailed Budget Itemization*

<b>Direct Expenses, Approximate</b>	
<b>Journal advertisements, 12 months</b> Four-color, full-page advertising series in selected pain management journals	\$ 40,200
<b>Banner advertisements, 6 months</b> Advertising campaign at select professional organization web sites, to occur in conjunction with annual congresses and association meetings	\$ 4,200
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$ 600
<b>Approximate Total, Direct Expenses</b>	<b>\$ 45,000</b>

<b>Indirect Expenses</b>	
<b>Graphic design / production services</b>	\$ 8,750
<b>Medical / scientific services</b>	\$ 2,000
<b>Administrative and accounting fees</b>	\$ 750
<b>Project management</b>	\$ 5,000
<b>Total, Indirect Expenses</b>	<b>\$ 16,500</b>



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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain Accredited Article Series
<b>Program Overview</b>	Medical Learning Solutions is proposing to develop and produce an accredited series of eight journal articles, directed toward physicians, pharmacists, nurses and other health care professionals who are involved in the care of patients with chronic pain. This series of accredited articles will be initially published in the <i>Practical Pain Management Journal</i> ; all articles will be available for credit online at the Emerging Solutions in Pain web site, as well.
<b>CE Provider</b>	<p>Based on the need to educate clinicians in the assessment and treatment of chronic pain patients who may be at risk for abuse, addiction and diversion, the The Emerging Solutions in Pain Accredited Article Series will be accredited by a third party CE vendor of our choice.</p> <p>All articles in the Accredited Article Series will be accredited for:</p> <ul style="list-style-type: none"> <li>• CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each activity will be approved for a maximum of one hour of category 1 credit toward the AMA Physician's Recognition Award.</li> <li>• CPE credit for pharmacists by the Accreditation Council for Pharmacy Education. Each activity will be approved for a maximum of 1.0 credit hour (0.1 CEU) for Continuing Pharmacy Education</li> <li>• CNE credit for nurses. Each activity will be approved for a maximum of 1.0 Contact Hours.</li> </ul>
<b>Intended Audience</b>	The primary audience of The Emerging Solutions in Pain Accredited Article Series includes physicians, pharmacists, nurses and other health care professionals who provide care to patients with pain.
<b>Program Objectives</b>	<p>The purpose of The Emerging Solutions in Pain Accredited Article Series is to educate clinicians on key topics relating to the Emerging Solutions in Pain initiatives. These topics may include, but are not limited to, the following:</p> <ol style="list-style-type: none"> <li>(1) Assessing functionality in patients prescribed opioids for chronic pain</li> <li>(2) Urine drug testing and other methods for monitoring patients who are prescribed opioids</li> <li>(3) Determining relative risk of opioid abuse</li> <li>(4) Issues relating to drug testing in patients who are prescribed opioids</li> <li>(5) Standards of care in pain management</li> <li>(6) The importance of interdisciplinary teams in effective pain management</li> <li>(7) Neurobiology of addiction</li> <li>(8) Legal issues associated with the prescription of opioids</li> </ol>





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## *Program Summary*

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<b>Format</b>	A series of eight four-page accredited articles in the <i>Practical Pain Management Journal</i>
<b>Post-Activity Feedback</b>	<p>Course evaluation forms will be required of all participants who seek to receive continuing education credit. Medical Learning Solutions will work with the third party CE vendor to summarize the information collected from these forms in a formal report to evaluate program effectiveness.</p> <p>Participants will evaluate the following as excellent, good, fair or poor:</p> <ol style="list-style-type: none"> <li>(1) Overall content</li> <li>(2) Faculty teaching effectiveness</li> <li>(3) Format</li> </ol> <p>Participants will also respond to the following questions:</p> <ol style="list-style-type: none"> <li>(1) How well did the program achieve its educational objectives?</li> <li>(2) Do you feel the program material was useful and practice-oriented?</li> <li>(3) Do you feel that the information provided in this educational activity will aid in improving patient care in your practice?</li> <li>(4) Do you feel that fair balance was maintained for all therapeutic options?</li> <li>(5) Would you participate in future educational activities?</li> </ol>
<b>Distribution</b>	Medical Learning Solutions and the third party CE vendor will announce and promote The Emerging Solutions in Pain Accredited Article Series primarily through advertisement at the Emerging Solutions in Pain web site.
<b>Request for Sponsor Support</b>	As a supplement to these primary methods, Medical Learning Solutions and the third party CE vendor may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.
<b>Total Budget:</b>	\$304,841



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Proposal Number: 06-003

Date: November 28, 2005

### Emerging Solutions in Pain Accredited Journal Article Series

A Series of 4-Page Articles Inserted in *Practical Pain Management Journal* and Posted  
Online at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com)

November 28, 2005

<b>Program Parameters</b>	
Number of 2006 issues	8
Total 2006 articles	8
Pages per article	4
Circulation per article	39,000

<b>Cost Summary</b>			
	One-Time Charges	Per Article Costs	Total, Eight Article Series
Approximate Total, Direct Expenses; Development and Production	\$ -	\$ 27,000	\$ 216,000
Total, Indirect Expenses; Development and Production	\$ 2,000	\$ 10,855	\$ 86,841
Subtotal	\$ 2,000	\$ 37,855	\$ 302,841
<b>Cost of Eight Emerging Solutions in Pain Accredited Journal Article Series</b>			<b>\$ 304,841</b>

<i>Per Issue Cost</i>	<b>\$ 0.98</b>
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Proposal Number: 06-003

Date: November 28, 2005

## Emerging Solutions in Pain Accredited Journal Article Series

A Series of 4-Page Articles Inserted in *Practical Pain Management Journal* and Posted  
Online at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com)

November 28, 2005

### Detailed Budget Itemization

<b>Approximate Direct Expenses, Development and Production</b>			
	One-Time Charges	Per Article Costs	Total, Eight Article Series
Clinical expert honoraria		\$ 3,000	\$ 24,000
Insert page charges, <i>PPMJ</i> Four-page article printed on matte cover stock as journal insert		\$ 10,000	\$ 80,000
Accreditation of program for CME, CPE, CNE		\$ 8,000	\$ 64,000
Continuing Education participant certificates (estimate 750 certificates per program)		\$ 6,000	\$ 48,000
<b>Approximate Total, Direct Expenses, Development and Production</b>	\$ -	\$ 27,000	\$ 216,000

<b>Indirect Expenses, Development and Production</b>			
	One-Time Charges	Per Article Costs	Total, Eight Article Series
Program development Includes coordination with clinical expert for receipt of article; coordination with accreditor, internal teams, <i>PPMJ</i> staff		\$ 1,200	\$ 9,600
Medical services Includes development of supporting verbiage (needs assessment, objectives, etc.) and self-assessment; editorial services; fact-checking services; proofreading		\$ 2,400	\$ 19,200
Production services Includes layout and typesetting of articles, supporting web pages for online posting		\$ 275	\$ 2,200
Programming of finished monograph for Web-posting, archiving		\$ 950	\$ 7,600
Database creation, management	\$ 2,000	\$ -	\$ -
Administrative and accounting fees		\$ 2,566	\$ 20,528
Project management		\$ 3,464	\$ 27,713
<b>Total, Indirect Expenses, Development and Production</b>	\$ 2,000	\$ 10,855	\$ 86,841



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## **Grant Request Part B: Live Emerging Solutions in Pain Educational Events and Activities**

### **Program Overview: Summary of Work Completed in 2005**

#### **1. ESP MEET THE EXPERTS BOOTH**

Another key Emerging Solutions in Pain initiative for 2005 is the ESP Meet the Experts exhibit booth, which is an informational and interactive exhibit booth that features mini-presentations by leading experts in pain and addiction medicine at select national healthcare association conferences. The goals of the Meet the Expert booth are several-fold:

1. Introduce the Emerging Solutions in Pain initiative to clinicians attending the meeting
2. Distribute ESP resources to clinicians, including the Emerging Solutions in Pain Tool Kit CD-ROM and Mini-Disc Publication
3. Provide clinicians with an opportunity to meet with national leaders in the field of pain management, in an intimate setting designed to foster interaction and discussion
4. Capture clinical expert presentations for video replay at the Emerging Solutions in Pain web site
5. Allow clinicians to explore the Emerging Solutions in Pain web site and the Tool Kit CD-ROM through interactive kiosks
6. Make clinicians aware that new and innovative resources are being added to the ESP web site on a continuing basis

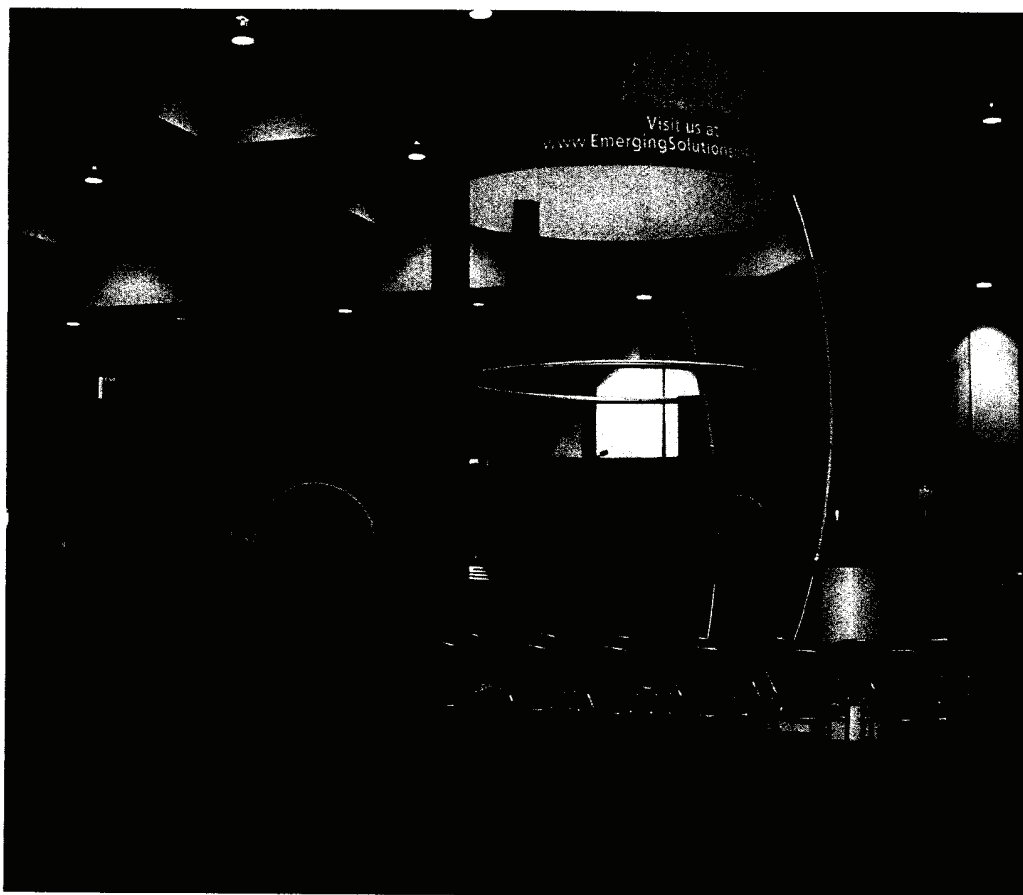
Through 2005, the Meet the Expert Booth has disseminated Emerging Solutions in Pain information and resources to clinicians at multiple meetings:

<b>Meeting</b>	<b>Date</b>	<b>Location</b>
AAPM	February, 2005	Palm Springs, CA
APS	March, 2005	Boston, MA
ASAM	April, 2005	Dallas, TX
AAFP	September, 2005	San Francisco, CA
AAPM&R	October, 2005	Philadelphia, PA



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## ***Grant Request Part B: Live Emerging Solutions in Pain Educational Events and Activities***



### **2. THE ESP RESPECT (RESPONSIBLE PAIN EDUCATION CAN BE THERAPEUTIC) MEETING SERIES**

This accredited series of regional meetings is directed toward physicians, pharmacists, nurses, and other allied health care professionals who provide care to patients with chronic pain. The RESPECT meetings focus on the role of opioids in pain management, concerns over addiction, and the potential for diversion. One of the goals of this series is to educate clinicians on resources that are available within their own community for building interdisciplinary teams and networks to improve the quality of care for patients with chronic pain. As such, these programs are accredited for physicians, pharmacists and nurses; topics addressed include:

1. Standards of care for determining a patient's treatment plan
2. Interdisciplinary team approaches to pain management



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## ***Grant Request Part B: Live Emerging Solutions in Pain Educational Events and Activities***

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### 3. Two – three case studies of patients in the actual community

Each meeting participant receives a RESPECT binder with all slides presented in the program, as well as tools and information specific to the treatment of patients with pain in the local community. Resources in this binder include:

1. The Emerging Solutions in Pain Tool Kit CD-ROM
2. The American Pain Foundation TARGET Chronic Pain Card
3. Opioid Risk Tool (both clinician and patient forms)
4. The Hamilton Rating Scale for Depression
5. Return Visit Clinician Checklist and Patient Questionnaire
6. Internet resources, organized by:
  - a. Federal government resources
  - b. State government resources
  - c. Legal resources
  - d. Pain management resources
  - e. Professional Associations
  - f. Online Continuing Education (CE) resources
7. State-specific information from the state medical board(s)

The faculty for each RESPECT meeting is composed of two nationally-known faculty and two to three regional speakers, thus creating a dynamic presentation that addresses challenges associated with pain management on both a national and regional level.

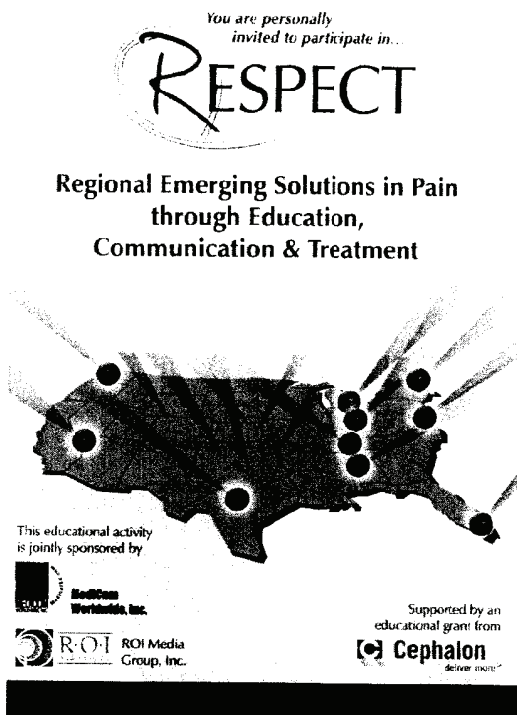
To date, there have been seven RESPECT meetings involving 47 physicians, 113 pharmacists, 72 nurses and 38 other allied health care specialists.



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## **Grant Request Part B: Live Emerging Solutions in Pain Educational Events and Activities**

### **Exhibit B-1**



### **Program Overview: Proposed 2006 Activities**

The following activities are recommended as the Live Emerging Solutions in Pain Educational Events and Activities in 2006.

1. Continuance of the Meet the Expert exhibit booth at select, larger association meetings and expansion of the Meet the Expert mini-booth at smaller association meetings
2. Recreation of the RESPECT meeting series to focus on the provision of trained Emerging Solutions in Pain faculty to regional and local meetings of clinician associations, grand rounds programs and other similar venues
3. Adaptation of the current RESPECT meeting content to focus on the educational needs of single-clinician groups at regional and local meetings of clinician associations





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Proposal Number: 06-003  
Date: November 28, 2005

**Emerging Solutions in Pain**  
**Summary of Proposed Budget, Grant Request Part B**  
*Live Emerging Solutions in Pain Educational Events and Activities*  
November 28, 2005

<b>Cost Summary</b>	
<b>Meet the Experts Booth</b>	
Approximate Total, Direct Costs	\$ 380,150
Indirect Costs	\$ 208,290
Cost of the 2006 Meet the Expert Booth Series	\$ 588,440
<b>RESPECT Meetings</b>	
Approximate Total, Direct Costs	\$ 170,950
Indirect Costs	\$ 204,616
Cost of a 20-Activity RESPECT Meeting Series	\$ 375,566
<b>Total Budget, 2006 Live Emerging Solutions in Pain Educational Events and Activities</b>	<b>\$ 964,006</b>

Approval Signature \_\_\_\_\_

Date \_\_\_\_\_

**Note: no work may begin until Medical Learning Solutions receives, via email or fax, this approval with signature and date**



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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain Meet the Experts Booth
<b>Program Overview</b>	<p>Medical Learning Solutions is proposing to continue utilizing the Meet the Experts Booth as an informational and interactive display for educating clinicians in the Emerging Solutions in Pain initiatives at national congresses and association meetings. In 2006, Medical Learning Solutions is proposing to tailor Booth activities to the size and specific purpose of the congress or association. Thus, at larger meetings, the full Meet the Expert Booth will be utilized, while a smaller Emerging Solutions in Pain Booth will be displayed at smaller congress and association meetings.</p> <p>Functionality for the full-size Meet the Expert Booth will include a seating area for meeting attendees to interact with Emerging Solutions in Pain clinical experts; computer terminals featuring interactive displays highlighting the Emerging Solutions in Pain initiatives, membership registration for the Emerging Solutions in Pain Web Site, and the Emerging Solutions in Pain Tool Kit. The smaller Emerging Solutions in Pain Booth will focus on interactive displays of the Tool Kit and video highlights of previous Meet the Expert presentations; membership registration; and distribution of the Emerging Solutions in Pain Tool Kit.</p>
<b>Intended Audience</b>	The primary audience of the Emerging Solutions in Pain Meet the Experts Booth will be physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain and who attend selected national association meetings and congresses. Currently suggested meetings include the 2006 meetings of the AAPM, AAPM&R, AANP, AMCP and ASAM.
<b>Program Objectives</b>	<p>The purpose of the Emerging Solutions in Pain Meet the Expert Booth is to disseminate information concerning the Emerging Solutions in Pain initiative to clinicians practicing in the field of pain management, and to educate those clinicians on the assessment and monitoring of pain patients, and on good practice management techniques. Clinicians visiting the booth will have opportunities to:</p> <ol style="list-style-type: none"> <li>(1) Interact with Emerging Solutions in Pain clinical experts in small discussion groups, focusing on tools and strategies that will contribute to a proper balance of pain control and abuse/diversion minimization (full-size Meet the Expert Booth only)</li> <li>(2) On computer terminals, view multi-media, interactive programs highlighting the issues associated with minimization of abuse, addiction and diversion, the Emerging Solutions in Pain Tool Kit and associated case studies</li> <li>(3) Receive copies of the Emerging Solutions in Pain Tool Kit CD-ROM and other support materials, such as the Mini-Disc Publication</li> <li>(4) Gain exposure to the resources available at the Emerging Solutions in Pain Web Site, and register as a "member", thereby expediting their ability to access online resources</li> </ol>
<b>Format</b>	An interactive meeting booth, to be presented at national association meetings and congresses. The full-size Meet the Expert Booth will feature live peer-to-peer interactions with Emerging Solutions in Pain clinical experts, as well as interactive, multimedia programs that highlight the Emerging Solutions in Pain initiatives. The smaller Emerging Solutions in Pain Booth will focus on educating clinicians in the availability of the Emerging Solutions in Pain initiatives.



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## ***Program Summary***

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<b>Distribution</b>	The Emerging Solutions in Pain Meet the Expert Booth will be available at selected national association meetings and congresses; meetings identified to date include the AAPM, AAPM&R, AANP, AMCP and ASAM. The announcement of the Booth will be made via direct mail to registered meeting attendees and members, and via journal and/or banner advertisements. Information at the Booth will be provided by Emerging Solutions in Pain clinical experts and by Medical Learning Solutions staff members.
<b>Request for Sponsor Support</b>	<p>Medical Learning Solutions is promoting the Emerging Solutions in Pain Meet the Experts Booth through a variety of methods, including direct mail, publication of a multimedia Mini-Disc, and journal and banner advertisements.</p> <p>As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely as a supplement to MLS' primary methods of announcement and promotion.</p>
<b>Total Budget:</b>	\$588,440



Proposal Number: 06-003

Date: November 28, 2005

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**2006 Emerging Solutions in Pain Exhibition Booth Series**  
***Proposed Budget***  
November 28, 2005

<b><i>Program Parameters</i></b>	
<b>Number of Exhibitions of the Full-Size Meet the Expert Booth</b>	<b>2</b>
<b>Number of Exhibitions of the Smaller Emerging Solutions in Pain Booth</b>	<b>3</b>

<b><i>Cost Summary</i></b>		
	<b>Per Meeting</b>	<b>Total</b>
One-Time Approximate Direct Expenses	\$ -	\$ 47,000
Approximate Total, Direct Expenses: Full-Size Booth (AAPM, AAPM&R)	\$ 111,570	\$ 193,500
Approximate Total, Direct Expenses: Mini ESP Booth (ASAM, AANP, AMCP)	\$ 46,550	\$ 139,650
Total, Indirect Expenses	\$ 64,598	\$ 208,290
<b>Total Cost of the 2006 Emerging Solutions in Pain Exhibition Booth Series</b>		<b>\$ 588,440</b>



Proposal Number: 06-003

Date: November 28, 2005

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**2006 Emerging Solutions in Pain Exhibition Booth Series**  
**Proposed Budget**  
November 28, 2005

*Detailed Budget Itemization*

<b>Approximate Total, Direct Expenses</b>		
<b>One-Time Approximate Direct Expenses</b>		
	Per Meeting	Total
Update of existing mini-booth; new graphic panels for full-size booth		\$ 15,000
Booth give-aways		\$ 30,000
Miscellaneous (non-fulfillment shipping, faxes, etc.)		\$ 2,000
<i>Subtotal, One-Time Approximate Direct Expenses</i>		\$ 47,000
<b>Full-Size Booth (AAPM, AAPM&amp;R)</b>		<i>2 meetings total</i>
Exhibit space (includes liability insurance)	\$ 15,400	\$ 30,800
Booth set-up/tear-down (floor plan, shop prep, installation and dismantling including labor supervision, travel)	\$ 25,720	\$ 51,440
Equipment rental (computer units, plasma screen, switcher unit, audio w/ lav mic, electrical, telecommunication links, chairs, carpeting, etc.)	\$ 10,590	\$ 21,180
Shipping of booth to AAPM meeting site only	\$ 8,820	\$ 8,820
Shipping of booth to AAPM&R meeting site only (note additional shipping charges for Hawaii location of AAPM&R)	\$ 20,820	\$ 20,820
Shipping of supplies (mini-discs, Tool Kits, etc) to meeting site - delivery to booth charges	\$ 2,200	\$ 4,400
Badge Reader System (3 units)	\$ 770	\$ 1,540
Booth advertisement		
Advertisement in meeting catalog/publication (full page, 4/c)	\$ 2,925	\$ 5,850
Booth posters, printing	\$ 825	\$ 1,650
KOL expenses: two KOL faculty		
Honoraria	\$ 12,000	\$ 24,000
Travel: air, hotel, ground, OOP	\$ 4,300	\$ 8,600
ROI expenses: three ROI staff		
Travel: air, hotel, ground, OOP	\$ 6,900	\$ 13,800
Exhibitor registration	\$ 300	\$ 600
<i>Subtotal, Approximate Direct Expenses for Full-Size Booth</i>		\$ 111,570
		\$ 193,500



Proposal Number: 06-003

Date: November 28, 2005

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**2006 Emerging Solutions in Pain Exhibition Booth Series**  
***Proposed Budget***  
November 28, 2005

***Detailed Budget Itemization***

<b><i>Approximate Total, Direct Expenses (continued)</i></b>		
	Per Meeting	Total
<b>Mini Booth (AANP, AMCP, ASAM)</b>		<i>3 meetings total</i>
Exhibit space (includes liability insurance)	\$ 1,430	\$ 4,290
Booth Rental for 8X10 Space	\$ 3,850	\$ 11,550
Booth set-up/tear-down (floor plan, shop prep, installation and dismantling including labor supervision, travel)	\$ 15,950	\$ 47,850
Equipment rental (computer units, plasma screen, switcher unit, audio w/ lav mic, electrical, telecommunication links, chairs, carpeting, etc.)	\$ 6,475	\$ 19,425
Shipping of booth to meeting site	\$ 7,975	\$ 23,925
Shipping of supplies (mini-discs, Tool Kits, etc) to meeting site - delivery to booth charges	\$ 2,200	\$ 6,600
Booth advertisement		
Advertisement in meeting catalog/publication	\$ 2,310	\$ 6,930
Booth posters, printing	\$ 660	\$ 1,980
ROI expenses: three ROI staff		
Travel: air, hotel, ground, OOP	\$ 5,500	\$ 16,500
Exhibitor registration	\$ 200	\$ 600
<b><i>Subtotal, Approximate Direct Expenses for Mini Booth</i></b>	<b>\$ 46,550</b>	<b>\$ 139,650</b>



Proposal Number: 06-003

Date: November 28, 2005

101 Washington St, Suite 110  
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## 2006 Emerging Solutions in Pain Exhibition Booth Series

### *Proposed Budget*

November 28, 2005

#### *Detailed Budget Itemization*

<b>Total, Indirect Expenses</b>		
	Per Meeting	Total
<b>Medical / scientific services</b> Includes development of content for meeting advertisements; ; coordination of presentation content with ESP KOLs	\$ 4,000	\$ 20,000
<b>Graphic design / production services</b> Includes development of display graphics for booth panels, graphics for interactive booth displays; graphic design, typesetting and layout of booth posters and advertisements (direct mail plus meeting catalog); proofreading; coordination with print vendors; etc.	\$ 2,000	\$ 10,000
<b>Conference management services</b> staffing booth during meeting; coordination with KOLs pre-meeting, post-meeting and during meeting; coordination with conference vendors, coordination of booth advertising; etc.		
<b>Conference management services: Full-Size Booth (2 total)</b>	\$ 26,700	\$ 53,400
<b>Conference management services: Mini Booth (3 total)</b>	\$ 17,300	\$ 51,900
<b>Administrative and accounting fees</b>	\$ 5,460	\$ 27,301
<b>Project management</b>	\$ 9,138	\$ 45,689
<b>Total, Indirect Expenses</b>	<b>\$ 64,598</b>	<b>\$ 208,290</b>





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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain RESPECT Meeting Series
<b>Program Overview</b>	<p>Medical Learning Solutions is proposing to adapt the 2005 RESPECT meetings into a new series that focuses on the provision of trained Emerging Solutions in Pain faculty to regional and local meetings of clinician associations, grand rounds programs and other similar venues. The 2006 RESPECT Meeting Series will therefore focus on providing practical clinical information via an accredited lecture series to health care professionals practicing in local clinics, hospitals and office settings.</p> <p>In this series, Medical Learning Solutions is proposing to update the 2005 RESPECT Meeting slide modules with information that will be appropriate for smaller groups of clinicians, such as will attend local and regional association meetings and grand rounds presentations. Select Emerging Solutions in Pain faculty who express interest and availability will then be trained remotely via teleconference in the new data; these individuals will form a RESPECT Meeting Speakers' Bureau. Medical Learning Solutions will work with local and regional association meetings and hospitals hosting grand rounds presentations to identify meetings of clinicians which will benefit from an accredited presentation focusing on Emerging Solutions in Pain/RESPECT Meeting topics. After a need has been identified, Medical Learning Solutions will coordinate all logistical arrangements for the presentation with a trained, available Faculty member.</p>
<b>CE Provider</b>	<p>Based on the need to educate clinicians in the assessment and treatment of chronic pain patients who may be at risk for abuse, addiction and diversion, The Emerging Solutions in Pain RESPECT Meeting Series will be accredited by a third party CE vendor of our choice.</p> <p>The Meeting Series will be accredited for:</p> <ul style="list-style-type: none"> <li>• CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each activity will be approved for a maximum of one hour of category 1 credit toward the AMA Physician's Recognition Award.</li> <li>• CPE credit for pharmacists by the Accreditation Council for Pharmacy Education. Each activity will be approved for a maximum of 1.0 credit hour (0.1 CEU) for Continuing Pharmacy Education</li> <li>• CNE credit for nurses. Each activity will be approved for a maximum of 1.0 Contact Hours.</li> </ul>
<b>Intend d Audience</b>	The primary audience of The Emerging Solutions in Pain RESPECT Meeting Series includes clinicians who provide care to patients with pain. These clinicians will include physicians, pharmacists and nurses, but may be extended to other clinical and non-clinical members of a multi-disciplinary treatment team, such as social workers, case managers, etc.



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## *Program Summary*

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<b>Program Objectives</b>	The purpose of the RESPECT Meeting Series is to educate clinicians on the key tenets of the Emerging Solutions in Pain initiative, focusing on the role of appropriate assessment and monitoring techniques, and good practice management strategies, in achieving effective interactions between members of the treatment team. In addition, other topics may be included, based upon recommendations made by the Emerging Solutions in Pain Faculty Advisory Committee.
<b>Format</b>	A series of live, peer-to-peer activities scheduled in conjunction with local and regional association meetings and at hospital or clinic-based grand rounds programs throughout the United States. This proposal is for 20 RESPECT meetings.
<b>Post-Activity Feedback</b>	<p>Course evaluation forms will be required of all participants who seek to receive continuing education credit. Medical Learning Solutions will work with the third party CE vendor to summarize the information collected from these forms in a formal report to evaluate program effectiveness.</p> <p>Participants will evaluate the following as excellent, good, fair or poor:</p> <ol style="list-style-type: none"> <li>(1) Overall content</li> <li>(2) Faculty teaching effectiveness</li> <li>(3) Format</li> <li>(4) Audio/visual</li> </ol> <p>Participants will also respond to the following questions:</p> <ol style="list-style-type: none"> <li>(1) How well did the program achieve its educational objectives?</li> <li>(2) Do you feel the program material was useful and practice-oriented?</li> <li>(3) Do you feel that the information provided in this educational activity will aid in improving patient care in your practice?</li> <li>(4) Do you feel that fair balance was maintained for all therapeutic options?</li> <li>(5) Would you participate in future educational activities?</li> </ol>
<b>Distribution</b>	Medical Learning Solutions and the third party CE vendor will announce and promote The Emerging Solutions in Pain RESPECT Meeting Series primarily through arrangement with the local/regional association hosting the meeting; or the hospital sponsoring the grand rounds presentation. Medical Learning Solutions will also advertise availability of these meetings via advertisement on the Emerging Solutions in Pain web site.
<b>Request for Sponsor Support</b>	As a supplement to these primary methods, Medical Learning Solutions and the third party CE vendor may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.
<b>Total Budget:</b>	\$375,566



Proposal Number: 06-003  
Date: November 28, 2005

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## Emerging Solutions in Pain 2006 RESPECT Meeting Series

### *Projected Budget Estimate*

November 28, 2005

<b>Program Parameters</b>	
Number of regional association symposia	10
Faculty presenter per activity	1
Approximate number, health care professional attendees per meeting	30
Direct mail invitations to health care professionals	150

<b>Cost Summary</b>		
	One-time only costs	Each group of 10 meetings
Approximate Total, Direct Meeting Series Expenses	\$ -	\$ 75,725
Total, Indirect Meeting Series Expenses	\$ 47,663	\$ 64,726
Approximate Total, Direct Meeting Support Expenses	\$ 19,500	\$ -
Total, Indirect Meeting Support Expenses	\$ 27,500	\$ -
Subtotal, one-time only costs	\$ 94,663	\$ -
Subtotal, 20-meeting RESPECT series	\$ -	\$ 280,903
<b>Cost of 2006 Emerging Solutions in Pain 20-Meeting RESPECT Series</b>		<b>\$ 375,566</b>



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Proposal Number: 06-003  
Date: November 28, 2005

**Emerging Solutions in Pain 2006 RESPECT Meeting Series**  
**Projected Budget Estimate**  
November 28, 2005

*Detailed Budget Itemization*

<b>Direct Meeting Expenses, Approximate</b>		
	One-time only costs	Each group of 10 meetings
<b>Direct mail invitations, mail services, postage</b>	\$ -	\$ 4,725
Personalized invitations to be mailed to every potential participant; includes printing, assembly, mail services and postage. Postage estimated at \$0.37 per direct mail piece		
<b>Direct mail list purchase</b>	\$ -	\$ -
<b>Print materials</b>	\$ -	\$ 3,500
Includes printing of shell materials for adaptation and use in individualized symposia kits for every symposium; kits to include accreditation information, speaker biographical and disclosure information, agenda, reference materials and handout materials, where appropriate		
<b>Speaker honoraria</b>	\$ -	\$ 25,000
<b>Speaker travel (air, OOP, hotel)</b>	\$ -	\$ 12,000
<b>Ground transportation</b>	\$ -	\$ 2,000
<b>Catering</b>	\$ -	\$ 15,000
<b>Audio/visual services</b>	\$ -	\$ 5,000
<b>Onsite CME coordination</b>	\$ -	\$ 7,500
<b>Shipping/Fed Ex</b>	\$ -	\$ 1,000
<b>Approximate Total, Direct Meeting Expenses</b>	\$ -	\$ 75,725

<b>Indirect Meeting Expenses</b>		
	One-time only costs	Each group of 10 meetings
<b>Program development</b>	\$ 45,000	\$ -
Includes all labor associated with initial program set-up and development, including creation of text for print support materials, graphic design, typesetting and layout of all support materials, and development and creation of final program appearance		
<b>Medical Services</b>	\$ 18,000	\$ 20,000
Includes all labor associated with content of each symposium, including identification and production of resources specific for each region and clinicians in each association; review and coordination of content with faculty		
<b>Meeting management</b>		\$ 18,000
Includes coordination with association for date of symposium and all meeting-related logistical details; coordination with faculty for dates, travel and all other program details		
<b>Accreditation of program for CME, CPE, CNE</b>	\$ 15,000	\$ -
<b>Continuing Education participant certificates</b>		\$ 4,500
<b>Administrative and accounting fees</b>	\$ 6,240	\$ 9,458
<b>Project management</b>	\$ 8,423	\$ 12,768
<b>Total, Indirect Meeting Expenses</b>	\$ 47,663	\$ 64,726



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Proposal Number: 06-003  
Date: November 28, 2005

## Emerging Solutions in Pain 2006 RESPECT Meeting Series

### Projected Budget Estimate

November 28, 2005

#### Detailed Budget Itemization

<b>Direct Meeting Support Expenses, Approximate</b>		
	One-time only costs	Each group of 10 meetings
<b>Slide module updates</b>		
Medical writing	\$ 8,500	\$ -
Speaker honoraria	\$ 3,500	\$ -
<b>Production of non-accredited video from one RESPECT meeting</b>		
Equipment rental	\$ 3,000	\$ -
Travel	\$ 4,500	\$ -
<b>Approximate Total, Direct Meeting Support Expenses</b>	<b>\$ 19,500</b>	<b>\$ -</b>

<b>Indirect Meeting Support Expenses</b>		
	One-time only costs	Each group of 10 meetings
<b>Slide module updates</b>		
Program development	\$ 2,300	\$ -
Medical services	\$ 7,950	\$ -
<b>Production of non-accredited video from one RESPECT meeting</b>		
Program development	\$ 1,775	\$ -
Editing, post production	\$ 9,975	\$ -
<b>Administrative and accounting fees</b>	<b>\$ 3,320</b>	<b>\$ -</b>
<b>Project management</b>	<b>\$ 4,480</b>	<b>\$ -</b>
<b>Total, Indirect Meeting Support Expenses</b>	<b>\$ 27,500</b>	<b>\$ -</b>



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## **Grant Request Part C: Programs to Further Expand the Reach of the Emerging Solutions in Pain Educational Events and Activities**

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### **Program Overview: Proposed 2006 Activities**

The following activities are recommended as a series of programs that will further expand the reach of the Emerging Solutions in Pain Educational Events and Activities in 2006.

1. Development and implementation of a full-day seminar program, to be held for clinical attendees of a national congress, focusing on the intersection of pain management and addiction medicine
2. Additional RESPECT meetings, held at regional and local meetings of clinician associations, grand rounds programs and other similar venues

### **1. The Emerging Solutions in Pain Full-Day Lecture Program**

The American Society for Addiction Medicine (ASAM) has historically held an accredited, full-day lecture one day prior to the convening of its annual meeting for those ASAM members attending the meeting. This lecture, known as the Common Threads program, has focused on topical issues relating to the convergence of pain and addiction medicine. For logistical reasons, this meeting will not be offered by ASAM to its members at the 2006 meeting. However, the educational need of these clinicians, to increase their knowledge and understanding of the pain management and the impact of addiction on effective pain therapy, continues to exist.

Medical Learning Solutions is therefore proposing to create an accredited full-day lecture program that will educate ASAM members on topics relevant to the Emerging Solutions in Pain initiatives. Through a series of presentations by Emerging Solutions in Pain faculty, this program will focus on a scientific and clinical evaluation of the fields of pain management and addiction, and will include relevant case studies for discussion and presentation.

### **2. The ESP RESPECT (RESponsible Pain Education Can be Therapeutic) Meeting Series**

The RESPECT Meeting Series has been described previously in the Grant Request Part B, in which a series of 20 RESEPECT Meetings were proposed, to be held in conjunction with local and regional association meetings and grand rounds presentations. The recommendation for this portion of the Grant Request is for an additional 10 RESPECT meetings in this series. The additional 10 meetings will utilize the same program infrastructure, content and trained faculty as the first 20 meetings, thereby cost-effectively extending the reach of this portion of the 2006 Emerging Solutions in Pain initiative.



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Proposal Number: 06-003  
Date: November 28, 2005

**Emerging Solutions in Pain**  
**Summary of Proposed Budget, Grant Request Part C**  
*Programs to Further Expand the Reach of the Emerging Solutions in Pain Educational Events and Activities*  
November 28, 2005

<b>Cost Summary</b>	
<b>Full-day ESP Symposium</b>	
Approximate Total, Direct Expenses	\$ 132,850
Indirect Expenses	\$ 108,600
Cost of One Full-Day ESP Symposium Held at the 2006 ASAM Meeting	\$ 241,450
<b>RESPECT Meeting Series Extension</b>	
Approximate Total, Direct Expenses	\$ 75,725
Indirect Expenses	\$ 64,726
Cost of 10-Program Extension of the 2006 RESPECT Meeting Series	\$ 140,451
<b>Total Budget, 2006 Programs to Further Expand the Reach of the Emerging Solutions in Pain Educational Events and Activities</b>	<b>\$ 381,901</b>

Approval Signature \_\_\_\_\_

Date \_\_\_\_\_

**Note: no work may begin until Medical Learning Solutions receives, via email or fax, this approval with signature and date**





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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain Accredited Full-Day Lecture Program
<b>Program Overview</b>	<p>Medical Learning Solutions is proposing to create an accredited full-day lecture program that will educate ASAM members on topics relevant to the Emerging Solutions in Pain initiatives. Through a series of presentations by Emerging Solutions in Pain faculty, this program will focus on a scientific and clinical evaluation of the fields of pain management and addiction, and will include relevant case studies for presentation and discussion.</p> <p>The core group of proposed faculty includes:</p> <ol style="list-style-type: none"> <li>(1) Howard Heit, MD, FACP, FASAM</li> <li>(2) Douglas Gourlay, MD, MSc, FRCPC</li> <li>(3) Seddon Savage, MD, FASAM</li> <li>(4) Steven Passik, PhD</li> </ol> <p>Other faculty will be recruited based upon recommendations by the core faculty. Specific lecture topics will be identified based upon a consensus of the core faculty, but may include topics such as:</p> <ol style="list-style-type: none"> <li>(1) Evaluating the risk of opioid abuse in the chronic pain patient</li> <li>(2) Pharmacologic therapies for the chronic pain patient with a history of drug abuse or addiction</li> <li>(3) Legal issues in prescribing opioids to the chronic pain patient</li> <li>(4) New pharmacologic agents for treating chronic pain patients</li> </ol>
<b>Intended Audience</b>	The primary audience of The Emerging Solutions in Pain Accredited Full-Day Lecture Program includes clinicians who provide care to patients with pain and who specialize in addiction medicine.
<b>Program Objectives</b>	The purpose of the Emerging Solutions in Pain Accredited Full-Day Lecture Program is to educate clinicians on topical issues relating to the convergence of pain and addiction medicine. In addition, other topics may be included, based upon recommendations made by the core faculty identified above and by the Emerging Solutions in Pain Faculty Advisory Committee.
<b>Format</b>	One full-day seminar program held one day prior to the Annual ASAM Conference, held in San Diego, California. This program will be comprised primarily as didactic lecture. An audience response system will also be utilized throughout the program to enhance audience participation and a more interactive experience.
<b>Activity Feedback</b>	<p>To help establish a return on education metric for this program, Medical Learning Solutions will develop with the moderator a series of opening questions that will utilize the audience response keypad system. These questions will gather basic audience demographics, educational understanding of content prior to the educational activity, ratings scales on specific clinical techniques, etc. This would occur during the introduction of the program, similar to a pre-test. Data received from this activity would be correlated to information gathered during the post-test, thereby establishing prior- vs post-program educational metrics.</p> <p>Course evaluation forms and a written post-test will be required of all participants who seek to receive continuing education credit. Medical Learning Solutions will</p>



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## *Program Summary*

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work with the third party CE vendor to summarize the information collected from these forms in a formal report to evaluate program effectiveness.

- (A) Participants will evaluate the following as excellent, good, fair or poor:
  - (1) Overall content
  - (2) Faculty teaching effectiveness
  - (3) Format
  - (4) Audio/visual
- (B) Participants will also respond to the following questions:
  - (1) How well did the program achieve its educational objectives?
  - (2) Do you feel the program material was useful and practice-oriented?
  - (3) Do you feel that the information provided in this educational activity will aid in improving patient care in your practice?
  - (4) Do you feel that fair balance was maintained for all therapeutic options?
  - (5) Would you participate in future educational activities?
- (C) Participants will also complete a post-test specific to the content topics, ACPE accreditation required.

### **CE Provider**

Based on the need to educate clinicians in the issues associated with treating chronic pain patients who may be at high risk for abuse, addiction or diversion of controlled substances, The Emerging Solutions in Pain Accredited Full-Day Lecture Program will be accredited by a third party CE vendor of our choice.

The Lecture Program will be accredited for:

- CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each activity will be approved for a maximum of seven hours of category 1 credit toward the AMA Physician's Recognition Award.
- CPE credit for pharmacists by the Accreditation Council for Pharmacy Education. Each activity will be approved for a maximum of 7.0 credit hours (0.7 CEU) for Continuing Pharmacy Education
- CNE credit for nurses. Each activity will be approved for a maximum of 7.0 Contact Hours.

### **Distribution**

Medical Learning Solutions and the third party CE vendor will announce and promote The Emerging Solutions in Pain Accredited Full-Day Lecture Program primarily through direct mail to ASAM members. Medical Learning Solutions will also advertise availability of this meeting via advertisement on the Emerging Solutions in Pain website.

### **Request for Sponsor Support**

As a supplement to these primary methods, Medical Learning Solutions and the third party CE vendor may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.

### **Total Budget:**

\$241,450



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Proposal Number: 06-003  
Date: November 28, 2005

**Emerging Solutions in Pain Full-Day Accredited Symposium**  
***Proposed Budget***  
November 28, 2005

***Program Description***

This proposed budget is for the development, production and management of a full-day CME-accredited stand-alone live event to coincide with the ASAM Annual Conference in San Diego on May 4, 2006. This program would support the Emerging Solutions in Pain mission of providing medical education in the area of pain management and the issues of misuse, abuse, and addiction.

<b><i>Program Parameters</i></b>	
Presenting faculty @ activity	6
Health care professional attendees @ meeting	250
Direct mail invitations to health care professionals per activity	5000

<b><i>Cost Summary</i></b>	
Approximate Total, Direct Expenses	\$ 132,850
Total, Indirect Expenses	\$ 108,600
<b>Cost of Emerging Solutions in Pain Full-Day Accredited Symposium</b>	<b>\$ 241,450</b>



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Proposal Number: 06-003

Date: November 28, 2005

**Emerging Solutions in Pain Full-Day Accredited Symposium**  
**Proposed Budget**  
November 28, 2005

*Detailed Budget Itemization*

<b>Direct Expenses, Approximate</b>	
<b>Direct mail invitations, mail services, postage</b>	
Printing	\$ 2,700
Postage	\$ 1,950
Fax Blast	\$ 750
Email Blast	\$ 250
<b>Direct mail list purchase</b>	\$ 2,000
<b>Print materials</b>	
Printing meeting kits to include accreditation information, speaker biographical and disclosure information, agenda, handout materials, current journal articles by faculty, etc. and 4/c binder	\$ 4,500
Set design pieces (banners, podium signs, gobo, directional signage, etc.)	\$ 2,500
<b>Speaker honoraria (6 faculty members)</b>	\$ 20,000
<b>Speaker travel (air, OOP, hotel)</b>	\$ 11,550
<b>ROI staff travel</b>	\$ 5,600
<b>Ground transportation</b>	\$ 1,750
<b>Venue rental fee, service fees, etc.</b>	\$ 6,100
<b>Travel, site visit</b>	\$ 2,000
<b>Food &amp; Beverage (Continental Breakfast, Buffet Lunch, Afternoon Break for 250)</b>	\$ 24,000
<b>Audio/visual services</b>	\$ 14,000
<b>Audience response system</b>	\$ 10,000
<b>Accreditation of program for CME, CPE, CNE</b>	\$ 15,000
<b>Continuing Education participant certificates</b>	\$ 4,500
<b>Onsite CME coordination</b>	\$ 1,500
<b>Miscellaneous (non-fulfillment shipping, faxes, FedEx, etc.)</b>	\$ 2,200
<b>Approximate Total, Direct Expenses</b>	<b>\$ 132,850</b>

<b>Indirect Expenses</b>	
<b>Program development</b>	\$ 37,700
Includes all labor associated with initial program set-up and development, including creation of program content, text for print support materials, graphic design, typesetting and layout of all support materials, and development and creation of final program appearance	
<b>Medical and scientific writing</b>	\$ 12,100
<b>Site visit</b>	\$ 2,500
<b>Meeting coordination</b>	\$ 18,500
Includes faculty management, meeting logistics, travel and all other program details	
<b>Telephone recruitment</b>	\$ 8,500
<b>Onsite meeting management</b>	\$ 3,200
<b>Registration database development and management (includes online registration)</b>	\$ 1,500
<b>Administrative and accounting fees</b>	\$ 4,268
<b>Project management</b>	\$ 20,332
<b>Total, Indirect Expenses</b>	<b>\$ 108,600</b>

\* Tax and gratuity figures have not been included in this estimated budget



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## *Program Summary*

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<b>Program Title</b>	The Emerging Solutions in Pain RESPECT Meeting Series
<b>Program Overview</b>	<p>Medical Learning Solutions is proposing to adapt the 2005 RESPECT meetings into a new series that focuses on the provision of trained Emerging Solutions in Pain faculty to regional and local meetings of clinician associations, grand rounds programs and other similar venues. The 2006 RESPECT Meeting Series will therefore focus on providing practical clinical information via an accredited lecture series to health care professionals practicing in local clinics, hospitals and office settings.</p> <p>Medical Learning Solutions will work with local and regional association meetings and hospitals hosting grand rounds presentations to identify meetings of clinicians which will benefit from an accredited presentation focusing on Emerging Solutions in Pain/RESPECT Meeting topics. After a need has been identified, Medical Learning Solutions will coordinate all logistical arrangements for the presentation with a trained, available Faculty member.</p>
<b>CE Provider</b>	<p>Based on the need to educate clinicians in the assessment and treatment of chronic pain patients who may be at risk for abuse, addiction and diversion, The Emerging Solutions in Pain RESPECT Meeting Series will be accredited by a third party CE vendor of our choice.</p> <p>The Meeting Series will be accredited for:</p> <ul style="list-style-type: none"> <li>• CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each activity will be approved for a maximum of one hour of category 1 credit toward the AMA Physician's Recognition Award.</li> <li>• CPE credit for pharmacists by the Accreditation Council for Pharmacy Education. Each activity will be approved for a maximum of 1.0 credit hour (0.1 CEU) for Continuing Pharmacy Education</li> <li>• CNE credit for nurses. Each activity will be approved for a maximum of 1.0 Contact Hours.</li> </ul>
<b>Int nded Audience</b>	The primary audience of The Emerging Solutions in Pain RESPECT Meeting Series includes clinicians who provide care to patients with pain. These clinicians will include physicians, pharmacists and nurses, but may be extended to other clinical and non-clinical members of a multi-disciplinary treatment team, such as social workers, case managers, etc.
<b>Program Objectives</b>	The purpose of the RESPECT Meeting Series is to educate clinicians on the key tenets of the Emerging Solutions in Pain initiative, focusing on the role of appropriate assessment and monitoring techniques, and good practice management strategies, in achieving effective interactions between members of the treatment team. In addition, other topics may be included, based upon



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## ***Program Summary***

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recommendations made by the Emerging Solutions in Pain Faculty Advisory Committee.

**Format** A series of live, peer-to-peer activities scheduled in conjunction with local and regional association meetings and at hospital or clinic-based grand rounds programs throughout the United States. This proposal is for 10 RESPECT meetings.

**Post-Activity Feedback** Course evaluation forms will be required of all participants who seek to receive continuing education credit. Medical Learning Solutions will work with the third party CE vendor to summarize the information collected from these forms in a formal report to evaluate program effectiveness.

Participants will evaluate the following as excellent, good, fair or poor:

- (1) Overall content
- (2) Faculty teaching effectiveness
- (3) Format
- (4) Audio/visual

Participants will also respond to the following questions:

- (1) How well did the program achieve its educational objectives?
- (2) Do you feel the program material was useful and practice-oriented?
- (3) Do you feel that the information provided in this educational activity will aid in improving patient care in your practice?
- (4) Do you feel that fair balance was maintained for all therapeutic options?
- (5) Would you participate in future educational activities?

**Distribution** Medical Learning Solutions and the third party CE vendor will announce and promote The Emerging Solutions in Pain RESPECT Meeting Series primarily through arrangement with the local/regional association hosting the meeting; or the hospital sponsoring the grand rounds presentation. Medical Learning Solutions will also advertise availability of these meetings via advertisement on the Emerging Solutions in Pain web site.

**Request for Sponsor Support** As a supplement to these primary methods, Medical Learning Solutions and the third party CE vendor may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.

**Total Budget:** \$140,451



Proposal Number: 06-003  
Date: November 28, 2005

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**Extension of 2006 Emerging Solutions in Pain RESPECT Meeting Series**  
***Projected Budget Estimate***  
November 28, 2005

<b>Program Parameters</b>	
Number of regional association symposia	10
Faculty presenter per activity	1
Approximate number, health care professional attendees per meeting	30
Direct mail invitations to health care professionals	150

<b>Cost Summary</b>		
	One-time only costs	Each group of 10 meetings
Approximate Total, Direct Meeting Series Expenses	\$ -	\$ 75,725
Total, Indirect Meeting Series Expenses	\$ -	\$ 64,726
<b>Cost of 10-Meeting Extension of 2006 Emerging Solutions in Pain RESPECT Series</b>	<b>\$</b>	<b>140,451</b>





101 Washington St, Suite 110  
Morrisville, PA 19067

Proposal Number: 06-003  
Date: November 28, 2005

**Extension of 2006 Emerging Solutions in Pain RESPECT Meeting Series**  
**Projected Budget Estimate**  
November 28, 2005

**Detailed Budget Itemization**

<b>Direct Meeting Expenses, Approximate</b>		
	One-time only costs	Each group of 10 meetings
<b>Direct mail invitations, mail services, postage</b>	\$ -	\$ 4,725
Personalized invitations to be mailed to every potential participant; includes printing, assembly, mail services and postage. Postage estimated at \$0.37 per direct mail piece		
<b>Direct mail list purchase</b>	\$ -	\$ -
<b>Print materials</b>	\$ -	\$ 3,500
Includes printing of shell materials for adaptation and use in individualized symposia kits for every symposium; kits to include accreditation information, speaker biographical and disclosure information, agenda, reference materials and handout materials, where appropriate		
<b>Speaker honoraria</b>	\$ -	\$ 25,000
<b>Speaker travel (air, OOP, hotel)</b>	\$ -	\$ 12,000
<b>Ground transportation</b>	\$ -	\$ 2,000
<b>Catering</b>	\$ -	\$ 15,000
<b>Audio/visual services</b>	\$ -	\$ 5,000
<b>Onsite CME coordination</b>	\$ -	\$ 7,500
<b>Shipping/Fed Ex</b>	\$ -	\$ 1,000
<b>Approximate Total, Direct Meeting Expenses</b>	\$ -	\$ 75,725

<b>Indirect Meeting Expenses</b>		
	One-time only costs	Each group of 10 meetings
<b>Program development</b>	\$ -	\$ -
Includes all labor associated with initial program set-up and development, including creation of text for print support materials, graphic design, typesetting and layout of all support materials, and development and creation of final program appearance		
<b>Medical Services</b>	\$ -	\$ 20,000
Includes all labor associated with content of each symposium, including identification and production of resources specific for each region and clinicians in each association; review and coordination of content with faculty		
<b>Meeting management</b>		\$ 18,000
Includes coordination with association for date of symposium and all meeting-related logistical details; coordination with faculty for dates, travel and all other program details		
<b>Accreditation of program for CME, CPE, CNE</b>	\$ -	\$ -
<b>Continuing Education participant certificates</b>		\$ 4,500
<b>Administrative and accounting fees</b>	\$ -	\$ 9,458
<b>Project management</b>	\$ -	\$ 12,768
<b>Total, Indirect Meeting Expenses</b>	\$ -	\$ 64,726

**EDUCATIONAL GRANT DRAFT REQUEST**

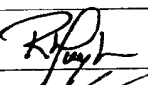
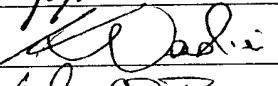
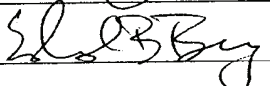
The attached material has been reviewed and is approved:

Payee: Medical Learning Solutions, Inc.

Amount: \$381,901

Type of Program: *Emerging Solutions in Pain* Grant Request part C

Submitted for Review: November 30, 2005

DEPARTMENT	NAME	SIGNATURE	DATE
Scientific Communications	Rod Hughes		12-1-05
Medical Affairs	Kiumars Vadieli		12-1-05
Legal & Government	Ed Berg		12/1/05

Return to: Candice McCarthy 35663 – Scientific Communications



## MEDICAL EDUCATION AGREEMENT

Cephalon, Inc.  
41 Moores Road  
P.O. Box 4011  
Frezer, PA 19355

As a condition of Cephalon, Inc.'s contribution of funds to support an independent medical education program (with or without CME credits), the Scientific and Educational Activity provider agrees to the following terms and conditions:

This Agreement ("Agreement") is entered into as of December 1, 2005 by and between Cephalon, Inc. ("Cephalon") and Medical Learning Solutions ("Provider") regarding a medical education program sponsored by Cephalon entitled "Emerging Solutions in Pain" Part C with ongoing activities and development throughout calendar year 2006. The parties' mutual objectives are to provide a balanced, independent, scientifically rigorous program to promote the education of attendees.

1. Statement of Purpose. This program is for scientific and educational purposes only and not to promote any commercial drug products.

2. Control of Content and Selection of Presenters and Moderators. The provider is ultimately responsible for the control of content and selection of presenters and moderators. Cephalon or its agents may respond to requests initiated by the provider for suggestions of presenters or sources of possible presenters. Cephalon will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Cephalon and speaker; and will provide this information in writing. Provider will seek suggestions from other sources, and will, in its sole discretion, select presenters and moderators.

3. Disclosure of Financial Relationships. Provider will direct speakers and moderators to disclose to the audience commercial support or funding or other significant financial relationships between the speakers and moderators and Cephalon and/or any other commercial company whose products are pertinent to the content of the presentation. Provider will disclose Cephalon's support at this program.

4. Involvement in Content. There will be no "scripting," emphasis, or influence on content by Cephalon or its agents. However, Cephalon may provide technical support to speakers, e.g., furnishing slides or data, upon their request.

5. Ancillary Promotional Activities. No promotional activities will be permitted in the same room as, or in the obligatory path to, the educational activity. No product advertisements will be permitted within the program or handouts.

6. Objectivity and Balance. Provider will advise presenters that data regarding Cephalon products (or competing products) are to be objectively selected and presented. Provider will provide the opportunity for speakers and the audience to discuss information, both favorable and unfavorable, about the product(s) and/or alternative treatments.

7. Limitations of Data. Provider will request the speakers, to the extent possible, to disclose limits on the data, e.g., that it involves ongoing research, interim analyses, preliminary data, or unsupported opinion.

8. Discussion of Unapproved Uses. Provider will request that presenters disclose when a product is not approved in the United States for the use under discussion.

9. ACTIQ Risk Management Program. Provider is aware that ACTIQ® (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- ACTIQ is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- ACTIQ is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.
- ACTIQ is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

10. Opportunity for Debate. Provider will ensure opportunities for questioning by attendees and scientific debate with and between presenters.

11. Independence of Provider in the Use of Contributed Funds.

(a) funds should be in the form of an educational grant made payable to the provider organization.

(b) Provider must be advised of all other support by Cephalon of the CME activity (e.g., distributing brochures, preparing slides). If Provider disapproves of this activity, it shall promptly notify Cephalon.

(c) no other funds from Cephalon will be paid to the program director, faculty, or others involved with this CME activity, e.g., additional honoraria.

12. General.

(a) Cephalon agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.

(b) Provider agrees to: (1) abide by the ACCME Standards for Commercial Support of Continuing Medical Education; (2) acknowledge educational support from Cephalon in program brochures, syllabi, and other program materials; and (3) upon request, furnish Cephalon with a report concerning the expenditure of the funds provided by Cephalon.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

Medical Learning Solutions, Inc.

CEPHALON, INC.

By: *Sheri L. Gavinsky*  
 Name: Sheri L. Gavinsky  
 Title: President Medical Learning Solutions, Inc.

By: *Rod Hughes*  
 Name: Rod Hughes, PhD  
 Title: Vice President Scientific Communications



**Cephalon**

Show this Purchase Order Number  
on all correspondence, invoices,  
shipping papers and packages.

# PURCHASE ORDER

No. **017639**

NOT VALID UNTIL A NUMBER IS ASSIGNED

DIRECT ALL INVOICES TO ACCOUNTS PAYABLE DEPARTMENT

DATE: Dec. 9, 2005	DUE DATE: Dec. 9, 2005
--------------------	------------------------


**SHIP TO:** Cephalon, Inc.  
145 Brandywine Parkway  
West Chester, PA 19380

ORIGINATOR Mary Ann Berlin  
OF P.O.

**FAX** 800-329-9755

[illegible]

1. Please send one copy of your invoice.
2. Order is to be entered in accordance with prices, delivery and specifications shown above.
3. Notify us immediately if you are unable to ship as specified.

  
 AUTHORIZED BY  
 Rod Hughes, VP - Sci. Communications  
 PRINT NAME

Lesley Russell, Sr. VP - Clin. Research



**M·L·S**  
Medical Learning Solutions

Medical Learning Solutions  
101 Washington Street  
Morrisville, PA 19067

Submitted  
A/P

3/17/07

**COPY**  
**Invoice**

Date	Invoice #
2/10/2006	1318A

<b>Bill To</b> Cephalon, Inc. 41 Moores Road Frazer, PA 19355 Attn: Ed Hoey
---

P.O. No.	Terms	Project
017639	UPON RECEIPT	Cephalon

Quantity	Description	Rate	Amount
	FirstThird Billing of Emerging Solutions in Pain Program 2006 (grant) Part C	127,300.00	127,300.00
Federal Tax ID 90-0135153 Thank you!		<b>Total</b>	\$127,300.00

2/11/07  
Rod J. Hughes, P  
Vice President  
Scientific Comm





## New Vendor Authorization

This form must be completed for all new vendors. Contact Accounts Payable / Purchasing to determine if this is a new vendor.

Complete Vendor Contact Information, Vendor "Remit-To" information (if different from Vendor Contact Information), and Approval information.

Obtain completed Form W-9, Request for Taxpayer Identification Number and Certification, from vendor.

Submit to Accounts Payable completed New Vendor Authorization Form, completed Form W-9, and purchase order, invoice, check request, wire transfer request. Payments to new vendors cannot be processed without this information.

### Vendor Contact Information

This section must be completed

Vendor Name

Medical Learning Solutions, Inc.

Street Address

101 Washington Street

Suite 110

City

State

Zip

Morrisville

PA

19067

Contact name

Sheri Gavinski, President

Contact Phone #

Contact Fax #

800-329-9755

### Vendor "Remit-To" Information

Complete if payment address differs from Vendor Contact Information

Vendor Name

Remit Address

City

State

Zip

### Approval

Initiated by

Mary Ann Berlin

Approved by

Rod J Hughes, VP Sci. Comm.

### Accounting Use Only

Federal ID - SSN

Form W-9 received

Entered by

Yes

No

Approved by

1099 Reportable

Yes

No

Vendor ID

Remit-To Code

Form **W-9**  
(Rev. November 2005)  
Department of the Treasury  
Internal Revenue Service

# Request for Taxpayer Identification Number and Certification

Give form to the  
requester. Do not  
send to the IRS.

Print or type  
See Specific Instructions on page 2.

Name (as shown on your income tax return)  
**ROI Media Group, Inc.**

Business name, if different from above  
**Medical Learning Solutions, Inc.**

Check appropriate box: ☐ Individual/  
Sole proprietor ☒ Corporation ☐ Partnership ☐ Other ▶ \_\_\_\_\_ ☒ Exempt from backup  
withholding

Address (number, street, and apt. or suite no.)  
**101 Washington Street**

City, state, and ZIP code  
**Morrisville, PA 19067**

List account number(s) here (optional)

Requester's name and address (optional)

## Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on Line 1 to avoid backup withholding. For individuals, this is your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the Part I instructions on page 3. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN* on page 3.

**Note.** If the account is in more than one name, see the chart on page 4 for guidelines on whose number to enter.

Social security number								
or								
Employer identification number								
9	0	0	1	3	5	1	5	3

## Part II Certification

Under penalties of perjury, I certify that:

- The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me), and
- I am not subject to backup withholding because: (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding, and
- I am a U.S. person (including a U.S. resident alien).

**Certification instructions.** You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and generally, payments other than interest and dividends, you are not required to sign the Certification, but you must provide your correct TIN. (See the instructions on page 4.)

Sign Here Signature of U.S. person ▶  Date ▶ 12/9/05

## Purpose of Form

A person who is required to file an information return with the IRS, must obtain your correct taxpayer identification number (TIN) to report, for example, income paid to you, real estate transactions, mortgage interest you paid, acquisition or abandonment of secured property, cancellation of debt, or contributions you made to an IRA.

**U.S. person.** Use Form W-9 only if you are a U.S. person (including a resident alien), to provide your correct TIN to the person requesting it (the requester) and, when applicable, to:

- Certify that the TIN you are giving is correct (or you are waiting for a number to be issued),
- Certify that you are not subject to backup withholding, or
- Claim exemption from backup withholding if you are a U.S. exempt payee.

In 3 above, if applicable, you are also certifying that as a U.S. person, your allocable share of any partnership income from a U.S. trade or business is not subject to the withholding tax on foreign partners' share of effectively connected income.

**Not.** If a requester gives you a form other than Form W-9 to request your TIN, you must use the requester's form if it is substantially similar to this Form W-9.

For federal tax purposes, you are considered a person if you are:

- An individual who is a citizen or resident of the United States,
- A partnership, corporation, company, or association created or organized in the United States or under the laws of the United States, or
- Any estate (other than a foreign estate) or trust. See Regulations sections 301.7701-6(a) and 7(a) for additional information.

**Special rules for partnerships.** Partnerships that conduct a trade or business in the United States are generally required to pay a withholding tax on any foreign partners' share of income from such business. Further, in certain cases where a Form W-9 has not been received, a partnership is required to presume that a partner is a foreign person, and pay the withholding tax. Therefore, if you are a U.S. person that is a partner in a partnership conducting a trade or business in the United States, provide Form W-9 to the partnership to establish your U.S. status and avoid withholding on your share of partnership income.

The person who gives Form W-9 to the partnership for purposes of establishing its U.S. status and avoiding withholding on its allocable share of net income from the partnership conducting a trade or business in the United States is in the following cases:

- The U.S. owner of a disregarded entity and not the entity,

Cat. No. 10231X

Form **W-9** (Rev. 11-2005)

G11788



www.cephalon.com

Cephalon, Inc.  
 41 Moores Road  
 P.O. Box 4011  
 Frazer, PA 19355  
 Phone 610-344-0200  
 Fax 610-344-0065

## INDEPENDENT EDUCATIONAL PROGRAM ("IEP") GRANT AGREEMENT

This Agreement is entered into as of this 20th day of November, 2006 by and between Cephalon ("Cephalon"), located at 41 Moores Road, Post Office Box 4011, Frazer, PA 19355, and Medical Learning Solutions, Inc. ("IEP Provider") located at 101 Washington Street, Morrsville, PA 19067 and MediCom Worldwide, Inc. ("Educational Partner") located at 101 Washington Street, Morrsville, PA 19067.

WHEREAS, Cephalon has reviewed IEP Provider's grant request to support a medical education program ("Program"); and

WHEREAS, Cephalon has determined that the Program has the potential to significantly further medical knowledge and improve patient care; and

WHEREAS, it is the intent of the parties to ensure that the Program will be independent, objective, balanced and scientifically rigorous, so that it will not be viewed by the United States Food and Drug Administration ("FDA") as promotional and that Cephalon will not be viewed as responsible for its content; and

WHEREAS, Cephalon agrees to provide funding for the Program under the conditions set forth below.

NOW THEREFORE, IEP Provider and Cephalon agree to the following terms under this Agreement:

1. Title of Program. The IEP is entitled, Emerging Solutions in Pain Toolkit and 2007 Initiatives and a copy of the grant request for the Program is attached hereto as Exhibit A.
2. Type of Program. The Program is:
  - ☒ accredited (e.g., continuing medical education or "CME"); or
  - ☐ an independent program where CE credits will not be offered.
3. IEP Provider. The IEP Provider is the following type of entity:
  - ☐ Accredited continuing medical education provider
  - ☐ University/Hospital
  - ☐ Professional Organization
  - ☒ Medical Education Company
4. Educational Partner. The IEP Provider ☒ shall ☐ shall not use a third party that will provide assistance in support of the Program ("Educational Partner"). The name of the Educational Partner is MediCom Worldwide, Inc.



5. Educational Components. The expected components of the Program (e.g., number of live meetings, CD ROM, web-based, etc.) are as follows:
  - (a) Series of Eight (8) Print Monographs Published in Practical Pain Management Journal;
  - (b) A Series of Live Events (Major conference satellite symposia, regional pain conferences, etc.);
6. Program Purpose. The Program is for scientific and educational purposes only and is not intended to promote a Cephalon product directly or indirectly. The Program is not a repeat performance of a prior program.
7. Grant Amount Funding Arrangements.
  - (a) Cephalon will provide support for the Program by means of an educational grant in the total amount of \$2,064,510, as set forth in the Budget attached hereto, or a pro rata amount based on the actual work performed and expenses incurred by IEP Provider, in accordance with the Budget. Payment of the grant shall be made in accordance with a schedule agreed to by the parties. All payments due hereunder shall be made by Cephalon within forty-five (45) days of its receipt of an invoice for same, provided IEP Provider is in compliance with the terms of this Agreement. The parties acknowledge and agree that \$1,051,180 of the total Budget is based on estimated out-of-pocket expenses, as identified in the Budget.
  - (b) Within thirty (30) days of completion of the Program, IEP Provider shall provide Cephalon with a detailed reconciliation of actual out-of-pocket expenses incurred, and to the extent Cephalon has overpaid IEP Provider for same, IEP Provider shall provide a refund to Cephalon within thirty (30) days thereafter. Such detailed reconciliation shall be forwarded to Cephalon at the address above to the attention of Rod J Hughes, Ph.D., Vice President, Scientific Communications.
  - (c) IEP Provider may not use funds provided by Cephalon to pay travel, lodging, honoraria or personal expenses for non-faculty attendees. Grant funds may be used to reduce the overall registration fees for attendees. Grant funds may not be used to purchase capital equipment or to provide general operational support for an institution. Funds for hospitality shall not be provided except that funds may be used for modest meals or receptions that are held as part of the Program, but such events shall not compete with nor take precedence over educational events. The appropriateness of any reception shall be at the sole discretion of the IEP Provider, and IEP Provider shall have final decision making authority in connection with any such activities.
  - (d) Funds may be used by the IEP Provider to permit medical students, residents, fellows or other health care professionals in training to travel to





and attend the Program; provided, however, that the selection of such students, residents or fellows who receive funds is made by either the academic or training institution or, if by the IEP Provider, such selection shall be made with the full concurrence of the academic or training institution.

- (e) In accordance with the Accreditation Council for Continuing Medical Education ("ACCME") Standards and to assist Cephalon in complying with its internal auditing procedures, IEP Provider agrees to verify the manner in which the grant is used. Accordingly, within thirty (30) days following a request from Cephalon, IEP Provider shall provide to Cephalon:
    - i. A written statement verifying that the Program occurred, and
    - ii. An itemized list of expenditures supported by the grant.
8. Objectivity and Balance. IEP Provider shall retain full responsibility for control of the content of the Program and shall ensure that the following requirements are met:
- (a) The Program material/information will be objective, balanced and free from commercial bias. All topics shall be treated in an impartial, unbiased manner. All discussions shall include a range of views about each class of drug and disease treatment options. Information shall not unfairly represent a spectrum of views favoring a product or class of products marketed by Cephalon or any other company. The title of the Program will fairly and accurately represent the scope of the presentation.
  - (b) IEP Provider agrees that neither Cephalon nor its agents shall control the content of the Program. IEP Provider agrees that there will be no scripting, targeting of points for emphasis, or other activities by Cephalon or its agents that are designed to influence the content of the Program. If requested in writing by the IEP Provider, medical/scientific representatives from Cephalon may attend content development meetings or other planning meetings, for the purpose of addressing any scientific inaccuracies they observe. Personnel from Cephalon must not discuss or in any way attempt to control (either during the meeting or at breaks or meals), the content of the program. An appropriate medical/scientific representative from Cephalon may provide a presentation at a content development meeting at the request of the provider, or may respond to specific questions at such meeting regarding the results of a Cephalon-sponsored research study, provided the information presented conforms to the generally accepted standards of experimental design, data collection and analysis, and provided any presentation is accompanied by a detailed outline of the presentation, which can be used by the IEP Provider/Educational Partner to confirm the scientific objectivity of the presentation.



- (c) If the IEP Provider, in its sole discretion, requests a Cephalon medical representative to review the Program for medical accuracy and completeness, Cephalon will comply with such request. The parties acknowledge there is no obligation or any condition requiring IEP Provider to make such a request. Any such request must be made after the Program materials are fully developed and such request must be made by the IEP Provider only to a Cephalon medical representative that has responsibility for the therapeutic area that will be covered by the Program. IEP Provider will not ask any marketing or sales representatives at Cephalon to comment on the material. All final decisions regarding whether to modify the material based on any comments provided by the Cephalon medical representative shall be in the sole discretion of IEP Provider.
  - (d) If a product marketed by Cephalon is the subject of discussion, the data will be objectively selected and presented, with an accurate reflection of favorable and unfavorable information about the product and shall also include a balanced discussion of prevailing information on alternative products and /or therapies.
  - (e) Any suggestions of superiority of one product or treatment over another will be supported by the body of available data, and will not result from selective presentation or emphasis on data favorable to particular treatment.
  - (f) IEP Provider represents that neither it nor the Educational Partner (if any) has either an open complaint or decision from the ACCME or the Food and Drug Administration that a program provided by the IEP Provider or the Educational Partner failed to meet standards of independence, balance, objectivity, or scientific rigor.
9. Risk Minimization Action Plan. Cephalon provides the following Risk Minimization Action Plan ("RiskMAP") information to all IEP Providers. Neither Cephalon nor its agents shall influence or control whether a product marketed by Cephalon is the subject of discussion. A RiskMAP is a strategic safety program designed to meet specific goals and objectives in minimizing known risks of a product while preserving its benefits. Any product marketed by Cephalon that is approved with a RiskMAP, and the key safety-related health outcomes outlined in that RiskMAP, are listed in Exhibit B. IEP Provider agrees that it is aware of the RiskMAP(s) and the key safety messages.
10. Faculty Selection. IEP Provider shall retain full responsibility for the selection of the presenters, authors, moderators, and/or other faculty (hereinafter referred to collectively as "Faculty"). Cephalon, through its Scientific Communications Department, may respond only to IEP Provider-initiated, written requests (or requests from the Educational Partner) for suggestions of Faculty or sources of possible Faculty. In response to such requests at least three (3) names will be suggested (if possible) for each open position and this information will be provided in writing. IEP Provider will record the role of Cephalon in suggesting



Faculty; will seek suggestions from other sources; and will make its selection of Faculty based on objective criteria. IEP Provider shall not be obligated to request or accept such assistance from Cephalon or its agents as a condition of receiving the educational grant hereunder.

11. Disclosures. IEP Provider will ensure meaningful disclosure of limitations of data (e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion). IEP Provider will require that Faculty disclose when a product is not approved in the United States for the use under discussion.
12. Question and Answer Session. To the extent the Program is a presentation, IEP Provider will ensure meaningful opportunities for questioning by the audience.
13. Financial Relationships. IEP Provider will ensure meaningful disclosure to the audience of Cephalon funding and any significant relationship between individual Faculty and Cephalon. All meaningful disclosure(s) shall also be made in any written materials, including but not limited to announcements, brochures, syllabi and enduring material. Disclosures shall not mention product trade names.
14. Metrics/Copies of Program Material.
  - (a) IEP Provider and/or Educational Partner shall provide certain outcome measurements and metrics to Cephalon as requested by the Scientific Communications Department. Such metrics shall be provided either after the conclusion of a single live event or monthly for a year-long accredited program and may at Cephalon's request include the number of program participants, number of certifications, assessment of the program and faculty, and demonstration of learning by program participants.
  - (b) After the Program has occurred, IEP Provider shall provide Cephalon with 5 copies of all Program materials in CD ROM or electronic format and 20 copies in print format.
15. Representations and Warranties. IEP Provider represents that:
  - (a) Neither it nor the Educational Partner, if any, provides marketing, advertising, public relations, market research, medical education services or other consulting services (e.g., support for advisory boards) to any other department within Cephalon ("Marketing Activities");
  - (b) If IEP Provider or the Educational Partner has an affiliated company that provides Marketing Activities to Cephalon, IEP Provider has instituted appropriate controls and safeguards to ensure the Program (i) remains independent, objective, balanced and scientifically rigorous, (ii) is not intended to promote a Cephalon product directly or indirectly, and (iii) is not in any way biased due to the affiliated company's relationship with Cephalon;





- (c) IEP has determined that it is appropriate to use the Educational Partner in light of the requirements under this Agreement; and
  - (d) If IEP Provider or its Educational Partner employs a former Cephalon employee who worked at Cephalon anytime during the most recent year and who had marketing responsibility in the therapeutic area that will be covered by the Program, then that former employee will not have any role in the planning, development or delivery of the Program.
16. Invitations/Enduring Materials. The Program audience will be selected by the IEP Provider. The IEP Provider shall be responsible for distributing materials about the Program, including invitations, reminder notices, and business reply cards that can be used by third parties to obtain any enduring Program material from the IEP Provider. Notwithstanding the foregoing, IEP Provider hereby authorizes Cephalon to distribute a subset of Program invitations/reminder notices that have been prepared or approved by the IEP Provider. Notwithstanding the foregoing, IEP Provider hereby authorizes and requires Cephalon to distribute a subset of business reply cards that can be used by third parties to obtain the enduring Program material from the IEP Provider. The business reply cards must be developed or approved by the IEP Provider.]
17. Ancillary Promotional Activities. To the extent the Program is a live presentation, no promotional activities or product advertisements will be permitted in the same room as or in an oblique path to the Program. If the Program is a teleconference or webcast, no product advertisements or promotional activities will be permitted immediately prior to, during, or immediately after the delivery of the Program. If the Program is in print format, no product advertisements or promotional materials will be interleaved within the pages of the Program. If the Program is made available electronically, no product advertisements or promotional materials will appear within the Program material or interleaved between computer windows or screens of the Program
18. Compliance with Guidelines. IEP Provider represents that the Program, including development of the Program and Program materials, shall conform to the American Medical Association ("AMA") Guidelines on Gifts to Physicians, the AMA Ethical Opinion on Continuing Medical Education, the ACCME Standards for Commercial Support, the FDA December 3, 1997 Final Guidance for Industry-Supported Scientific and Educational Activities, and the Pharmaceutical Research and Manufacturers Association ("PhRMA") Code on Interactions with Healthcare Professionals.
19. Logistical Status Reports. IEP Provider and/or Educational Partner shall provide periodic reports to Cephalon regarding the management and logistics of program components.



20. Miscellaneous.

- (a) No party shall use the other party's or its affiliates' name or trademarks for publicity or advertising purposes, except with the prior written consent of the other party.
- (b) IEP Provider agrees to obtain all consents, authorizations, approvals and releases that may be necessary for the production of the Program and of any written materials prepared in connection therewith. IEP Provider agrees to indemnify Cephalon with respect to any claims, actions or demands, including reasonable attorneys' fees that may arise in any manner out of IEP Provider's failure to secure such consents, authorizations, approvals or releases.
- (c) No term, condition or other provision of any attachment or addendum to this Agreement shall supersede any term, condition or other provision of this Agreement and with respect to any inconsistency or ambiguity, the Agreement shall control.



IN WITNESS WHEREOF, the parties, by their duly authorized representatives,  
agree to comply with all the terms and conditions of this Agreement.

**MEDICAL LEARNING SOLUTIONS, INC.**

By: [Signature]  
Name: Sheri L. Gavinski  
Title: President

The above signatory is a duly authorized  
corporate officer of the IEP Provider.

Date: 12-6-06

Tax ID #: 90-0135153

**MEDICOM WORLDWIDE, INC.**

By: [Signature]  
Name: DAN MEYER  
Title: Executive Director

The above signatory is a duly authorized  
corporate officer of the Educational Partner.

Date: 12/6/06

Tax ID #: 23-3063738

**CEPHALON, INC.**

By: [Signature]  
Name: Rod J. Hughes, Ph.D.  
Title: Vice President, Scientific Communications

Date:





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October 25, 2006



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October 25, 2006



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October 25, 2006

Bhaval Shah-Bell, PhD  
 Cephalon, Inc.  
 41 Moores Road  
 Frazer, PA 19355

Dear Dr. Shah-Bell:

Medical Learning Solutions, Inc. has recently completed a comprehensive needs assessment to identify the educational needs of clinicians who provide care to patients with chronic pain. This needs assessment was compiled from the following sources:

- Evaluation summaries of completed and ongoing 2006 Emerging Solutions in Pain programs and activities
- Clinical advisory review
- Survey of health care professionals, including participants in completed and ongoing 2006 Emerging Solutions in Pain programs
- Literature search

Based on the identified educational need, Medical Learning Solutions is requesting an educational grant from Cephalon, Inc. to support the continuation and further development of the **Emerging Solutions in Pain**, or **ESP**, initiatives. This will include the continuation of selected **ESP** programs instituted in 2006, as well as the development and implementation of a diverse series of new activities designed to further increase the knowledge and practice management skills of those clinicians who provide care to patients with chronic pain. The **ESP** initiatives will continue to focus on balancing the clinical need to provide adequate analgesia to patients with chronic pain with the legal and societal need to monitor for potential issues of abuse, addiction and diversion of controlled substances.

These activities will be designed and planned as follows:

- Web-Associated Tactics: Maintenance of Current Functionality
- New Web Site Activities and Functionality
- New Content Development
  - Seven Instruments of Assessment for All Pain Patients
  - Case Vignette Series
  - How to Read a Urine Drug Testing
  - Pain and Addiction 101
  - Urine Drug Testing Consensus Document
  - Sample Patient File
- Print-based Tactics
  - *Practical Pain Management* Monograph Series
  - 2006 Monograph Collection
- Emerging Solutions in Pain Exhibit Booth
- Audience Expansion Tactics
  - ESP Scholarship Fund
  - Electronic Journal Club
- ESP Marketing Campaign



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The budget to fund these activities is approximately \$2,064,510. Please refer to the detailed budget section of this proposal for complete grant funding proposals. These scientific events will comply with all ACCME, FDA, AMA, and ACPE regulations for industry-supported professional continuing education.

MLS will work with MediCom Worldwide, Inc., a third party CE vendor, in the planning, execution and development of the accredited activities associated with the **ESP** initiatives. MediCom Worldwide is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians and is approved by the Accreditation Council for Pharmacy Education to provide pharmacy continuing education, as well as an approved provider of nursing continuing education through the California State Board of Registered Nursing.

Thank you in advance for your consideration of this request.

Respectfully,

A handwritten signature in cursive script, which appears to read "Sheri L. Gavinski".

Sheri L. Gavinski  
President,  
Medical Learning Solutions, Inc.





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## ***Program Overview: The 2006 Emerging Solutions in Pain Initiative***

**Emerging Solutions in Pain (ESP)** is an enduring and dynamic disease awareness and continuing education initiative focused on providing relevant practice-based tools, information and resources to healthcare clinicians who utilize opioids in their pain management practices. **ESP** is developed by clinicians for physicians, pharmacists, nurses and other healthcare professionals who are active in the field of pain management. The initiative is designed with regard to adult learning principles, and content is offered using a blended learning approach. The ESP initiatives ensure that clinicians are able to experience educational activities and tools through a diverse array of program types and formats, thereby increasing interest and retention of key learning objectives and educational messages. The **ESP** initiative, which was launched in February of 2005, was created specifically to address the issues and critical unmet needs in the field of pain management.

### **MISSION**

The mission of Emerging Solutions in Pain is to address some of the most critical issues in pain management today. These issues involve balancing the fundamental rights of patients and clinicians with the challenge of identifying patients who are at greater or lesser risk for opioid misuse, abuse and addiction, and with the challenges associated with the complex regulations involved in prescribing controlled substances. Through the expertise of a cadre of leading pain and addiction medicine experts, the **ESP** program will provide clinicians with guidance in the implementation of good practice management techniques, emphasizing favorable interaction with regulatory and law enforcement agencies, as well as effective assessment, monitoring and documentation strategies, which will contribute to the overall goal of optimizing outcomes for their patients with pain.

### **OVERALL EDUCATIONAL OBJECTIVE**

One of the ways these challenges can be met is through the continuance of educational programs that focus on pain management in general, and, specifically, the effective use of opioids in patients with chronic pain. The goal of such programs must be to support clinicians in improving patient care while reducing the potential for abuse, addiction, diversion, and medical regulatory/malpractice liability exposures arising from poor pain management practices, and with the challenges associated with the complex regulations involved in prescribing controlled substances.

### **INTENDED AUDIENCE**

The primary audience of the Emerging Solutions in Pain initiatives are physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain.

### **ADVISORS**

The **ESP** initiative is based upon ongoing input and expertise from a renowned group of clinical experts with backgrounds in pain management, addiction medicine, anesthesiology and neurology. These experts include those individuals listed in Exhibit 4, below. Based on input from these experts, the Emerging Solutions in Pain initiative was dedicated to the development, production and dissemination of information and tools focused on assessment, monitoring and best practices for treating patients with opioids. These experts also provided extensive guidance and input in terms of the most effective methods for delivering this information to practicing clinicians.



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## ***Program Overview: The 2006 Emerging Solutions in Pain Initiative***

### **Exhibit 4a: The Emerging Solutions in Pain Faculty Advisory Board**

*Daniel Bennett, MD*  
Private Practice, Pain Management  
Westminster, CO

*Daniel Brookoff, MD*  
Private Practice, Pain Management  
Westminster, CO

*David B. Brushwood, RPh, JD*  
Professor, Pharmacy Health Care Admin  
University of Florida  
Gainesville, FL

*Doug Gourlay, MD*  
The Wasser Pain Management Centre  
Mount Sinai Hospital  
Toronto, Ontario, Canada

*Jeffrey A. Gudin, MD*  
Clinical Director, Pain Management Center  
Englewood Hospital and Medical Center  
Englewood, NJ

*Howard A. Heit, MD, FACP, FASAM*  
Assistant Clinical Professor of Medicine,  
Georgetown University School of Medicine  
Washington, DC

*David Joranson, MSW*  
Pain and Policy Studies Group  
University of Wisconsin  
Madison, WI

*Christine Miaskowski, RN, PhD*  
Department of Physiological Nursing  
University of California  
San Francisco, CA

*Steven D. Passik, PhD*  
Associate Professor  
Memorial Sloan Kettering Cancer Center  
New York, NY

*Joseph Shurman, MD*  
Anesthesiologist and Pain Consultant  
Scripps Memorial Hospital  
La Jolla, CA

*Steve Stanos, DO*  
Rehabilitative Institute of Chicago  
Chicago, IL

*Jennifer Strickland, PharmD*  
Private Practice, Pain Management  
Lakeland, FL

*Lynn R. Webster, MD, FACPM, FASAM*  
Alpine Pain and Addiction Medicine  
Salt Lake City, UT



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## ***Program Overview: The 2006 Emerging Solutions in Pain Initiative***

### **Exhibit 4b: Other Contributing Faculty to the Emerging Solutions in Pain Initiatives**

Gerald M. Aronoff, MD, DABPM, FAAEP  
Fernando T. Avila, MD  
Jennifer Bolen, JD  
Chester C. Buckenmaier, MD  
Andrea Cheville, MD  
Candance Coggins, MS, MA, CARN, NP  
Peggy Compton, RN, PhD  
Doris Cope, MD  
Lara Dhingra, PhD

Daniel M. Gruener, MD  
April Hazard-Vallerand, RN, PhD  
Jayson Hymes, MD, MPH, FACPM  
Benjamin Johnson, Jr, MD  
Bill McCarberg, MD  
Rafael Miguel, MD  
Michael Moskowitz, MD, MPH  
Richard Payne, MD

### ***EmergingSolutionsinPain.com***

The core educational component of this initiative is the ESP web site [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com), which offers the latest educational disease awareness information in the field of pain management. The web site provides health care professionals with an extensive array of tools for assessing the potential for misuse, abuse and addiction in their patients with chronic pain, for monitoring their pain patients, and for accessing information regarding "best practices" in the long-term management of these patients.

The Tool Kit (also available as a CD-ROM) is the primary foundation of the web site and is a collection of slide/audio presentations and downloadable printer-friendly practical, educational tools and resources for use in clinical practice. It is an extensive array of clinical tools that may be used: to effectively assess a patient's pain as well as their potential for opioid misuse, abuse, and addiction; to monitor the patient who is prescribed opioids; and to implement best practices in the management of patients with chronic pain. The Emerging Solutions in Pain Tool Kit CD-Rom received the highest honor, a Gold Davey Award, in the Interactive Multimedia – Education (academic) category from the International Academy of the Visual Arts in 2005.

Registered members of [EmergingSolutionsinPain.com](http://EmergingSolutionsinPain.com) also have access to monthly expert clinical commentaries daily updates of news articles and headlines, online CE-accredited programs with printable certificates upon completion, video and slide/audio case studies, relevant literature and journal articles, a multimedia library of video clips and FAQs, and other diverse resources. The site also lists a schedule of upcoming events such as the Meet the Expert Booth and online registration for live peer-to-peer meetings that are part of the Emerging Solutions in Pain initiative is available when applicable. During 2006 the following content was added to the ESP website:

- 24 abstracts of medical journal articles relevant to the ESP initiative posted to the "In the Know" section from 18 different source journals
- 9 clinical commentaries
- 10 online case studies posted to "CE Activities" section
- 8 online monographs in pdf format with online evaluation and printable CE certificate
- 5 downloadable podcasts posted to "Multimedia Library"
- 29 video FAQs posted to "Test Your Knowledge" section
- 12 live events listed posted on the "Meetings and Events" section
- 10 new links add to the "Resources" section of the website with reciprocal links on other pain or healthcare association web sites

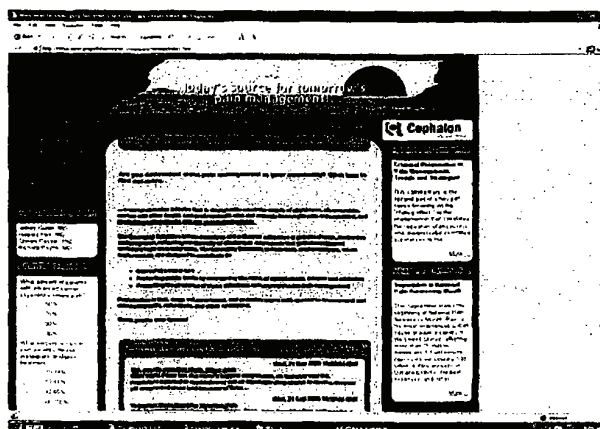


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### *Program Overview: The 2006 Emerging Solutions in Pain Initiative*

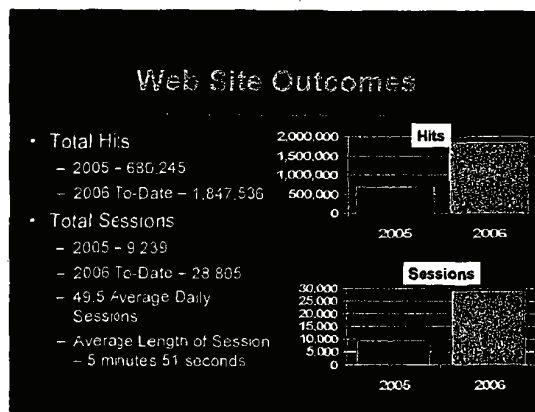
In addition, members are required to register prior to accessing the fundamental Emerging Solutions in Pain resources and tools. This enables tracking of information pertaining to member specialty and Tool use, and provides a method for updating site users with information regarding new programs and tools as they become available. As of October 2, 2006, membership at ESP.com increased 325%, for a total of 2,001 clinician members.

**Exhibit 5: The Emerging Solutions in Pain Home Page**



Since the launch of the Emerging Solutions in Pain website in February, 2005, almost 1.9 million hits to the site has resulted in more than 112 Gigabytes of information being downloaded directly from the ESP site to practicing clinicians; more than 198 Megabytes of information is downloaded daily. Exhibit 6 demonstrates the trend of recent activity on the Emerging Solutions in Pain website, in terms of visitor hits and sessions over time. An individual visitor defines a "session" as a series of clicks on ESP during a specific period of time; a session is initiated when the visitor arrives at ESP, and it ends when the browser is closed or after a period of inactivity. An average web-user session lasts approximately 3 minutes, the average ESP session is nearly 6 minutes. In addition, the significant number of monthly sessions is not surprising, given the many diverse tools available to practicing clinicians, both as printable documents and as electronic downloads.

**Exhibit 6: Emerging Solutions in Pain Web Site Outcomes**





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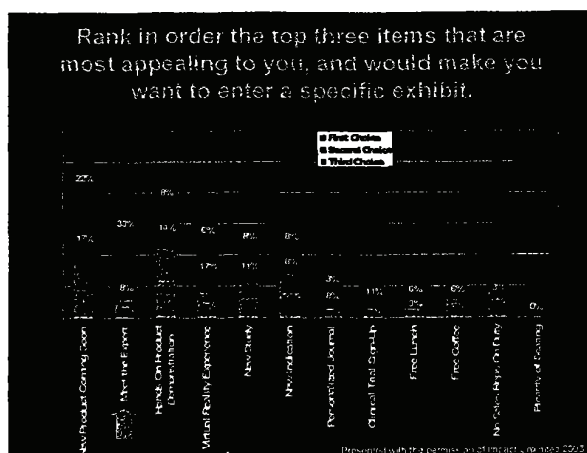
## ***Program Overview: The 2006 Emerging Solutions in Pain Initiative***

### **MEET THE EXPERTS EXHIBIT BOOTH**

The exhibit booth is an informational and interactive display for educating clinicians in the Emerging Solutions in Pain initiatives at national congresses and association meetings. In 2006, Medical Learning Solutions tailored Booth activities to the size and specific purpose of the congress or association. Thus, at larger meetings, the full Meet the Expert Booth will be utilized, while a smaller Emerging Solutions in Pain Booth is displayed at smaller congress and association meetings.

Functionality for the full-size Meet the Expert Booth includes a few intimate seating area for meeting attendees to interact with Emerging Solutions in Pain clinical experts allowing conference attendees face-to-face interaction with key opinion leaders in pain and addiction medicine. In a recent survey, physicians were asked to rank in order the top three items that are most appealing to them, and would provide sufficient inducement to enter a specific exhibit. Exhibit 7 shows that 33% of physicians in this survey identified Meet the Experts as their top choice, and, overall, it was one of the top-ranked items at exhibits.

### **Exhibit 7: Physician Ranking Outcomes**



In 2006, MLS and the ESP booth will attend the:

- American Academy of Pain Medicine,
- American Pain Society
- American Society of Addiction Medicine
- American Academy of Pain Management
- American Academy of Physical Medicine and Rehabilitation
- American Society of Regional Anesthesia and Pain Medicine
- American Academy of Addiction Psychiatry

The purpose of the Emerging Solutions in Pain Meet the Expert Booth is to disseminate information concerning the Emerging Solutions in Pain initiative to clinicians practicing in the field of pain management, and to educate those clinicians on the assessment and monitoring of pain patients, and on good practice management techniques. Clinicians visiting the booth will have opportunities to:



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### ***Program Overview: The 2006 Emerging Solutions in Pain Initiative***

- (1) Interact with Emerging Solutions in Pain clinical experts in small discussion groups, focusing on tools and strategies that will contribute to a proper balance of pain control and abuse/diversion minimization (full-size Meet the Expert Booth only)
- (2) On computer terminals, view multi-media, interactive programs highlighting the issues associated with minimization of misuse, abuse, and addiction, the Emerging Solutions in Pain Tool Kit, associated case studies and video FAQs authored by ESP KOLs
- (3) Receive copies of the Emerging Solutions in Pain Tool Kit CD-ROM and other support materials, such as the Mini-Disc Publication
- (4) Gain exposure to the resources available at the Emerging Solutions in Pain Web Site, and register as a "member", thereby expediting their ability to access online resources
- (5) Register for a raffle giveaway of multiple video iPods



#### ***SERIES OF EIGHT PRINT MONOGRAPHS PUBLISHED IN PRACTICAL PAIN MANAGEMENT JOURNAL***

In 2006, a CE-accredited series of eight print monographs, directed toward physicians, pharmacists, nurses and other health care professionals involved in the care of patients with chronic pain was published in the *Practical Pain Management Journal*. The series is also available for credit online at the Emerging Solutions in Pain web site. Each monograph is accredited for one CME, CPE, and CNE credit hour of continuing education. The following are the monographs that have been published:

- *Determining the Risk of Opioid Abuse* by Lynn R. Webster, MD
- *The Connection Between Cigarette Smoking and Aberrant Drug-Taking Behavior in Opioid Therapy for Chronic Pain* by Lara Dhingra, PhD and Steven Passik, PhD
- *VIGIL: A five-step process approach to opioid prescribing and dispensing; An interview with David B. Brushwood, RPh, JD*
- *Relating Central Sensitization and Hyperalgesia to Opioid Pain Management and Preemptive Analgesia* by Jeffrey A. Gudin, MD
- *Pain Patients at Risk of Abuse and Those with Comorbid Psychopathology: A Guide to Identification and Treatment* by Rafael Miguel, MD
- *The unequal burden of pain: confronting racial and ethnic disparities in pain* by April Hazard-Vallerand, RN, PhD
- *Multidisciplinary and interdisciplinary management of chronic pain* by Steve Stanos, DO
- *What Role Does Age Play in the Management of Chronic Pain in Adult Patients?* by Bill H. McCarberg, MD

Course evaluation forms regarding the program effectiveness will be required of all participants who seek to receive continuing education credit as will a post-test on educational content.





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## ***Program Overview: The 2006 Emerging Solutions in Pain Initiative***

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### **LIVE EVENTS**

In 2006, a series of live events (major conference satellite symposia, regional pain conferences, etc.) sponsored by ESP focused on providing practical clinical information via accredited lectures to health care professionals practicing in local clinics, hospitals and office settings. The program content focuses on a scientific and clinical evaluation of the fields of pain management and addiction, and includes relevant case studies for presentation and discussion. Lecture topics included topics such as:

- (1) Evaluating the risk of opioid abuse in the chronic pain patient;
- (2) Pharmacologic therapies for the chronic pain patient with a history of drug abuse or addiction;
- (3) Legal issues in prescribing opioids to the chronic pain patient; and
- (4) New pharmacologic agents for treating chronic pain patients

A full-day pre-conference satellite symposia entitled "Emerging Solutions in Pain: The Interface of Pain and Addiction" was presented at the 2006 American Academy of Pain Management Annual Conference. The core group of faculty included:

- Howard Heit, MD, FACP, FASAM
- Douglas Gourlay, MD, MSc, FRCPC
- Seddon Savage, MD, FASAM, and
- Joyce Lowinson, MD
- Peggy Compton, RN, PhD
- Brian Ginsberg, MD
- Steve Stanos, DO

The symposia topics included:

- Interface of Pain and Addiction
- Basic Neurobiology of Pain and Addiction
- The Risk of Opioid Misuse, Abuse and Addiction
- Non-medication Approaches to Pain Management
- Rational Pharmacotherapy of Pain
- Federal Regulations of Controlled Substances
- Issues of Diversion
- Pain, Dependency and Universal Precautions
- Urine Drug Testing and the Clinical Practice

Two regional CE-accredited dinner symposiums at the Greater Philadelphia Pain Society and the Southern Pain Society will be supported in the Fall of 2006 entitled "Emerging Solutions In Pain: Assessing Risk Throughout the Patient Treatment Plan". The educational activity focuses on two components to appropriately develop a patient treatment plan: 1) assessing patient's risk of misuse, abuse or addiction; and 2) monitoring a patient's progress and assuring compliance with the treatment plan. The faculty for both programs are Dr. Lynn Webster presenting "New Approaches to Assessing Pain and Risk When Developing a Treatment Plan" and Dr. Steven Passik presenting "Being Cognizant of Aberrant Behavior Throughout the Treatment Plan and Setting Appropriate Boundaries"





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### ***Program Overview: The 2006 Emerging Solutions in Pain Initiative***

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The final live event for 2006 is a satellite symposium at the Annual Assembly of the American Academy of Physical Medicine and Rehabilitation. This event is an 1.5 hour breakfast program and has been developed to focus on assessing patient's risk of misuse, abuse or addiction; patient triage and the utilization of either multidisciplinary treatment teams or specialist referrals; and the reinforcement of both key learning points through the use of clinical case vignettes and an audience response system allowing the participants to be active learners in the program. The faculty for this program will be Dr. Doug Gourlay and Dr. Stephen Stanos.



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## *Needs Assessment*

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In the United States alone, an estimated 50 million people suffer from some form of chronic pain, and another 25 million people suffer acute pain resulting from surgery or an accident.<sup>1</sup> Significantly, approximately two thirds of patients have been living with their pain for more than five years,<sup>2</sup> resulting in an alarming decrease, not only in quality of life, but in productivity for these individuals, as well. In 2003 Stewart and colleagues evaluated the impact of pain on productivity by estimating lost productive time and economic cost due to painful conditions. They found reduced work performance, and not absenteeism, was responsible for 76.6% of lost employee productive time, corresponding to an economic loss of \$61.2 billion per year.<sup>3</sup>

It is well-established that chronic pain is a multi-faceted problem requiring intervention from a range of specialists in different disciplines.<sup>4</sup> Over the last decade, governments, professional organizations and institutions across the country have taken positive steps to improve physician training in pain management and palliative care, in accordance with recommendations issued by the World Health Organization.<sup>5</sup> These factors are indicators of the increasing recognition of pain relief and palliative care as appropriate subjects for ongoing professional education.

The increased focus on appropriate pain management has also resulted in certain challenges that impact health care professionals and patients alike. Some of these challenges result from confusion on the part of either patients or health care professionals, or both, regarding the potential of narcotic pain medications for abuse, addiction, misuse and diversion. In a recent survey<sup>13</sup>, respondents were asked to rate satisfaction with treating their patients with chronic pain and to identify issues that would reduce and or prevent their willingness to prescribe opioids. The results of this survey were significant:

- Providers rated satisfaction with treating their patients with chronic pain as quite low (M= 1.90, SD=0.81), on a scale where 0=not at all satisfied and 4=very satisfied.
- A higher proportion (37.5%) of providers who rated themselves as more likely to prescribe opioids, however, also rated themselves a highly satisfied with their pain care
- Only 16.7% of the providers who were least likely to prescribe opioids rated themselves a highly satisfied.
- On a scale of 0=insufficient, 1=adequate, 2=good, and 3=very good, the mean rating of chronic pain education for NP/PA programs was 0.5, for medical school 0.35 and for postgraduate medical education 0.7. The majority of attending physicians rated their medical school education and residency training about chronic pain treatment as insufficient.

Other challenges result from increased media attention regarding the prevalence of abuse and diversion, or from a lack of education and understanding regarding regulations for appropriate prescription of scheduled agents. Patients, for example, may hesitate to use narcotics over fears of addiction, while health care professionals may be reluctant to prescribe opioids over concerns of increased scrutiny or investigation by local, state or federal law enforcement officials. When these types of concerns are combined with controversies surrounding the lack of scientific data on addiction, complex regulatory policies, and vague practice guidelines, the barriers to successful pain management become significant; undertreatment of pain is an all-too-common result.

One often-cited barrier in prescribing opioid analgesics to patients with chronic pain is the perception that physicians who treat their patients with these medications will come under increased scrutiny from the DEA and other regulatory and/or law enforcement agencies. This perception is due, in part, to documented increases in the diversion and sale of prescription drugs. The source for much of this information is a unique epidemiologic network, the National Forensic Laboratory Information System (NFLIS). As of November 2005, NFLIS included 41 state, systems, 88 local or municipal laboratories, and



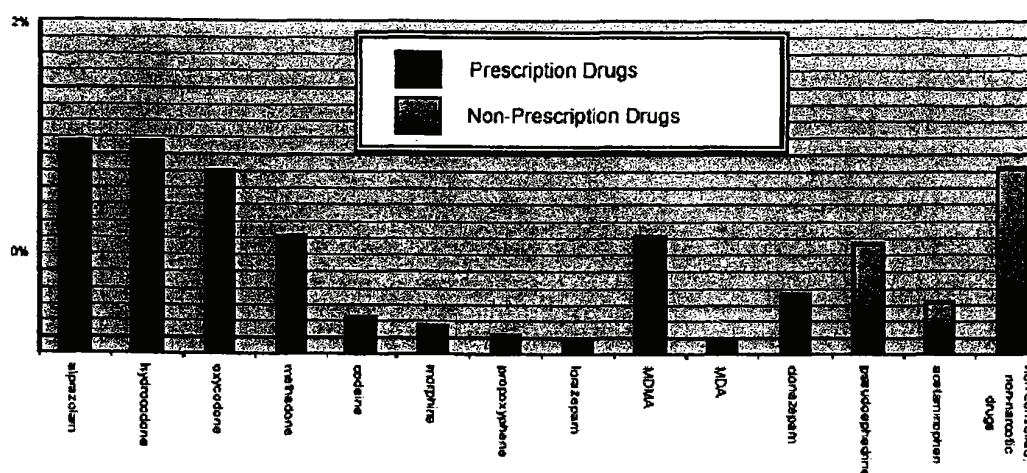
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## Needs Assessment

1 territorial laboratory, representing a total of 258 individual labs designed to inform drug abuse prevention and treatment agencies, public health officials, policymakers, and the general public about current and emerging drug abuse patterns. The 2005 mid-year report findings were based on the analysis of an estimated 883,776 drug by state and local forensic laboratories nationally.<sup>9</sup> Cannabis/THC (296,390 items), cocaine (287,547 items), methamphetamine (120,808 items), and heroin (46,608 items) were the four most frequently identified drugs, accounting for 85% of all analyzed drug items.

Of the top 25 drugs identified 12 were controlled substances available in pharmaceutical products. Included were six narcotic analgesics: hydrocodone (11,225 items), oxycodone (9,716 items), methadone (3,684 items), codeine (1,965 items), morphine (1,618 items), and propoxyphene (1,088 items). Benzodiazepines included alprazolam (11,294 items), diazepam (3,309 items), clonazepam (3,291 items), and lorazepam (706 items). The top 25 also included two club drugs: 3,4-methylenedioxymethamphetamine (MDMA) (6,238 items) and 3,4-methylenedioxyamphetamine (MDA) (698 items). Exhibit 1

**Exhibit 1: Forensic laboratory analysis: most common prescription/non-prescription drugs**

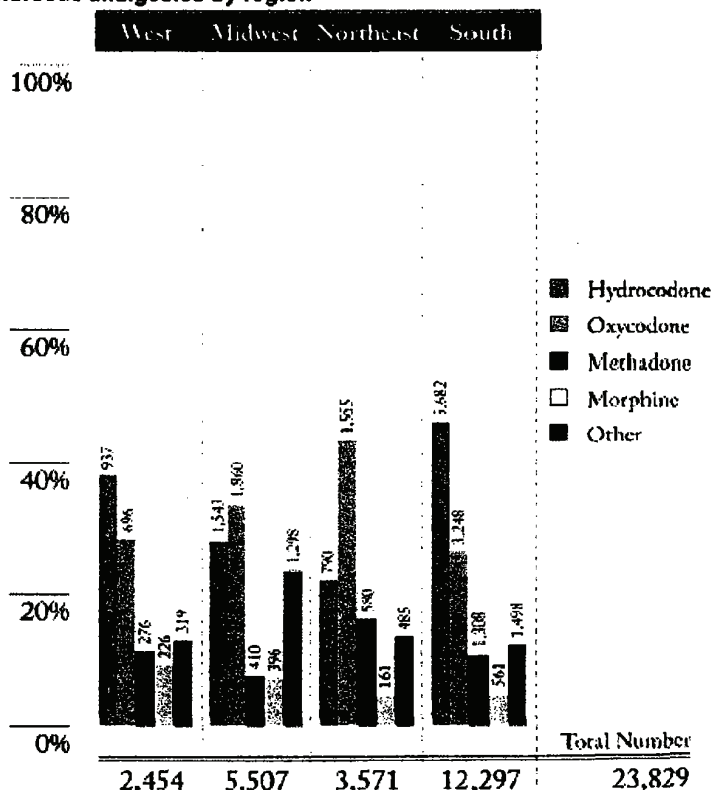




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## Needs Assessment

**Exhibit 2: Distribution of narcotic analgesics by region**



As can be seen in Exhibit 1 and Exhibit 2, there are clearly issues with abuse, misuse and diversion associated with some narcotic agents in certain geographic locations. Moreover, in March of 2004 the Office of National Drug Control Policy stated, "6.2 million Americans were current abusers of prescription drugs."<sup>6</sup> This information, while extremely important, is not, however, a justification for undertreatment of pain, even in those patients who may be identified at higher risk for abuse, misuse, addiction or diversion. Many studies have shown, in fact, that properly managed medical use of opioid analgesic drugs is effective and rarely causes clinical addiction, which is defined as compulsive, often uncontrollable use.<sup>7</sup> The key to this statement is "properly managed medical use", which consists of a comprehensive pain management program of assessment, monitoring and documentation, consistently utilized for all patients with chronic pain.

If properly managed medical use of opioids is a cornerstone of effective pain management, however, even today, many health care professionals lack the understanding, knowledge and tools for appropriate use of narcotic medications. Critically, pain management is not a significant area of focus in many medical schools, and physicians often graduate with misconceptions regarding appropriate pain management practices and techniques. In a recent study of medical students' attitudes toward pain and the use of opioid analgesics, half of senior medical students surveyed believed addiction risks associated with opioids are substantial, and more than one third were concerned about drug regulatory agency investigations.



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## *Needs Assessment*

Moreover, these seniors were more pessimistic than freshmen surveyed about relieving chronic pain, and they appeared to have less understanding about the sources of pain in cancer patients.<sup>8</sup>

### NEEDS ASSESSMENT SURVEYS

To further define the educational needs of clinicians active in the field of pain management, a series of surveys were conducted in late 2005 and 2006, physicians were asked about their practices and the therapies that they utilize to provide analgesia. The survey was conducted among 724 participants, with a selection of evaluation questions and responses from this survey summarized in Exhibit 3, below.

### Exhibit 3: Meeting Program Evaluation Forms

<b><i>Do you manage patients who are experiencing acute pain?</i></b>	
Many	48%
Few	28%
None	8%
<b><i>Do you manage patients who are experiencing chronic pain?</i></b>	
Many	50%
Few	23%
None	6%
<b><i>How do you currently manage pain patients?</i></b>	
Opioids	26%
Combination of all methods	16%
Non-opioids	12%
OTC medications	11%
Psychological/social therapy	3%
Physical therapy	2%
Other	2%
<b><i>If you don't utilize opioid analgesics, why?</i></b>	
Concerns over issues of abuse, misuse, addiction and diversion	34%
Concerns over federal and state regulations	12%
Don't feel opioids are necessary	6%

This information collected from meeting participants has been separately validated through suggestions for future topics which were collected from program evaluation forms submitted in conjunction with accredited live and self-study ESP activities during 2006. These topics included:

1. The pharmacist's role in pain management; pharmacists as barriers
2. Risk assessment and opioid prescribing
3. Opioid-induced hyperalgesia leading to tolerance and increased opioid use/abuse
4. Differential monitoring techniques for low-, moderate- and high-risk patient
5. Strategies for patients who violate their opioid agreement



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## *Needs Assessment*

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6. Emergency room management of the chronic pain patient seeking opioids/pain medications
7. Urine drug screening
8. Legal aspects of opiate use in chronic pain patients
9. Patient opioid contracts/therapy relationships

### **CONCLUSION**

In a study published 33 years ago, Marks and Sachar revealed that health care professionals practice with considerable misinformation about pain management, as well as with significant mistaken beliefs about opioid addiction<sup>11</sup>. More recent studies indicate that, despite recent advances in the field of pain management and the recognition of pain as a prevalent problem, many physicians remain uneducated in these areas. Many physicians demonstrate a fundamental lack of knowledge with respect to the pharmacology of opioid therapy, including an inability to convert equianalgesic dosages from one medication to another. In medical decision making, physicians confuse physical dependence, tolerance, and psychologic dependence. They often mistakenly interpret a satisfactory analgesic drug effect as euphoria<sup>12</sup>.

Moreover, physicians are strongly influenced by their perceptions of drug regulatory agencies. Although regulations based on the Controlled Substances Act do not limit medical prescribing, physicians are concerned that their prescribing practices are scrutinized by external authorities, such as state and federal agencies and licensing boards. Fear of reprisal from these agencies, including fear of loss of license, is prevalent<sup>12</sup>.

According to a report published by the National Center on Addiction and Substance Abuse, our nation is in the midst of an epidemic. This report estimated that between 1992 and 2003, the number of Americans abusing controlled prescription drugs jumped 94%, which was twice the increase in the number of people abusing marijuana, five times the number abusing cocaine, and 60 times the number abusing heroin. Americans who self-reported abuse of prescription drugs nearly doubled from 7.8 to 15.1 million during this period<sup>14</sup>. Clearly, this epidemic must be addressed by all relevant regulatory, law enforcement and governmental agencies involved in addiction and substance abuse issues. Clinicians, however, must be involved specifically in the issue of prescription drug abuse. Every effort must be made by those clinicians who prescribe controlled substances to appropriately identify those individuals at risk for opioid misuse, abuse or addiction, with the goal of effectively addressing the patient's therapeutic needs while not contributing to a worsening of issues related to misuse, abuse or addiction of prescription medications. This goal may only be met, however, through education on the issues associated with prescribing controlled substances, on the risks of opioid misuse, abuse and addiction, and on practice management and prescribing strategies that will minimize the potential for law enforcement or regulatory agency intervention. When education is supplemented with tools that will support clinicians in appropriate prescribing of controlled substances, focusing on issues of assessment, monitoring and "best practice" information, safe and effective treatment of pain becomes a more attainable goal for many clinicians who provide care to patients with chronic pain.

When the results of reports such as the one published by National Center on Addiction and Substance Abuse are combined with literature searches, clinical expert assessments and recent surveys, it is clear that there is an ongoing need to provide education to healthcare professionals relative to supporting effective pain management with proactive strategies that are designed to minimize the risk of opioid misuse, abuse and addiction. These are the fundamental goals of the Emerging Solutions in Pain initiative, which are targeted directly at supporting clinicians in improving patient care while reducing the





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potential for abuse, addiction, diversion, and medical regulatory/malpractice liability exposures arising from poor pain management practices.

One of the ways these challenges can be met is through the continuance of educational programs that focus on pain management in general, and, specifically, the effective use of opioids in patients with chronic pain. The objectives of the Emerging Solutions in Pain initiative are to provide clinicians with education and tools that:

- Support clinicians in pain management, and ultimately patient care, for all patients with pain, regardless of their risk for opioid misuse, abuse or addiction
- Reduce the potential for misuse, abuse and addiction of controlled substances, and specifically opioid medications, arising from poor pain management practices
- Improve the understanding and knowledge of clinicians concerning the challenges associated with the complex regulations involved in prescribing controlled substances

To continue to address the ongoing unmet need, MLS is proposing to continue and extend the 2006 Emerging Solutions in Pain initiatives through the following tactics:

1. Maintenance of current functionality at the Emerging Solutions in Pain website, [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com)
2. Development and implementation of new Internet-based activities and functionality, including two new columns featuring member-driven content and KOL review; a member feedback area; and an electronic newsletter
3. New content development, including tools focusing on comprehensive assessment of pain patients; multimedia courses on pain and addiction; a consensus document focusing on urine drug testing and a reference tool for UDT interpretation; and a sample patient file; all new tools and resources will be distributed via the Emerging Solutions in Pain web site
4. Continuing education initiatives associated with the *Practical Pain Management Journal* series, featuring a four-article in-publication monograph series focusing on topics relevant to Emerging Solutions in Pain; and a collection and re-issuance of the eight 2006 monograph series
5. Continuance of the Meet the Expert exhibit booth at three larger association meetings
6. Continuance of the Meet the Expert mini-booth at four smaller association meetings
7. Development of new tactics to expand the current audience of Emerging Solutions in Pain to non-physician health care professionals; tactics include a scholarship fund and a resident and fellow-based electronic journal club
8. Expanded awareness campaign to include coordinated advertising in multiple media formats

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### 2007 ESP Budget Estimate: Summary

October 25, 2006

Category	Tactic	Estimated Costs	Notes
Web-Associated Tactics: Maintenance of Current Functionality	Website programming, maintenance	\$ 69,038	Programming of site infrastructure for deployment of educational content in multiple media types; development of underlying security, data collection and tracking protocols
	Updated graphic design and layout of website	\$ 35,000	New graphics, images carried through on all pages
	Clinical expert commentary	\$ 53,063	One clinical expert commentary per month
	In the Know	\$ 25,078	Journal article summaries: two abstracts per month
	Breakthrough News	\$ 3,000	Daily news feed of pain-focused news headlines
	Resources	\$ 19,740	Identification of base resources, links, suggested articles
New Web Site Activities and Functionality	Ask the Experts	\$ 30,840	Column in which ESP members may submit questions to ESP faculty; MLS will coordinate posting of faculty responses; 1 column per month, 12 columns total
	State Your Case	\$ 40,760	ESP member submission of cases with KOL review and commentary; 1 case study per quarter, 4 cases total
	Member feedback area	\$ 7,500	Page where ESP members may provide direct feedback for topics, site improvements, etc.
	ESP Electronic Newsletter Series	\$ 86,320	Teaser E-mail newsletter that would link reader back to the web site for full copy



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### 2007 ESP Budget Estimate: Summary

October 25, 2006

Category	Tactic	Estimated Costs	Notes
New Content Development	Seven instruments of assessment for all pain patients	\$ 39,363	Based on ongoing work by Peggy Compton, RN, PhD and/or Steve Passik, PhD
	Pain and Addiction 101	\$ 98,485	Content & video footage from American Academy of Pain Management 1-day symposium as base: Neurobiology/Peggy Compton; Multidimensional experience of pain and addiction/Seddon Savage; Pharmacotherapy/Brian Ginsberg; Multidimensional solutions in pain management non-medication approaches/Steve Stanos; Universal Precautions/Doug Gourlay
	Urine drug testing: how to read a UDT multimedia piece	\$ 36,413	Pop-up graphic bubbles; Voice-over of physician's thoughts as he/she is reading report; Patient history or exam statistics as roll over data in certain areas
	Urine drug testing consensus document	\$ 126,350	Based upon round table discussion among multiple clinical experts from different specialties; Heit and Gourlay as chairs; result is position paper that sets standard in the area of UDT for patients with chronic pain; includes possible association endorsement
	Sample patient file	\$ 28,463	List of the proper documentation in a patient file
Print-based tactics	Practical Pain Management monograph series	\$ 219,948	4 issues, each accredited for one hour; 8-page format
	2006 monograph collection	\$ 54,384	Accredited collection of 2006 articles



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### 2007 ESP Budget Estimate: Summary

October 25, 2006

Category	Tactic	Estimated Costs	Notes
Exhibit Booth	Refurbishing of current booth	\$ 127,500	Based on reformatting of existing booth
	MP3 docking station		For downloading of ESP podcasts at booth
	Survey station		For collecting feedback on ESP on current programs, future activities from meeting attendees
	Faces of pain giveaway		Set of 5 ESP-branded faces of pain; quantity: 2000 sets
	Symposia audio series		Teaser audio available next day for download with full audio available online post meeting
20x20 Island Exhibit Booth	Three meetings total	\$ 407,095	Final meeting schedule TBD
10x20 Mini Exhibit Booth	Four meetings total	\$ 311,593	Final meeting schedule TBD
Audience Expansion Tactics	ESP Scholarship Fund	\$ 30,507	Scholarship application process on ESP web site administered by MLS based upon recommendations by ESP faculty; potential recipients include RNs, residents and fellows; one scholarship awarded per major pain meeting; scholarship would include conference registration fees, airfare, hotel and small stipend; recipient will write abstracts of conference plenary sessions that can be posted on the ESP web site
	Electronic journal club	\$ 132,570	Web-based journal club with residents and fellows as target audience
ESP Marketing	Advertising Campaign	\$ 81,500	Includes both print and banner advertisements
<b>Total</b>		<b>\$ 2,064,510</b>	



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## ***Program Summary: ESP Website: Maintenance of Current Functionality***

**Program Title** The Emerging Solutions in Pain Web Site

**Program Overview** The core educational component of this initiative is the ESP web site [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com), which offers the latest educational disease awareness information in the field of pain management. The web site provides health care professionals with an extensive array of tools for assessing the potential for abuse, addiction and diversion in their patients with chronic pain, for monitoring their pain patients, and for accessing information regarding "best practices" in the long-term management of these patients.

The Tool Kit (also available as a CD-ROM) is the primary foundation of the web site and is a collection of slide/audio presentations and downloadable printer-friendly practical, educational tools and resources for use in clinical practice. It is an extensive array of clinical tools that may be used to effectively assess a patient's pain as well as their potential for opioid misuse, abuse and addiction; to monitor the patient who is prescribed opioids; and to implement best practices in the management of patients with chronic pain. The Emerging Solutions in Pain Tool Kit CD-Rom received the highest honor, a Gold Davey Award, in the Interactive Multimedia – Education (academic) category from the International Academy of the Visual Arts in 2005.

Registered members of [EmergingSolutionsinPain.com](http://EmergingSolutionsinPain.com) also have access to monthly clinical expert commentaries, daily updates of news articles and headlines, online CE-accredited programs with printable certificates upon completion, video and slide/audio case studies, relevant literature and journal articles, a multimedia library of video clips and FAQs, and other diverse resources. The site also lists a schedule of upcoming events, such as the Meet the Expert Booth, and online registration for live peer-to-peer meetings that are part of the Emerging Solutions in Pain initiative.

Members are required to register prior to accessing the fundamental Emerging Solutions in Pain resources and tools. This enables tracking of information pertaining to member specialty and Tool use, and provides a method for updating site users with information regarding new programs and tools as they become available. In 2006, there was a membership increase of 325% for a total of 2,001 clinician members, as of October 2, 2006.

**Intended Audience** The primary audience of the Emerging Solutions in Pain Web Site are physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain.

**Program Objectives** In 2007, one goal of the Emerging Solutions in Pain Web Site will be to continue to provide clinicians with tools and resources for assessing and monitoring the risk potential of their patients for opioid misuse, abuse and addiction. New goals for the Emerging Solutions in Pain web site include the following:

- (1) Expand the reach of this web site and the important information it contains to the following groups:



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### ***Program Summary: ESP Website: Maintenance of Current Functionality***

- a. Non-physician members of the pain management community, e.g., nurses, physician assistants, pharmacists
  - b. Pain specialists, addictionologists and other physicians who have not yet registered at the web site
  - c. Medical students who have an interest in treating pain as part of their studies
- (2) Provide new resources and tools for clinicians who are involved in pain management. These tools and resources will be detailed in the following section.
  - (3) Update the graphic design and layout of the web site and carry this look throughout all the functional pages of the site

**Format** A multimedia Web Site, with separate sections for assessing and monitoring patients whose chronic pain is being treated with opioids; for "best practice" information; for journal articles relevant to the Emerging Solutions in Pain initiative; for other Emerging Solutions in Pain information and programs

**Distribution** The Emerging Solutions in Pain Web Site will be available to all health care professionals via the Internet at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com). Free registration will be required to access the majority of information on the Web Site, including all of the Emerging Solutions in Pain Tools and journal articles

**Request for Sponsor Support** Medical Learning Solutions will announce and promote the Emerging Solution in Pain Web Site through journal advertisements, banner advertisements and announcement brochures for the Emerging Solutions in Pain initiative.

As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. sales representatives in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.

**Total Budget:** \$204,919



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**The Emerging Solutions in Pain Website: Maintenance of 2006 Functionality**  
**Proposed Budget**  
October 25, 2006

<b>Cost Summary</b>	
<i>Website Programming, Maintenance</i>	
Approximate Total, Direct Expenses	\$ 5,000
Total, Indirect Expenses	\$ 64,038
Subtotal, Website Programming, Maintenance	\$ 69,038
<i>Updated Graphic Design &amp; Layout</i>	
Approximate Total, Direct Expenses	\$ 2,350
Total, Indirect Expenses	\$ 32,650
Subtotal, Updated Graphic Design & Layout	\$ 35,000
<i>Clinical Expert Commentary</i>	
Approximate Total, Direct Expenses	\$ 25,660
Total, Indirect Expenses	\$ 27,403
Subtotal, Clinical Expert Commentary	\$ 53,063
<i>In the Know Summaries</i>	
Approximate Total, Direct Expenses	\$ 720
Total, Indirect Expenses	\$ 24,358
Subtotal, In the Know Summaries	\$ 25,078
<i>Breakthrough News</i>	
Approximate Total, Direct Expenses	\$ 3,000
Total, Indirect Expenses	\$ -
Subtotal, Breakthrough News	\$ 3,000
<i>Web Resources and Links</i>	
Approximate Total, Direct Expenses	\$ 3,000
Total, Indirect Expenses	\$ 16,740
Subtotal, Web Resources and Links	\$ 19,740
<b>ESP Website: Maintenance of 2006 Functionality</b>	<b>\$ 204,919</b>





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**The Emerging Solutions in Pain Website: Maintenance of 2006 Functionality**  
**Proposed Budget**  
October 25, 2006

<b>Detailed Budget Itemization: Website Programming, Maintenance</b>	
<i>Direct Expenses, Approximate</i>	
Infrastructure programming	\$ 4,650
Miscellaneous (non-fulfillment shipping, taxes, etc.)	\$ 350
<b>Approximate Total, Direct Expenses</b>	<b>\$ 5,000</b>
<i>Indirect Expenses</i>	
<b>Project management</b>	
Coordination with third-party programmers	\$ 1,965
Coordination with internal programming team	\$ 6,900
Coordination with other internal teams	\$ 1,800
<b>IT / programming services</b>	
Programming of 2007 graphics	\$ 6,250
Programming of 2007 content: routine	\$ 3,000
Programming of 2007 content: new	\$ 19,700
<b>Annual website maintenance</b>	
Hosting and co-location fees	\$ 12,000
Routine website maintenance	\$ 9,000
Technical support	\$ 3,000
<b>Administrative and accounting fees</b>	<b>\$ 423</b>
<b>Total, Indirect Expenses</b>	<b>\$ 64,038</b>

<b>Detailed Budget Itemization: Updated Graphic Design &amp; Layout</b>	
<i>Direct Expenses, Approximate</i>	
Stock photography / illustrations	\$ 2,000
Miscellaneous (non-fulfillment shipping, taxes, etc.)	\$ 350
<b>Approximate Total, Direct Expenses</b>	<b>\$ 2,350</b>
<i>Indirect Expenses</i>	
<b>Project management</b>	
Coordination with third-party programmers, outside vendors	\$ 1,200
Coordination with internal graphic design team	\$ 3,812
Coordination with other internal teams	\$ 600
<b>Graphic design / production services</b>	
Production of new graphics for ESP.com	\$ 20,350
Adaptation of 2007 web design for journal advertisements and other ESP initiatives	\$ 2,000
<b>Medical / scientific services</b>	<b>\$ 1,375</b>
<b>Copy writing</b>	<b>\$ 3,125</b>
<b>Administrative and accounting fees</b>	<b>\$ 188</b>
<b>Total, Indirect Expenses</b>	<b>\$ 32,650</b>



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**The Emerging Solutions in Pain Website: Maintenance of 2006 Functionality**  
**Proposed Budget**  
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<b>Detailed Budget Itemization: Clinical Expert Commentaries (12 Commentaries Total)</b>	
<i>Direct Expenses, Approximate</i>	
Clinical expert honoraria: pre-recording, review Honoraria for 12 clinical experts to produce 12 clinical commentaries	\$ 24,000
Transcription	\$ 660
Miscellaneous (phone, fax, non-fulfillment Fed Ex)	\$ 1,000
<b>Approximate Total, Direct Expenses</b>	<b>\$ 25,660</b>
<i>Indirect Expenses</i>	
<b>Project management</b>	
Coordination with speakers for content delivery, audio recording	\$ 2,250
Coordination with internal teams	\$ 2,250
Preparation and coordination of status meetings/updates	\$ 900
<b>Content development</b>	
Coordination of content with faculty	\$ 1,800
Editing of transcript from audio recording	\$ 12,000
Coordination of content with internal teams	\$ 2,400
Proof-reading	\$ 1,500
Fact-checking	\$ 1,500
<b>Posting of content</b>	\$ 750
<b>Administrative and accounting fees</b>	\$ 2,053
<b>Total, Indirect Expenses</b>	<b>\$ 27,403</b>

<b>Detailed Budget Itemization: In the Know Summaries (24 Summaries Total)</b>	
<i>Direct Expenses, Approximate</i>	
Reference purchase	\$ 720
<b>Approximate Total, Direct Expenses</b>	<b>\$ 720</b>
<i>Indirect Expenses</i>	
<b>Project management</b>	
Coordination with internal teams	\$ 2,700
Preparation and coordination of status meetings/updates	\$ 900
<b>Content development</b>	
Research and identification of appropriate journal articles for summary	\$ 4,800
Writing of article summaries	\$ 9,900
Proof-reading	\$ 3,000
Fact-checking	\$ 1,500
<b>Posting of content</b>	\$ 1,500
<b>Administrative and accounting fees</b>	\$ 58
<b>Total, Indirect Expenses</b>	<b>\$ 24,358</b>



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**The Emerging Solutions in Pain Website: Maintenance of 2006 Functionality**  
**Proposed Budget**  
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<b>Detailed Budget Itemization: Breakthrough News</b>	
<i>Direct Expenses, Approximate</i>	
12 month real-time news feed from Topix.net	\$ 3,000
<b>Approximate Total, Direct Expenses</b>	<b>\$ 3,000</b>
<i>Indirect Expenses</i>	
Project management	\$ -
Administrative and accounting fees	\$ -
<b>Total, Indirect Expenses</b>	<b>\$ -</b>

<b>Detailed Budget Itemization: Resources</b>	
<i>Direct Expenses, Approximate</i>	
Licensing fees for PDFs	\$ 3,000
<b>Approximate Total, Direct Expenses</b>	<b>\$ 3,000</b>
<i>Indirect Expenses</i>	
<b>Project management</b>	
Research and identification of appropriate new resources for posting on ESP website	\$ 4,200
Maintenance of current links	\$ 3,600
Recruitment of new links	\$ 7,200
<b>Posting of content</b>	\$ 1,500
<b>Administrative and accounting fees</b>	\$ 240
<b>Total, Indirect Expenses</b>	<b>\$ 16,740</b>



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## ***Program Summary: New Web-based Activities and Functionality***

**Program Title** The Emerging Solutions in Pain Web Site: New Activities and Functionality

**Program Overview** The Emerging Solutions in Pain web site has experienced significantly increased utilization, as measured by membership, session length and information downloaded, since the launch of the site in early 2005. A fundamental component of a successful Internet-based initiative, however, is a constant stream of new information and resources for users. MLS is therefore proposing to increase the content and functionality of the Emerging Solutions in Pain web site through incorporation of additional new activities and functionality. The proposed new functionality includes four new web-based initiatives:

(1) *The ESP Ask the Experts Column*

Through this new web-based functionality, ESP members may submit questions online pertaining to issues of pain management and/or addiction. All ESP KOLs will be asked to participate in the Ask the Expert Column, with honoraria based upon the total number of questions answered on a monthly basis. MLS will screen all questions submitted and forward selected questions to the appropriate ESP KOL. MLS will coordinate posting of KOL responses, with all new questions and responses being posted monthly.

(2) *The ESP State Your Case Column*

In this program, clinician members of the ESP web site are asked to submit cases that highlight the issues and challenges of treating patients with chronic pain while minimizing risk of misuse, abuse or addiction of opioids. MLS will review all cases submitted through the ESP State Your Case Column, and will submit selected cases to one of a pre-identified panel of ESP KOLs. The KOL will select the final case for his/her review, and will write specific commentary on the case. MLS will post the original case and the KOL comments and reviews; ESP members will have access to the State Your Case Library, which will include the original submission and the ESP KOL review and comments. Members may submit questions pertaining to the case for a specified period of time, which MLS will screen and forward to the KOL reviewer for written responses. Finally, as an incentive, MLS will coordinate a conference call between the KOL and the clinician whose case is selected, so that the submitting clinician may benefit from a one-on-one consultation with a nationally known clinical expert. One case will be selected, reviewed and posted per quarter.

(3) *An ESP Member Feedback Area*

Through this new web-based functionality, ESP members will have a forum to submit ESP-specific feedback and suggestions for future topics, activities and tools. Suggestions will be submitted electronically through a dedicated page on the ESP web site, and will be received directly by MLS staff. All member comments and suggestions will be collected in a database and reviewed on a regular basis.

(4) *The ESP Electronic Newsletter Series*

Through this email-based program, current and potential ESP members will be exposed to highlights of new content, programs and resources available



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### ***Program Summary: New Web-based Activities and Functionality***

on the ESP web site, thereby reinforcing the value offered by the initiatives, the ease of use of the ESP tools and resources, and the diverse range of educational and informational programs and activities available to ESP members. All content will be called out by a title or headline that will also function as a clickable link directly back to the full story on the ESP web site. Content that will be highlighted include:

- Selected text from current and archived clinical expert commentaries, journal article summaries and "Breakthrough News" stories
- Overviews of case studies either in current discussion or archived in the State Your Case Column
- Selected text from the 2007 ESP/PPMJ Accredited Monograph series
- Announcements of ESP-sponsored live events, including the Meet the Experts booth and live symposia
- Surveys of newsletter recipients for content, tool and resource suggestions

<b>Intended Audience</b>	The primary audience of the Emerging Solutions in Pain Web Site are physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain.
<b>Program Objectives</b>	The primary objective of the proposed new activities and functionality will be to provide clinicians with additional practical tools and resources for treating their chronic pain patients with opioid analgesics while minimizing the risk of misuse, abuse and addiction. The addition of these new features will fulfill two secondary objectives, of encouraging and promoting regular return visits, and of recruiting new users who will benefit from the site's tools and resources.
<b>Format</b>	The Emerging Solutions in Pain web site
<b>Distribution</b>	The Emerging Solutions in Pain web site will be available to all individuals via the Internet at <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a> . Free registration will be required to access the majority of information on the site.
<b>Request for Sponsor Support</b>	<p>Medical Learning Solutions will announce and promote the Emerging Solution in Pain web site through journal advertisements, banner advertisements and announcement brochures for the Emerging Solutions in Pain initiative.</p> <p>As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. sales representatives in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.</p>
<b>Total Budget:</b>	\$165,420



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**The Emerging Solutions in Pain Website: New Activities and Functionality**  
**Proposed Budget**  
October 25, 2006

<b>Cost Summary</b>	
<i>Ask the Experts Column</i>	
Approximate Total, Direct Expenses	\$ 13,000
Total, Indirect Expenses	\$ 17,840
Subtotal, Ask the Experts Column	\$ 30,840
<i>State Your Case Column</i>	
Approximate Total, Direct Expenses	\$ 11,000
Total, Indirect Expenses	\$ 29,760
Subtotal, State Your Case Column	\$ 40,760
<i>Member Feedback Area</i>	
Approximate Total, Direct Expenses	\$ 350
Total, Indirect Expenses	\$ 7,150
Subtotal, Member Feedback Area	\$ 7,500
<i>ESP Electronic Newsletter Series</i>	
Approximate Total, Direct Expenses	\$ 1,000
Total, Indirect Expenses	\$ 85,320
Subtotal, ESP Electronic Newsletter Series	\$ 86,320
<b>ESP Website: New Activities and Functionality</b>	<b>\$ 165,420</b>



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## The Emerging Solutions in Pain Website: New Activities and Functionality

### Proposed Budget

October 25, 2006

<b>Detailed Budget Itemization: Ask the Experts Column</b>	
<i>Direct Expenses, Approximate</i>	
<b>Honoraria</b> All faculty honoraria for 12 months of Ask the Experts columns: one per month; faculty will respond in writing to questions from ESP members and submit to MLS for posting	\$ 12,000
<b>Miscellaneous (phone, fax, non-fulfillment Fed Ex)</b>	\$ 1,000
<b>Approximate Total, Direct Expenses</b>	<b>\$ 13,000</b>
<i>Indirect Expenses</i>	
<b>Project management</b> Monthly submission of selected question(s) to faculty Coordination for answer(s) from faculty Coordination with internal medical services, programming teams Updates to grantor	\$ 2,400 \$ 1,600 \$ 750 \$ 450
<b>Content development</b> Monthly review of all questions submitted by ESP members Selection of appropriate question(s) and answering faculty Editing of faculty answer	\$ 4,800 \$ 2,400 \$ 4,400
<b>Administrative and accounting fees</b>	\$ 1,040
<b>Total, Indirect Expenses</b>	<b>\$ 17,840</b>





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**The Emerging Solutions in Pain Website: New Activities and Functionality**  
**Proposed Budget**  
**October 25, 2006**

<b>Detailed Budget Itemization: State Your Case Column</b>	
<i>Direct Expenses, Approximate</i>	
<b>Honoraria</b> All faculty honoraria for 4 Ask the Experts columns: one per quarter; faculty will create an audio recording of a review and analysis of a case submitted by ESP members and selected by MLS; faculty will participate in a conference call with the ESP member who submitted the selected case	\$ 10,000
<b>Transcription</b>	\$ 400
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$ 600
<b>Approximate Total, Direct Expenses</b>	<b>\$ 11,000</b>
<i>Indirect Expenses</i>	
<b>Project management</b> Quarterly submission of selected case to faculty	\$ 1,800
Coordination of audio recording of faculty review and analyses	\$ 2,400
Coordination with internal teams	\$ 1,500
Preparation and coordination of status meetings/updates	\$ 900
<b>Content development</b> Quarterly review of all cases submitted by ESP members	\$ 4,800
Selection of appropriate case(s) and answering faculty	\$ 3,200
Editing of faculty case review and analysis	\$ 14,280
<b>Administrative and accounting fees</b>	\$ 880
<b>Total, Indirect Expenses</b>	<b>\$ 29,760</b>

<b>Detailed Budget Itemization: Member Feedback Area</b>	
<i>Direct Expenses, Approximate</i>	
<b>Miscellaneous (phone, fax, non-fulfillment Fed Ex)</b>	\$ 350
<b>Approximate Total, Direct Expenses</b>	<b>\$ 350</b>
<i>Indirect Expenses</i>	
<b>Project management</b> Coordination with internal teams	\$ 1,800
Preparation and coordination of status meetings/updates	\$ 450
<b>Content development</b> Monthly review of comments	\$ 2,400
Preparation of monthly summary recommendations	\$ 1,700
<b>Posting of new content/replies</b>	\$ 770
<b>Administrative and accounting fees</b>	\$ 30
<b>Total, Indirect Expenses</b>	<b>\$ 7,150</b>



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**The Emerging Solutions in Pain Website: New Activities and Functionality**  
**Proposed Budget**  
October 25, 2006

<b>Detailed Budget Itemization: ESP Electronic Newsletter Series</b>	
<i>Direct Expenses, Approximate</i>	
Miscellaneous (phone, fax, non-fulfillment Fed Ex)	\$ 1,000
<b>Approximate Total, Direct Expenses</b>	<b>\$ 1,000</b>
<i>Indirect Expenses</i>	
<b>Project management</b>	
Review and maintenance of newsletter subscription lists	\$ 2,700
Coordination with internal teams	\$ 5,400
Preparation and coordination of status meetings/updates	\$ 900
<b>Content development</b>	
Review of new ESP web-based content posted in last quarter	\$ 6,400
Selection of highlights for newsletter posting	\$ 7,440
Editing for newsletter posting	\$ 9,600
<b>Graphic development for 4 quarterly electronic newsletters</b>	<b>\$ 21,300</b>
<b>Programming of 4 quarterly electronic newsletters</b>	<b>\$ 31,500</b>
<b>Administrative and accounting fees</b>	<b>\$ 80</b>
<b>Total, Indirect Expenses</b>	<b>\$ 85,320</b>



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### ***Program Summary: New Content Development***

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<b>Program Title</b>	The Emerging Solutions in Pain Seven Instruments of Assessment
<b>Program Overview</b>	Medical Learning Solutions is proposing a slide audio addition to the original core tool kit to include a new module based on new information being studied by Peggy Compton, RN, PhD or Steven Passik, PhD regarding the seven key instruments of assessment for all pain patients anticipated to be released for publication in 2007.
<b>Intended Audience</b>	The primary audience of The Emerging Solutions in Pain Seven Instruments of Assessment Tool includes physicians, pharmacists, nurses and other health care professionals who provide care to patients with pain.
<b>Program Objectives</b>	The purpose of The Emerging Solutions in Pain Seven Instruments of Assessment is to educate clinicians on key topics relating to the Emerging Solutions in Pain initiatives. The tool will combine the latest findings from Dr. Passik's or Dr. Compton's peer-reviewed studies on appropriate assessment of pain and relative risk of opioid abuse. This will not only reinforce the ESP initiatives, but will also provide clinicians with a concise collection of assessment tools for their patients with chronic pain.
<b>Format</b>	Web-based slide audio learning module
<b>Distribution</b>	Medical Learning Solutions will announce and promote The Emerging Solutions in Pain Seven Instruments of Assessment slide audio learning module through the Emerging Solutions in Pain web site. The availability of this new tool will be highlighted in one of the ESP e-mail blasts, the ESP electronic newsletter, and the ESP exhibit booth.
<b>Request for Sponsor Support</b>	<p>Medical Learning Solutions will coordinate the promotion of the Emerging Solution in Pain Seven Instruments of Assessment through the means of distribution outlined above.</p> <p>As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. sales representatives in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely as a supplement to MLS' primary methods of announcement and promotion. Content developed for this program may also be repurposed as a CE-accredited enduring material and published on the ESP website at a later date.</p>
<b>Total Budget:</b>	\$39,363



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**Emerging Solutions in Pain: New Content Development  
Seven Instruments of Assessment Tool  
Proposed Budget  
October 25, 2006**

<b>Cost Summary</b>	
Approximate Total, Direct Expenses	\$ 6,250
Total, Indirect Expenses	\$ 33,113
<b>ESP: New Content Development, Seven Instruments of Assessment Tool</b>	<b>\$ 39,363</b>

<b>Detailed Budget Itemization: Seven Instruments Assessment Tool</b>	
<b>Direct Expenses, Approximate</b>	
Clinical expert honoraria, two faculty	\$ 5,000
Transcription	\$ 900
Miscellaneous (non-fulfillment shipping, faxes, etc.)	\$ 350
<b>Approximate Total, Direct Expenses</b>	<b>\$ 6,250</b>
<b>Indirect Expenses</b>	
<b>Project management</b>	
Coordination with faculty	\$ 3,300
Coordination with internal teams	\$ 1,800
Preparation and coordination of status meetings/updates	\$ 900
<b>Medical/scientific services</b>	
Research/preparation	\$ 1,400
Outline creation	\$ 2,400
Tool development	\$ 8,000
Incorporation of revisions	\$ 3,200
Proofreading	\$ 500
Fact-checking	\$ 500
<b>Graphic design</b>	
Creation of graphic user interface	\$ 750
Creation of animations	\$ 3,850
Typesetting, layout	\$ 1,000
<b>Programming</b>	\$ 5,200
<b>Administrative and accounting fees</b>	\$ 313
<b>Total, Indirect Expenses</b>	<b>\$ 33,113</b>



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### ***Program Summary: New Content Development***

<b>Program Title</b>	The Emerging Solutions in Pain Core Learning Module: Pain and Addiction 101 Series
<b>Program Overview</b>	<p>Medical Learning Solutions is proposing to develop and produce an accredited series of video/multimedia programs focusing on basic information in the fields of pain and addiction through adaptation of content and video footage from the 1-day pre-conference satellite symposium presented at the 2006 American Academy of Pain Management "Emerging Solutions in Pain: The Interface of Pain and Addiction". Modules will include the following topics::</p> <ul style="list-style-type: none"> <li>• Understand Basic Neurobiology of Addiction as it Relates to Pain, presented by Peggy Compton, RN, PhD</li> <li>• Understanding the Multidimensional Experience of Pain and Addiction, Synergy of Pain and Addiction, presented by Seddon Savage, MD</li> <li>• Rational Pharmacotherapy of Pain, presented by Brian Ginsberg, MD</li> <li>• Multidimensional Solutions in Pain Management Non-medication Approaches, presented by Steven Stanos, DO</li> <li>• Pain, Dependency and Universal Precautions, presented by Doug Gourlay, MD</li> </ul>
<b>CE Provider</b>	<p>Based on the need to educate clinicians in the assessment and treatment of chronic pain patients who may be at risk for abuse, addiction and diversion, the Pain and Addiction 101 Series will be accredited by a third-party CE vendor.</p> <p>The entire Series of Pain and Addiction 101 modules will be accredited for:</p> <ul style="list-style-type: none"> <li>• CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each activity will be approved for a maximum of 3.5 hours of category 1 credit toward the AMA Physician's Recognition Award.</li> <li>• CPE credit for pharmacists by the Accreditation Council for Pharmacy Education. Each activity will be approved for a maximum of 3.5 credit hours (0.35 CEU) for Continuing Pharmacy Education</li> <li>• CNE credit for nurses. Each activity will be approved for a maximum of 3.5 Contact Hours.</li> </ul>
<b>Intended Audience</b>	The primary audience of The Emerging Solutions in Pain/ Pain and Addiction 101 Series includes physicians, pharmacists, nurses and other health care professionals who provide care to patients with pain.
<b>Program Objectives</b>	The purpose of The Emerging Solutions in Pain/Pain and Addiction 101 Series is to educate clinicians on key topics relating to the Emerging Solutions in Pain initiatives.
<b>Format</b>	Multimedia web-based learning modules



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### ***Program Summary: New Content Development***

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#### **Post-Activity Feedback**

Course evaluation forms will be required of all participants who seek to receive continuing education credit. Medical Learning Solutions will work with the third party CE vendor to summarize the information collected from these forms in a formal report to evaluate program effectiveness.

Participants will evaluate the following as excellent, good, fair or poor:

- (1) Overall content
- (2) Faculty teaching effectiveness
- (3) Format

Participants will also respond to the following questions:

- (1) How well did the program achieve its educational objectives?
- (2) Do you feel the program material was useful and practice-oriented?
- (3) Do you feel that the information provided in this educational activity will aid in improving patient care in your practice?
- (4) Do you feel that fair balance was maintained for all therapeutic options?
- (5) Would you participate in future educational activities?

#### **Distribution**

Medical Learning Solutions and the third party CE vendor will announce and promote The Emerging Solutions in Pain/ Pain and Addiction 101 Series through the Emerging Solutions in Pain web site. The accredited multimedia learning modules will be highlighted in the ESP e-mail blasts, the ESP electronic newsletters, and the ESP exhibit booth.

#### **Request for Sponsor Support**

As a supplement to these primary methods, Medical Learning Solutions and the third party CE vendor may request the assistance of Cephalon, Inc. sales representatives in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.

**Total Budget:** \$98,485



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**Emerging Solutions in Pain: New Content Development**  
**Pain and Addiction 101**  
**Proposed Budget**  
**October 25, 2006**

<b>Cost Summary</b>	
Approximate Total, Direct Expenses	\$ 29,150
Total, Indirect Expenses	\$ 69,335
<b>ESP: New Content Development, Pain and Addiction 101</b>	<b>\$ 98,485</b>

<b>Detailed Budget Itemization: Pain and Addiction 101</b>	
<b>Direct Expenses, Approximate</b>	
Transcription	\$ 1,400
Accreditation of program for CME, CPE, CNE	\$ 7,500
Continuing Education participant certificates 700 CE certificates; additional certificates to be charged at \$15 each	\$ 10,500
Onsite equipment rental	\$ 4,500
Travel (film crew)	\$ 5,250
<b>Approximate Total, Direct Expenses</b>	<b>\$ 20,150</b>
<b>Indirect Expenses</b>	
<b>Project management</b>	
Review of footage for editing direction	\$ 6,200
Coordination with internal teams, accreditor	\$ 2,400
Preparation and coordination of status meetings/updates	\$ 1,200
<b>Medical/scientific services</b>	
Editing review	\$ 5,800
Creation of additional self-assessment questions	\$ 2,400
Creation of supporting documents for individual accredited self-study programs	\$ 750
Proofreading	\$ 2,250
<b>Graphic design</b>	
Creation of graphic user interface	\$ 1,000
Adaptation of presentation slides to video format	\$ 2,250
Creation of animations, highlights, additional graphics	\$ 3,500
Adaptation of symposium program material design for Internet program	\$ 500
Typesetting, layout	\$ 1,000
<b>Filming of symposium</b>	\$ 16,500
<b>Editing, programming</b>	\$ 20,500
<b>Data management</b>	
Management of participant database	\$ 250
Data analysis and reporting	\$ 500
<b>Administrative and accounting fees</b>	\$ 2,335
<b>Total, Indirect Expenses</b>	<b>\$ 69,335</b>





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### *Program Summary: New Content Development*

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<b>Program Title</b>	The Emerging Solutions in Pain Urine Drug Test Interpretation Tool
<b>Program Overview</b>	Medical Learning Solutions is proposing a multimedia tool that provides clinicians with answers to common questions regarding interpretation of urine drug testing results. The learning module will be supplemented with pop-up graphic bubbles that include definitions of specific results or metabolites, patient history or exam statistics, roll over data pop-ups in certain areas, etc. The format will be designed to engage the learner and create an interactive experience.
<b>Intended Audience</b>	The primary audience of The Emerging Solutions in Pain Urine Drug Test Interpretation Tool includes physicians, pharmacists, nurses and other health care professionals who provide care to patients with pain.
<b>Program Objectives</b>	The overall objective of the Urine Drug Test Interpretation Tool is to provide health care professionals with the basic understanding of urine drug testing results, terminology, and interpretation of results on the treatment of patients with pain and possible issues of abuse, misuse and addiction.
<b>Format</b>	Multimedia web-based learning module
<b>Distribution</b>	The Emerging Solutions in Pain Urine Drug Test Interpretation Tool will be available on the Emerging Solutions in Pain web site. The Urine Drug Test Interpretation Tool will be highlighted in one of the ESP e-mail blasts, the ESP electronic newsletter, and the ESP exhibit booth.
<b>Request for Sponsor Support</b>	<p>Medical Learning Solutions will coordinate the Emerging Solution in Pain Urine Drug Test Interpretation Tool through the means of distribution outlined above.</p> <p>As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. sales representatives in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely as a supplement to MLS' primary methods of announcement and promotion. Content developed for this program may also be repurposed as a CE-accredited enduring material and published on the ESP website at a later date.</p>
<b>Total Budget:</b>	\$36,413



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**Emerging Solutions in Pain: New Content Development**  
**Urine Drug Test Interpretation Tool**  
**Proposed Budget**  
**October 25, 2006**

<b>Cost Summary</b>	
Approximate Total, Direct Expenses	\$ 6,250
Total, Indirect Expenses	\$ 30,163
<b>ESP: New Content Development, Urine Drug Test Interpretation Tool</b>	<b>\$ 36,413</b>

<b>Detailed Budget Itemization: How to Read a UDT Tool</b>	
<b>Direct Expenses, Approximate</b>	
Clinical expert honoraria, two faculty	\$ 5,000
Transcription	\$ 900
Miscellaneous (non-fulfillment shipping, faxes, etc.)	\$ 350
<b>Approximate Total, Direct Expenses</b>	<b>\$ 6,250</b>
<b>Indirect Expenses</b>	
<b>Project management</b>	
Coordination with faculty	\$ 3,300
Coordination with internal teams	\$ 1,800
Preparation and coordination of status meetings/updates	\$ 900
<b>Medical/scientific services</b>	
Research/preparation	\$ 800
Outline creation	\$ 1,600
Tool development	\$ 6,400
Incorporation of revisions	\$ 950
Proofreading	\$ 1,250
Fact-checking	\$ 1,000
<b>Graphic design</b>	
Creation of graphic user interface	\$ 750
Creation of animations	\$ 3,850
Typesetting, layout	\$ 1,000
<b>Programming</b>	\$ 6,250
<b>Administrative and accounting fees</b>	\$ 313
<b>Total, Indirect Expenses</b>	<b>\$ 30,163</b>



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### ***Program Summary: New Content Development***

<b>Program Title</b>	The Emerging Solutions in Pain Urine Drug Testing Consensus Document
<b>Program Overview</b>	Medical Learning Solutions is proposing the development of a consensus document based on the opinions of 5 to 7 key opinion leaders in the area of urine drug testing within the pain management and addiction medicine specialties. Dr. Howard Heit and Dr. Douglas Gourlay would serve as chairs of this initiative. The focus of the paper will be to provide healthcare professionals with a resource which presents a consolidated consensus opinion regarding the standards of use and interpretation of UDT in the field of pain management, as well as the implications of urine drug testing results on the treatment of chronic pain patients and possible issues of abuse, misuse and addiction. It is our hope that the faculty that are chosen will be affiliated with the major Pain Societies and might be able to assist in the possible endorsement from the associations. The consensus document would be submitted for publication with a peer-reviewed journal.
<b>Intended Audience</b>	The primary audience of The Emerging Solutions in Pain Accredited Monograph Series includes physicians, pharmacists, nurses and other health care professionals who provide care to patients with pain.
<b>Program Objectives</b>	The overall program objective is to provide healthcare professionals with a resource which presents a consolidated consensus opinion regarding the standards of use and interpretation of UDT in the field of pain management, as well as the implications of urine drug testing results on the treatment of chronic pain patients and possible issues of abuse, misuse and addiction.
<b>Format</b>	The consensus document will be submitted for publication with a leading peer-reviewed pain management journal.
<b>Distribution</b>	Reprints of the consensus document will be available at the Emerging Solution in Pain Exhibit Booth and on the Web Site for download.
<b>Request for Sponsor Support</b>	<p>Medical Learning Solutions will coordinate the Emerging Solution in Pain Awareness Campaign through the means of distribution outlined above.</p> <p>As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. sales representatives in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely as a supplement to MLS' primary methods of announcement and promotion. Content developed for this program may also be repurposed as a CE-accredited enduring material and published on the ESP website at a later date.</p>
<b>Total Budget:</b>	\$132,570



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**Emerging Solutions in Pain: New Content Development  
Urine Drug Testing Consensus Document  
Proposed Budget  
October 25, 2006**

<b>Cost Summary</b>	
Approximate Total, Direct Expenses	\$ 42,300
Total, Indirect Expenses	\$ 84,050
<b>ESP: New Content Development, Urine Drug Testing Consensus Document</b>	<b>\$ 126,350</b>

<b>Detailed Budget Itemization: Urine Drug Testing Consensus Document</b>	
<b>Direct Expenses, Approximate</b>	
<b>Print materials</b>	
Meeting kits to include agenda, handout materials in 4/c binder	\$ 1,500
<b>Speaker honoraria (4 faculty members + 1 moderator/chair)</b>	\$ 15,000
<b>Speaker travel (air, OOP, hotel)</b>	\$ 5,750
<b>ROI staff travel (air, OOP, hotel)</b>	\$ 3,450
<b>Ground transportation</b>	\$ 1,000
<b>Venue rental fee</b>	\$ 1,000
<b>Food &amp; beverage (dinner, buffet breakfast, buffet lunch, two breaks)</b>	\$ 4,500
<b>Audio/visual services</b>	\$ 6,000
<b>Bridging for 2 pre-meeting conference calls</b>	\$ 600
<b>References</b>	\$ 1,500
<b>Transcription</b>	\$ 1,500
<b>Miscellaneous (non-fulfillment shipping, faxes, FedEx, etc.)</b>	\$ 500
<b>Approximate Total, Direct Expenses</b>	<b>\$ 42,300</b>



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**Emerging Solutions in Pain: New Content Development**  
**Urine Drug Testing Consensus Document**  
***Proposed Budget***  
**October 25, 2006**

<b>Detailed Budget Itemization: Urine Drug Testing Consensus Document (con't)</b>	
<i>Indirect Expenses</i>	
<b>Project management</b>	
Coordination with faculty	\$ 8,300
Coordination with internal teams	\$ 3,400
Preparation and coordination of status meetings/updates	\$ 2,400
Coordination of possible document publication, association endorsements	\$ 12,400
<b>Medical writing</b>	
Transcript review and supporting research	\$ 2,100
Outline creation	\$ 1,400
Creation of consensus document text	\$ 17,600
Incorporation of revisions	\$ 2,400
Proofreading	\$ 1,500
Fact-checking	\$ 2,800
<b>Graphic design</b>	
Creation of meeting slides	\$ 3,750
Typesetting, layout of all meeting support materials	\$ 2,250
Coordination of production of meeting materials	\$ 1,500
Typesetting, layout of final consensus document	\$ 4,500
<b>Meeting management</b>	
Venue coordination	\$ 3,000
Travel coordination for faculty and staff	\$ 5,400
Coordination of associated meeting logistics	\$ 1,300
<b>Onsite management (3 staff members)</b>	\$ 4,800
<b>Administrative and accounting fees</b>	\$ 3,250
<b>Total, Indirect Expenses</b>	<b>\$ 84,050</b>



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### ***Program Summary: New Content Development***

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<b>Program Title</b>	The Emerging Solutions in Pain Sample Patient File
<b>Program Overview</b>	Medical Learning Solutions is proposing a multimedia version of a sample patient file showing the appropriate documentation needed in a pain patient's chart. A checklist of items including a sample opioid agreement, initial patient assessment and history, VIGIL sticker, UDT initial results, etc. will be included. Each item will also include call-out notes of important sidebars and tips.
<b>Intended Audience</b>	The primary audience of The Emerging Solutions in Pain Sample Patient File includes physicians, pharmacists, nurses and other health care professionals who provide care to patients with pain.
<b>Program Objectives</b>	The overall objective of the Sample Patient File is to provide guidance to clinicians in the appropriate documentation for a pain patient's chart. Establishing standard operating procedures within a clinical practice will assist clinicians in complying with state and federal regulations, and will contribute to improved outcomes in care.
<b>Format</b>	Multimedia web-based learning module
<b>Distribution</b>	The Emerging Solutions in Pain Sample Patient File will be available on the Emerging Solutions in Pain web site. The sample patient file will be highlighted in one of the ESP e-mail blasts, the ESP electronic newsletter, and the ESP exhibit booth.
<b>Request for Sponsor Support</b>	<p>Medical Learning Solutions will coordinate the Emerging Solution in Pain Sample Patient File through the means of distribution outlined above.</p> <p>As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. sales representatives in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely as a supplement to MLS' primary methods of announcement and promotion. Content developed for this program may also be repurposed as a CE-accredited enduring material and published on the ESP website at a later date.</p>
<b>Total Budget:</b>	\$28,463



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**Emerging Solutions in Pain: New Content Development**  
**Sample Patient File Tool**  
**Proposed Budget**  
 October 25, 2006

<b>Cost Summary</b>	
Approximate Total, Direct Expenses	\$ 6,250
Total, Indirect Expenses	\$ 22,213
<b>ESP: New Content Development, Sample Patient File Tool</b>	<b>\$ 28,463</b>

<b>Detailed Budget Itemization: Sample Patient File Tool</b>	
<b>Direct Expenses, Approximate</b>	
Clinical expert honoraria: content development, 2 faculty	\$ 5,000
Transcription	\$ 900
Miscellaneous (non-fulfillment shipping, faxes, etc.)	\$ 350
<b>Approximate Total, Direct Expenses</b>	<b>\$ 6,250</b>
<b>Indirect Expenses</b>	
<b>Project management</b>	
Coordination with faculty	\$ 3,300
Coordination with internal teams	\$ 1,800
Preparation and coordination of status meetings/updates	\$ 900
<b>Medical / scientific services</b>	
Research/preparation	\$ 600
Outline creation	\$ 900
Tool development	\$ 4,450
Incorporation of revisions	\$ 850
Proofreading	\$ 575
Fact-checking	\$ 625
<b>Graphic design</b>	
Creation of graphic user interface	\$ 750
Creation of animations, graphics, charts	\$ 3,800
Typesetting, layout	\$ 450
<b>Programming</b>	\$ 2,500
<b>Administrative and accounting fees</b>	\$ 713
<b>Total, Indirect Expenses</b>	<b>\$ 22,213</b>





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### ***Program Summary: Print-Based Tactics***

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<b>Program Title</b>	The Emerging Solutions in Pain Accredited Monograph Series
<b>Program Overview</b>	Medical Learning Solutions is proposing to develop and produce an accredited series of four, 8-page monographs, directed toward physicians, pharmacists, nurses and other health care professionals involved in the care of patients with chronic pain. This series of accredited monographs will initially be published in the <i>Practical Pain Management Journal</i> ; all monographs will be available for credit online at the Emerging Solutions in Pain web site, as well.
<b>CE Provider</b>	<p>Based on the need to educate clinicians in the assessment and treatment of chronic pain patients who may be at risk for abuse, addiction and diversion, the The Emerging Solutions in Pain Accredited Monograph Series will be accredited by a third party CE vendor.</p> <p>All articles in the Accredited Monograph Series will be accredited for:</p> <ul style="list-style-type: none"> <li>• CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each activity will be approved for a maximum of one hour of category 1 credit toward the AMA Physician's Recognition Award.</li> <li>• CPE credit for pharmacists by the Accreditation Council for Pharmacy Education. Each activity will be approved for a maximum of 1.0 credit hour (0.1 CEU) for Continuing Pharmacy Education</li> <li>• CNE credit for nurses. Each activity will be approved for a maximum of 1.0 Contact Hours.</li> </ul>
<b>Intended Audience</b>	The primary audience of The Emerging Solutions in Pain Accredited Monograph Series includes physicians, pharmacists, nurses and other health care professionals who provide care to patients with pain.
<b>Program Objectives</b>	<p>The purpose of The Emerging Solutions in Pain Accredited Monograph Series is to educate clinicians on key topics relating to the Emerging Solutions in Pain initiatives. These topics may include, but are not limited to, the following:</p> <ol style="list-style-type: none"> <li>(1) Assessing functionality in patients prescribed opioids for chronic pain</li> <li>(2) Urine drug testing and other methods for monitoring patients who are prescribed opioids</li> <li>(3) Issues relating to drug testing in patients who are prescribed opioids</li> <li>(4) Standards of care in pain management</li> <li>(5) Neurobiology of addiction</li> <li>(6) Legal issues associated with the prescription of opioids</li> </ol>
<b>Format</b>	A series of four, eight-page accredited monographs in the <i>Practical Pain Management Journal</i>



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### ***Program Summary: Print-Based Tactics***

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#### **Post-Activity Feedback**

Course evaluation forms will be required of all participants who seek to receive continuing education credit. Medical Learning Solutions will work with the third party CE vendor to summarize the information collected from these forms in a formal report to evaluate program effectiveness.

Participants will evaluate the following as excellent, good, fair or poor:

- (1) Overall content
- (2) Faculty teaching effectiveness
- (3) Format

Participants will also respond to the following questions:

- (1) How well did the program achieve its educational objectives?
- (2) Do you feel the program material was useful and practice-oriented?
- (3) Do you feel that the information provided in this educational activity will aid in improving patient care in your practice?
- (4) Do you feel that fair balance was maintained for all therapeutic options?
- (5) Would you participate in future educational activities?

#### **Distribution**

Medical Learning Solutions and the third party CE vendor will announce and promote The Emerging Solutions in Pain Accredited Monograph Series primarily through advertisement at the Emerging Solutions in Pain web site.

#### **Request for Sponsor Support**

As a supplement to these primary methods, Medical Learning Solutions and the third party CE vendor may request the assistance of Cephalon, Inc. sales representatives in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.

**Total Budget:** \$219,948



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**Emerging Solutions in Pain: Print-Based Tactics**  
**2007 PPMJ Accredited Monograph Series**  
**Proposed Budget**  
 October 25, 2006

<b>Cost Summary</b>	
Approximate Total, Direct Expenses	\$ 164,000
Total, Indirect Expenses	\$ 55,948
<b>ESP: Print-Based Tactics, 2007 PPMJ Accredited Monograph Series</b>	<b>\$ 219,948</b>

<b>Detailed Budget Itemization: PPMJ Monograph Series</b>	
<b>Direct Expenses, Approximate</b>	
Clinical expert honoraria	\$ 20,000
Insert page charges, <i>Practical Pain Management Journal</i> Eight-page article printed on matte cover stock as journal insert	\$ 88,000
Accreditation of program for CME, CPE, CNE	\$ 32,000
Continuing Education participant certificates (estimate 750 certificates per program)	\$ 24,000
<b>Approximate Total, Direct Expenses</b>	<b>\$ 164,000</b>
<b>Indirect Expenses</b>	
<b>Project management</b>	
Coordination with faculty	\$ 1,800
Coordination with internal teams, PPMJ staff, accreditor	\$ 1,800
Preparation and coordination of status meetings/updates	\$ 300
<b>Medical services</b>	
Topic/author identification/research	\$ 4,800
Transcript review	\$ 2,400
Outline creation	\$ 3,200
Creation of monographs based on transcription, review with faculty	\$ 12,350
Development of supporting verbiage (needs assessment, objectives, etc.) and self-assessment	\$ 2,400
Incorporation of revisions	\$ 4,800
Proofreading	\$ 3,000
Fact-checking	\$ 8,000
<b>Production services</b>	
Layout and typesetting of articles	\$ 1,750
Creation of supporting web pages for online posting	\$ 250
<b>Programming of monographs, archiving</b>	\$ 3,800
<b>Data management</b>	\$ 2,000
<b>Administrative and accounting fees</b>	\$ 3,298
<b>Total, Indirect Expenses</b>	<b>\$ 55,948</b>



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### ***Program Summary: Print-Based Tactics***

<b>Program Title</b>	The Emerging Solutions in Pain 2006 Monograph Collection
<b>Program Overview</b>	Medical Learning Solutions is proposing to collect and reaccredit the series of 8 monographs developed during 2006, and release the collection as a single print printed document.
<b>CE Provider</b>	<p>Based on the need to educate clinicians in the assessment and treatment of chronic pain patients who may be at risk for abuse, addiction and diversion, the The Emerging Solutions in Pain 2006 Accredited Monograph Series will be accredited by a third party CE vendor.</p> <p>All monographs in the collection will be accredited for:</p> <ul style="list-style-type: none"> <li>• CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each activity will be approved for a maximum of one hour of category 1 credit toward the AMA Physician's Recognition Award.</li> <li>• CPE credit for pharmacists by the Accreditation Council for Pharmacy Education. Each activity will be approved for a maximum of 1.0 credit hour (0.1 CEU) for Continuing Pharmacy Education</li> <li>• CNE credit for nurses. Each activity will be approved for a maximum of 1.0 Contact Hours.</li> </ul>
<b>Intended Audience</b>	The primary audience of The Emerging Solutions in Pain 2006 Accredited Monograph Collection includes physicians, pharmacists, nurses and other health care professionals who provide care to patients with pain.
<b>Program Objectives</b>	<p>The purpose of The Emerging Solutions in Pain 2006 Accredited Monograph Collection is to educate clinicians on key topics relating to the Emerging Solutions in Pain initiatives. The topics that will be included in the collection are:</p> <ol style="list-style-type: none"> <li>1) <i>Determining the Risk of Opioid Abuse</i> by Lynn R. Webster, MD</li> <li>2) <i>The Connection Between Cigarette Smoking and Aberrant Drug-Taking Behavior in Opioid Therapy for Chronic Pain</i> by Lara Dhingra, PhD and Steven Passik, PhD</li> <li>3) <i>VIGIL: A five-step process approach to opioid prescribing and dispensing</i>; An interview with David B. Brushwood, RPh, JD</li> <li>4) <i>Relating Central Sensitization and Hyperalgesia to Opioid Pain Management and Preemptive Analgesia</i> by Jeffrey A. Gudin, MD</li> <li>5) <i>Pain Patients at Risk of Abuse and Those with Comorbid Psychopathology: A Guide to Identification and Treatment</i> by Rafael Miguel, MD</li> <li>6) <i>The unequal burden of pain: confronting racial and ethnic disparities in pain</i> by April Hazard-Vallerand, RN, PhD</li> </ol>



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### ***Program Summary: Print-Based Tactics***

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- 7) *Multidisciplinary and interdisciplinary management of chronic pain* by Steve Stanos, DO
- 8) *What Role Does Age Play in the Management of Chronic Pain in Adult Patients?* by Bill H. McCarberg, MD

#### **Post-Activity Feedback**

Course evaluation forms will be required of all participants who seek to receive continuing education credit. Medical Learning Solutions will work with the third party CE vendor to summarize the information collected from these forms in a formal report to evaluate program effectiveness.

Participants will evaluate the following as excellent, good, fair or poor:

- (1) Overall content
- (2) Faculty teaching effectiveness
- (3) Format

Participants will also respond to the following questions:

- (1) How well did the program achieve its educational objectives?
- (2) Do you feel the program material was useful and practice-oriented?
- (3) Do you feel that the information provided in this educational activity will aid in improving patient care in your practice?
- (4) Do you feel that fair balance was maintained for all therapeutic options?
- (5) Would you participate in future educational activities?

#### **Distribution**

Medical Learning Solutions and the third party CE vendor will announce and promote The Emerging Solutions in Pain 2006 Accredited Monograph Collection primarily as a giveaway at the Emerging Solutions in Pain exhibit booth.

#### **Request for Sponsor Support**

As a supplement to these primary methods, Medical Learning Solutions and the third party CE vendor may request the assistance of Cephalon, Inc. sales representatives in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.

**Total Budget:** \$54,384



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**Emerging Solutions in Pain: Print-Based Tactics**  
**2006 Accredited Monograph Collection**  
**Proposed Budget**  
**October 25, 2006**

<b>Cost Summary</b>	
Approximate Total, Direct Expenses	\$ 43,350
Total, Indirect Expenses	\$ 11,034
<b>ESP: Print-Based Tactics, 2006 Accredited Monograph Collection</b>	<b>\$ 54,384</b>

<b>Detailed Budget Itemization: 2006 Monograph Collection</b>	
<b>Direct Expenses, Approximate</b>	
<b>Printing, quantity 2,000</b> Includes printing of 40-page saddle-stitched booklet, reproducing all 2006 PPMJ monographs	\$ 30,000
<b>Accreditation of program for CME, CPE, CNE</b>	\$ 5,000
<b>Continuing Education participant certificates (estimate 750 certificates per program)</b>	\$ 8,000
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$ 350
<b>Approximate Total, Direct Expenses</b>	<b>\$ 43,350</b>
<b>Indirect Expenses</b>	
<b>Project management</b>	
Coordination with internal teams, accreditor	\$ 2,400
Preparation and coordination of status meetings/updates	\$ 600
<b>Medical/scientific services</b>	
Editing review	\$ 1,400
Creation of supporting documents for individual accredited self-study programs	\$ 800
Proofreading	\$ 1,000
<b>Graphic design</b>	
Typesetting, layout	\$ 3,125
Coordination with print vendor	\$ 625
<b>Administrative and accounting fees</b>	\$ 1,084
<b>Total, Indirect Expenses</b>	<b>\$ 11,034</b>



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### ***Program Summary: Exhibition Booth Series***

**Program Title** The Emerging Solutions in Pain Meet the Expert Exhibit Booth

**Program Overview** Medical Learning Solutions is proposing to continue utilizing the Meet the Experts Booth as an informational and interactive display for educating clinicians in the Emerging Solutions in Pain initiatives at national congresses and association meetings. A recent survey by a leading pharmaceutical journal suggested that clinician attendees perceive the greatest benefit from self-directed exposure to information presented in an exhibit hall, and that information presented by pharmaceutical representatives may be viewed as being biased and/or of lesser value.<sup>1</sup> The experience of the 2005 and 2006 Emerging Solutions in Pain exhibit booth series strongly supports these survey findings, as clinician response to the educational, non-branded information presented at the ESP booth is uniformly positive. At the ESP booth, clinicians may interact with key opinion leaders in an informal, one-on-one session, may learn about the informational tools and resources available through the ESP initiative, and may receive self-study educational programs and activities. In 2007, Medical Learning Solutions is proposing to tailor Booth activities to the size and specific purpose of the congress or association. Thus, at larger meetings, the full Meet the Expert Booth will be utilized, while a smaller Emerging Solutions in Pain Booth will be displayed at smaller congress and association meetings.

Over the past two years MLS has repurposed a booth that was designed and built for another purpose. As a cost-savings measure, MLS has created new graphics, design elements, functional space, and interactive elements to tie in with the existing structure and with the overall theme of Emerging Solutions in Pain. This structure is dated and constructed of heavy materials, adding to the cost of shipping and drayage, as well as on-site labor charges due to the difficulty in set-up challenges. In 2007, MLS will therefore update both the graphic imagery and design of the booth to coincide with that of the web site and to streamline the functionality of the exhibit booth and space. Functionality for the full-size Meet the Expert Booth will include a seating area for meeting attendees to interact with Emerging Solutions in Pain clinical experts; computer terminals featuring interactive displays highlighting the Emerging Solutions in Pain initiatives, membership registration for the Emerging Solutions in Pain Web Site, and the Emerging Solutions in Pain Tool Kit. The smaller Emerging Solutions in Pain Booth will focus on interactive displays of the Tool Kit and video highlights of previous Meet the Expert presentations; membership registration; and distribution of the Emerging Solutions in Pain Tool Kit.

**Intended Audience** The primary audience of the Emerging Solutions in Pain Meet the Experts Booth will be physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain and who attend selected national association meetings and congresses. MLS is proposing to utilize the full-size exhibit booth at three national association meetings, and the mini exhibit booth at four national association meetings in 2007; each association conference demographic profile and other scientific agenda, and public relations information and will be analyzed on a continuing basis throughout the year to determine the best audience reach and utilization of exhibit booth funds. Possible meetings for both options are listed in below.





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### ***Program Summary: Exhibition Booth Series***

#### **Potential Meetings, Full-Size (20' x 20' island) Exhibit Booth**

- American Academy of Pain Medicine
- American Pain Society
- American Academy of Pain Management
- American Academy of Physical Medicine and Rehabilitation

#### **Potential Meetings, Mini (10' x 20" in-line) Exhibit Booth**

- American Society for Addiction Medicine
- American Society for Pain Management Nurses
- International Conference on Pain and Chemical Dependency
- American Association for the Treatment of Opioid Dependence
- Academy of Managed Care Pharmacy
- American Academy of Physician Assistants
- American Society of Regional Anesthesia and Pain Medicine

#### **Program Objectives**

The purpose of the Emerging Solutions in Pain Meet the Expert Booth is to disseminate information concerning the Emerging Solutions in Pain initiative to clinicians practicing in the field of pain management, and to educate those clinicians on the assessment and monitoring of pain patients, and on good practice management techniques. Clinicians visiting the booth will have opportunities to:

- (1) Interact with Emerging Solutions in Pain clinical experts in small discussion groups, focusing on tools and strategies that will contribute to a proper balance of pain control and risk minimization (full-size Meet the Expert Booth only)
- (2) View multi-media, interactive programs highlighting the issues associated with minimization of misuse, abuse and addiction, the Emerging Solutions in Pain Tool Kit and associated case studies
- (3) Utilize interactive survey terminals to allow participants to earn one of the set of five faces of pain stress relievers giveaway
- (4) Review ESP symposia audio tracks through next day download post all live meetings, via an MP3 docking station available at the booth for those healthcare professionals that were unable to attend the symposium during the conference
- (5) Receive copies of the Emerging Solutions in Pain Tool Kit CD-ROM and other support materials, such as the Mini-Disc Publication and the ESP Accredited Monograph collection.
- (6) Gain exposure to the resources available at the Emerging Solutions in Pain Web Site, and register as a "member", thereby expediting their ability to access online resources

#### **Format**

An interactive meeting booth, to be presented at national association meetings and congresses. The full-size Meet the Expert Booth will feature live peer-to-peer interactions with Emerging Solutions in Pain clinical experts, as well as interactive, multimedia programs that highlight the Emerging Solutions in Pain initiatives. The smaller Emerging Solutions in Pain Booth will focus on educating clinicians in the availability of the Emerging Solutions in Pain initiatives.



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### ***Program Summary: Exhibition Booth Series***

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**Distribution** The Emerging Solutions in Pain Meet the Expert Booth will be available at selected national association meetings and congresses; meetings identified to date include the AAPM, APS, ASPMN, ICPCD, AATOD, AMCP, AAPMgmt, AAPA, ASRA and ASAM. The announcement of the Booth will be made via direct mail to registered meeting attendees and members, and via journal and/or banner advertisements. Information at the Booth will be provided by Emerging Solutions in Pain clinical experts and by Medical Learning Solutions staff members.

**Request for Sponsor Support** Medical Learning Solutions is promoting the Emerging Solutions in Pain Meet the Experts Booth through a variety of methods, including direct mail, publication of a multimedia Mini-Disc, and journal and banner advertisements.

As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. sales representatives in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely as a supplement to MLS' primary methods of announcement and promotion. Content developed for this program may also be repurposed as a CE-accredited enduring material and published on the ESP website at a later date.

**Total Budget:** \$846,189

<sup>1</sup> Mapes, S and Padden K. Conventional Wisdom. *Pharma Exec.* March 2006.



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## 2007 Emerging Solutions in Pain Exhibition Booth Series

### Proposed Budget

October 25, 2006

<b>Program Parameters</b>	
Number of Exhibitions of the Full-Size 20x20 ESP Booth	3
Number of Exhibitions of the Mini 10x20 ESP Booth	4

<b>Cost Summary</b>		
	Per Meeting	Total
<i>One-Time Expenses</i>		
Approximate Total, Direct Expenses	\$ -	\$ 90,500
Indirect Expenses	\$ -	\$ 37,000
Subtotal, One-Time Expenses	\$ -	\$ 127,500
<i>Full-Size, 20x20 Exhibit Booth Series, 3 Meetings Total</i>		
Approximate Total, Direct Expenses	\$ 88,400	\$ 265,200
Total, Indirect Expenses	\$ 47,298	\$ 141,895
Subtotal, Full-Size 20x20 Exhibit Booth Series, 3 Meetings Total	\$ 135,698	\$ 407,095
<i>Mini 10x20 Exhibit Booth Series, 4 Meetings Total</i>		
Approximate Total, Direct Expenses	\$ 39,750	\$ 159,000
Total, Indirect Expenses	\$ 38,148	\$ 152,593
Subtotal, Mini 10x20 Exhibit Booth Series, 4 Meetings Total	\$ 77,898	\$ 311,593
<b>Total Cost of the 2007 ESP Exhibition Booth Series</b>	<b>\$</b>	<b>846,189</b>



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**2007 Emerging Solutions in Pain Exhibition Booth Series**  
**Proposed Budget**  
October 25, 2006

<b>Detailed Budget Itemization: One-Time Expenses, 2007 ESP Exhibition Booth Series</b>		
<b>Direct Expenses, Approximate</b>		
	<b>Per Meeting</b>	<b>Total</b>
<b>Refurbishing of current 20x20 booth</b>		\$ 50,000
<b>MP3 docking station</b>		\$ 5,000
<b>Survey station</b>		\$ 2,500
<b>Faces of pain booth giveaway, 2000 quantity</b>		\$ 30,000
<b>Symposia audio series</b>		\$ 2,000
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>		\$ 1,000
<b>Subtotal, One-Time Approximate Direct Expenses</b>		<b>\$ 90,500</b>
<b>Indirect Expenses</b>		
	<b>Per Meeting</b>	<b>Total</b>
<b>Project management</b>		
Coordination with internal teams		\$ 4,500
Coordination with third-party booth vendor		\$ 3,500
Preparation and coordination of status meetings/updates		\$ 1,500
<b>Medical/scientific services</b>		
Creation of new text for booth graphics		\$ 3,200
Creation of supporting text for new booth functionality		\$ 2,750
Proofreading		\$ 2,250
<b>Graphic design</b>		
Graphic design for new booth graphics		\$ 9,500
Graphic design, layout for docking station, survey station, giveaway		\$ 2,750
Programming for incorporation of new booth hardware functionality		\$ 4,250
Coordination with third-party vendors		\$ 1,000
<b>Administrative, accounting fees</b>		\$ 1,800
<b>Subtotal, One-Time Indirect Expenses</b>		<b>\$ 37,000</b>



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**2007 Emerging Solutions in Pain Exhibition Booth Series**  
**Proposed Budget**  
October 25, 2006

<b>Detailed Budget Itemization: Full-Size, 20x20 Exhibit Booth Series</b>		
<b>Direct Expenses, Approximate</b>		
	<b>Per Meeting</b>	<b>Total, 3 Meetings</b>
<b>Exhibit space plus liability insurance</b>	\$ 14,800	\$ 44,400
<b>Booth set-up/tear-down</b>	\$ 22,900	\$ 68,700
Includes floor plan, shop prep, installation and dismantling including labor supervision, travel		
<b>Equipment rental</b>	\$ 10,600	\$ 31,800
Includes rental of computer units, plasma screen, switcher unit, audio w/ lav mic, electrical, telecommunication links, chairs, carpeting, etc.		
<b>Shipping of booth to meeting site</b>	\$ 8,800	\$ 26,400
<b>Shipping of supplies</b>	\$ 2,100	\$ 6,300
Includes shipping of mini-discs, Tool Kits, etc. to meeting site and delivery to booth charges		
<b>Badge Reader System (3 units)</b>	\$ 800	\$ 2,400
<b>Booth advertisement</b>		
Advertisement in meeting catalog/publication (full page, 4/c)	\$ 3,000	\$ 9,000
Booth posters, printing	\$ 900	\$ 2,700
<b>KOL expenses: two KOL faculty</b>		
Honoraria	\$ 12,000	\$ 36,000
Travel: air, hotel, ground, OOP	\$ 4,300	\$ 12,900
Faculty registration	\$ 1,000	\$ 3,000
<b>ROI expenses: three ROI staff</b>		
Travel: air, hotel, ground, OOP	\$ 6,900	\$ 20,700
Exhibitor registration	\$ 300	\$ 900
<b>Approximate Total, Direct Expenses</b>	<b>\$ 88,400</b>	<b>\$ 265,200</b>



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**2007 Emerging Solutions in Pain Exhibition Booth Series**  
**Proposed Budget**  
October 25, 2006

<b>Detailed Budget Itemization: Full-Size, 20x20 Exhibit Booth Series (con't)</b>		
<b>Indirect Expenses</b>		
	<b>Per Meeting</b>	<b>Total, 3 Meetings</b>
<b>Project management</b>		
Coordination with conference vendors	\$ 1,800	\$ 5,400
Coordination with KOLs for The Doctor is In schedule	\$ 2,700	\$ 8,100
Coordination of pre-meeting processes	\$ 6,150	\$ 18,450
Coordination of booth advertising and other support materials	\$ 1,800	\$ 5,400
Coordination with internal teams	\$ 1,950	\$ 5,850
Preparation and coordination of status meetings/updates	\$ 600	\$ 1,800
<b>Medical / scientific services</b>		
Development of copy for meeting advertisements	\$ 450	\$ 1,350
Development of copy for plasma screen loop, other booth support materials	\$ 1,050	\$ 3,150
Proofreading	\$ 1,000	\$ 3,000
<b>Graphic design / production services</b>		
Adaptation of display graphics for plasma loop and all associated tickers	\$ 2,000	\$ 6,000
Typesetting and layout of booth posters	\$ 750	\$ 2,250
Typesetting and layout of advertisements (direct mail plus meeting catalog)	\$ 1,750	\$ 5,250
Coordination with third-party print vendors	\$ 500	\$ 1,500
<b>Conference management services</b>		
Management of pre-meeting booth set-up	\$ 3,000	\$ 9,000
Management of post-meeting booth tear-down	\$ 3,350	\$ 10,050
Staffing of booth during meeting	\$ 14,700	\$ 44,100
Coordination with KOLs during meeting	\$ 1,950	\$ 5,850
<b>Administrative and accounting fees</b>	\$ 1,798	\$ 5,395
<b>Total, Indirect Expenses</b>	<b>\$ 47,298</b>	<b>\$ 141,895</b>



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**2007 Emerging Solutions in Pain Exhibition Booth Series**  
**Proposed Budget**  
**October 25, 2006**

<b>Detailed Budget Itemization: Mini, 10x20 Exhibit Booth Series</b>		
<b>Direct Expenses, Approximate</b>		
	<b>Per Meeting</b>	<b>Total, 4 Meetings</b>
<b>Exhibit space plus liability insurance</b>	\$ 6,250	\$ 25,000
<b>Booth set-up/tear-down</b>	\$ 8,000	\$ 32,000
Includes floor plan, shop prep, installation and dismantling including labor supervision, travel		
<b>Equipment rental</b>	\$ 6,750	\$ 27,000
Includes rental of computer units, plasma screen, switcher unit, audio w/ lav mic, electrical, telecommunication links, chairs, carpeting, etc.		
<b>Shipping of booth to meeting site</b>	\$ 8,000	\$ 32,000
<b>Shipping of supplies</b>	\$ 2,200	\$ 8,800
Includes shipping of mini-discs, Tool Kits, etc. to meeting site and delivery to booth charges		
<b>Booth advertisement</b>		
Advertisement in meeting catalog/publication (full page, 4/c)	\$ 3,000	\$ 12,000
Booth posters, printing	\$ 750	\$ 3,000
<b>ROI expenses: three ROI staff</b>		
Travel: air, hotel, ground, OOP	\$ 4,600	\$ 18,400
Exhibitor registration	\$ 200	\$ 800
<b>Approximate Total, Direct Expenses</b>	<b>\$ 39,750</b>	<b>\$ 159,000</b>





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**2007 Emerging Solutions in Pain Exhibition Booth Series**  
**Proposed Budget**  
October 25, 2006

<b>Detailed Budget Itemization: Mini, 10x20 Exhibit Booth Series (con't)</b>		
<b>Indirect Expenses</b>		
	<b>Per Meeting</b>	<b>Total, 4 Meetings</b>
<b>Project management</b>		
Coordination with conference vendors	\$ 1,500	\$ 6,000
Coordination of pre-meeting processes	\$ 5,700	\$ 22,800
Coordination of booth advertising and other support materials	\$ 1,750	\$ 7,000
Coordination with internal teams	\$ 1,950	\$ 7,800
Preparation and coordination of status meetings/updates	\$ 600	\$ 2,400
<b>Medical / scientific services</b>		
Development of copy for meeting advertisements	\$ 450	\$ 1,800
Development of copy for plasma screen loop, other booth support materials	\$ 1,050	\$ 4,200
Proofreading	\$ 1,000	\$ 4,000
<b>Graphic design / production services</b>		
Adaptation of display graphics for plasma loop and all associated tickers	\$ 2,000	\$ 8,000
Typesetting and layout of booth posters	\$ 750	\$ 3,000
Typesetting and layout of advertisements (direct mail plus meeting catalog)	\$ 1,750	\$ 7,000
Coordination with third-party print vendors	\$ 500	\$ 2,000
<b>Conference management services</b>		
Management of pre-meeting booth set-up	\$ 2,850	\$ 11,400
Management of post-meeting booth tear-down	\$ 3,000	\$ 12,000
Staffing of booth during meeting	\$ 12,400	\$ 49,600
<b>Administrative and accounting fees</b>	\$ 898	\$ 3,593
<b>Total, Indirect Expenses</b>	<b>\$ 38,148</b>	<b>\$ 152,593</b>



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### ***Program Summary: Audience Expansion Tactics***

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<b>Program Title</b>	The Emerging Solutions in Pain Scholarship Fund
<b>Program Overview</b>	ESP Scholarship Fund is a program designed to grow the number of new ESP members and to develop new thought leaders in the specialty of pain management and addiction management. It is also designed to introduce and involve up-and-coming physicians and nurses into the pain management community and to provide benefits to ESP by encouraging them to research and write. Scholarship recipients will receive registration fees, airfare, hotel and small stipend. The recipient will be asked to write abstracts of conference plenary sessions that will be posted on the ESP web site.
<b>Intended Audience</b>	The potential recipients include residents, fellows and RNs, who provide care to patients with chronic pain.
<b>Program Objectives</b>	The overall objective of the scholarship fund is to expand the audience of Emerging Solutions in Pain to residents, fellows and nurses in the area of pain management and addiction medicine at the beginning of their careers.
<b>Distribution</b>	Scholarship application process on ESP web site administered by MLS based upon recommendations by ESP faculty.
<b>Request for Sponsor Support</b>	<p>Medical Learning Solutions will coordinate the Emerging Solution in Pain Scholarship Fund through the means of distribution outlined above.</p> <p>As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc sales force. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion. Content developed for this program may also be repurposed as a CE-accredited enduring material and published on the ESP website at a later date.</p>
<b>Total Budget:</b>	\$32,507



101 Washington St, Suite 110  
Morrisville, PA 19067

**Emerging Solutions in Pain: Audience Expansion Tactics**  
**ESP Scholarship Fund**  
**Proposed Budget**  
**October 25, 2006**

<b>Cost Summary</b>	
Approximate Total, Direct Expenses	\$ 20,350
Total, Indirect Expenses	\$ 10,157
<b>ESP: Audience Expansion Tactics, Quarterly Electronic Journal Club</b>	<b>\$ 30,507</b>

<b>Detailed Budget Itemization: ESP Scholarship Fund</b>	
<b>Direct Expenses, Approximate</b>	
ESP clinician scholarship, quantity: four	\$ 20,000
Includes registration, travel and stipend for selected clinician to one national association meeting/congress	
Miscellaneous (non-fulfillment shipping, faxes, etc.)	\$ 350
<b>Approximate Total, Direct Expenses</b>	<b>\$ 20,350</b>
<b>Indirect Expenses</b>	
<b>Project management</b>	
Coordination with ESP KOLs for recruitment of, references for and/or selection of potential scholarship awardees	\$ 2,100
Selection of scholarship awardees	\$ 2,700
Coordination with scholarship awardees	\$ 1,200
Coordination with internal teams	\$ 750
Preparation and coordination of status meetings/updates	\$ 450
<b>Medical/scientific services</b>	\$ 800
For creation of verbiage announcing scholarship fund, other associated text	
<b>Graphic design</b>	
Layout and typesetting of documents associated with scholarship announcement	\$ 750
Adaptation of print documents to web	\$ 250
<b>Data management</b>	\$ 750
<b>Administrative and accounting fees</b>	\$ 407
<b>Total, Indirect Expenses</b>	<b>\$ 10,157</b>



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### ***Program Summary: Audience Expansion Techniques***

<b>Program Title</b>	The Emerging Solutions in Pain (ESP) Electronic Journal Club
<b>Program Overview</b>	<p>Medical Learning Solutions is proposing a quarterly accredited electronic journal club targeted to residents and fellows who have an interest in increasing their knowledge and understanding in the fields of pain management and addiction.</p> <p>MLS is recommending that a panel of ESP KOLs be convened to review relevant journal articles in an online forum on a quarterly basis. The recommended program protocol would be as follows:</p> <ol style="list-style-type: none"> <li>(1) An ESP KOL would recommend a relevant article</li> <li>(2) MLS would email the article to all registered members of the ESP Electronic Journal Club</li> <li>(3) The ESP KOL panel would write brief reviews and commentaries of the article which would all be posted on the Journal Club page of the ESP website</li> <li>(4) Registered members of the journal club may submit questions concerning either the articles or reviews to MLS, who would then submit questions to the most appropriate KOL</li> <li>(5) MLS would track each journal club member's review of the article and associated KOL review and commentaries</li> <li>(6) Journal club members who completed all sections would receive CE credit upon completion of the associated self-assessment and evaluation</li> <li>(7) The completed programs will be archived on the website for reference by the ESP membership</li> </ol>
<b>Intended Audience</b>	The primary audience will include residents and pain fellows; secondary audiences will include physicians, nurses, physician assistants, and other health care professionals who provide care to patients with chronic pain.
<b>Program Objectives</b>	<p>The overall objective of the 2007 ESP Electronic Journal Club is to increase awareness of the Emerging Solutions Pain initiatives, and the accompanying tools and resources, among residents and fellows with an interest in increasing their understanding of pain management. Articles will be selected based on publication in peer-reviewed medical research journals, and on topics relating to the Emerging Solutions in Pain initiatives. These topics may include, but are not limited to, the following:</p> <ol style="list-style-type: none"> <li>(1) Assessing functionality in patients prescribed opioids for chronic pain</li> <li>(2) Urine drug testing and other methods for monitoring patients who are prescribed opioids</li> <li>(3) Determining relative risk of opioid abuse</li> <li>(4) Issues relating to drug testing in patients who are prescribed opioids</li> <li>(5) Standards of care in pain management</li> <li>(6) The importance of interdisciplinary teams in effective pain management</li> <li>(7) Neurobiology of addiction</li> <li>(8) Legal issues associated with the prescription of opioids</li> <li>(9) Evidence-based medicine</li> <li>(10) Research design</li> <li>(11) Application guidance of empirical findings into everyday practice</li> </ol>



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### ***Program Summary: Audience Expansion Techniques***

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<b>Format</b>	The 2007 ESP Electronic Journal Club will be presented as an Internet-based program, in which members will read the selected articles and associated reviews generated through ESP-generated emails or directly on the ESP website.
<b>Distribution</b>	Invitations will be extended to residents and fellows to register for and participate in the ESP Electronic Journal Club through multiple sources, including the ESP website, ESP blast e-mails and the ESP Electronic Newsletter Series. Supplemental recruitment will also occur through announcement at other ESP-sponsored events, such as at the ESP exhibit booth and at ESP-sponsored live symposia.
<b>Request for Sponsor Support</b>	<p>Medical Learning Solutions will coordinate the Emerging Solution in Pain Electronic Journal Club through the means of distribution outlined above.</p> <p>As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc sales force in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion. Content developed for this program may also be repurposed as a CE-accredited enduring material and published on the ESP website at a later date.</p>
<b>Total Budget:</b>	\$132,570



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Morrisville, PA 19067

**Emerging Solutions in Pain: Audience Expansion Tactics**  
**Quarterly Electronic Journal Club**  
**Proposed Budget**  
**October 25, 2006**

<b>Cost Summary</b>	
Approximate Total, Direct Expenses	\$ 66,350
Total, Indirect Expenses	\$ 66,220
<b>ESP: Audience Expansion Tactics, Quarterly Electronic Journal Club*</b>	<b>\$ 132,570</b>

\* Four articles total

<b>Detailed Budget Itemization: Quarterly Electronic Journal Club</b>	
<b>Direct Expenses, Approximate</b>	
Clinical expert honoraria	\$ 10,000
Accreditation of program for CME, CPE, CNE	\$ 32,000
Continuing Education participant certificates (estimate 750 certificates per program)	\$ 24,000
Miscellaneous (non-fulfillment shipping, faxes, etc.)	\$ 350
<b>Approximate Total, Direct Expenses</b>	<b>\$ 66,350</b>
<b>Indirect Expenses</b>	
<b>Project management</b>	
Coordination with faculty	\$ 8,400
Coordination with internal teams, accreditor	\$ 1,200
Participant communication	\$ 1,800
Coordination of participant comments/questions	\$ 6,000
Preparation and coordination of status meetings/updates	\$ 600
<b>Medical/scientific services</b>	
Topic/author identification/research	\$ 2,400
Creation of article summary	\$ 6,600
Development of supporting verbiage (needs assessment, objectives, etc.) and self-assessment	\$ 2,400
Review, editing of comments	\$ 9,200
Proofreading	\$ 3,000
Fact-checking	\$ 6,000
<b>Graphic design</b>	
Typesetting, layout of all participant communications	\$ 1,000
Typesetting, layout of program-related materials	\$ 2,900
<b>Programming, journal distribution</b>	\$ 9,400
<b>Archiving</b>	\$ 4,000
<b>Administrative and accounting fees</b>	\$ 1,320
<b>Total, Indirect Expenses</b>	<b>\$ 66,220</b>



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### ***Program Summary: Pain Awareness Campaign***

<b>Program Title</b>	The Emerging Solutions in Pain Awareness Campaign
<b>Program Overview</b>	Medical Learning Solutions is proposing to increase the number of health care professionals who are aware of the Emerging Solutions in Pain initiative through the development and implementation of a coordinated series of advertising campaigns in 2007. The goal of this awareness campaign is to expand the reach of the Emerging Solutions in Pain initiatives to health care professionals who will benefit from the educational information presented at the web site, on the Tool Kit CD-ROM, and at Emerging Solutions in Pain live events such as the exhibit booth at various conferences, and symposia.
<b>Intended Audience</b>	The primary audience will include physicians, pharmacists, nurses, physician assistants, and other health care professionals who provide care to patients with chronic pain.
<b>Program Objectives</b>	<p>The overall objective of the 2007 Awareness Campaign is to increase the number of health care professionals who are active in the Emerging Solutions in Pain community. The specific objectives will include, but are not limited to:</p> <ol style="list-style-type: none"> <li>(1) Increase the number of registered users at <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a></li> <li>(2) Increase the number of user sessions at <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a></li> <li>(3) Increase the total amount of information downloaded at <a href="http://www.EmergingSolutionsinPain.com">www.EmergingSolutionsinPain.com</a></li> </ol>
<b>Format</b>	Journal and banner advertisements
<b>Distribution</b>	<p>The 2007 Emerging Solutions in Pain Awareness Campaign will include, but is not limited to:</p> <ol style="list-style-type: none"> <li>(1) Journal advertisements in <i>Practical Pain Management Journal</i>, <i>Journal of Pain</i>, <i>Pain Management Nursing</i>, <i>Pain Medicine</i>, <i>The Physiatrist Newsletter</i></li> <li>(2) Banner advertisements at select professional pain management organization web sites including American Academy Physical Medicine and Rehabilitation (AAPM&amp;R) web site and advertising on journal home pages of <i>Journal of Pain</i>, <i>Pain Management Nursing</i> and <i>Pain Medicine</i> publications</li> </ol>
<b>Request for Sponsor Support</b>	<p>Medical Learning Solutions will coordinate the Emerging Solution in Pain Awareness Campaign through the means of distribution outlined above.</p> <p>As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. sales force in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.</p>
<b>Total Budget:</b>	\$81,500





101 Washington St, Suite 110  
Morrisville, PA 19067

**Emerging Solutions in Pain: Awareness Campaign**  
**Proposed Budget**  
October 25, 2006

<b>Cost Summary</b>	
Approximate Total, Direct Expenses	\$ 49,300
Total, Indirect Expenses	\$ 32,200
<b>2007 ESP Awareness Campaign</b>	<b>\$ 81,500</b>

<b>Detailed Budget Itemization</b>	
<b>Direct Expenses, Approximate</b>	
Journal advertisements	\$ 36,200
Banner advertisements	\$ 12,500
Miscellaneous (non-fulfillment shipping, faxes, etc.)	\$ 600
<b>Approximate Total, Direct Expenses</b>	<b>\$ 49,300</b>
<b>Indirect Expenses</b>	
<b>Project management</b>	
Coordination with internal teams	\$ 1,500
Coordination with third-party vendors	\$ 11,250
Preparation and coordination of status meetings/updates	\$ 750
<b>Graphic design / production services</b>	
Creation and subsequent adaptation of print advertisements	\$ 6,075
Creation and subsequent adaptation of banner advertisements	\$ 1,625
Programming of Flash-animations of banner advertisements	\$ 1,500
<b>Medical / scientific services</b>	\$ 8,750
<b>Administrative and accounting fees</b>	\$ 750
<b>Total, Indirect Expenses</b>	<b>\$ 32,200</b>



## Exhibit B

### ACTIQ Risk Management Program

Provider is aware that ACTIQ® (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- ACTIQ is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- ACTIQ is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.
- ACTIQ is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.



## FENTORA Risk Management Program

Provider is aware that FENTORA™ (fentanyl buccal tablet) [C-II] was approved subject to a Risk Minimization Action Plan (RiskMAP). The RiskMAP includes key safety messages that are essential to the safe use of this product. They are:

- FENTORA is indicated for the management of breakthrough pain in patients with cancer who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- FENTORA is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- No misuse of FENTORA should occur.
- Unintended (accidental) exposure to FENTORA should not occur.
- Patients considered opioid tolerant are those who are taking at least 60 mg oral morphine/day, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that FENTORA can be fatal to a child. Keep all units away from children and discard properly.
- FENTORA is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

**INDEPENDENT EDUCATIONAL PROGRAM ("IEP") GRANT AGREEMENT**

This Agreement is entered into as of this 6th day of December, 2006 by and between Cephalon ("Cephalon"), located at 41 Moores Road, Post Office Box 4011, Frazer, PA 19355, and Medical Learning Solutions, Inc. ("IEP Provider") located at 101 Washington Street, Morrisville, PA 19067 and MediCom Worldwide, Inc. ("Educational Partner") located at 101 Washington Street, Morrisville, PA 19067.

WHEREAS, Cephalon has reviewed IEP Provider's grant request to support a medical education program ("Program"); and

WHEREAS, Cephalon has determined that the Program has the potential to significantly further medical knowledge and improve patient care; and

WHEREAS, it is the intent of the parties to ensure that the Program will be independent, objective, balanced and scientifically rigorous, so that it will not be viewed by the United States Food and Drug Administration ("FDA") as promotional and that Cephalon will not be viewed as responsible for its content; and

WHEREAS, Cephalon agrees to provide funding for the Program under the conditions set forth below.

NOW THEREFORE, IEP Provider and Cephalon agree to the following terms under this Agreement:

1. Title of Program. The IEP is entitled 2007 Emerging Solutions in Pain Lecture Series, and a copy of the grant request for the Program is attached hereto as Exhibit A.
2. Type of Program. The Program is:  
  
☒ accredited (e.g., continuing medical education or "CME"); or  
☐ an independent program where CE credits will not be offered.
3. IEP Provider. The IEP Provider is the following type of entity:  
  
☐ Accredited continuing medical education provider  
☐ University/Hospital  
☐ Professional Organization  
☒ Medical Education Company
4. Educational Partner. The IEP Provider ☒ shall ☐ shall not use a third party that will provide assistance in support of the Program ("Educational Partner"). The name of the Educational Partner is MediCom Worldwide, Inc.



5. Educational Components. The expected components of the Program (e.g., number of live meetings, CD ROM, web-based, etc.) are as follows:

- (a) two half-day accredited symposia; and
- (b) one full-day accredited symposium.

6. Program Purpose. The Program is for scientific and educational purposes only and is not intended to promote a Cephalon product directly or indirectly. The Program is not a repeat performance of a prior program.

7. Grant Amount Funding Arrangements.

- (a) Cephalon will provide support for the Program by means of an educational grant in the total amount of \$525,397. If the Program is canceled or terminated prior to completion, IEP Provider shall return the grant, or any unused portion thereof, to Cephalon within thirty (30) days of such termination or cancellation. IEP Provider shall have full responsibility for all funding arrangements of the Program, including any funding to be provided to IEP Provider's Educational Partner. Payment of the grant shall be made in accordance with a schedule agreed to by the parties. All payments due hereunder shall be made by Cephalon within forty-five (45) days of its receipt of an invoice for same, provided IEP Provider is in compliance with the terms of this Agreement.
- (b) Within thirty (30) days of completion of the Program, IEP Provider shall provide Cephalon with a detailed reconciliation of actual out-of-pocket expenses incurred, and to the extent Cephalon has overpaid IEP Provider for same, IEP Provider shall provide a refund to Cephalon within thirty (30) days thereafter. Such detailed reconciliation shall be forwarded to Cephalon at the address above to the attention of Rod J Hughes, Ph.D., Vice President, Scientific Communications.
- (c) IEP Provider may not use funds provided by Cephalon to pay travel, lodging, honoraria or personal expenses for non-faculty attendees. Grant funds may be used to reduce the overall registration fees for attendees. Grant funds may not be used to purchase capital equipment or to provide general operational support for an institution. Funds for hospitality shall not be provided except that funds may be used for modest meals or receptions that are held as part of the Program, but such events shall not compete with nor take precedence over educational events. The appropriateness of any reception shall be at the sole discretion of the IEP Provider, and IEP Provider shall have final decision making authority in connection with any such activities.
- (d) Funds may be used by the IEP Provider to permit medical students, residents, fellows or other health care professionals in training to travel to and attend the Program; provided, however, that the selection of such students, residents or fellows who receive funds is made by either the



academic or training institution or, if by the IEP Provider, such selection shall be made with the full concurrence of the academic or training institution.

(e) In accordance with the Accreditation Council for Continuing Medical Education ("ACCME") Standards and to assist Cephalon in complying with its internal auditing procedures, IEP Provider agrees to verify the manner in which the grant is used. Accordingly, within thirty (30) days following a request from Cephalon, IEP Provider shall provide to Cephalon:

- i. A written statement verifying that the Program occurred, and
- ii. An itemized list of expenditures supported by the grant.

8. Objectivity and Balance. IEP Provider shall retain full responsibility for control of the content of the Program and shall ensure that the following requirements are met:

(a) The Program material/information will be objective, balanced and free from commercial bias. All topics shall be treated in an impartial, unbiased manner. All discussions shall include a range of views about each class of drug and disease treatment options. Information shall not unfairly represent a spectrum of views favoring a product or class of products marketed by Cephalon or any other company. The title of the Program will fairly and accurately represent the scope of the presentation.

(b) IEP Provider agrees that neither Cephalon nor its agents shall control the content of the Program. IEP Provider agrees that there will be no scripting, targeting of points for emphasis, or other activities by Cephalon or its agents that are designed to influence the content of the Program. If requested in writing by the IEP Provider, medical/scientific representatives from Cephalon may attend content development meetings or other planning meetings, for the purpose of addressing any scientific inaccuracies they observe. Personnel from Cephalon must not discuss or in any way attempt to control (either during the meeting or at breaks or meals), the content of the program. An appropriate medical/scientific representative from Cephalon may provide a presentation at a content development meeting at the request of the provider, or may respond to specific questions at such meeting regarding the results of a Cephalon-sponsored research study, provided the information presented conforms to the generally accepted standards of experimental design, data collection and analysis, and provided any presentation is accompanied by a detailed outline of the presentation, which can be used by the IEP Provider/Educational Partner to confirm the scientific objectivity of the presentation.

(c) If the IEP Provider, in its sole discretion, requests a Cephalon medical representative to review the Program for medical accuracy and completeness, Cephalon will comply with such request. The parties



acknowledge there is no obligation or any condition requiring IEP Provider to make such a request. Any such request must be made after the Program materials are fully developed and such request must be made by the IEP Provider only to a Cephalon medical representative that has responsibility for the therapeutic area that will be covered by the Program. IEP Provider will not ask any marketing or sales representatives at Cephalon to comment on the material. All final decisions regarding whether to modify the material based on any comments provided by the Cephalon medical representative shall be in the sole discretion of IEP Provider.

- (d) If a product marketed by Cephalon is the subject of discussion, the data will be objectively selected and presented, with an accurate reflection of favorable and unfavorable information about the product and shall also include a balanced discussion of prevailing information on alternative products and /or therapies.
  - (e) Any suggestions of superiority of one product or treatment over another will be supported by the body of available data, and will not result from selective presentation or emphasis on data favorable to particular treatment.
  - (f) IEP Provider represents that neither it nor the Educational Partner (if any) has either an open complaint or decision from the ACCME or the Food and Drug Administration that a program provided by the IEP Provider or the Educational Partner failed to meet standards of independence, balance, objectivity, or scientific rigor.
9. Risk Minimization Action Plan. Cephalon provides the following Risk Minimization Action Plan ("RiskMAP") information to all IEP Providers. Neither Cephalon nor its agents shall influence or control whether a product marketed by Cephalon is the subject of discussion. A RiskMAP is a strategic safety program designed to meet specific goals and objectives in minimizing known risks of a product while preserving its benefits. Any product marketed by Cephalon that is approved with a RiskMAP, and the key safety-related health outcomes outlined in that RiskMAP, are listed in Exhibit B. IEP Provider agrees that it is aware of the RiskMAP(s) and the key safety messages.
10. Faculty Selection. IEP Provider shall retain full responsibility for the selection of the presenters, authors, moderators, and/or other faculty (hereinafter referred to collectively as "Faculty"). Cephalon, through its Scientific Communications Department, may respond only to IEP Provider-initiated, written requests (or requests from the Educational Partner) for suggestions of Faculty or sources of possible Faculty. In response to such requests at least three (3) names will be suggested (if possible) for each open position and this information will be provided in writing. IEP Provider will record the role of Cephalon in suggesting Faculty; will seek suggestions from other sources; and will make its selection of Faculty based on objective criteria. IEP Provider shall not be obligated to





request or accept such assistance from Cephalon or its agents as a condition of receiving the educational grant hereunder.

11. Disclosures. IEP Provider will ensure meaningful disclosure of limitations of data (e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion). IEP Provider will require that Faculty disclose when a product is not approved in the United States for the use under discussion.
12. Question and Answer Session. To the extent the Program is a presentation, IEP Provider will ensure meaningful opportunities for questioning by the audience.
13. Financial Relationships. IEP Provider will ensure meaningful disclosure to the audience of Cephalon funding and any significant relationship between individual Faculty and Cephalon. All meaningful disclosure(s) shall also be made in any written materials, including but not limited to announcements, brochures, syllabi and enduring material. Disclosures shall not mention product trade names.
14. Metrics/Copies of Program Material.
  - (a) IEP Provider and/or Educational Partner shall provide certain outcome measurements and metrics to Cephalon as requested by the Scientific Communications Department. Such metrics shall be provided either after the conclusion of a single live event or monthly for a year-long accredited program and may at Cephalon's request include the number of program participants, number of certifications, assessment of the program and faculty, and demonstration of learning by program participants.
  - (b) After the Program has occurred, IEP Provider shall provide Cephalon with 5 copies of all Program materials in CD ROM or electronic format and 20 copies in print format.
15. Representations and Warranties. IEP Provider represents that:
  - (a) Neither it nor the Educational Partner, if any, provides marketing, advertising, public relations, market research, medical education services or other consulting services (e.g., support for advisory boards) to any other department within Cephalon ("Marketing Activities");
  - (b) If IEP Provider or the Educational Partner has an affiliated company that provides Marketing Activities to Cephalon, IEP Provider has instituted appropriate controls and safeguards to ensure the Program (i) remains independent, objective, balanced and scientifically rigorous, (ii) is not intended to promote a Cephalon product directly or indirectly, and (iii) is not in any way biased due to the affiliated company's relationship with Cephalon;
  - (c) IEP has determined that it is appropriate to use the Educational Partner in light of the requirements under this Agreement; and



- (d) If IEP Provider or its Educational Partner employs a former Cephalon employee who worked at Cephalon anytime during the most recent year and who had marketing responsibility in the therapeutic area that will be covered by the Program, then that former employee will not have any role in the planning, development or delivery of the Program.
16. Invitations/Enduring Materials. The Program audience will be selected by the IEP Provider. The IEP Provider shall be responsible for distributing materials about the Program, including invitations, reminder notices, and business reply cards that can be used by third parties to obtain any enduring Program material from the IEP Provider. Notwithstanding the foregoing, IEP Provider hereby authorizes Cephalon to distribute a subset of Program invitations/reminder notices that have been prepared or approved by the IEP Provider.
17. Ancillary Promotional Activities. To the extent the Program is a live presentation, no promotional activities or product advertisements will be permitted in the same room as or in an obligate path to the Program. If the Program is a teleconference or webcast, no product advertisements or promotional activities will be permitted immediately prior to, during, or immediately after the delivery of the Program. If the Program is in print format, no product advertisements or promotional materials will be interleaved within the pages of the Program. If the Program is made available electronically, no product advertisements or promotional materials will appear within the Program material or interleaved between computer windows or screens of the Program
18. Compliance with Guidelines. IEP Provider represents that the Program, including development of the Program and Program materials, shall conform to the American Medical Association ("AMA") Guidelines on Gifts to Physicians, the AMA Ethical Opinion on Continuing Medical Education, the ACCME Standards for Commercial Support, the FDA December 3, 1997 Final Guidance for Industry-Supported Scientific and Educational Activities, and the Pharmaceutical Research and Manufacturers Association ("PhRMA") Code on Interactions with Healthcare Professionals.
19. Logistical Status Reports. IEP Provider and/or Educational Partner shall provide periodic reports to Cephalon regarding the management and logistics of program components.
20. Miscellaneous.
- (a) No party shall use the other party's or its affiliates' name or trademarks for publicity or advertising purposes, except with the prior written consent of the other party.
- (b) IEP Provider agrees to obtain all consents, authorizations, approvals and releases that may be necessary for the production of the Program and of any written materials prepared in connection therewith. IEP Provider agrees to indemnify Cephalon with respect to any claims, actions or demands, including reasonable attorneys' fees that may arise in any



manner out of IEP Provider's failure to secure such consents, authorizations, approvals or releases.

- (c) No term, condition or other provision of any attachment or addendum to this Agreement shall supersede any term, condition or other provision of this Agreement and with respect to any inconsistency or ambiguity, the Agreement shall control.

IN WITNESS WHEREOF, the parties, by their duly authorized representatives, agree to comply with all the terms and conditions of this Agreement.

**MEDICAL LEARNING SOLUTIONS, INC.**

By: *Sheri L. Gavinski*  
 Name: Sheri L. Gavinski  
 Title: President

The above signatory is a duly authorized corporate officer of the IEP Provider.

Date: 12-14-06  
 Tax ID #: 90-0735153

**CEPHALON, INC.**

By: *R. Hughes*  
 Name: Rod J. Hughes, Ph.D.  
 Title: Vice President, Scientific Communications

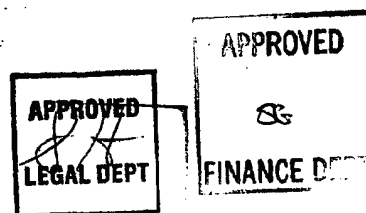
Date: 12-11-06

**MEDICOM WORLDWIDE, INC.**

By: *Joan Meyer*  
 Name: JOAN MEYER  
 Title: PRESIDENT

The above signatory is a duly authorized corporate officer of the Educational Partner.

Date: 12-14-06  
 Tax ID #: 23-3063738





101 Washington Street  
Morrisville, Pennsylvania 19067  
Phone 215.337.6100  
Fax 215.337.0960

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November 14, 2006



101 Washington Street  
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November 16, 2006

Bhaval Shah-Bell, PhD  
Cephalon, Inc.  
41 Moores Road  
Frazer, PA 19355

Dear Dr. Shah-Bell:

Medical Learning Solutions, Inc. has recently completed a comprehensive needs assessment to identify the educational needs of clinicians who provide care to patients with chronic pain. This needs assessment was compiled from the following sources:

- Evaluation summaries of completed and ongoing 2006 Emerging Solutions in Pain programs and activities
- Clinical advisory review
- Survey of health care professionals, including participants in completed and ongoing 2006 Emerging Solutions in Pain programs
- Literature search

Based on the identified educational need, Medical Learning Solutions is requesting an educational grant from Cephalon, Inc. to support a live lecture series that will support the continuation and further development of the **Emerging Solutions in Pain**, or **ESP**, initiatives. This lecture series will include two half-day accredited symposia, and one full-day accredited symposium, all to be held in conjunction with regional or national meetings and congresses of clinical pain societies. The **2007 Emerging Solutions in Pain Lecture Series** will focus on balancing the clinical need to provide adequate analgesia to patients with chronic pain with the legal and societal need to monitor for potential issues of abuse, addiction and diversion of controlled substances.

The budget to fund these activities is approximately \$525,397. Please refer to the detailed budget section of this proposal for complete grant funding proposals. These scientific events will comply with all ACCME, FDA, AMA, and ACPE regulations for industry-supported professional continuing education.

MLS will work with MediCom Worldwide, Inc., a third party CE vendor, in the planning, execution and development of the accredited activities associated with the **2007 Emerging Solutions in Pain Lecture Series**. MediCom Worldwide is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians and is approved by the Accreditation Council for Pharmacy Education to provide pharmacy continuing education, as well as an approved provider of nursing continuing education through the California State Board of Registered Nursing.

Thank you in advance for your consideration of this request.

Respectfully,

Sheri L. Gavinski  
President,  
Medical Learning Solutions, Inc.



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Pain is one of the most common symptoms for which patients seek the assistance of health care professionals.<sup>1</sup> While pain management can be looked at as pure science, there are obstacles to overcome in the effective treatment of pain. The Americans Living with Pain Survey (ALPS)<sup>2</sup> notes patient concerns with potential side effects (56%), medication addiction (50%), the need for increased usage over time (50%), and the possibility of having to take these drugs for the remainder of their lives (49%). A number of studies identified similar concerns<sup>3,4,5,6,7,8</sup> including: 1) potential for addiction, 2) potential for abuse/misuse, 3) fear of side effects, 4) fear of audit by a regulatory body, and 5) cost. These sentiments were echoed by healthcare providers acknowledging the need for the education of physicians and medical students as essential to the prevention and treatment of pain disorders, as well as the recognition of addictive disorders with regard to opioid analgesics. 40% of a stratified random sample of US physicians indicated that regulatory pressured affected their prescribing practices of opioids.<sup>9</sup>

The tension associated with expanding the use of opioids to treat populations for which there is not yet a broad consensus about treatment, including the heterogeneous population with chronic noncancer pain, has an important historical context in the ever-changing perception of the balance between medical need and the risk of misuse, abuse, addiction and diversion. At different times during the past century, the balance has shifted, sometimes emphasizing the perceived need to limit the social harm associated with abuse, addiction, and diversion, and sometimes emphasizing the need to provide greater access to beneficial medicines for patients who have legitimate needs. During most of the past few decades, the societal concern about drug abuse, as filtered through the actions of the government, law enforcement agencies and regulatory agencies, seemed to far outweigh the needs of patients. Clinicians and patient advocates tried to make the case that this perspective worsened the undertreatment of pain<sup>10,11</sup>.

Although the clinical literature on opioid pharmacotherapy is very limited in assessing the specific issue of abuse, addiction and diversion, the data that have been published have, on the whole, been reassuring. It must be recognized, however, that the data may not directly assess the situations encountered in the clinical setting. Controlled trials commonly exclude patients with a history of substance abuse and cannot be used to clarify the risk of aberrant drug-related behavior in the larger population. Surveys of patients who receive opioids for acute pain demonstrate outcomes during short-term therapy in a monitored environment that appear to have little relevance for the issues during chronic therapy. Surveys of patients with chronic cancer pain also have been reassuring, but this may relate to the observation that cancer largely afflicts an older population and the base rate of addictive disorders in this group is lower than the overall population. Alternatively, it may relate to a lower prevalence of specific types of psychiatric and psychosocial comorbidity in these populations. The precise reason has not been clearly established and it is important to recognize that a low rate of drug abuse in the cancer population does not establish a low risk in the larger population with chronic pain.

Surveys of patients with chronic nonmalignant pain have yielded mixed results. Few have included adequate measures of abuse behavior or addiction. The existing literature suggests that the risk of abuse, addiction and diversion is relatively low overall, but becomes significant among the patients referred to pain management programs. This literature should remind all clinicians that the risk of abuse, addiction and diversion cannot be eliminated. If a clinician prescribes opioids or other potentially abusable drugs, he or she will encounter the phenomenology of chemical dependency.

Thus, effective pain management may require any clinician working with chronic pain patients has, as a minimum, a working knowledge of addiction medicine. The balance gradually has shifted during the past decade toward a greater willingness to initiate chronic opioid therapy for diverse types of chronic pain. Other factors that contributed to this shift included: a growing recognition of the prevalence and cost of



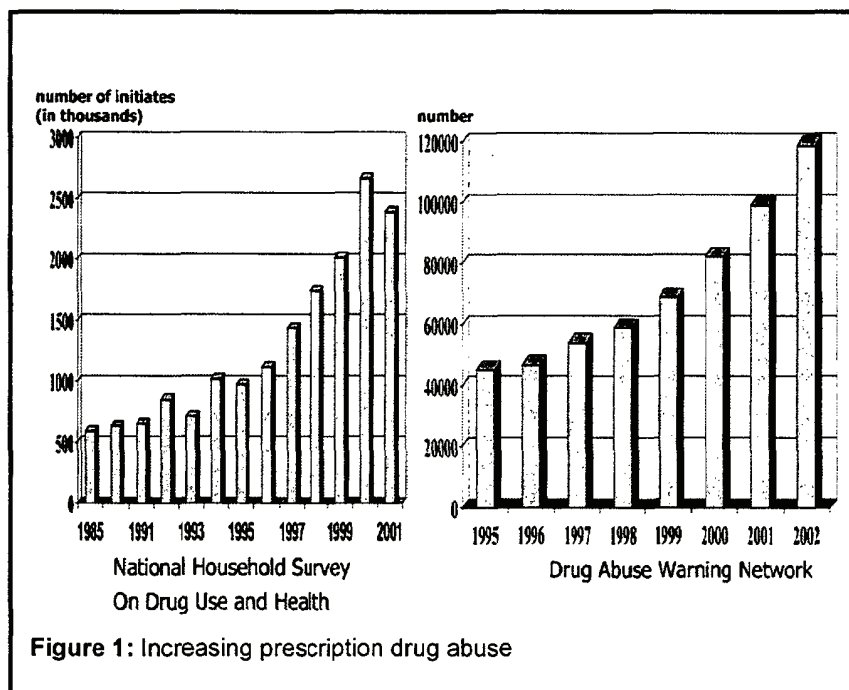


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under-treated pain, acknowledgment that physician fear of regulation may exacerbate under-treatment and the passage of various state Intractable Pain Treatment Acts in an effort to address this problem, the development of model regulations by the Federation of State Boards of Medical Examiners, and the development and marketing of long-acting opioids, as well as of rapid-onset opioid agents, which have been associated with higher street value and greater abuse potential<sup>12</sup>.

Unfortunately, the increased shift toward greater acceptability and use of opioids has been accompanied by evidence of growing prescription drug abuse. This has been demonstrated in various national databases. The National Household Survey on Drug Use and Health surveys more than 50,000 people annually and assesses a variety of parameters, including the number of people reporting taking an opioid for non-medical reasons for the first time. The number of these "initiates" has quintupled since the 1980s. Another database, the Drug Abuse Warning Network, surveys emergency departments around the country for events that involve specific drugs. There has been a 163% increase in opioid "mentions" between 1995 and 2002 (Figure 1).<sup>13</sup>



A new paradigm is needed that encourages clinicians, regulators and law enforcement to have respect for their mutually important goals. This paradigm should incorporate a "principle of balance." A balanced approach implies that 1) clinicians will recognize the importance of reducing abuse, addiction and diversion, and will acquire the knowledge and skills necessary to collaborate in this, and 2) regulators acknowledge the essential role of opioid drugs and will do nothing that undermines their appropriate medical use.<sup>14</sup>





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The importance of understanding the clinical implications of the interface between pain and chemical dependency is clear when the potential prevalence of opioid use is described. Opioids are needed for most patients with acute pain related to surgery, trauma or specific diseases such as sickle cell anemia. The prevalence of pain severe enough to warrant opioid therapy in the cancer population is about 30% among those patients receiving active antineoplastic therapies, and as high as 80% of those with far-advanced illness. The prevalence of at least partially disabling pain in the general American population is similarly very high. Although the prevalence of chronic pain in various populations with addictive disease is not known, at least one large survey suggested that about one-third of addicts in treatment programs report chronic severe pain. The prevalence of acute and chronic pain does not allow accurate predictions of the overall need for opioid therapy. The prevalence rates do strongly suggest, however, that millions of Americans annually require opioids for acute pain, and millions more would benefit from opioid therapy administered for chronic pain. Given the need for specific skill sets to ensure the safe and effective use of opioid drugs, clinicians should also learn to distinguish patients who can be treated without referral from those who may benefit from consultation with a pain specialist or a specialist in addiction medicine, and to distinguish both groups from those patients whose complexity is such that referral is the more prudent course.<sup>2,15,16</sup>

From the perspective of balance, clinicians must now recognize that the use of these drugs requires 1) knowledge of the principles of prescribing so that the effectiveness of therapy can be optimized, and 2) knowledge of risk assessment and management so that the risks related to the abuse liability of opioid drugs can be appropriately minimized.

#### ***Medical Education Program Evaluations***

To further elucidate educational needs of clinicians active in the field of pain management, a series of post-program evaluation forms were conducted in late 2005 and 2006. Physicians were asked about their practices and the therapies that they utilize to provide analgesia. The survey was conducted among 724 participants, with a selection of evaluation questions and responses from this survey summarized below.

#### *Meeting Program Evaluation Forms<sup>17</sup>*

<b><i>Do you manage patients who are experiencing acute pain?</i></b>	
Many	48%
Few	28%
None	8%
<b><i>Do you manage patients who are experiencing chronic pain?</i></b>	
Many	50%
Few	23%
None	6%
<b><i>How do you currently manage pain patients?</i></b>	
Opioids	26%
Combination of all methods	16%
Non-opioids	12%
OTC medications	11%
Psychological/social therapy	3%
Physical therapy	2%
Other	2%



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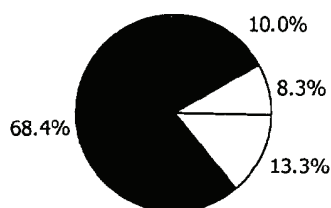
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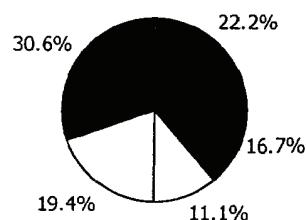
When properly managed, medical use of opioids is the cornerstone of effective pain management. As evidenced by the increasing trend in opioid misuse and by the recent and relevant literature, it appears that many healthcare professionals are amenable to and in need of continuing education programs focused on chronic pain, appropriate and safe opioid therapy, and best-practice patient management.

To further define the educational needs of clinicians' active in the field of pain management, our group conducted a survey in 2006 in which we asked 183 physicians about their practices and their need for education on pain and dependency/addiction issues. The first section of the survey identified who the respondents were by specialty and type of practice. Results are demonstrated below in Figure 2, Figure 3 and Figure 4.

**Figure 2: Clinicians Specializing in Pain Management**



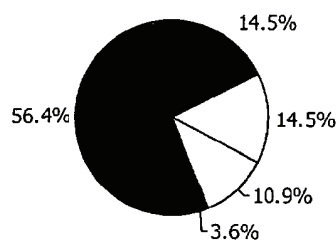
**Figure 3: Physician Specialties from Table 1**



■ Physicians ■ Nurses □ Pharmacists □ Other

■ PMR ■ Psychiatry □ Neurologist □ Anesthesiologist ■ Primary Care

**Figure 4: Type of Practice**



■ Office Based ■ Clinic Based □ Pain Center  
□ Hospital Based ■ Pharmacy



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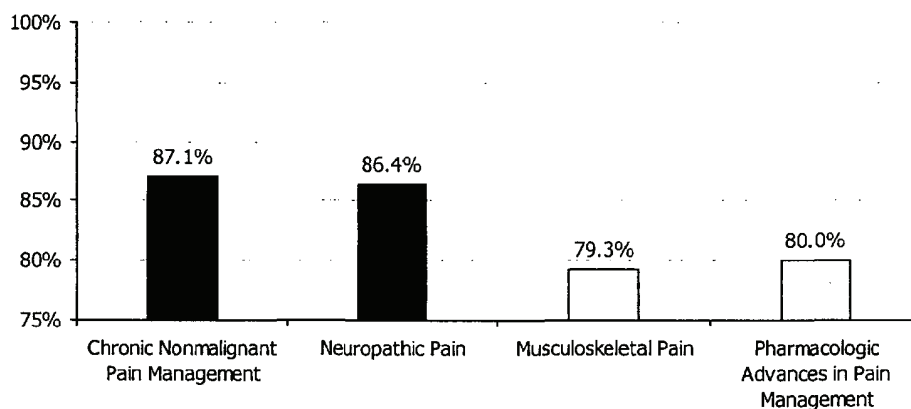
To further understand the educational needs represented in this survey, the respondents were asked about the pain and chemically dependent patients they manage. Results follow in Table 1 below.

**Table 1: Managing Patients who are:**

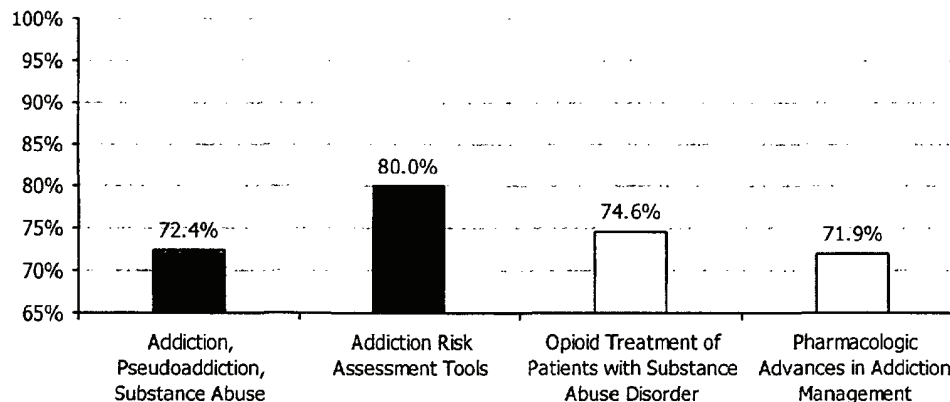
	<b>Many</b>	<b>Few</b>	<b>None</b>
Experiencing Acute Pain	59.3%	35.6%	5.1%
Experiencing Chronic Pain	93.2%	6.8%	0%
Chemically Dependent	42.4%	44.1%	11.9%

The respondents were asked to indicate topics of highest interest in the two categories of pain management and chemical dependency. The top four results are illustrated below in Figure 5 and Figure 6; full results of the survey are provided in Table 2.

**Figure 5: Pain Management**



**Figure 6: Chemical Dependency**





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**Table 2: Full Results of Needs Assessment Survey**

	No Interest	Some Interest	High Interest
<b>Pain Management</b>			
Genetics of Pain	10.5%	47.4%	42.1%
Acute Pain Management	3.6%	44.6%	51.8%
Chronic Nonmalignant Pain Management	1.6%	11.3%	87.1%
Neuropathic Pain	1.7%	11.9%	86.4%
Cancer Pain Management	17.2%	44.8%	38.0%
Musculoskeletal Pain	1.7%	19.0%	79.3%
Principles to Optimize Opioid Analgesics	1.7%	22.0%	76.3%
Updates on NSAIDs and Adjuvant Analgesics	0.0%	33.9%	66.1%
Cannabinoids in Pain Management	14.3%	46.4%	39.3%
Complementary and Alternative Medicine (CAM) for Pain	10.0%	38.3%	51.7%
Interventional Pain Management	15.3%	35.6%	49.1%
Psychological Interventions for Pain Management	3.5%	29.8%	66.7%
Pharmacologic Advances in Pain Management	1.7%	18.3%	80.0%
<b>Chemical Dependency</b>			
Addiction, Pseudoaddiction, Substance Abuse	5.2%	22.4%	72.4%
Chemical Dependency Management	8.5%	35.6%	55.9%
Mechanisms of Craving	8.6%	44.8%	46.6%
Genetics of Addiction	14.0%	33.3%	52.7%
Physical Dependence and Tolerance	5.2%	31.0%	63.8%
Addiction Risk Assessment Tools	5.5%	14.5%	80.0%
Complementary and Alternative Medicine (CAM) for Pain	10.3%	34.5%	55.2%
Opioid Treatment of Patients with Substance Abuse Disorder	6.8%	18.6%	74.6%
Epidemiology and Management of Prescription Drug Abuse	5.3%	29.8%	64.9%
Changing Role of State and Prescription Drug Abuse	5.2%	31.0%	63.8%
Pharmacologic Advances in Addiction Management	5.3%	22.8%	71.9%

**Research and Publications**

The Cochrane Collaboration recently published their "Evidence-based Pain Management and Palliative Care" in Issue One for 2006 of the Cochrane Library. This edition of the Library contains 83 new reviews of which the three have potential relevance for practitioners in pain and palliative medicine.<sup>18</sup> Several studies published in 2006 underscore the growing problem of opioid abuse in America.<sup>19,20,21,22</sup> Educational programs designed to address the growing risk, to demonstrate tools that can help assess and monitor patients for risk of misuse, and yet emphasize the need to treat chronic pain patients adequately will help clinicians minimize the individual and public risk associated with prescription opioids.

On September 6, 2006, the Drug Enforcement Administration (DEA) announced from their office in Arlington, Virginia, its proposed regulations on the Issuance of Multiple Prescriptions for Schedule II



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Controlled Substances and their Policy for Dispensing Controlled Substances for the Treatment of Pain. This proposal, along with the clarification of its policy on dispensing controlled substances for the treatment of pain, reopens the dialogue between the DEA and health care professionals for the benefit of prescribers, patients, and society. It is essential that all pain management practitioners become acquainted with the new proposed regulations.<sup>27,23</sup>

To insure due diligence with state and federally mandated regulations for Schedule II controlled substances, a host of tools exist for clinicians to use prior to and throughout duration of opioid treatment. Recent publications continue to address a need for practitioners to become aware of instruments that can assist them in the process of patient risk stratification and monitoring. Questionnaires designed to determine potential patient misuse of opioids, standardized treatment approach (e.g. universal precautions) that include routine opioid treatment plans, and periodically scheduled test-monitoring (e.g. urine drug testing), all contribute to safe-prescribing practices and help minimize misuse.<sup>24,25,26,27,28,29,30</sup>

*Expert Opinion*

*Raymond Sinatra, MD, PhD – Director Inpatient Pain Management Services, Yale University School of Medicine*

"Clearly pain is undertreated in many hospitals. As a baseline, physicians are taught very little about the assessment or management of pain in their medical training. In 2001, the Joint Commission on Healthcare Accreditation (JCAHO) enacted a series of guidelines aimed at improving pain management in hospitals, nursing homes, rehabilitation centers and ambulatory medical facilities. JCAHO mandated that health care practitioners be educated about pain scales, analgesic medications and nonpharmacological techniques for pain control."<sup>31</sup>

*Daniel Bennett, MD – Assistant Clinical Professor of Anesthesiology and Pain Medicine at the University of Colorado*

"Some physicians rely on laboratory data/objective physical findings and such, I believe you miss the mark in pain treatment by focusing only on these traditional (ie, allopathic) approaches. This is not to say that we should not use these in the definition of structural pathology (one would be remiss to not do this). We cannot directly measure pain, and thus what we observe is the summation of how the particular pain signal (ie, stimulus) affects the individual person (ie, pain behavior). Obviously, what is presented to us is the summation of the layering of the supratentorial processes that make us individual as human beings."

"Therefore, my philosophy in treating people who live with pain is to recognize their individuality, and incorporate what I understand of pathophysiology with the effects to them as a person. This allows the individual direction of care to optimize the functional outcome, which I believe is the most important determinate in successful treatment."<sup>32</sup>

*Donald R. Taylor, MD – a board certified anesthesiologist and pain medicine physician in private practice in Marietta, Georgia*

"The shift from the PRN pain management model to a model based upon around-the-clock dosing with breakthrough pain (rescue) medications represents a shift from an old to a new pain treatment paradigm."<sup>33</sup>



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*Lynn Webster, MD, FACPM, FASAM – Medical Director, Lifetree Pain Clinic; Medical Director and CEO, Lifetree Clinical Research, Salt Lake City, Utah*

“According to the 2003 National Survey on Drug Use and Health, new nonmedical users of pain relievers more than quadrupled during the 10-year period of the 1990s. Many of these first-time users are young people. Substance abuse is a leading cause of preventable illness and death in the United States, and opioid analgesics are among the most frequently abused prescriptions. To keep opioids available to treat pain, as we must, doctors who treat pain are called on to help prevent abuse and addiction, too.”<sup>34</sup>

*Joyce Lowinson, MD – Professor Emeritus of Psychiatry, Albert Einstein College of Medicine, Bronx, New York, Adjunct Faculty, The Rockefeller University, NY, NY*

“Undertreatment of pain is a global public health problem. Pain is the complaint that brings the highest percentage of patients to their doctor’s offices. There have been great strides in understanding in recent decades in the treatment of pain, yet the problem remains.”<sup>35</sup>

The experts acknowledge that pain assessment and management models are changing, while misuse of opioid is on the rise. Practitioners need continuing education in pain assessment and management, including risk minimization through patient assessment and monitoring.

#### **Conclusion**

When the results of literature searches, clinician surveys and expert opinion are combined, it is clear that additional curriculum and training are required to help provide information on the delivery of pain relief and dependency issues. The goal of such programs must be to support clinicians in improving patient care while reducing the potential for abuse, addiction, diversion, and medical regulatory/malpractice liability exposures arising from poor pain management practices.

To prepare physicians to treat chronic pain appropriately, this educational activity will focus on the pathophysiology, assessment, and management of pain and provide information on the risks and benefits of opioid analgesics in pain management. Another area of our program focus will be on the topic of prescription drug abuse and addiction. In March 2004 the Office of National Drug Control Policy stated, “6.2 million American’s were current abusers of prescription drugs.”<sup>36</sup> This information, while extremely important and relevant, has raised numerous questions regarding the treatment of pain patients, misuse, abuse, diversion of drugs and addiction. Fortunately, addiction rarely occurs among people who use a pain reliever. Many studies have shown that properly managed medical use of opioid analgesic drugs is safe and rarely causes clinical addiction, which is defined as compulsive, often uncontrollable use.<sup>37</sup> The key is “properly managed medical use”; this program will define the body of knowledge necessary for health care providers to provide safe and effective therapy of pain, to identify and manage addictive disorders in patients with pain and to treat pain in individuals with addictive disorders. It will include essential knowledge in overlapping areas of interest in the fields of pain medicine and addiction medicine. Clinicians will also learn about precautions medical professionals can take in their practices when treating pain patients. Throughout the symposium the audience will be engaged in interactive question/answer sessions and case studies to demonstrate practical physician/patient interaction.





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## *2007 Emerging Solutions in Pain Lecture Series Grant Request Program Summary*

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**Program Title**                      The 2007 Emerging Solutions in Pain Lecture Series

**Program Overview**            Medical Learning Solutions is proposing to develop and produce a core lecture program that will be used in a series of accredited live meetings to educate and inform clinicians on issues and challenges associated with opioid misuse, abuse and addiction. This lecture program will utilize a multidisciplinary panel of clinical expert faculty, and will draw upon, expand and update topics and information presented at the 2006 American Academy of Pain Management "Emerging Solutions in Pain: The Interface of Pain and Addiction". The core lecture program will include the following foundation topics:

- Basic neurobiology of pain and addiction
- The multidimensional and synergistic experience of pain and addiction
- Rational pharmacotherapy of pain
- The challenges of appropriate pain management: misuse, abuse, addiction and diversion of opioids
- Pain, dependency and universal precautions
- Federal regulations and appropriate prescription of controlled substances
- Clinical pearls: case vignettes highlighting appropriate pain management in challenging clinical situations

The 2007 Emerging Solutions in Pain Lecture Series will be presented as a series of half- and full-day meetings. The educational needs of the audience attending major meetings and congresses have been analyzed, to determine if a half-day lecture or full-day lecture is most appropriate for the needs of the individual audience. Half-day lectures will be developed for specialty audiences of clinicians with a background in pain management, who do not require fundamental education in the neurobiology and pharmacology of pain medicine. Clinicians with a reduced background or experience in pain management will participate in the full-day program, which will begin with a foundation of neurobiology and pharmacotherapy. The following meetings have been identified as among those that may be appropriate for presentation of the 2007 Emerging Solutions in Pain Lecture Series. Selection of final meeting series will be based on the completed analysis of the educational needs of anticipated meeting attendees.

- The Southern Pain Society: Half-day lecture
- The Midwest Pain Society: Half-day lecture
- The Western Pain Society: Half-day lecture
- The American Academy of Physical Medicine and Rehabilitation: Full-day lecture
- The American Academy of Pain Management: Full-day lecture
- American Society of Pain Educators: Full-day lecture

The core group of proposed faculty includes:

- Howard Heit, MD, FACP, FASAM
- Douglas Gourlay, MD, MSc, FRCP
- Peggy Compton, RN, PhD



101 Washington Street  
Morrisville, Pennsylvania 19067  
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## *2007 Emerging Solutions in Pain Lecture Series Grant Request Program Summary*

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- Steven Stanos, DO
- Steven Passik, PhD

### **CE Provider**

Based on the need to educate clinicians in the assessment and treatment of chronic pain patients who may be at risk for abuse, addiction and diversion, the 2007 Emerging Solutions in Pain Lecture Series will be accredited by a third-party CE vendor.

All lectures and meetings in the 2007 Emerging Solutions in Pain Lecture Series will be accredited for:

- CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each half-day activity will be approved for a maximum of 3 hours of category 1 credit toward the AMA Physician's Recognition Award, and the single full-day activity will be approved for a maximum of 6 hours of category 1 credit toward the AMA Physician's Recognition Award.
- CPE credit for pharmacists by the Accreditation Council for Pharmacy Education. Each half-day activity will be approved for a maximum of 3 credit hours (0.3 CEU) for Continuing Pharmacy Education, and the single full-day activity will be approved for a maximum of 6 credit hours (0.6 CEU) for Continuing Pharmacy Education.
- CNE credit for nurses. Each half-day activity will be approved for a maximum of 3 Contact Hours, and the single full-day activity will be approved for a maximum of 6 Contact Hours.

### **Intended Audience**

The primary audience of the 2007 Emerging Solutions in Pain Lecture Series includes physicians, pharmacists, nurses and other health care professionals who provide care to patients with pain.

### **Program Objectives**

The purpose of the 2007 Emerging Solutions in Pain Lecture Series is to educate clinicians on key topics relating to the Emerging Solutions in Pain initiatives; specific learning objectives will include the following:

- Identify and distinguish between addiction, tolerance, physical dependence, and pseudoaddiction and summarize how to manage each appropriately
- Review accepted mechanisms of pathology and neurobiology of chronic pain
- Describe traditional and novel pharmacologic interventions for chronic pain
- Identify the components of an effective pain management patient treatment plan



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- Compare and contrast current assessment tools that rate patient pain levels, activities of daily living, risk of abuse & addiction, and quality of life
- Summarize regulatory issues impacting health care providers relative to prescribing opioids
- Identify the complexities associated with the treatment of pain and the strategies required for successful outcomes

### **Literature Surveillance**

Medical Learning Solutions will conduct monthly literature reviews throughout 2007, surveying peer-reviewed pain management journals for identification of the latest developments in the field of pain management. MLS will forward the results of these surveys to the Emerging Solutions in Pain Steering Committee on a monthly basis, such that these clinical experts will utilize the information provided in the development of educational materials associated with all accredited activities associated with the Emerging Solutions in Pain initiative.

### **Format**

Two half-day and one full-day meeting held in conjunction with regional and national meetings of pain management associations and societies. This program will be comprised primarily of didactic lecture, interspersed with case studies, panel discussions and question/answer sessions.

### **Post-Activity Feedback**

Course evaluation forms will be required of all participants who seek to receive continuing education credit. Medical Learning Solutions will work with the third party CE vendor to summarize the information collected from these forms in a formal report to evaluate program effectiveness.

Participants will evaluate the following as excellent, good, fair or poor:

- (1) Overall content
- (2) Faculty teaching effectiveness
- (3) Format

Participants will also respond to the following questions:

- (1) How well did the program achieve its educational objectives?
- (2) Do you feel the program material was useful and practice-oriented?
- (3) Do you feel that the information provided in this educational activity will aid in improving patient care in your practice?
- (4) Do you feel that fair balance was maintained for all therapeutic options?
- (5) Would you participate in future educational activities?

### **Distribution**

Medical Learning Solutions and the third party CE vendor will announce and promote the 2007 Emerging Solutions in Pain Lecture Series through the Emerging Solutions in Pain web site and via direct mail to the target audiences of the



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***2007 Emerging Solutions in Pain Lecture Series Grant Request  
Program Summary***

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**Request for  
Sponsor Support**

associated regional and national meetings. The live meetings will also be highlighted in the ESP e-mail blasts, the ESP electronic newsletters, and the ESP exhibit booth.

As a supplement to these primary methods, Medical Learning Solutions and the third party CE vendor may request the assistance of the Cephalon, Inc. sales force in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion. Content developed for this program will also be repurposed in 2008 as a CE-accredited monograph, subject to the 2008 needs analysis, program planning and grant proposal processes.

**Total Budget:** \$525,397



101 Washington St, Suite 110  
Morrisville, PA 19067

Proposal Number: 07-014a  
Date: November 16, 2006

**2007 Emerging Solutions in Pain Lecture Series**  
***Projected Budget Estimate***  
November 16, 2006

<b>Program Parameters</b>		
	Each half-day symposium	Each full-day symposium
<b>Number of accredited symposia</b>	2	1
<b>Faculty presenters per symposia</b>	3	5
<b>Approximate number, health care professional attendees per meeting</b>	200	400
<b>Direct mail invitations to health care professionals per meeting</b>	8,000	50,000

<b>Cost Summary</b>			
	One-time only costs	Each half-day symposium	Each full-day symposium
Approximate Total, Direct Expenses	\$ 30,500	\$ 91,770	\$ 132,350
Total, Indirect Expenses	\$ 45,380	\$ 42,903	\$ 47,821
Subtotal, one-time only costs	\$ 75,880		
Subtotal, each symposium		\$ 134,673	\$ 180,171
<b>Cost of the 2007 Emerging Solutions in Pain Lecture Series</b>		<b>\$</b>	<b>525,397</b>

*\*Based upon adaptation of 2006 AAPManagement full-day symposium*



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Proposal Number: 07-014a  
Date: November 16, 2006

**2007 Emerging Solutions in Pain Lecture Series**  
**Projected Budget Estimate**  
November 16, 2006

*Detailed Budget Itemization*

<b>Direct Expenses, Approximate</b>			
	One-time only costs	Each half-day symposium	Each full-day symposium
<b>Direct mail invitations, mail services, postage</b> Personalized invitations to be mailed to every potential participant; includes printing, assembly, mail services and postage. Postage estimated at \$0.39 per direct mail piece	\$ -	\$ 8,320	\$ 4,500
<b>Direct mail list purchase</b>	\$ -	\$ 2,000	\$ 2,000
<b>Print materials</b> Includes printing of shell materials for adaptation and use in individualized symposia kits for every symposium; kits to include accreditation information, speaker biographical and disclosure information, agenda, reference materials and handout materials, where appropriate	\$ -	\$ 5,000	\$ 10,000
Set design pieces (banners, podium signs, gobo, directional signage, etc.)	\$ 15,000	\$ 1,200	\$ 1,200
<b>Speaker honoraria</b> Half-day symposia; 3 faculty members: \$3,000 honoraria per faculty member Full-day symposia; 1 chairperson/faculty member: \$4,000 honoraria; 4 faculty members: \$3,000 honoraria per faculty member	\$ -	\$ 9,000	\$ 16,000
<b>Speaker travel (air, OOP, hotel)</b>	\$ -	\$ 7,000	\$ 12,000
<b>MLS staff travel (4 staff members)</b>	\$ -	\$ 6,600	\$ 6,600
<b>Ground transportation</b>	\$ -	\$ 600	\$ 1,000
<b>Association Fee</b>	\$ -	\$ 12,000	\$ 30,000
<b>Travel, site visit</b>	\$ -	\$ 1,350	\$ 1,350
<b>Catering</b>	\$ -	\$ 18,000	\$ 24,000
<b>Audio/visual services</b>	\$ -	\$ 14,000	\$ 14,000
<b>Accreditation of program for CME, CPE, CNE</b>	\$ 15,000	\$ -	\$ -
<b>Continuing Education participant certificates</b> 200 CE certificates for each half-day symposia; 400 CE certificates for full-day symposium	\$ -	\$ 3,000	\$ 6,000
<b>Onsite CME coordination</b>	\$ -	\$ 1,500	\$ 1,500
<b>Reference purchase</b>	\$ 500	\$ -	\$ -
<b>Shipping/Fed Ex</b>	\$ -	\$ 2,200	\$ 2,200
<b>Approximate Total, Direct Expenses</b>	\$ 30,500	\$ 91,770	\$ 132,350





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**2007 Emerging Solutions in Pain Lecture Series**  
**Projected Budget Estimate**  
November 16, 2006

**Detailed Budget Itemization**

<b>Indirect Expenses</b>			
	One-time only costs	Each half-day symposium	Each full-day symposium
<b>Project management</b>			
Coordination of adaptation of 2006 AAPM symposium to half-day symposium		\$ 1,800	
Coordination of adaptation of 2006 AAPM symposium to full-day (6 hr) symposium			\$ 1,200
Negotiation with associations		\$ 5,200	\$ 3,600
Communication with state medical boards		\$ 1,200	\$ 1,200
Coordination with accreditor	\$ 3,300	\$ 300	\$ 300
Coordination with faculty	\$ 900	\$ 900	\$ 1,800
Coordination with internal teams	\$ 1,800	\$ 900	\$ 1,800
Preparation and coordination of status meetings/updates		\$ 300	\$ 500
<b>Medical services</b>			
Update of content from 2006 AAPM symposium, including establishment of core content for entire lecture series and monthly literature surveys	\$ 10,500		
Adaptation core content to half-day symposium		\$ 1,450	
Update of accreditation information, text for meeting materials reflecting changes in location, date of each program, possible changes in faculty		\$ 900	\$ 2,000
Proofreading	\$ 3,000	\$ 1,000	\$ 1,000
Fact-checking	\$ 4,500	\$ 250	\$ 500
<b>Graphic design</b>			
Graphic design of look/feel for entire series	\$ 2,500		
Creation of core slides	\$ 10,200		
Adaptation of core slides for each meeting		\$ 1,500	\$ 3,000
Typesetting, layout of core meeting support materials	\$ 2,000		
Adaptation of core meeting support materials for each meeting		\$ 2,200	\$ 2,700
Typesetting, layout of core set design pieces, posters, ads	\$ 4,000		
Adaptation of core set design pieces, posters, ads for each meeting		\$ 1,300	\$ 1,800
Participant package assembly		\$ 300	\$ 600
<b>Site visit (1 staff member)</b>		\$ 1,350	\$ 1,350
<b>Meeting management</b>			
Venue coordination		\$ 3,000	\$ 3,000
Travel coordination for faculty and staff		\$ 4,200	\$ 5,400
Coordination of associated meeting logistics		\$ 1,300	\$ 1,300
<b>Supplemental recruitment</b>			
Preparation of fax, email blasts		\$ 2,000	\$ 2,000
Coordination with associations for member recruitment		\$ 1,600	\$ 1,600
<b>Onsite management (4 staff members)</b>		\$ 7,200	\$ 7,200
<b>Registration database development/management (includes online reg)</b>	\$ 1,500		
<b>Administrative and accounting fees</b>	\$ 1,180	\$ 2,753	\$ 3,971
<b>Total, Indirect Expenses</b>	\$ 45,380	\$ 42,903	\$ 47,821



## Exhibit B

## ACTIQ Risk Management Program

Provider is aware that ACTIQ® (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- ACTIQ is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- ACTIQ is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.
- ACTIQ is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.



## FENTORA Risk Management Program

Provider is aware that FENTORA™ (fentanyl buccal tablet) [C-II] was approved subject to a Risk Minimization Action Plan (RiskMAP). The RiskMAP includes key safety messages that are essential to the safe use of this product. They are:

- FENTORA is indicated for the management of breakthrough pain in patients with cancer who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- FENTORA is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- No misuse of FENTORA should occur.
- Unintended (accidental) exposure to FENTORA should not occur.
- Patients considered opioid tolerant are those who are taking at least 60 mg oral morphine/day, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that FENTORA can be fatal to a child. Keep all units away from children and discard properly.
- FENTORA is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.



## INDEPENDENT EDUCATIONAL PROGRAM ("IEP") GRANT AGREEMENT

This Agreement is entered into as of this 27<sup>th</sup> day of July, 2007 by and between Cephalon ("Cephalon"), located at 41 Moores Road, Post Office Box 4011, Frazer, PA 19355, and Medical Learning Solutions, Inc. ("IEP Provider") located at 101 Washington Street, Morrisville, PA 19067 and MediCom Worldwide, Inc. ("Educational Partner") located at 101 Washington Street, Morrisville, PA 19067

WHEREAS, Cephalon has reviewed IEP Provider's grant request to support a medical education program ("Program"); and

WHEREAS, Cephalon has determined that the Program has the potential to significantly further medical knowledge and improve patient care; and

WHEREAS, it is the intent of the parties to ensure that the Program will be independent, objective, balanced and scientifically rigorous, so that it will not be viewed by the United States Food and Drug Administration ("FDA") as promotional and that Cephalon will not be viewed as responsible for its content; and

WHEREAS, Cephalon agrees to provide funding for the Program under the conditions set forth below.

NOW THEREFORE, IEP Provider and Cephalon agree to the following terms under this Agreement:

1. Title of Program. The IEP is entitled "continued support for the Emerging Solutions in Pain initiative," and a copy of the grant request for the Program is attached hereto as Exhibit A.
2. Type of Program. The Program is:  
☒ accredited (e.g., continuing medical education or "CME"); or  
☐ an independent program where CE credits will not be offered.
3. IEP Provider. The IEP Provider is the following type of entity:  
☒ Accredited continuing medical education provider  
☐ University/Hospital  
☐ Professional Organization  
☐ Medical Education Company



4. Educational Partner. The IEP Provider X shall \_\_\_\_ shall not use a third party that will provide assistance in support of the Program ("Educational Partner"). The name of the Educational Partner is MediCom Worldwide, Inc.
5. Educational Components. The expected components of the Program (e.g., number of live meetings, CD ROM, web-based, etc.) are as follows:
  - (a) The Emerging Solutions in Pain website;
  - (b) Emerging Solutions in Pain Foundation initiatives;
  - (c) Emerging Solutions in Pain Awareness Building initiatives;
  - (d) Print-based Tactics; and
  - (e) Emerging Solutions in Pain exhibition booth series.
6. Program Purpose. The Program is for scientific and educational purposes only and is not intended to promote a Cephalon product directly or indirectly. The Program is not a repeat performance of a prior program.
7. Grant Amount Funding Arrangements.
  - (a) Cephalon will provide support for the Program by means of an educational grant in the total amount of \$1,829,504. If the Program is canceled or terminated prior to completion, IEP Provider shall return the grant, or any unused portion thereof, to Cephalon within thirty (30) days of such termination or cancellation. IEP Provider shall have full responsibility for all funding arrangements of the Program, including any funding to be provided to IEP Provider's Educational Partner. Payment of the grant shall be made in accordance with a schedule agreed to by the parties. All payments due hereunder shall be made by Cephalon within forty-five (45) days of its receipt of an invoice for same, provided IEP Provider is in compliance with the terms of this Agreement.

Cephalon will provide support for the Program by means of an educational grant in the total amount of \$1,829,504 as set forth in the budget attached hereto, or a pro rata amount based on the actual work performed and expenses incurred by IEP Provider, in accordance with the Budget. If the Program is canceled or terminated prior to completion, IEP Provider shall return the grant, or any unused portion thereof, to Cephalon within thirty (30) days of such termination or cancellation. IEP Provider shall have full responsibility for all funding arrangements of the Program, including any funding to be provided to IEP Provider's Educational Partner. Payment of the grant shall be made in accordance with a schedule agreed to by the parties. All payments due hereunder shall be made by Cephalon within forty-five (45) days of its receipt of an invoice for same, provided IEP Provider is in compliance with the terms of this Agreement. The parties acknowledge and agree that \$926,495 of the total Budget is based on estimated out-of-pocket expenses, as identified in the Budget.



- (b) Within thirty (30) days of completion of the Program, IEP Provider shall provide Cephalon with a detailed reconciliation of actual out-of-pocket expenses incurred, and to the extent Cephalon has overpaid IEP Provider for same, IEP Provider shall provide a refund to Cephalon within thirty (30) days thereafter. Such detailed reconciliation shall be forwarded to Cephalon at the address above to the attention of Rod J Hughes, Ph.D., Vice President, Scientific Communications.
  - (c) IEP Provider may not use funds provided by Cephalon to pay travel, lodging, honoraria or personal expenses for non-faculty attendees. Grant funds may be used to reduce the overall registration fees for attendees. Grant funds may not be used to purchase capital equipment or to provide general operational support for an institution. Funds for hospitality shall not be provided except that funds may be used for modest meals or receptions that are held as part of the Program, but such events shall not compete with nor take precedence over educational events. The appropriateness of any reception shall be at the sole discretion of the IEP Provider, and IEP Provider shall have final decision making authority in connection with any such activities.
  - (d) Funds may be used by the IEP Provider to permit medical students, residents, fellows or other health care professionals in training to travel to and attend the Program; provided, however, that the selection of such students, residents or fellows who receive funds is made by either the academic or training institution or, if by the IEP Provider, such selection shall be made with the full concurrence of the academic or training institution.
  - (e) In accordance with the Accreditation Council for Continuing Medical Education ("ACCME") Standards and to assist Cephalon in complying with its internal auditing procedures, IEP Provider agrees to verify the manner in which the grant is used. Accordingly, within thirty (30) days following a request from Cephalon, IEP Provider shall provide to Cephalon:
    - i. A written statement verifying that the Program occurred, and
    - ii. An itemized list of expenditures supported by the grant.
8. Objectivity and Balance. IEP Provider shall retain full responsibility for control of the content of the Program and shall ensure that the following requirements are met:
- (a) The Program material/information will be objective, balanced and free from commercial bias. All topics shall be treated in an impartial, unbiased manner. All discussions shall include a range of views about each class of drug and disease treatment options. Information shall not unfairly represent a spectrum of views favoring a product or class of products marketed by Cephalon or any other company. The title of the Program will fairly and accurately represent the scope of the presentation.



- (b) IEP Provider agrees that neither Cephalon nor its agents shall control the content of the Program. IEP Provider agrees that there will be no scripting, targeting of points for emphasis, or other activities by Cephalon or its agents that are designed to influence the content of the Program. If requested in writing by the IEP Provider, medical/scientific representatives from Cephalon may attend content development meetings or other planning meetings, for the purpose of addressing any scientific inaccuracies they observe. Personnel from Cephalon must not discuss or in any way attempt to control (either during the meeting or at breaks or meals), the content of the program. An appropriate medical/scientific representative from Cephalon may provide a presentation at a content development meeting at the request of the provider, or may respond to specific questions at such meeting regarding the results of a Cephalon-sponsored research study, provided the information presented conforms to the generally accepted standards of experimental design, data collection and analysis, and provided any presentation is accompanied by a detailed outline of the presentation, which can be used by the IEP Provider/Educational Partner to confirm the scientific objectivity of the presentation.
- (c) If the IEP Provider, in its sole discretion, requests a Cephalon medical representative to review the Program for medical accuracy and completeness, Cephalon will comply with such request. The parties acknowledge there is no obligation or any condition requiring IEP Provider to make such a request. Any such request must be made after the Program materials are fully developed and such request must be made by the IEP Provider only to a Cephalon medical representative that has responsibility for the therapeutic area that will be covered by the Program. IEP Provider will not ask any marketing or sales representatives at Cephalon to comment on the material. All final decisions regarding whether to modify the material based on any comments provided by the Cephalon medical representative shall be in the sole discretion of IEP Provider.
- (d) If a product marketed by Cephalon is the subject of discussion, the data will be objectively selected and presented, with an accurate reflection of favorable and unfavorable information about the product and shall also include a balanced discussion of prevailing information on alternative products and /or therapies.
- (e) Any suggestions of superiority of one product or treatment over another will be supported by the body of available data, and will not result from selective presentation or emphasis on data favorable to particular treatment.
- (f) IEP Provider represents that neither it nor the Educational Partner (if any) has either an open complaint or decision from the ACCME or the Food and Drug Administration that a program provided by the IEP Provider or





the Educational Partner failed to meet standards of independence, balance, objectivity, or scientific rigor.

9. Risk Minimization Action Plan. Cephalon provides the following Risk Minimization Action Plan ("RiskMAP") information to all IEP Providers. Neither Cephalon nor its agents shall influence or control whether a product marketed by Cephalon is the subject of discussion. A RiskMAP is a strategic safety program designed to meet specific goals and objectives in minimizing known risks of a product while preserving its benefits. Any product marketed by Cephalon that is approved with a RiskMAP, and the key safety-related health outcomes outlined in that RiskMAP, are listed in Exhibit B. IEP Provider agrees that it is aware of the RiskMAP(s) and the key safety messages.
10. Faculty Selection. IEP Provider shall retain full responsibility for the selection of the presenters, authors, moderators, and/or other faculty (hereinafter referred to collectively as "Faculty"). Cephalon, through its Scientific Communications Department, may respond only to IEP Provider-initiated, written requests (or requests from the Educational Partner) for suggestions of Faculty or sources of possible Faculty. In response to such requests at least three (3) names will be suggested (if possible) for each open position and this information will be provided in writing. IEP Provider will record the role of Cephalon in suggesting Faculty; will seek suggestions from other sources; and will make its selection of Faculty based on objective criteria. IEP Provider shall not be obligated to request or accept such assistance from Cephalon or its agents as a condition of receiving the educational grant hereunder.
11. Disclosures. IEP Provider will ensure meaningful disclosure of limitations of data (e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion). IEP Provider will require that Faculty disclose when a product is not approved in the United States for the use under discussion.
12. Question and Answer Session. To the extent the Program is a presentation, IEP Provider will ensure meaningful opportunities for questioning by the audience.
13. Financial Relationships. IEP Provider will ensure meaningful disclosure to the audience of Cephalon funding and any significant relationship between individual Faculty and Cephalon. All meaningful disclosure(s) shall also be made in any written materials, including but not limited to announcements, brochures, syllabi and enduring material. Disclosures shall not mention product trade names.
14. Metrics/Copies of Program Material.
  - (a) IEP Provider and/or Educational Partner shall provide certain outcome measurements and metrics to Cephalon as requested by the Scientific Communications Department. Such metrics shall be provided either after the conclusion of a single live event or monthly for a year-long accredited program and may at Cephalon's request include the number of program participants, number of certifications, assessment of the program and faculty, and demonstration of learning by program participants.



- (b) After the Program has occurred, IEP Provider shall provide Cephalon with 1 copy of all Program materials in CD ROM or electronic format and 50 copies in print format.

15. Representations and Warranties. IEP Provider represents that:

- (a) Neither it nor the Educational Partner, if any, provides marketing, advertising, public relations, market research, medical education services or other consulting services (e.g., support for advisory boards) to any other department within Cephalon ("Marketing Activities");
- (b) If IEP Provider or the Educational Partner has an affiliated company that provides Marketing Activities to Cephalon, IEP Provider has instituted appropriate controls and safeguards to ensure the Program (i) remains independent, objective, balanced and scientifically rigorous, (ii) is not intended to promote a Cephalon product directly or indirectly, and (iii) is not in any way biased due to the affiliated company's relationship with Cephalon;
- (c) IEP has determined that it is appropriate to use the Educational Partner in light of the requirements under this Agreement; and
- (d) If IEP Provider or its Educational Partner employs a former Cephalon employee who worked at Cephalon anytime during the most recent year and who had marketing responsibility in the therapeutic area that will be covered by the Program, then that former employee will not have any role in the planning, development or delivery of the Program.

16. Invitations/Enduring Materials. The Program audience will be selected by the IEP Provider. The IEP Provider shall be responsible for distributing materials about the Program, including invitations, reminder notices, and business reply cards that can be used by third parties to obtain any enduring Program material from the IEP Provider.

17. Ancillary Promotional Activities. To the extent the Program is a live presentation, no promotional activities or product advertisements will be permitted in the same room as or in an oblique path to the Program. If the Program is a teleconference or webcast, no product advertisements or promotional activities will be permitted immediately prior to, during, or immediately after the delivery of the Program. If the Program is in print format, no product advertisements or promotional materials will be interleaved within the pages of the Program. If the Program is made available electronically, no product advertisements or promotional materials will appear within the Program material or interleaved between computer windows or screens of the Program

18. Compliance with Guidelines. IEP Provider represents that the Program, including development of the Program and Program materials, shall conform to the American Medical Association ("AMA") Guidelines on Gifts to Physicians, the



AMA Ethical Opinion on Continuing Medical Education, the ACCME Standards for Commercial Support, the FDA December 3, 1997 Final Guidance for Industry-Supported Scientific and Educational Activities, and the Pharmaceutical Research and Manufacturers Association ("PhRMA") Code on Interactions with Healthcare Professionals.

19. Logistical Status Reports. IEP Provider and/or Educational Partner shall provide periodic reports to Cephalon regarding the management and logistics of program components.

20. Miscellaneous.

- (a) No party shall use the other party's or its affiliates' name or trademarks for publicity or advertising purposes, except with the prior written consent of the other party.
- (b) IEP Provider agrees to obtain all consents, authorizations, approvals and releases that may be necessary for the production of the Program and of any written materials prepared in connection therewith. IEP Provider agrees to indemnify Cephalon with respect to any claims, actions or demands, including reasonable attorneys' fees that may arise in any manner out of IEP Provider's failure to secure such consents, authorizations, approvals or releases.
- (c) No term, condition or other provision of any attachment or addendum to this Agreement shall supersede any term, condition or other provision of this Agreement and with respect to any inconsistency or ambiguity, the Agreement shall control.

[THE REMAINDER OF THIS PAGE IS INTENTIONALLY LEFT BLANK.]



IN WITNESS WHEREOF, the parties, by their duly authorized representatives, agree to comply with all the terms and conditions of this Agreement.

**MEDICAL LEARNING SOLUTIONS, INC.**

By: *Sheri L. Gavinski*  
 Name: *Sheri L. Gavinski*  
 Title: *President*

The above signatory is a duly authorized corporate officer of the IEP Provider.

Date: *August 24, 2007*

Tax ID #: *90035153*

**MEDICOM WORLDWIDE, INC.**

By: *Joan Meyer*  
 Name: *JOAN MEYER*  
 Title: *President*

The above signatory is a duly authorized corporate officer of the Educational Partner.

Date: *8-24-07*

Tax ID #: *23- 3063738*

**CEPHALON, INC.**

By: *Rod J. Hughes*  
 Name: *Rod J. Hughes, Ph.D.*  
 Title: *Vice President, Scientific Communications*

Date:





Exhibit A  
Copy of Grant Request



101 Washington Street  
Morrisville, Pennsylvania 19067  
Phone 215.337.6103  
Fax 215.337.0960

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101 Washington Street  
Morrisville, Pennsylvania 19067  
Phone 215.337.6103  
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July 5, 2007

Bhaval Shah-Bell, PhD  
Cephalon, Inc.  
41 Moores Road  
Frazer, PA 19355

Dear Dr. Shah-Bell:

Medical Learning Solutions, Inc. has recently completed a comprehensive needs assessment to identify the educational needs of clinicians who provide care to patients with chronic pain. This needs assessment was compiled from the following sources:

- Analysis of utilization data for the Emerging Solutions in Pain web site
- Clinical advisory review
- Evaluation summaries of completed and ongoing 2007 Emerging Solutions in Pain programs and activities
- Literature search

Based on the identified educational need, Medical Learning Solutions is requesting an educational grant from Cephalon, Inc. to support the continuation and further development of the **Emerging Solutions in Pain**, or **ESP**, initiatives. This will include the continuation of selected **ESP** programs that initially launched in 2006 and 2007, as well as a faculty advisory board meeting and the development and production of the **ESP** Tool Kit Volume II, as foundation tactics that require updating to provide the most current and relevant information and resources to clinicians who treat patients with chronic pain. The **ESP** initiatives will continue to focus on balancing the clinical need to provide adequate analgesia to patients with chronic pain with the legal and societal need to monitor for potential issues of abuse, addiction and diversion of controlled substances.

These activities will be designed and planned as follows:

- The Emerging Solutions in Pain Web Site
  - Site Management
  - Membership Management
  - Clinical Expert Commentaries
  - In the Know Summaries
  - In the News Feature
  - Web Resources and Links
  - Ask the Experts Column
  - State Your Case Column
  - Quarterly Electronic Journal Club
- Emerging Solutions in Pain Foundation Initiatives
  - The 2007/2008 Faculty Advisory Board Meeting
  - The Emerging Solutions in Pain Tool Kit, Volume II
- Emerging Solutions in Pain Awareness Building Initiatives
  - The Beacon e-Newsletter
  - The ESP Scholarship Fund
  - The 2008 Awareness Campaign
- Print-based Tactics
  - *Practical Pain Management* Monograph Series





101 Washington Street  
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- 2007 Monograph Collection
- Emerging Solutions in Pain Exhibition Booth Series

The budget to fund these activities is approximately \$1,829,504. Please refer to the detailed budget section of this proposal for complete grant funding proposals. These scientific events will comply with all ACCME, FDA, AMA, and ACPE regulations for industry-supported professional continuing education.

MLS will work with MediCom Worldwide, Inc., a third party CE vendor, in the planning, execution and development of the accredited activities associated with the **ESP** initiatives. MediCom Worldwide is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians and is approved by the Accreditation Council for Pharmacy Education to provide pharmacy continuing education, as well as an approved provider of nursing continuing education through the California State Board of Registered Nursing.

Thank you in advance for your consideration of this request.

Respectfully,

A handwritten signature in cursive script, appearing to read 'Sheri L. Gavinski'.

Sheri L. Gavinski  
President,  
Medical Learning Solutions, Inc.



## ***2008 Emerging Solutions in Pain Educational Needs Assessment***

### **Current Clinical Environment Demonstrates an Educational Need**

#### ***Under-Prescribing of Pain Continues While Prescription Drug Abuse Is Increasing***

Chronic pain is one of the most frequently reported reasons for visits to health care providers.<sup>1,2</sup> A recent survey demonstrated that the average number of patients with moderate-to-severe chronic pain who sought care from a palliative care physician was 94.2 per month, with 44.7 patients per month seeking care from primary care physicians for pain management.<sup>2</sup> Another survey reported that almost 40% of adult patients attending primary care community clinics presented with complaints of pain.<sup>3</sup> When asked to evaluate the success of their efforts to manage chronic pain, *68% of physicians acknowledged that their management efforts are inadequate and 60% expressed the belief that physician education about effective strategies for pain control would improve their efforts to effectively control the pain experienced by their patients.*<sup>2</sup> When asked about the primary factors that contributed to sub-optimal pain management were reluctance to prescribe opioid analgesics for non-cancer related pain, 35% of these respondents indicated that they would never prescribe an opioid for non-cancer related pain of any degree of severity. *Concerns about addiction and side-effects, as well as about polypharmacy for patients with comorbid conditions and the potential for drug-drug interactions were also barriers to use of opioids for pain management.*<sup>1,2</sup>

Yet, in contrast to these reports of under-prescribing, recent data demonstrate that, as opioids and other analgesics recognized as addictive are increasingly prescribed for patients without cancer pain, the rate of misuse of these medicinal drugs is on the rise. In 2002, 4 to 6 million patients in the United States were receiving long-term opioid therapy and 12% of all medications prescribed during ambulatory office visits were opioids.<sup>4</sup> A 2005 survey by the Substance Abuse and Mental Health Services Administration (SAMHSA) *reported that 56% more Americans abuse opioid prescription drugs than abuse cocaine, heroin, hallucinogens, and inhalants combined.*<sup>5</sup> These activities have created a serious public health problem, as evidenced by the following reported data collected by the National Center on Addiction and Substance Abuse (NCASC) from 1992 to 2003.<sup>6</sup>

- The number of Americans abusing drugs increased by 94%<sup>6</sup>
- Abuse by children, ages 12-17, increased by 212%<sup>6</sup>
- A 542% increase in addiction to prescribed opioids alone was also reported<sup>6</sup>

Data from multiple sources support the important results of the NCASC survey. Surveys conducted by SAMSHA for the *2005 National Household Survey on Drug Use and Health (NSDUH)* indicate significant increases in reported misuse.<sup>5,7</sup>

- 112 million Americans age 12 or older (46% of the population) reported illicit drug use at least once in their lifetime
- 14% reported use of a drug within the past year
- 8% reported use of a drug within the past month.

In addition, the 2006 Denver Health's Researched Abuse, Diversion, and Addiction-related Surveillance (RADARS®) have reported data collected pertaining to the diversion of prescribed drugs.<sup>8</sup> The 2006 RADARS report indicated that prescription drug abuse impacts every state, with abuse more prevalent in suburban and rural area than inner cities. When RADARS conducted a nationwide analysis of 2006 data on abuse, misuse and diversion of prescription opioids, 93 percent of reporting three-digit ZIP codes had at least one case of prescription drug abuse, misuse or diversion to the black market in 2006.



## 2008 Emerging Solutions in Pain Educational Needs Assessment

**Figure 1. 2006 RADAR Reporting**

2006 Prescription Drug Abuse or Diversion Cases  
Reported to RADARS System (shaded red)



[http://www.radars.org/Portals/1/RADARS%20release\\_05-22-2007\\_Complete%20Document\\_8.pdf](http://www.radars.org/Portals/1/RADARS%20release_05-22-2007_Complete%20Document_8.pdf)

Unfortunately, the link between the increase in opioid prescribing for pain and the increasing rates of opioid abuse is not clear. Physicians often perceive that they have little or no control over how patients use prescriptions once patients leave the office, and *data from the National Survey on Drug Use and Health suggest that only 14% of opioid misusers obtained their drugs from a physician*. More than half of all people who misuse prescription pain relievers obtain the drugs from a friend or relative, and another one-third obtain them from such sources as drug dealers or the Internet.<sup>5</sup> This information may be interpreted to mean that comprehensive and risk-contained patient management may need to include not only the patient, but family members or those who reside with or support the healthcare of the patient. It may also be interpreted that some patients may be ineffectively treated and are seeking drugs from other sources to alleviate pain. Either scenario suggests that prescribers and patients need to be better informed to recognize aberrant behaviors, improve communications, improve pain assessment, and increase knowledge of appropriate and effective pharmacotherapies.

### **Governmental and Regulatory Responses to Prescription Drug Abuse Data**

The data from these various surveys and reports are currently being translated into guidance and recommendations from governmental agencies involved either directly or peripherally in the prescribing of controlled substances. In a 2004 White House press release related to National Drug Control Strategy, for example, the following guidance was issued: *"Physicians must perform risk assessments on patients at risk for potential abuse. This is particularly true for patients entering opiate therapy for chronic pain."*<sup>9</sup> In April 2003, The Federation of State Medical Boards of the United State, Inc., called upon their membership for an update to its *Model Policy for the Use of Controlled Substances for the Treatment of Pain*. The goal of the revised model policy is to provide state medical boards with an updated template regarding appropriate pain management in compliance with applicable state and federal laws and regulations.<sup>10</sup> The basis of the Policy is described verbatim, as follows<sup>10</sup>:

"The *Model Policy* is designed to communicate certain messages to licensees: that the state medical board views pain management to be important and integral to the practice of medicine; that opioid analgesics may be necessary for the relief of pain; that the use of opioids for other than legitimate medical purposes pose a threat the individual and society; that physicians have a responsibility to minimize the potential for the abuse and diversion of controlled substances; and that physicians will not be sanctioned solely for prescribing opioid analgesics for legitimate medical purposes. In addition, this policy is not mean to constrain or dictate medical decision-making."



## **2008 Emerging Solutions in Pain Educational Needs Assessment**

The policy went on to express the following:

*"Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction."*<sup>10</sup>

The Policy offers the following practice-based guidance to physicians who prescribe controlled substances for the treatment of chronic pain<sup>10</sup>:

- Complete patient evaluation
- Written treatment plan
- Informed patient consent and agreement for treatment
- Periodic review of the course of treatment
- Willingness to refer
- Maintenance of complete and current medical record

Similarly, the Drug Enforcement Agency (DEA) continues to update its position concerning opioids and prescription drug abuse. The DEA released their final policy statement in September of 2006, which offered the following edict:

*"As a condition of being a DEA registrant, a physician has a responsibility to exercise a much greater degree of oversight to prevent diversion and abuse in the case of a known or suspected addict than in the case of a patient for whom there are no indicators of drug abuse. Under no circumstances may a physician dispense controlled substances with the knowledge they will be used for a nonmedical purpose or that they will be resold by the patient. Some physicians who treat patients having a history of drug abuse require each patient to sign a contract agreeing to certain terms designed to prevent diversion and abuse, such as periodic urinalysis. While such measures are not mandated by the CSA or DEA regulations, they can be very useful."*<sup>11</sup>

### **Clinical Expert Opinion Concerning the Challenges of Opioids and Addiction**

At the 2007 National Institutes of Health Drug Abuse Conference on Pain, Opioids, and Addiction, experts in pain and addiction management discussed ways to reduce prescription pain-killer misuse without causing undertreatment of pain, emphasizing the need for better use of available information to guide prescribing and novel approaches to block medication misuse. *"The abuse of opiate analgesics is an urgent issue. But the fact that these medications have the potential to produce addiction in no way decreases their value. The challenge comes in terms of understanding better the risks for becoming addicted ... and minimizing these risks."* said Nora Volkow, MD, Director of the National Institutes on Drug Abuse.<sup>12</sup>

The 7<sup>th</sup> Annual International Conference on Pain and Chemical Dependency was held in New York City, June 21-24, 2007. The entire conference was devoted to educating clinicians about improved pain management practice methodologies designed to contain risk for their patients, for themselves and for their practice related to the prescribing and use of opioids. The following is a quote from the Chairman of the conference, Dr. Russell Portenoy:



## **2008 Emerging Solutions in Pain Educational Needs Assessment**

*"It is a challenging era: increasing recognition of the potential benefits of opioid therapy for chronic pain, but great concern about the rising toll of prescription drug abuse; increasing fear about the intrusion of regulators and law enforcement into clinical practice, but more willingness to seek balance between medicine and drug control policies for the public good; and increasing complexity of both pain medicine and addiction medicine, but efforts in each field to reach out to the other. In such an era, a timely conference devoted to best practices and evidence at the interface between pain and chemical dependency is of great utility to clinicians of every type."*

*--Russell Portenoy, MD, 2007<sup>13</sup>*

In addition to the past 12-months of *In the Know* reviews at the Emerging Solutions in Pain web site, a search of recently published literature demonstrates numerous publications that support the need to educate physicians regarding improved understanding of controlled substance pharmacotherapy,<sup>28-32</sup> improved understanding and use of validated, appropriate pain and risk assessment techniques / tools / markers,<sup>33-40</sup> improved and frequent patient monitoring,<sup>15,41,42</sup> and application of best-practice risk containment.<sup>3,16,43-47</sup> An excerpt taken directly from a 2007 abstract, *National Drug Control Policy and Prescription Drug Abuse: Facts and Fallacies* by Dr. Laxmaiah Manchikanti states:

*"The multiple reasons for continued escalation of prescription drug abuse and overuse are lack of education among all segments including physicians, pharmacists, and the public; ineffective and incoherent prescription monitoring programs with lack of funding for a national prescription monitoring program NASPER; and a reactive approach on behalf of numerous agencies."<sup>14</sup>*

Another excerpt from a 2007 abstract reporting on a questionnaire study of physician's knowledge related to urine drug testing (UDT), states the following:

*"Physicians who employ UDT to monitor patients receiving chronic opioid therapy are not proficient in test interpretation. This study highlights the need for improved physician education; it is imperative for physicians to work closely with certified laboratory professionals when ordering and interpreting these tests."<sup>15</sup>*

Another published 2006 report of survey results of physicians (n=248) on the use of opioids in chronic pain yielded this conclusion:

*"The survey suggests physicians are concerned about drug abuse, addiction, adverse effects, tolerance, and medication interaction. Their comfort level in prescribing opioids varies with the patient characteristics. Urine toxicology testing is underutilized...."<sup>16</sup>*





## ***2008 Emerging Solutions in Pain Educational Needs Assessment***

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### **The Emerging Solutions in Pain Educational Initiative: Fulfilling an Educational Need**

#### **The Emerging Solutions in Pain Mission Statement**

**Emerging Solutions in Pain (ESP)** is an ongoing educational initiative developed to address some of today's most critical issues in pain management. These issues involve balancing fundamental rights of patients and clinicians with the challenge of risk containment for opioid misuse, abuse and addiction associated with medical prescribing and use of controlled substances. Through evidence-based scientific data, validated tools, and the expertise of a cadre of leading pain and addiction medicine experts, the ESP program provides clinicians with guidance in the implementation of best practice management techniques. Site features and programs emphasize favorable interaction with regulatory and law enforcement agencies, as well as effective assessment, monitoring and documentation strategies; all of which contribute to the overall goal of optimizing outcomes for patients in pain.

#### **Global Educational Objectives**

In 2008, Emerging Solutions in Pain will continue to create educational tools, resources and activities that support the goals and objectives outlined by the ESP Mission Statement. These global objectives are designed to fulfill the educational needs of clinicians who provide care to patients with chronic pain, and include the following:

- (1) Educate clinicians on practices, techniques and tools that support safe and effective prescribing of opioids
- (2) Increase clinician understanding of best practices associated with minimization of the risk of opioid misuse, abuse and addiction
- (3) Develop educational tools and resources that support appropriate risk assessment, effective ongoing monitoring programs and documentation strategies for patients who are prescribed opioids
- (4) Educate clinicians on the guidelines and federal and state regulations pertaining to the prescribing of controlled substances

#### **Intended Audience and the Ongoing Need for Awareness Building Activities**

The Emerging Solutions in Pain (ESP) initiatives were launched in 2005 with the goal of providing education, tools and resources to clinicians that support safe and effective prescribing of opioids while minimizing the risk potential of opioid misuse, abuse and addiction. While awareness among health care professionals of Emerging Solutions in Pain as a critical resource in the field of pain management is increasing, as measured through increased utilization of the ESP web site and other ESP programs, the data detailed above also supports the ongoing need for awareness-building initiatives among the intended audience of key clinician groups. These groups include, but are not limited to, the following:

- (1) Pain specialists, addictionologists and other physicians who are not yet members of the ESP web site
- (2) Non-physician members of the pain management community, e.g., nurses, physician assistants, pharmacists
- (3) Residents and fellows who have an interest in treating pain as part of their studies
- (4) Pain specialists, addictionologists and other physician and non-physician members of Emerging Solutions in Pain who are not regular users of the resources, tools and information available through the ESP initiative



## ***2008 Emerging Solutions in Pain Educational Needs Assessment***

### **The Emerging Solutions in Pain Web Site**

One of the foundations of ESP is the Emerging Solutions in Pain web site, which is a repository for all information produced, developed or deployed through any ESP activity. This clinical site requires membership to access many of the information, tools and resources housed within, which allows Medical Learning Solutions to monitor utilization on both global and individual tool scales.

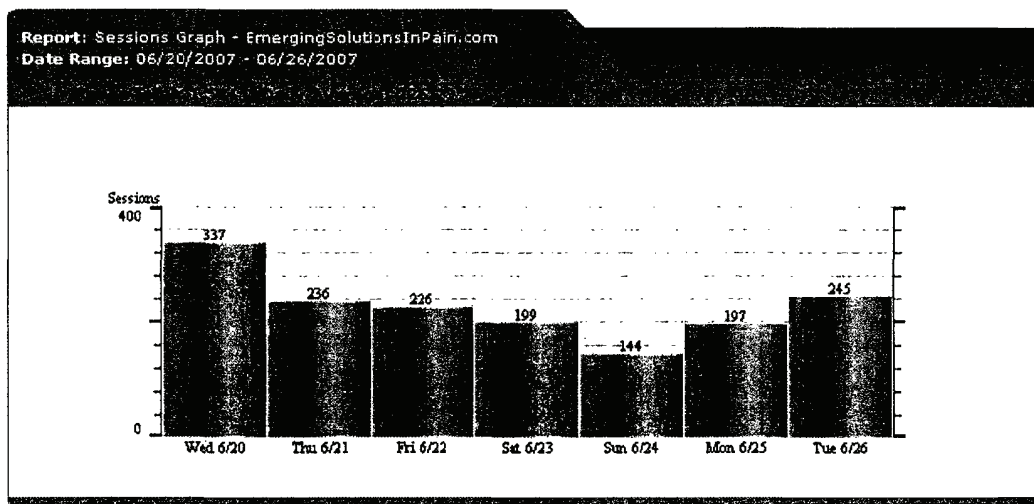
An analysis of the frequency, depth and usage of the global web site is a strong indicator that clinicians are actively in need of the information, tools and resources produced through the ESP initiatives.

	Feb 1, 2005 – Apr 30, 2007	Jan 1, 2007 – Apr 30, 2007	Percent Increase: Last 4 Months vs Last 27 Months
Frequency, Measured by Number of User Sessions	60,827	20,419	33%
Depth, Measured by Number of Hits	3,460,797	903,725	26%
Usage, Measured by Average Bytes Transferred Per Day	264.08 MB	493.43 MB	186%

The significant growth of frequency, depth and usage in the last four months supports the ongoing need of clinicians who treat patients with chronic pain for education, information, tools and resources that support minimizing risk of opioid misuse, abuse and addiction. This data also demonstrates and validates the utility and degree of use of the pain management practice tools, continuing-education activities, and expert guidance that comprise the comprehensive ESP initiative.

Further analysis of session data indicates the strong upward trend of frequency, again supporting the ongoing educational need for programs and activities that support safe and effective prescribing of opioids.

### *Daily Sessions*



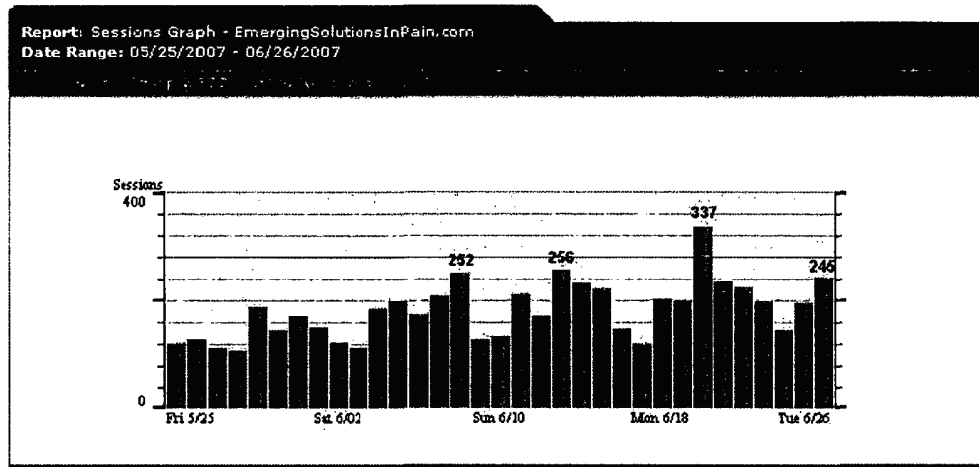




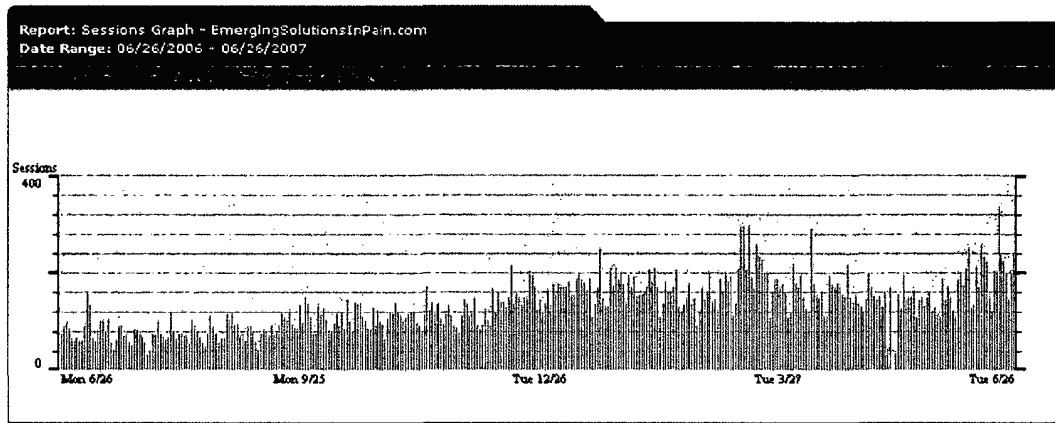
## 2008 Emerging Solutions in Pain Educational Needs Assessment

In the daily session graph, note the average number of sessions per day is more than 262. Of note, the average length per session is significantly over 7 minutes, which reflects an approximate 75% increase over session length from the similar time period in 2006. Similar upward utilization trends are seen in the monthly and yearly session charts, shown below.

### Monthly Sessions



### Yearly Sessions



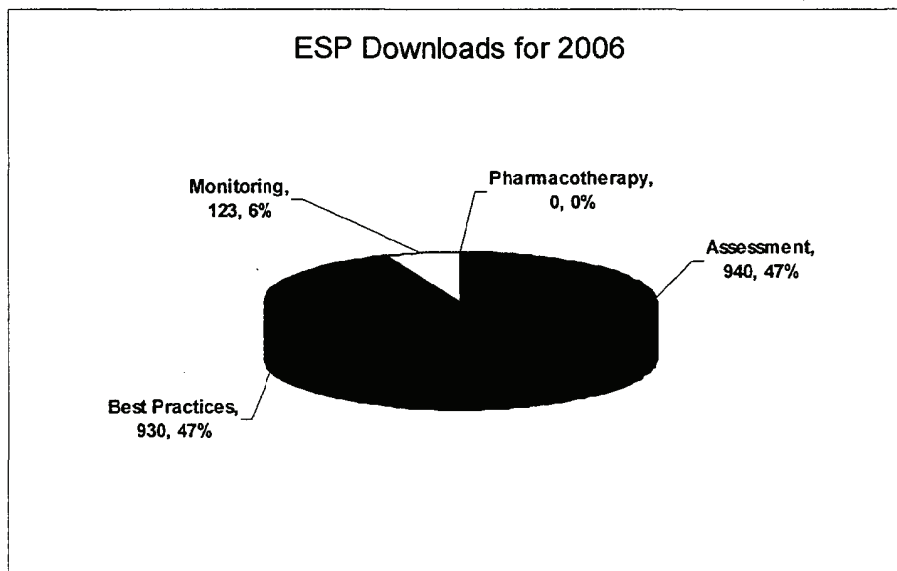
The content for ESP was selected, developed and designed specifically to fulfill the dynamic educational needs of practitioners associated with pain management many of whom prescribe controlled substance therapies. The four primary areas of ESP content are: **Pharmacotherapy, Assessment, Monitoring and Best Practices**. It is clear from the data below summarizing page-views and downloads across these areas that these primary areas of content are not only most frequently accessed, but in both 2006 and



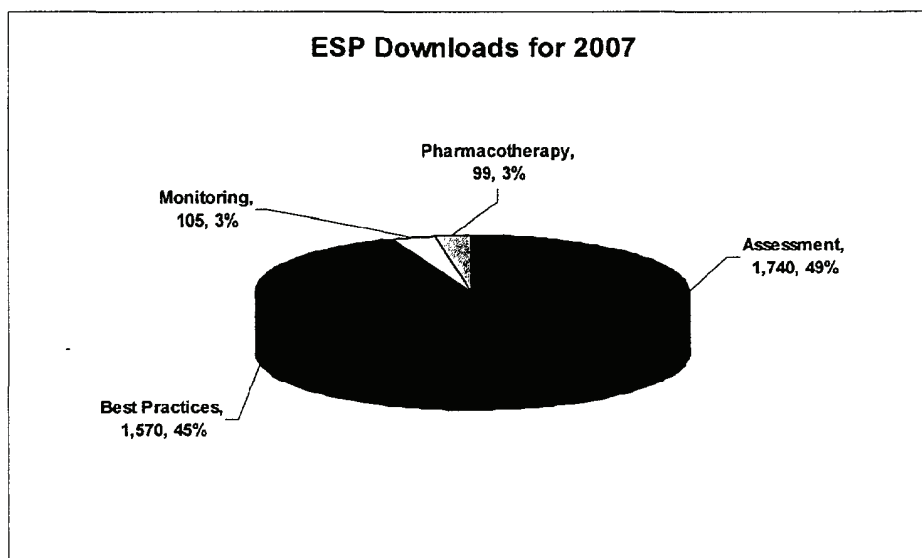
## ***2008 Emerging Solutions in Pain Educational Needs Assessment***

2007, these percentages of users demonstrate a consistent need, especially in the areas of pain management and risk assessment, and best practice.

**Figures 1A, 1B. Annual Usage Percent-2007; 2006: PDF Selections per Topic Area<sup>17</sup>**



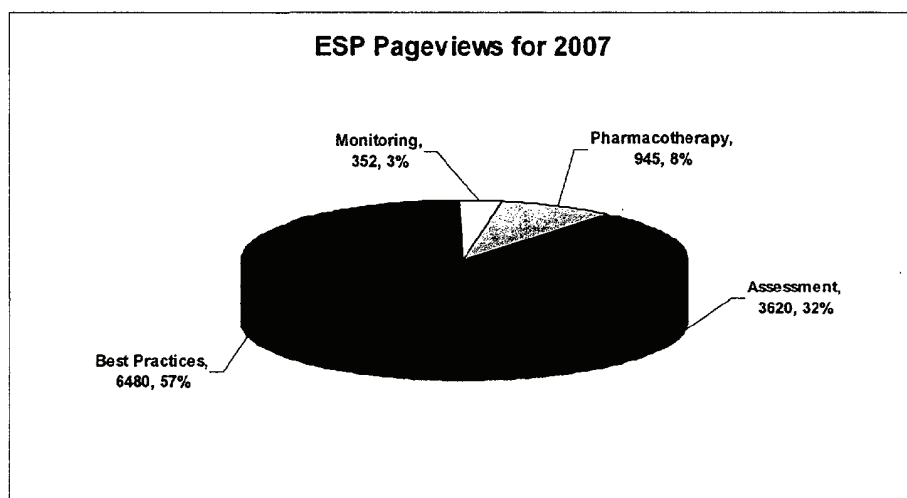
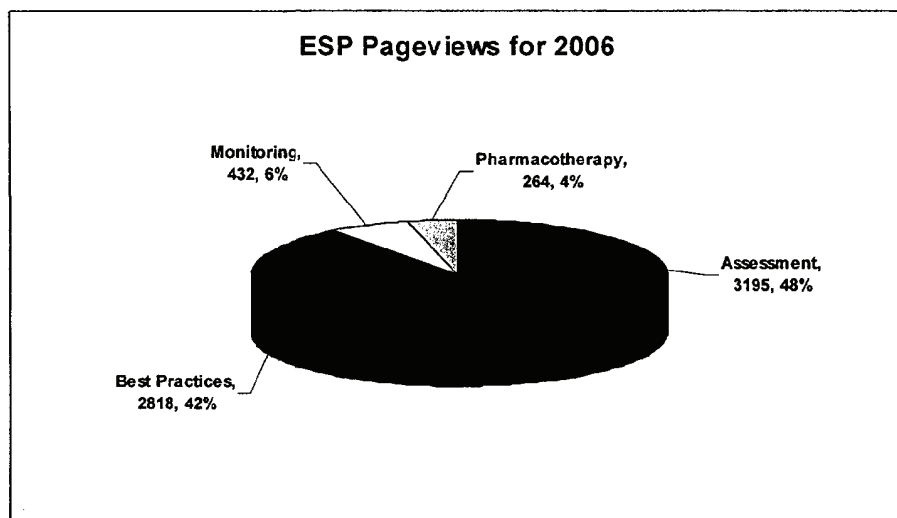
*\*Note that no programs were available for download in the pharmacotherapy section of the ESP website in 2006.*





## ***2008 Emerging Solutions in Pain Educational Needs Assessment***

Figures 2A, 2B. Percentage of User Page-views per Topic Area, 2006; 2007<sup>18</sup>





## **2008 Emerging Solutions in Pain Educational Needs Assessment**

These graphs summarize extensive data pertaining to the view of individual tools, resources and education on the ESP web site. Of members visiting the ESP site, the most common page categories which were viewed included the following:

<b>Page(s)</b>	<b>Views Between Jan 1 and Apr 30, 2007</b>
The Emerging Solutions in Pain Tool Kit	6,516 views
Continuing Education Programs	3,882 views
Clinical Expert Commentaries	2,718 views

The following tools were the 11 most frequently downloaded from the ESP web site between January 1 and April 30, 2007, with number of downloads provided in the right column. The distribution of content of these downloads indicates significant concern and need on the part of clinicians for further education, tools and resources in the areas of opioid prescribing and use, pain and risk assessment, and regulations and guidelines pertaining to controlled substances.

Acute Pain Analgesic Ladder	410
Equianalgesic Dosing Chart	355
Numeric Assessment Scale	189
Faces of Pain Assessment Scale	186
Opioid therapy for chronic nonmalignant pain clinician's perspective. <i>J Law Med Ethics</i> . 1996;24(4):296-309. Portenoy RK.	137
Model Policy for the Use of Controlled Substances for the Treatment of Pain. Copyright May 1998 by the Federation of State Medical Boards of the United States, Inc.	134
From Confrontation to Collaboration: Collegial Accountability and the Expanding Role of Pharmacists in the Management of Pain. <i>J Law Med Ethics</i> . 2001;29(1):69-93. Brushwood DB.	126
Controlled substances and pain management regulatory oversight, formularies, and cost decisions. <i>J Law Med Ethics</i> . 1996;24(4):210-316. Pisano DJ.	100
The Opioid Risk Tool (ORT) Patient Form	96
The Opioid Risk Tool (ORT) Clinical Form	84
Achieving the Right Balance in Oversight of Physician opioid prescribing for pain: The role of State Medical Boards. <i>J Law Med Ethics</i> . 2003;31(1):21-40. Hoffmann DE, Tarzian AJ.	81



## **2008 Emerging Solutions in Pain Educational Needs Assessment**

### **Results from the 2006/2007 ESP Accredited Monograph Series in *Practical Pain Management Journal* (Please refer to Appendix A for additional supportive monograph data)**

The Emerging Solutions in Pain Accredited Monograph Series was initiated in 2006; a total of 12 accredited articles will be released in this Series through December, 2007. The monographs in this series have addressed a diverse collection of topics in pain management and addiction medicine, including:

- Determining the Risk of Opioid Abuse
- The Connection Between Cigarette Smoking and Aberrant Drug-Taking Behavior in Opioid Therapy for Chronic Pain
- VIGIL: A Five-Step Process Approach to Opioid Prescribing and Dispensing
- Relating Central Sensitization and Hyperalgesia to Opioid Pain Management and Preemptive Analgesia
- Pain Patients at Risk of Abuse and Those with Comorbid Psychopathology: A Guide to Identification and Treatment
- A Closer Look at Racial/Ethnic Disparities in Pain Management
- Evaluating Interdisciplinary Approaches to Chronic Pain Management
- What Role Does Age Play in the Management of Chronic Pain in Adult Patients?
- Treating Chronic Pain in the Shadow of Addiction

More than 3,962 clinicians have participated in the first nine issues of the monograph series, with average ratings for content and overall quality as 95% rating these two factors as either "Excellent" or "Good"; please refer to Appendix A, pages 77 – 78. In addition, access rates for each monograph when posted online are maintained at a continuous level for the subsequent 11 months, supporting the ongoing need for these educational activities.

The PPMJ monograph series has thus proven to be one of the most effective tactics of the ESP initiative. Presented are learners' post activity evaluations data derived from nine previously published PPMJ educational monographs. Categories addressed include: appraisal of content; format evaluation; assessment of satisfaction relative to stated educational learning objectives; and appraisal of utility of content relative to the learner's clinical practice needs.

Educational needs or successes demonstrated from resulting data include:

1. Subjects/topics of monographs are considered of valuable utility to the majority of clinical practitioners, with a range of 90%-100%. [All]
2. Areas demonstrating scores of  $\leq 7\%$  in the rating category of "fair" or "poor" may require additional education in order to present content in an alternate method to improve satisfaction of originally stated educational goals.
  - a. *Example:* 10% of participants evaluated content as fair in relationship to satisfying stated learning objectives. [Moskowitz]
  - b. *Example:* Assessment tools may be an area to increase educational concentration, as evidenced by 7% of participants stating the content did not adequately express the learning objective. [Webster]

The underlying message that may be interpreted from these data is that the monograph series is and continues to be a valuable educational resource to the majority of participating clinicians. As monograph topics are generally selected to support the mission of ESP, the cumulative quantitative and qualitative response from participants underscores the impact of this program and need for its continuance.



## ***2008 Emerging Solutions in Pain Educational Needs Assessment***

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### **ESP Advisor/Faculty Guidance**

Emerging Solutions in Pain was developed for physicians, pharmacists, nurses and other health care professionals through consultation with clinical experts in the fields of pain management and addiction medicine. Initial consultation occurred through two faculty advisory board meetings in November, 2003 and in May, 2004. These meetings resulted in the development of the Emerging Solutions Pain Tool Kit and all supporting tools and resources. A third faculty advisory board meeting occurred in January, 2006, which focused on faculty review of previous ESP initiatives and recommendations for future programs.

Ongoing faculty consultation and input is a key foundation of the Emerging Solutions in Pain initiatives, and is critical to the continued success of this initiative. As part of our research for developing the educational needs assessment for 2008, the ESP team interviewed several ESP initiative advisors and faculty to gain their strategic and tactical guidance. Summaries of their expert comments are listed below, assigned to specific ESP topics of pharmacology; assessment; monitoring; and best practice. Guidance was also provided that did not address any of the existing topics. These outlier suggestions pertained to areas of communication and controversies surrounding pain management and potential misuse issues.

### ***Pharmacology***

Several experts suggested greater inclusion of pharmacist-targeted programs to address dispensing issues surrounding opioid prescribing, the pharmacist as part of the interdisciplinary team, and assessment and monitoring practices. [Brushwood, Strickland; personal communications; Medical Learning Solutions; April 2007]

### ***Assessment and Monitoring***

Practitioners need additional education to support safe and effective prescribing of opioids, to include: proactive assessment and monitoring of sleep disorders and endocrinopathic effects. Both of these comorbid conditions may interfere with effective therapy and compromise goal attainment, especially related to functionality. [Webster, Shurman; personal communications; Medical Learning Solutions; April, 2007]

Hyperalgesia is a condition that may be identified and diagnosed through accurate assessment and monitoring. Not many practitioners understand hyperalgesia related to opioid therapy and its effects. [Passik; personal communications; Medical Learning Solutions; April 2007]

Documentation is critical. Various assessment and monitoring tools exist for practitioners to use that will help satisfy due diligence. Too many practitioners are unaware of these tools and many either do not use them or know how to use them effectively. [Bolen; personal communications; Medical Learning Solutions; April, 2007]

### ***Best Practice***

Clinicians need more information and tools related to legal, regulatory and ethical considerations and risk containment surrounding prescribed controlled substances; including abuse, misuse, addiction and diversion. [Brushwood, Shurman, Bolen, Webster; personal communications; Medical Learning Solutions; April, 2007]

Education related to a multi-or inter-disciplinary approach in pain management is needed by most clinicians for them to understand the shared-risk model of pain management and the associated beneficial outcomes affecting patient care. Tools, resources and education designed to support interdisciplinary communications is needed. [Brushwood, Strickland; personal communications, Medical Learning Solutions; April, 2007]



## ***2008 Emerging Solutions in Pain Educational Needs Assessment***

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Very little information is available and what exists is rarely discussed in regard to exit strategy for the non-compliant patient prescribed opioid therapy for pain. Prescribers need more information and tools designed to help them devise an ethical and clinically appropriate plan with their patient prior to therapeutic crisis. [Shurman; personal communications, Medical Learning Solutions; April, 2007]

Practitioners need to be aware and develop an improved appreciation for issues surrounding disparity in treatment of chronic pain. This includes, but is not limited to, age-discrimination, race and gender discrimination, and discrimination towards patients who are economically disadvantaged. [Vallerand; personal communications, Medical Learning Solutions; April, 2007]

### ***Communications/Communications Delivery***

Not only do practicing and seasoned pain management clinicians need education related to concepts related to pain management, but fellows and residents also need this information as a supplement to the standard curriculum, which is often weak in addressing these important topics. [Webster, Passik, Vallerand; personal communications, Medical Learning Solutions; April, 2007]

Clinicians need just-in-time or nano educational presentations of information; on-demand, tightly focused and in efficient, short-attention time frames (i.e. no longer than 30 minutes). Interactive, peer-to-peer learning and case-based communications is also needed and may be achieved via on-demand webcasts. Summaries of major meetings, list serves posted on the web for 24-7 accessibility is also a desire of most clinicians; as are e-mail notifications of clinically important issues (i.e. e-newsletters, e-mail announcements). [Webster, Passik, Vallerand; personal communications, Medical Learning Solutions; April, 2007]

### ***Controversies***

Many controversies exist related to issues in pain management. Practitioners need to hear an evidence-based dialogue relative to conflicting data and viewpoints. A point-counterpoint debate may be an excellent format to deliver this information meant to deepen awareness and provide clinical guidance. [Shurman; personal communications, Medical Learning Solutions; April, 2008]

The input and guidance of the Emerging Solutions in Pain Faculty Advisory Board has been critical in the identification of the educational needs of clinicians in the fields of pain management and addiction medicine, and in the development of all programs, tools and resources associated with Emerging Solutions in Pain. The series of interviews conducted with key ESP faculty resulting in the above guidance is invaluable; as detailed in the section of this grant proposal that focuses on the 2007/2008 Faculty Advisory Board Meeting, a meeting of current faculty will also be critical in the further identification and continuing development of relevant tools, activities and resources in the 2008 Emerging Solutions in Pain initiatives.

### ***The Emerging Solutions in Pain Tool Kit***

A fundamental example of the importance of faculty input and guidance to the Emerging Solutions in Pain initiatives is the ESP Tool Kit. The original Emerging Solutions in Pain Tool Kit was developed based on a series of Advisory Board meetings with clinical experts in the fields of pain management and addiction medicine in late 2003 and mid-2004. Based on the faculty guidance obtained at these meetings, the current structure and contents of the Tool Kit were identified and developed, as outlined below:

1. Introduction and Background
2. Assessment Module
  - a. Pain Assessment
  - b. Risk Assessment





## ***2008 Emerging Solutions in Pain Educational Needs Assessment***

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3. Monitoring Module
  - a. Return Visit Monitoring
  - b. Urine Drug Testing
4. Best Practices
  - a. Opioid Agreements
  - b. Federal and State Regulations
  - c. Effective Clinician/Pharmacist Interactions

The current ESP Tool Kit has been distributed, either via access on the Emerging Solutions in Pain web site or direct distribution of a multimedia CD-ROM, to approximately 48,000 clinicians. This trend in clinician accessing of the Tool Kit is occurs with relative continuity, with only small fluctuations in the distribution of the Tool Kit over time.

Since the original Tool Kit was finalized in 2004, multiple new, important developments have occurred in the fields of pain management and addiction medicine. These developments include, but are not limited to, critical changes in the Federal regulations pertaining to the prescribing of controlled substances and in the development and/or validation of new assessment tools. The current Tool Kit does not address or include these new developments and resources. In addition, as detailed above, statistics reflecting increasing amounts of prescription drug abuse and addiction in the United States clearly indicate the need for increased information, tools and resources that not only support appropriate clinician management of patients with chronic pain who are prescribed opioids, but also support safe and effective utilization of these agents that contributes to minimization of the risk of opioid misuse, abuse and addiction.

### **The Emerging Solutions in Pain Meet the Expert Exhibit Booth Series**

The Emerging Solutions in Pain Meet the Expert Exhibit Booth Series has been a key feature of the Emerging Solutions in Pain initiatives since the series was launched in February, 2005. In that time period, the ESP Booth has been exhibited at 18 national association meetings and congresses to date, with total exposure to more than 21,000 clinicians across all events, as measured by total meeting attendance. The Booth has been a key point of education concerning the mission, tools and resources of the ESP initiatives, and has been instrumental in recruiting more than 3,000 members to the ESP web site. In addition, more than 2,700 ESP Tool Kits and more than 3,000 ESP monographs have been distributed to clinicians through the deployment of the Meet the Expert Booth.

In addition to its function as a distribution point for key Emerging Solutions in Pain information and programs, the ESP Meet the Expert Booth is also a fundamental component in developing an interactive community among clinicians involved in the fields of pain management and/or addiction medicine, through the "Doctor Is In" function of the Booth. Through The Doctor Is In, ESP faculty members are present at scheduled times during exhibition hours, with the sole function of interacting with attendees of the meeting in an informal, one-on-one session. More than 17 ESP faculty members have successfully participated in this activity since the initial deployment of the Booth in February, 2005.

### **Chronic Pain: Trends in Increasing Prevalence Denote a Need for Continuing Education**

Chronic pain remains a significant challenge in the United States today; chronic pain is experienced by 50 million Americans and is the most common cause of medical visits and of long-term disability. One-third of Americans will experience chronic pain at some point in their lifetimes, with the burden of this condition anticipated to increase as the population ages and the incidence of chronic health conditions rises.<sup>1,19-24</sup> Cancer is a significant cause of pain and as patients survive cancer for longer periods of time. Today, 75% percent of children and two out of three adults will survive cancer, whereas 50 years ago just



## ***2008 Emerging Solutions in Pain Educational Needs Assessment***

one out of four survived; in many instances of long-term cancer survival, the pain associated with the disease evolves into a chronic pain state. Noncancer-related conditions such as back disorders, with low-back pain considered most prevalent, rheumatological conditions, neuropathies, degenerative joint disorders, cardiovascular disease, peripheral vascular disease, and other visceral conditions may also elicit chronic pain.<sup>1,19,21,23,25-27</sup> Current estimates suggest that only 25% to 40% of persons experiencing chronic pain achieve adequate pain management despite the fact that sufficient knowledge and resources are available to effectively manage pain in 90% of individuals with chronic pain.<sup>1,19,22</sup>

As chronic pain remains an increasing prevalent problem for our society, and as under-treatment of pain, and concerns over opioid prescribing remain consistent, it is clear that an educational gap exists for many clinicians who treat chronic pain. While a simplistic approach to these challenges is for physicians to choose simply not to prescribe opioids, opiophobia is not the answer. The solution lies in balancing pain management with recognition and management of inherent risks associated with opioid prescribing. Emerging Solutions in Pain has successfully developed, produced and implemented a significant number of educational activities, tools and resources for clinicians who treat chronic pain. Medical Learning Solutions is proposing, in this grant, to continue presentation of these critical resources, and thereby support the need to maximize treatment compliance, contain risk, improve care and affect therapeutic outcomes.

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**Note:**

Expert guidance statements were obtained via personal telephone conversations conducted by the internal MLS team members with faculty and advisors during the month of April, 2007.



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### 2008 ESP Budget Estimate: Summary

July 5, 2007

Category	Tactic	Estimated Costs	Notes
Web-Associated Tactics: Maintenance of Current Functionality	Site Management	\$ 72,713	Update of site infrastructure programming to reflect deployment of new educational content in multiple media types; management and analysis of site utilization data; hosting, co-location and maintenance/troubleshooting
	Membership Management	\$ 33,816	Development and maintenance of monthly and bi-monthly blast email campaigns to membership to increase awareness of new web features and resources; management and maintenance of member profiles
	Clinical Expert Commentaries	\$ 58,013	One clinical expert commentary per month
	In the Know	\$ 25,078	Journal article summaries: two abstracts per month
	In the News	\$ 4,866	Daily news feed of pain-focused news headlines
	Resources/Meetings and Events	\$ 10,865	Identification of base resources, links, suggested articles; updating of meetings and events page
	Ask the Experts	\$ 23,056	Column in which ESP members may submit questions to ESP faculty; MLS will coordinate audio recording and posting of faculty responses as MP3 files; 1 column per month, 9 columns total (April - December 2008)
	State Your Case	\$ 20,380	ESP member submission of cases with KOL review and commentary; 1 case study/quarter (Q3, Q4, 2008), 2 cases total
Foundation Initiatives	Electronic Journal Club	\$ 67,285	Web-based journal club with residents and fellows as target audience; 1 issue/quarter (Q3, Q4, 2008), 2 issues total
	Faculty Advisory Board Meeting	\$ 135,267	Meeting of ESP clinical experts and advisors to review current ESP initiatives and strategies and provide recommendations for future directions; review and revision of ESP Tool Kit Volume I for creation of ESP Tool Kit Volume II
	ESP Tool Kit Volume II	\$ 160,341	Update of current ESP Tool Kit (Volume I) to reflect information, tools and resources that have been developed/validated since original launch in February, 2005; update of all graphics and tools to 2007 ESP look/feel





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### 2008 ESP Budget Estimate: Summary

July 5, 2007

Category	Tactic	Estimated Costs	Notes
Awareness Building Initiatives	The Beacon e-Newsletter Series	\$ 86,320	Teaser E-mail newsletter that would link reader back to the web site for full copy
	ESP Scholarship Fund	\$ 34,460	Scholarship for residents, fellows and nurses; one scholarship awarded per major pain meeting; scholarship would include conference registration fees, airfare, hotel and small stipend; recipient will write abstracts of conference plenary sessions that can be posted on the ESP web site
	Awareness Campaign	\$ 104,200	Includes both print and banner advertisements
Print-based tactics	<i>Practical Pain Management Journal</i> Accredited Monograph Series	\$ 226,548	4 issues, each accredited for one hour; 8-page format
	2007 Monograph Collection	\$ 49,259	Accredited collection of the four issues of the 2007 PPMJ Accredited Monograph Series
Exhibit Booth	Booth maintenance, storage and general support	\$ 37,351	Includes storage of booth, new graphics as appropriate, updates to equipment and other support materials as needed
	20x20 Island Exhibit Booth, three meetings total	\$ 378,933	Final meeting schedule TBD
	10x20 Mini Exhibit Booth, four meetings total	\$ 300,754	Final meeting schedule TBD
<b>Total</b>		<b>\$ 1,829,504</b>	





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## ***Program Summary: The Emerging Solutions in Pain Website***

### **Program Title**

The Emerging Solutions in Pain Web Site

### **Program Overview**

The core educational component of the Emerging Solutions in Pain initiative is the web site [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com), which is a central repository for all programs, activities and resources developed in conjunction with the ESP initiative. By acting as a key point of distribution for the latest educational disease awareness information in the field of pain management, the ESP web site has become a fundamental resource to health care professionals in the field of pain management, as evidenced by 2006 – 2007 usage statistics presented in the Needs Assessment Section (pages 9 – 13). On the ESP web site, pain management specialists, addictionologists, nurses, pharmacists and residents/fellows may access an extensive array of educational information, resources and tools for assessing the potential for abuse, addiction and diversion in their patients with chronic pain, for monitoring their pain patients, and for accessing information regarding “best practices” in the long-term management of these patients.

Due to the increasing complexity of the Emerging Solutions in Pain web site, which reflects the complex and continually changing needs of health care professionals who provide care to patients with chronic pain, the site's three areas of core functionality will be addressed individually. These three areas are as follows:

- (1) Site and Member Management
- (2) Information Resources
- (3) Communication Resources

### ***Site, Member Management***

#### ***Budgets for site and member management attached, page 33 – 34***

One of the foundations of the Emerging Solutions in Pain web site is the requirement that registration is required to access much of the information available on the site. This requirement supports the concept that Emerging Solutions in Pain develops tools and resources solely for health care professionals, and does not provide any direct-to-patient information. Registration also enables tracking of information pertaining to member specialty and Tool use, and provides a method for updating site users with information regarding new programs and tools as they become available. Data management of member information and utilization tracking of individual tools, activities and resources will continue to be a critical function of the Emerging Solutions in Pain web site, as ongoing analysis of this information will support not only accurate assessment of the needs of health care professionals, but identification of the most needed tools and resources of this audience, as well.

In 2007, the Emerging Solutions in Pain web site was redesigned and re-launched, to increase engagement and utilization of tools and resources by both the new and returning user, and to ensure users may quickly and easily identify the information that is important to their own unique patients and practices. This redesign included the development of a new, streamlined navigation system that reflects the increasing complexity and depth of information available to registered members. In addition to the new navigation system, membership management features added to the ESP web site in 2007 that will continue to be available in 2008 include:

- (1) A new search function, which enables members to quickly and easily identify information and programs specific to their needs



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## ***Program Summary: The Emerging Solutions in Pain Website***

- (2) A member profile management system which allows for identification of preferences and favorite programs
- (3) Rotating "featured activities" call-outs to draw member attention to new programs and features of the web site
- (4) Increased member-only email communications to quickly and efficiently alert current and potential members of the newest functionality available at [EmergingSolutionsinPain.com](http://EmergingSolutionsinPain.com)

### ***Information Resources***

One of the fundamental goals of the Emerging Solutions in Pain web site is the development and dissemination of information, tools and resources to health care professionals who provide care to patients with chronic pain. These tools and resources are divided into three primary areas of information associated with minimizing the risk of opioid misuse, abuse and addiction; these areas are as follows:

- (1) Patient assessment, including assessment of a patient's potential risk for misuse, abuse or addiction of prescribed opioids
- (2) Ongoing monitoring and effective management of the chronic pain patient who is prescribed opioids and other controlled substances
- (3) "Best practice" information, associated with knowledge and information clinicians may utilize to safely and effectively prescribe opioids

The goal of the Information Resources on the ESP web site is to disseminate timely, relevant and accurate tools and resources in each of these three areas. The following Information Resources are currently available on the ESP website; based on analysis of current utilization, these resources should continue to be available to registered members through 2008:

- (1) *The Emerging Solutions in Pain Tool Kit*  
The Tool Kit, which is also available as a CD-ROM, is a collection of slide/audio presentations and downloadable, printer-friendly practical, educational tools and resources for use in clinical practice. It contains an extensive array of clinical tools that may be used to effectively assess a patient's pain as well as their potential for opioid misuse, abuse and addiction; to monitor the patient who is prescribed opioids; and to implement best practices in the management of patients with chronic pain. The current Emerging Solutions in Pain Tool Kit was developed in 2004; in 2008, Medical Learning Solutions is proposing to update necessary areas of content, such as those providing information on federal regulations pertaining to the prescribing of controlled substances, and to re-release the updated tools in the Emerging Solutions in Pain Tool Kit, Volume II (please refer to the Tool Kit Program Summary on pages 47 – 48)
- (2) *The Emerging Solutions in Pain Patient Education Tool Kit, a companion piece to the clinician Tool Kit outlined above*  
Based on feedback from ESP members and on interaction with health care professionals at live ESP events, Emerging Solutions in Pain will release a multimedia Patient Education Tool Kit in 2007, which will be distributed directly to health care professionals through the Emerging Solutions in Pain web site and at select ESP live activities through the latter half of 2007 and 2008. This collection of brief video modules and PDF handouts is intended to supplement and support clinician education of patients regarding the tools and resources currently available on the clinician Emerging Solutions in Pain Tool Kit.
- (3) *Continuing Education Programs and Activities*  
The Emerging Solutions in Pain web site is an important resource for clinicians who are interested in accredited programs and activities supporting safe and effective prescribing of opioids while minimizing the risk of opioid misuse, abuse and addiction. Each accredited



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## ***Program Summary: The Emerging Solutions in Pain Website***

activity on the ESP web site is available in multiple formats and/or viewing options, and each supports immediate printing of earned CE certificates. The accredited activities available at the ESP website include:

- a. Pain and Addiction 101, a five-part series of streaming video modules adapted from a 2006 full-day symposium focusing on issues at the interface of pain and addiction; audio-only and text formats are also available for this program
- b. The Emerging Solutions in Pain monograph series, including all PDFs of all print monographs published in the Practical Pain Management Journal
- c. Slide/audio case studies and vignettes that support each of the Emerging Solutions in Pain Tool Kit modules

### ***(4) Multimedia Knowledge Library***

The ESP multimedia Knowledge Library includes an extensive series of case studies, video clips and video-based FAQs that provide information for health care professionals who provide care to chronic pain patients. Topics addressed in the Knowledge Library include pharmacotherapy; assessment; abuse, misuse and addiction; best practices; and legal information.

### ***(5) Clinical Expert Commentaries***

#### ***Budget for ongoing development attached, page 35***

Each month, a different Emerging Solutions in Pain faculty member authors a new column in the ESP Clinical Expert Commentary series. Each Commentary addresses a topic associated with safe and effective prescribing of opioids and/or minimization of the risk of opioid misuse, abuse and addiction. To extend the reach of each installment in this series, each Commentary is archived upon release of the next column and is available for review by registered members. Prior to 2007, all Commentaries were available as text only; in 2007, the Clinical Expert Commentary series was expanded to reflect the diverse and differing learning preferences of the ESP membership through the addition of audio Commentaries and video Commentaries.

### ***(6) In the Know Series***

#### ***Budget for ongoing development attached, page 36***

The ESP In the Know series is a column that provides focused, easy-to-read summaries of relevant scientific articles published in peer-reviewed journals in the field of pain management. A new article is summarized every other week, with previous summaries archived for review by registered members.

### ***(7) In the News Feature***

#### ***Budget for ongoing development attached, page 37***

The ESP In the News series is a daily news feed of headlines and articles published online and in print in the field of pain management. The In the News feature is a real-time feed, and, as such, is updated throughout each 24-hour period.

### ***(8) Resources***

#### ***Budget for ongoing development attached, page 38***

The Resources section of the Emerging Solutions in Pain web site is a diverse collection of PDFs, articles and live links relevant to important information in the field of pain management. These include:

- a. Assessment tools available at the ESP web site include, but are not limited to, the Faces of Pain scale and the acute pain analgesic ladder



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## ***Program Summary: The Emerging Solutions in Pain Website***

- b. The Suggested Reading section includes a series of PDFs for numerous articles supporting safe and effective prescribing of pain management
- c. Links to online resources for information on government resources, legal resources and professional associations

### ***(9) ESP-related Live Events Information and Registration***

Members may view a schedule of upcoming ESP-related events. These events include national association meetings and congresses where the Meet the Expert Booth will be in attendance, as well as online registration for live peer-to-peer meetings that are part of the Emerging Solutions in Pain initiative.

### ***Communication Resources***

The challenges of treating chronic pain patients safely and effectively with opioid analgesics are numerous and diverse. Resolution of these challenges often requires the actions of, and treatment by, a multidisciplinary team of pain specialists, nurses, pharmacists and other allied health care professionals. Communication, understanding and information sharing among the diverse members of the pain management team are thus important components of chronic pain management. In 2007, Emerging Solutions in Pain initiated development, dissemination and implementation of a series of tools and resources that would support the development of a virtual "Emerging Solutions in Pain Community".

The Communication Resources currently available on the ESP website are designed to promote peer-to-peer communication, not only between registered members and the ESP faculty, but also directly between members of the ESP community itself. These resources have an additional goal of increasing the amount and diversity of information available at [EmergingSolutionsinPain.com](http://EmergingSolutionsinPain.com): by creating interactive tools that encourage member posting of information and dialog among members, the content available for review and dissemination on the ESP web site is significantly increased. In addition, because members are actively involved in contributing to these tools and resources, the resulting content, once validated, is an accurate and immediate assessment of the ongoing needs of the target audience of health care professionals who provide care to patients with chronic pain.

These resources and tools available in the ESP Communication Resources include:

#### ***(1) The ESP Ask the Experts Column***

##### ***Budget for ongoing development attached, page 39***

Through this web-based functionality, ESP members submit questions online pertaining to issues of pain management and/or addiction. MLS screens all questions submitted, and forwards selected questions to the appropriate ESP faculty member. The selected faculty member then creates an audio recording of his/her answer to the question, and MLS posts the recorded answer both as an MP3 file for audio playback and in a text-based format; the member who asked the question is notified via email as to the availability of the answer. MLS coordinates the monthly selection of questions from all submitted and the posting of the ESP faculty member's response. All Ask the Expert questions are archived upon posting of the newest question, and are available for review by registered members.

#### ***(2) The ESP State Your Case Column***

##### ***Budget for ongoing development attached, page 40***

In this program, clinician members of the ESP web site submit cases that highlight the issues and challenges of treating patients with chronic pain while minimizing risk of misuse, abuse or addiction of opioids. MLS utilizes a standard template developed specifically for this purpose,



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## ***Program Summary: The Emerging Solutions in Pain Website***

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to ensure accuracy and standardization of submitted information. MLS reviews all cases submitted through the ESP State Your Case Column, and submits selected cases to one of a pre-identified panel of ESP faculty members. The selected faculty member then creates an audio recording of his/her review of the case, and MLS posts the recorded review both as an MP3 file for audio playback and in a text-based format. Members may submit questions pertaining to the case for a specified period of time, which MLS will screen and forward to the faculty reviewer for written responses. Finally, as an incentive, MLS will coordinate a conference call between the faculty reviewer and the clinician whose case is selected, so that the submitting clinician may benefit from a one-on-one consultation with a nationally known clinical expert. One case will be selected, reviewed and posted per quarter.

### ***(3) The ESP Member Feedback Area***

Through this web-based functionality, ESP members have a forum to submit ESP-specific feedback and suggestions for future topics, activities and tools. Suggestions are submitted electronically through a dedicated page on the ESP web site, and are received directly by MLS staff. All member comments and suggestions are collected in a database and reviewed on a regular basis.

### ***(4) The ESP Electronic Journal Club***

#### ***Budget for ongoing development attached, page 41***

The ESP Electronic Journal Club is a quarterly accredited electronic journal club targeted to residents and fellows who have an interest in increasing their knowledge and understanding in the fields of pain management and addiction. Each of the four quarterly installments of the Journal Club are accredited for 0.25 CME credits, for those clinicians other than residents and fellows who have an interest in participating in this interactive and educational forum. The program protocol is as follows:

- a. An ESP faculty member recommends a relevant article
- b. MLS posts the article and/or the link to the PDF at a third party site (depending on copyright issues specific for the selected article) on the Journal Club section of the ESP web site. In addition, MLS emails the article and/or link to all registered members of the ESP Electronic Journal Club
- c. The ESP faculty member who selected the article then writes a brief review of the article, which he/she also audio records.
- d. MLS posts the recorded review both as an MP3 file for audio playback and in a text-based format on the Journal Club page of the ESP web site
- e. Registered members of the Journal Club may comment on the article or review through the forum function
- f. The completed programs will be archived on the website for reference by the ESP membership

### **Intended Audience**

The primary audience of the Emerging Solutions in Pain Web Site includes physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain.





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## ***Program Summary: The Emerging Solutions in Pain Website***

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### **Program Objectives**

In 2008, one goal of the Emerging Solutions in Pain Web Site will be to continue to provide clinicians with tools and resources for assessing and monitoring the risk potential of their patients for opioid misuse, abuse and addiction. Goals of the Emerging Solutions in Pain website include the following:

- (1) Increase usage, as tracked by membership, user sessions and hits, by 25% in 2008, through continuation of current programs and initiatives that have been identified as having value by ESP members
- (2) Reinforce the structural integrity of the existing site to ensure uninterrupted service to members despite significantly increased usage
- (3) Update rotating "featured programs" sections call-outs to draw member attention to each new program and feature of the web site
- (4) Update member-only email communications concerning the newest functionality available at EmergingSolutionsinPain.com
- (5) Continue to expand the reach of this web site and the important information it contains to the following groups:
  - a. Non-physician members of the pain management community, e.g., nurses, physician assistants, pharmacists
  - b. Pain specialists, addictionologists and other physicians who have not yet registered at the web site
  - c. Residents and fellows who have an interest in treating pain as part of their studies
- (6) Further build and develop the virtual "ESP Community" of health care professionals through:
  - a. Reinforcement of current communication-focused resources to current members
  - b. Development of additional forums related to existing forums and discussion resources
  - c. Additional announcement of this resource to new/non-members

### **Format**

A multimedia Web Site, with separate sections for assessing and monitoring patients whose chronic pain is being treated with opioids; for "best practice" information; for continuing education activities and journal articles relevant to the Emerging Solutions in Pain initiative; for other Emerging Solutions in Pain information and programs

### **Distribution**

The Emerging Solutions in Pain Web Site will be available to all health care professionals via the Internet at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com). Free registration will be required to access the majority of information on the Web Site, including all of the Emerging Solutions in Pain Tools and journal articles

### **Request for Sponsor Support**

Medical Learning Solutions will announce and promote the Emerging Solution in Pain Web Site through journal advertisements, banner advertisements and announcement brochures for the Emerging Solutions in Pain initiative.



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### ***Program Summary: The Emerging Solutions in Pain Website***

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As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. sales representatives in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.

#### **Total Budget**

The total budget to fund the activities outlined above is \$316,072.





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**The Emerging Solutions in Pain Website: Maintenance of 2007 Functionality**  
***Proposed Budget***  
**July 5, 2007**

<b>Cost Summary</b>	
<i>Site Management</i>	
Approximate Total, Direct Expenses	\$ 6,600
Total, Indirect Expenses	\$ 66,113
Subtotal, Site Management	\$ 72,713
<i>Membership Management</i>	
Approximate Total, Direct Expenses	\$ 3,950
Total, Indirect Expenses	\$ 29,866
Subtotal, Membership Management	\$ 33,816
<i>Clinical Expert Commentaries</i>	
Approximate Total, Direct Expenses	\$ 25,660
Total, Indirect Expenses	\$ 32,353
Subtotal, Clinical Expert Commentaries	\$ 58,013
<i>In the Know Summaries</i>	
Approximate Total, Direct Expenses	\$ 720
Total, Indirect Expenses	\$ 24,358
Subtotal, In the Know Summaries	\$ 25,078
<i>In the News Feature</i>	
Approximate Total, Direct Expenses	\$ 3,850
Total, Indirect Expenses	\$ 1,016
Subtotal, In the News Feature	\$ 4,866
<i>Web Resources and Links</i>	
Approximate Total, Direct Expenses	\$ 500
Total, Indirect Expenses	\$ 10,365
Subtotal, Web Resources and Links	\$ 10,865
<i>Ask the Experts Column</i>	
Approximate Total, Direct Expenses	\$ 9,750
Total, Indirect Expenses	\$ 13,306
Subtotal, Ask the Experts Column	\$ 23,056



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**The Emerging Solutions in Pain Website: Maintenance of 2007 Functionality**  
**Proposed Budget**  
July 5, 2007

<b>Cost Summary, con't</b>	
<i>State Your Case Column</i>	
Approximate Total, Direct Expenses	\$ 5,500
Total, Indirect Expenses	\$ 14,880
Subtotal, State Your Case Column	\$ 20,380
<i>Quarterly Electronic Journal Club</i>	
Approximate Total, Direct Expenses	\$ 34,175
Total, Indirect Expenses	\$ 33,110
Subtotal, Quarterly Electronic Journal Club	\$ 67,285
<b>ESP Website: Maintenance of 2007 Functionality</b>	<b>\$ 316,072</b>



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**The Emerging Solutions in Pain Website: Maintenance of 2007 Functionality**  
**Proposed Budget**  
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<b>Detailed Budget Itemization: Site Management</b>	
<i>Direct Expenses, Approximate</i>	
Infrastructure programming	\$ 6,250
Miscellaneous (non-fulfillment shipping, faxes, etc.)	\$ 350
<b>Approximate Total, Direct Expenses</b>	<b>\$ 6,600</b>
<i>Indirect Expenses</i>	
<b>Project management</b>	
Coordination with third-party programmers	\$ 1,965
Coordination with internal programming team	\$ 6,900
Coordination with other internal teams	\$ 1,800
<b>IT / programming services</b>	
Programming of miscellaneous / site-wide graphics	\$ 4,375
Programming of miscellaneous / site-wide functionality	\$ 8,750
<b>Annual website maintenance</b>	
Hosting and co-location fees	\$ 12,000
Routine website maintenance	\$ 9,000
Technical support	\$ 3,000
<b>Data management</b>	
Database programming, updating of databases	\$ 5,250
Data retrieval	\$ 1,800
Data analysis	\$ 10,850
<b>Administrative and accounting fees</b>	<b>\$ 423</b>
<b>Total, Indirect Expenses</b>	<b>\$ 66,113</b>



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**The Emerging Solutions in Pain Website: Maintenance of 2007 Functionality**  
**Proposed Budget**  
July 5, 2007

<b>Detailed Budget Itemization: Membership Management</b>	
<i>Direct Expenses, Approximate</i>	
Blast email distribution services	\$ 3,600
Miscellaneous (non-fulfillment shipping, faxes, etc.)	\$ 350
<b>Approximate Total, Direct Expenses</b>	<b>\$ 3,950</b>
<i>Indirect Expenses</i>	
<b>Project management</b>	
Coordination with outside vendor for blast email service	\$ 900
Coordination with internal graphic design team, other internal teams	\$ 1,350
Coordination with copy writer	\$ 1,800
Schedule identification, monitoring of message deployment	\$ 3,000
<b>Copy writing</b>	<b>\$ 9,000</b>
<b>Graphic design / production services</b>	
Graphic design / layout	\$ 6,750
Proofreading	\$ 2,250
<b>Membership profile / database maintenance</b>	<b>\$ 4,500</b>
<b>Administrative and accounting fees</b>	<b>\$ 316</b>
<b>Total, Indirect Expenses</b>	<b>\$ 29,866</b>



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**The Emerging Solutions in Pain Website: Maintenance of 2007 Functionality**  
**Proposed Budget**  
**July 5, 2007**

<b>Detailed Budget Itemization: Clinical Expert Commentaries (12 Commentaries Total)</b>	
<i>Direct Expenses, Approximate</i>	
<b>Clinical expert honoraria: pre-recording, review</b>	\$ 24,000
Honoraria for 12 clinical experts to produce 12 clinical commentaries	
<b>Transcription</b>	\$ 660
<b>Miscellaneous (phone, fax, non-fulfillment Fed Ex)</b>	\$ 1,000
<b>Approximate Total, Direct Expenses</b>	<b>\$ 25,660</b>
<i>Indirect Expenses</i>	
<b>Project management</b>	
Coordination with speakers for content delivery, audio or video recording	\$ 2,250
Coordination with internal teams	\$ 2,250
Preparation and coordination of status meetings/updates	\$ 900
<b>Content development: text-based commentaries (6 total)</b>	
Identification of content/topic/speaker	\$ 900
Editing of transcript from audio recording	\$ 4,800
Coordination of content with internal teams	\$ 900
Proof-reading	\$ 750
Fact-checking	\$ 750
<b>Content development: video-based commentaries (6 total)</b>	
Identification of content/topic/speaker	\$ 900
Filming	\$ 9,000
Editing of video footage	\$ 3,000
Editing of transcript from video recording	\$ 750
Coordination of content with internal teams	\$ 900
Proof-reading	\$ 750
Fact-checking	\$ 750
<b>Posting of content</b>	\$ 750
<b>Administrative and accounting fees</b>	\$ 2,053
<b>Total, Indirect Expenses</b>	<b>\$ 32,353</b>



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**The Emerging Solutions in Pain Website: Maintenance of 2007 Functionality**  
**Proposed Budget**  
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<b>Detailed Budget Itemization: In the Know Summaries (24 Summaries Total)</b>	
<i>Direct Expenses, Approximate</i>	
<b>Reference purchase</b>	\$ 720
<b>Approximate Total, Direct Expenses</b>	<b>\$ 720</b>
<i>Indirect Expenses</i>	
<b>Project management</b>	
Coordination with internal teams	\$ 2,700
Preparation and coordination of status meetings/updates	\$ 900
<b>Content development</b>	
Research and identification of appropriate journal articles for summary	\$ 4,800
Writing of article summaries	\$ 9,900
Proof-reading	\$ 3,000
Fact-checking	\$ 1,500
<b>Posting of content</b>	\$ 1,500
<b>Administrative and accounting fees</b>	\$ 58
<b>Total, Indirect Expenses</b>	<b>\$ 24,358</b>



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**The Emerging Solutions in Pain Website: Maintenance of 2007 Functionality**  
**Proposed Budget**  
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<b>Detailed Budget Itemization: In the News Feature</b>	
<b>Direct Expenses, Approximate</b>	
12 month real-time news feed from Topix.net	\$ 3,500
Miscellaneous (phone, fax, non-fulfillment Fed Ex)	\$ 350
<b>Approximate Total, Direct Expenses</b>	<b>\$ 3,850</b>
<b>Indirect Expenses</b>	
<b>Project management</b>	
Coordination and troubleshooting with third party vendor, Topix.net	\$ 450
Coordination with internal teams	\$ 450
<b>Administrative and accounting fees</b>	<b>\$ 116</b>
<b>Total, Indirect Expenses</b>	<b>\$ 1,016</b>





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**The Emerging Solutions in Pain Website: Maintenance of 2007 Functionality  
Proposed Budget  
July 5, 2007**

<b>Detailed Budget Itemization: Resources</b>	
<i>Direct Expenses, Approximate</i>	
Licensing fees for PDFs	\$ 500
<b>Approximate Total, Direct Expenses</b>	<b>\$ 500</b>
<i>Indirect Expenses</i>	
<b>Project management</b>	
Research and identification of appropriate new resources for posting on ESP website	\$ 4,200
Maintenance of current links	\$ 1,800
Recruitment of new links	\$ 3,600
<b>Posting of content</b>	<b>\$ 750</b>
<b>Administrative and accounting fees</b>	<b>\$ 15</b>
<b>Total, Indirect Expenses</b>	<b>\$ 10,365</b>



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**The Emerging Solutions in Pain Website: Maintenance of 2007 Functionality**  
**Proposed Budget**  
**July 5, 2007**

<b>Detailed Budget Itemization: Ask the Experts Column</b>	
<b>Direct Expenses, Approximate</b>	
<b>Honoraria</b>	\$ 9,000
All faculty honoraria for 9 months of Ask the Experts columns: one per month (April - December); faculty will create audio recording in answer to questions from ESP members and submit to MLS for posting as MP3 files	
<b>Miscellaneous (phone, fax, non-fulfillment Fed Ex)</b>	\$ 750
<b>Approximate Total, Direct Expenses</b>	<b>\$ 9,750</b>
<b>Indirect Expenses</b>	
<b>Project management</b>	
Question source verification	\$ 675
Monthly submission of selected question(s) to faculty	\$ 1,425
Coordination for audio recording of answer(s) from faculty	\$ 825
Coordination with internal medical services, programming teams	\$ 563
Updates to grantor	\$ 338
<b>Content development</b>	
Monthly review of all questions submitted by ESP members	\$ 3,600
Selection of appropriate question(s) and answering faculty	\$ 1,800
Editing of faculty answer	\$ 3,300
<b>Administrative and accounting fees</b>	\$ 780
<b>Total, Indirect Expenses</b>	<b>\$ 13,306</b>



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**The Emerging Solutions in Pain Website: Maintenance of 2007 Functionality**  
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July 5, 2007

<b>Detailed Budget Itemization: State Your Case Column</b>	
<b>Direct Expenses, Approximate</b>	
<b>Honoraria</b>	\$ 5,000
All faculty honoraria for 2 State Your Case columns: one per quarter (Q3, Q4, 2008); faculty will create an audio recording of a review and analysis of a case submitted by ESP members and selected by MLS; faculty will participate in a conference call with the ESP member who submitted the selected case	
<b>Transcription</b>	\$ 200
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$ 300
<b>Approximate Total, Direct Expenses</b>	\$ 5,500
<b>Indirect Expenses</b>	
<b>Project management</b>	
Quarterly submission of selected case to faculty	\$ 900
Coordination of audio recording of faculty review and analyses	\$ 1,200
Coordination with internal teams	\$ 750
Preparation and coordination of status meetings/updates	\$ 450
<b>Content development</b>	
Quarterly review of all cases submitted by ESP members	\$ 2,400
Selection of appropriate case(s) and answering faculty	\$ 1,600
Editing of faculty case review and analysis	\$ 7,140
<b>Administrative and accounting fees</b>	\$ 440
<b>Total, Indirect Expenses</b>	\$ 14,880



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**The Emerging Solutions in Pain Website: Maintenance of 2007 Functionality**  
**Proposed Budget**  
**July 5, 2007**

<b>Detailed Budget Itemization: Quarterly Electronic Journal Club</b>	
<b>Direct Expenses, Approximate</b>	
<b>Clinical expert honoraria</b>	\$ 6,000
One faculty per quarter/journal club issue (Q3, Q4, 2008); two faculty total	
<b>Accreditation of program for CME</b>	\$ 16,000
<b>Continuing Education participant certificates (estimate 750 certificates per program)</b>	\$ 12,000
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$ 175
<b>Approximate Total, Direct Expenses</b>	\$ 34,175
<b>Indirect Expenses</b>	
<b>Project management</b>	
Coordination with faculty	\$ 4,200
Coordination with internal teams, accreditor	\$ 600
Participant communication	\$ 900
Coordination of participant comments/questions	\$ 3,000
Preparation and coordination of status meetings/updates	\$ 300
<b>Medical/scientific services</b>	
Topic/author identification/research	\$ 1,200
Creation of article summary	\$ 3,300
Development of supporting verbiage (needs assessment, objectives, etc.) and self-assessment	\$ 1,200
Review, editing of comments	\$ 4,600
Proofreading	\$ 1,500
Fact-checking	\$ 3,000
<b>Graphic design</b>	
Typesetting, layout of all participant communications	\$ 500
Typesetting, layout of program-related materials	\$ 1,450
<b>Programming, journal distribution</b>	\$ 4,700
<b>Archiving</b>	\$ 2,000
<b>Administrative and accounting fees</b>	\$ 660
<b>Total, Indirect Expenses</b>	\$ 33,110



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## ***Program Summary: Foundation Initiatives***

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### **Program Title**

The 2008 Emerging Solutions in Pain Faculty Advisory Board Meeting

### **Program Overview**

Medical Learning Solutions is recommending that the Emerging Solutions in Pain Faculty Advisory Committee convene for a one-day meeting in late 2007 or early 2008. At this meeting, the Faculty will address the current needs of clinicians involved in the field of pain management, identify potential areas for the development of future Emerging Solutions in Pain programs and activities, and reach consensus on updated tools and resources for inclusion in the Emerging Solutions in Pain Tool Kit, Volume II.

Medical Learning Solutions is recommending that the 2008 Emerging Solutions in Pain Faculty Advisory Committee be comprised of two groups of clinical experts. One group, which will form approximately two-thirds of the final Board, will include currently active Emerging Solutions in Pain faculty members who have participated in prior ESP advisory board activities. The remaining third of the Advisory Board will be comprised of clinical experts who have had some contribution to the Emerging Solutions in Pain initiatives in the past 12 months, but have not participated in prior ESP advisory boards. While final selection of Advisory Board members will be based upon availability, the faculty will be selected from the following list of experts:

- Jennifer Bolen, JD
- Daniel Brookoff, MD
- David B. Brushwood, RPh, JD
- Ms. Patricia Goode
- Douglas Gourlay, MD, FRCPC, FASAM
- Peggy Compton, RN, PhD, FAAN
- April Hazard-Vallerand, PhD, RN, FAAN
- Howard A. Heit, MD, FACP, FASAM
- Aaron Gilson, PhD
- David Joranson, MSSW
- Christine Miaskowski, RN, PhD, FAAN
- Steven D. Passik, PhD
- Karen Ryan, MA
- Joseph Shurman, MD
- Steven Stanos, DO
- Jennifer Strickland, PharmD
- Lynn R. Webster, MD, FACPM, FASAM
- Penelope P. Ziegler, MD, FASAM

### **Intended Audience**

The primary audience who will benefit from a reconvention of an expanded Emerging Solutions in Pain Faculty Advisory Board will be physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain, and who utilize opioids in their pain practices. The needs of these clinicians will be specifically addressed at the Advisory Board Meeting, and new Emerging Solutions in Pain tools and resources will be recommended by the Faculty for their use in 2008 and 2009.



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## ***Program Summary: Foundation Initiatives***

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### **Program Objectives**

The purpose of the Emerging Solutions in Pain Faculty Advisory Committee is to provide guidance for future direction of the Emerging Solutions in Pain initiatives. This will require the accomplishment of the following objectives at the Advisory Board Meeting:

- (1) Summarize the activities and programs that comprised the 2005 – 2007 Emerging Solutions in Pain initiatives
- (2) Outline current trends in the use of opioids for the treatment of chronic pain, focusing on any new developments in laws or regulations pertaining to the prescription of controlled substances; new products and therapies that will be available for the treatment of chronic pain; and new reports pertaining to the assessment, monitoring or documentation of patients who are prescribed opioids
- (3) Based on the above:
  - a. Identify potential areas for the development of future Emerging Solutions in Pain programs and activities
  - b. Reach consensus on updated tools and resources for inclusion in the Emerging Solutions in Pain Tool Kit, Volume II

### **Format**

The format for this activity will be a one-day meeting, to be tentatively held in late 2007 or early 2008. The exact date and location of this meeting will be based on the schedules of the attending faculty.

### **Distribution**

Attendance at the 2008 Emerging Solutions in Pain Faculty Advisory Board Meeting will be determined by past participation in the Emerging Solutions in Pain initiatives, or, in the case of new faculty, by contributions to Emerging Solutions in Pain and in the fields of pain or addiction medicine.

### **Total Budget**

The total budget to fund this activity is \$135,267.



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## 2008 Emerging Solutions in Pain Foundation Initiatives

### The 2007/2008 ESP Faculty Advisory Board Meeting

#### *Proposed Budget*

July 5, 2007

<i>Cost Summary</i>		
Approximate Total, Direct Expenses	\$	81,060
Total, Indirect Expenses	\$	54,207
<b>2007/2008 Faculty Advisory Board Meeting</b>	<b>\$</b>	<b>135,267</b>





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## 2008 Emerging Solutions in Pain Foundation Initiatives

### The 2007/2008 ESP Faculty Advisory Board Meeting

#### *Proposed Budget*

July 5, 2007

<b>Program Parameters: 2007/2008 ESP Faculty Advisory Board Meeting</b>	
Attending faculty	11
Clinical expert moderator	1
Length of meeting	1 day
<b>Detailed Budget Itemization: 2007/2008 ESP Faculty Advisory Board Meeting</b>	
<i>Direct Expenses, Approximate</i>	
<b>Print materials</b>	
Meeting kits to include agenda, handout materials, slides of Tool Kit Volume I and of pre-work on Federal regulations, new assessment tools and 4/c binder	\$ 2,500
<b>Speaker honoraria (11 faculty member + 1 moderator)</b>	
Moderator (1)	\$ 5,000
Faculty (11 faculty, \$2,500 per faculty member)	\$ 27,500
<b>Speaker travel (12)</b>	
Air travel	\$ 9,000
Accommodations	\$ 8,400
Ground transportation	\$ 2,400
OOP	\$ 1,200
<b>ROI staff travel (4)</b>	
Air travel	\$ 3,000
Accommodations	\$ 4,200
Ground transportation	\$ 200
OOP	\$ 600
<b>Venue rental fee</b>	\$ 2,500
<b>Food &amp; Beverage (Dinner, Buffet Breakfast, Buffet Lunch, Two Breaks)</b>	\$ 4,560
<b>Audio/visual services</b>	\$ 6,500
<b>Transcription</b>	\$ 750
<b>Reference purchase</b>	\$ 1,500
<b>Miscellaneous (non-fulfillment shipping, faxes, FedEx, etc.)</b>	\$ 1,250
<b>Approximate Total, Direct Expenses</b>	<b>\$ 81,060</b>



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## 2008 Emerging Solutions in Pain Foundation Initiatives

### The 2007/2008 ESP Faculty Advisory Board Meeting

#### *Proposed Budget*

July 5, 2007

<b>Detailed Budget Itemization: 2007/2008 ESP Faculty Advisory Board Meeting (con't)</b>	
<i>Indirect Expenses</i>	
<b>Project management</b>	
Coordination with faculty	\$ 2,700
Coordination with internal teams	\$ 900
Preparation and coordination of status meetings/updates	\$ 450
<b>Medical services</b>	
Identification of faculty and alternate faculty	\$ 1,200
Content development for slides pertaining to current Tool Kit, updates required for Federal regulations and new assessment tools	\$ 8,400
Proofreading	\$ 1,125
Fact-checking	\$ 750
Creation of post-meeting executive summary	\$ 3,800
<b>Graphic design</b>	
Creation of meeting slides	\$ 3,250
Typesetting, layout of meeting support materials	\$ 1,500
Participant package assembly	\$ 625
Typesetting, layout of post-meeting executive summary	\$ 750
<b>Site visit (1 staff member)</b>	\$ 3,000
<b>Meeting management</b>	
Venue coordination	\$ 3,000
Travel coordination for faculty and staff	\$ 5,500
Coordination of associated meeting logistics	\$ 2,125
<b>AV services</b>	\$ 5,125
<b>Shipping services</b>	\$ 375
<b>Onsite management (4 staff members)</b>	\$ 7,200
<b>Administrative and accounting fees</b>	\$ 2,432
<b>Total, Indirect Expenses</b>	<b>\$ 54,207</b>



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## ***Program Summary: Foundation Initiatives***

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### **Program Title**

The Emerging Solutions in Pain Tool Kit, Volume Two

### **Program Overview**

Medical Learning Solutions is proposing to identify and develop new tools and content for the ESP Tool Kit, Volume Two, which will accurately reflect the current state of pain management and addiction medicine. These new tools and resources will be identified by, and developed in conjunction with, the panel of expert faculty members who will convene in the proposed Emerging Solutions in Pain Advisory Board meeting, as described on pages 42 – 43. While the final number and scope of the new updates will be determined based solely on the guidance provided by the expert faculty during the ESP Advisory Board meeting, updates to the Tool Kit will include, but will not be limited to, revision of the tool summarizing federal regulations pertaining to controlled substances, as well as inclusion of new tools in the risk assessment module.

The new tools and resources that will be included in Volume Two of the Tool Kit will be available via a new multi-media CD-ROM, as well as via a downloadable series at the ESP web site.

In addition, Medical Learning Solutions is proposing to package the ESP Tool Kit Volume II in two different collections:

- (1) As a stand-alone CD-ROM: this packaging will be used as the primary distribution for those clinicians who are seeking clinician-specific information in the areas of assessment, monitoring and best practices
- (2) Packaged with the Emerging Solutions in Pain Patient Tool Kit Companion CD-ROM, developed in 2007: this packaging will be used for those clinicians who are seeking additional tools specific to patient interaction and information

### **Intended Audience**

The primary audience of the ESP Tool Kit Volume Two will be physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain.

### **Program Objectives**

The objectives of the Emerging Solutions in Pain Tool Kit Volume Two are to provide updated tools, resources and information to clinicians who care for patients with chronic pain. Tools and resources will focus on the fundamental areas of assessment, monitoring and best practices previously identified.

### **Format**

A multimedia CD-ROM and online at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com)



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## ***Program Summary: Foundation Initiatives***

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### **Distribution**

The Emerging Solutions in Pain Tool Kit Volume Two will be available through the following avenues:

- (1) Through electronic download at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com)
- (2) Through distribution at the Emerging Solutions in Pain Meet the Expert Booth
- (3) Through ordering of the CD-ROM online at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com)
- (4) At live programs and activities developed by Emerging Solutions in Pain

### **Request for Sponsor Support**

Medical Learning Solutions will coordinate the distribution of the Emerging Solution in Pain Tool Kit Volume II through the tactics outlined above.

As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. sales force in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.

### **Total Budget**

The total budget to fund this activity is \$160,341.



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## 2008 Emerging Solutions in Pain Foundation Initiatives

### The Emerging Solutions in Pain Tool Kit, Volume II

#### *Proposed Budget*

July 5, 2007

<b>Cost Summary</b>	
Approximate Total, Direct Expenses	\$ 52,880
Total, Indirect Expenses	\$ 107,461
<b><i>The Emerging Solutions in Pain Tool Kit, Volume II</i></b>	<b>\$ 160,341</b>



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## 2008 Emerging Solutions in Pain Foundation Initiatives

### The Emerging Solutions in Pain Tool Kit, Volume II

#### *Proposed Budget*

July 5, 2007

<b>Detailed Budget Itemization: Emerging Solutions in Pain Tool Kit, Volume II</b>	
<i>Direct Expenses, Approximate</i>	
<b>Duplication: ESP Tool Kit CD-ROM, Quantity: 30,000</b>	\$ 25,980
Four color, CD sleeve mailer to house four-color silk-screened CD-ROM. 4/0 + varnish, score, fold, insertion of CD, shrinkwrapping.	
<b>Duplication: ESP Tool Kit / Patient Tool Kit two-CD-ROM set, Quantity: 5,000</b>	\$ 9,700
Four color, two page CD mailer with two inside pockets to house four-color silk-screened CD-ROM. 4/0 + varnish, score, fold, insertion of CD, shrinkwrapping.	
<b>Audio track recording</b>	\$ 3,500
Professional voice talent narration of Tool Kit instructions, KOL commentary, etc.	
<b>Clinical expert honoraria</b>	\$ 9,000
Preparation, review of audio commentary	
<b>Postage to ship CDs from online orders, (1,000 quantity targeted for online orders)</b>	\$ 1,500
<b>Reference purchase</b>	\$ 1,500
<b>Stock art purchase</b>	\$ 1,200
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$ 500
<b>Approximate Total, Direct Expenses</b>	<b>\$ 52,880</b>



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## 2008 Emerging Solutions in Pain Foundation Initiatives

### The Emerging Solutions in Pain Tool Kit, Volume II

#### **Proposed Budget**

July 5, 2007

<b>Detailed Budget Itemization: Emerging Solutions in Pain Tool Kit, Volume II (con't)</b>	
<b>Indirect Expenses</b>	
<b>Project management</b>	
Review of audio files for editing direction	\$ 6,150
Coordination with internal teams	\$ 2,400
Coordination with faculty for review, approval	\$ 3,150
Coordination with third party vendors for purchase of references, permissions	\$ 1,800
Preparation and coordination of status meetings/updates	\$ 1,200
<b>Medical/scientific services</b>	
Creation of Tool introduction script based on faculty guidance, advisory board information	\$ 21,400
Creation of Tool introduction slides for slide/audio based on approved script	\$ 8,400
Identification of supporting references, materials	\$ 5,200
Proofreading	\$ 4,875
Fact-checking	\$ 2,250
<b>Graphic design</b>	
Creation of updated graphic user interface	\$ 3,125
Creation of Tool introduction slides to slide/audio CD-ROM format	\$ 7,500
Creation of animations, highlights, additional graphics	\$ 4,625
Creation of Tool Kit look/feel based on current ESP identity	\$ 2,250
Typesetting, layout	\$ 2,250
<b>IT, programming services</b>	
Audio recording	\$ 1,800
Editing of audio track	\$ 5,875
CD-ROM programming	\$ 15,250
Adaptation of CD-ROM format for online posting	\$ 1,500
Programming of online order form for two-CD set	\$ 2,375
<b>Fulfillment of online requests for two-CD-ROM set</b>	\$ 2,500
<b>Administrative and accounting fees</b>	\$ 1,586
<b>Total, Indirect Expenses</b>	<b>\$ 107,461</b>





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## ***Program Summary: Awareness Building Initiatives***

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### **Program Title**

The Emerging Solutions in Pain Awareness Building Initiatives

### **Program Overview**

Medical Learning Solutions is proposing to increase the number of health care professionals who are regular users of the Emerging Solutions in Pain resources and tools through a series of targeted and focused awareness-building campaigns. These campaigns are divided into three format areas, and each has been identified as important in educating the above-named key groups of health care professionals.

#### **(1) *The 2008 Print and Internet Banner Awareness Campaign***

Medical Learning Solutions is proposing to target a diverse audience of health care professionals through a coordinated series of print and Internet banner advertisements. Through two separate but related series of advertising campaigns, MLS will reach more than 273,000 health care professionals. These two series are as follows:

- a. A general awareness print and Internet banner campaign
  - i. This campaign outlines the Emerging Solutions in Pain initiatives, benefits of membership and information for accessing the ESP programs.
  - ii. The print campaign will be primarily, but not solely, focused on the subscribers of the *Practical Pain Management Journal*, a non-peer-reviewed journal with distribution to 39,000 pain management physicians and other pain-focused health care providers per issue.
  - iii. Internet banners advertising the ESP initiatives will be placed on diverse medical association web sites, such as sites for the American Academy of Pain Management Nurses, the American Academy of Physical Medicine and Rehabilitation, the Journal of Pain and Pain Medicine.
- b. A targeted awareness campaign both in print and on the Internet supporting specific Emerging Solutions in Pain events, such as the 2008 Meet the Expert Booth Series and 2008 live events
  - i. These campaigns will be similar in design and scope to the general awareness campaign outlined above, thereby providing continuity and name recognition among the target audience
  - ii. Targeted awareness campaigns will be focused on the specialist audiences that are the primary audiences of each event. As such, these campaigns will focus primarily on pain management physicians, addictionologists and allied health care professionals who specialize in or have an interest in pain management and/or addiction
  - iii. Both print and Internet campaigns will be conducted through the print publications and Internet sites supporting each target event

#### **(2) *The 2008 Emerging Solutions in Pain Scholarship Program for Residents, Fellows and Nurses***

Medical Learning Solutions is proposing continuation of the 2007 Emerging Solutions in Pain Scholarship Program, as an initiative that successfully extended the reach of ESP to a new target audience of residents, fellows and directors of medical school programs. This program is designed with multiple purposes:

- a. Grow the number of new ESP members



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## ***Program Summary: Awareness Building Initiatives***

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- b. Develop new thought leaders in the specialty of pain management and addiction management
- c. Introduce up-and-coming physicians and nurses to the pain management community and involve this group in the critical interface of pain and addiction
- d. Increase the pool of clinical expert contributors to ESP, through submission by the Scholarship recipient of meeting and abstract summaries for publishing on the ESP web site

In this program, announcement of the Scholarship availability will be posted on the ESP web site, and through other ESP awareness initiatives. In addition, direct email blast campaigns will specifically target Directors of medical school programs which include formal pain management education programs. To be considered for one of the four ESP Scholarships, candidates must submit the following:

- a. Name and contact information
- b. A brief biography or CV
- c. A statement summarizing the candidate's experience in the field of pain management, or basis for interest in this field of medicine

Scholarship recipients will be selected following analysis of all submission packages through a numeric scoring system. Final selection will be based upon review of rating scores by a diverse group of staff from Medical Learning Solutions and from MLS' accreditor, MediCom Worldwide. Scholarship recipients will receive registration fees, airfare, hotel accommodations and a small stipend. Recipients will be asked to write abstracts of conference plenary sessions that will be posted on the ESP web site.

### ***(3) The Beacon Quarterly Newsletter***

Medical Learning Solutions in proposing to continue the development, production and implementation of The Beacon, an ESP-dedicated quarterly electronic newsletter supporting increased focus on new tools, resources and activities available through the ESP initiatives. The primary purpose of this newsletter series is to encourage more routine use of the Emerging Solutions in Pain tools and resources by current and potential ESP members.

Through this HTML-based newsletter, subscribers will be exposed to highlights of new content, programs and resources available on the ESP web site, thereby reinforcing the value offered by the initiatives, the ease of use of the ESP tools and resources, and the diverse range of educational and informational programs and activities available to ESP members. All content will be called out by a title or headline that will also function as a clickable link directly back to the full story on the ESP web site. Content that will be highlighted include:

- a. Selected text from current and archived clinical expert commentaries, journal article summaries, "In the News" stories and Ask the Expert columns
- b. Overviews of case studies either in current discussion or archived in the State Your Case Column
- c. Selected text from the 2008 ESP/PPMJ Accredited Monograph series
- d. Announcements of ESP-sponsored live events, including the Meet the Experts booth and live symposia
- e. Surveys of newsletter recipients for content, tool and resource suggestions



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## ***Program Summary: Awareness Building Initiatives***

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### **Intended Audience**

The primary audience of the 2008 Emerging Solutions in Pain Awareness Campaign will include physicians, pharmacists, nurses, physician assistants, residents, fellows and other health care professionals who provide care to patients with chronic pain. These groups will include not only health care professionals who have not yet been exposed to the Emerging Solutions in Pain initiatives, but also those individuals who may be familiar with ESP, but who are not regular users of the ESP tools, resources and activities.

### **Program Objectives**

The overall objective of the 2008 Awareness Campaign is to increase the number of health care professionals who are active, regular members the Emerging Solutions in Pain community. The specific objectives of the Awareness Campaign include, but are not limited to:

- (1) Increase the number of registered users at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com) in all target audience groups:
  - a. Pain specialists, addictionologists and other physicians who treat patients with chronic pain
  - b. Non-physician members of the pain management community, e.g., nurses, physician assistants, pharmacists
  - c. Residents and fellows who have an interest in treating pain as part of their studies
- (2) Increase the number of user sessions at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com)
- (3) Increase the total amount of information downloaded at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com)

### **Format and Distribution**

The 2008 Emerging Solutions in Pain Awareness Campaign will include, but is not limited to:

- (1) Journal advertisements in *Practical Pain Management Journal*, *Journal of Pain*, *Pain Management Nursing*, *Pain Medicine*, *The Physiatrist Newsletter*, *ASAM News*, *Regional Anesthesia and Pain Medicine*
- (2) Banner advertisements at select professional pain management organization web sites including American Academy Physical Medicine and Rehabilitation (AAPM&R) web site and advertising on journal home pages of *Journal of Pain*, *Pain Management Nursing* and *Pain Medicine* publications
- (3) The ESP Scholarship will be announced on the Emerging Solutions in Pain web site and through multiple email blast campaigns to appropriate target audiences.
- (4) The Beacon eNewsletter will be distributed to registered members of the Emerging Solutions in Pain community and other subscribers.

### **Request for Sponsor Support**

Medical Learning Solutions will coordinate the Emerging Solution in Pain Awareness Campaign through the means of distribution outlined above.

As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. sales force in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions,



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### ***Program Summary: Awareness Building Initiatives***

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and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.

#### **Total Budget**

The total budget to fund these activities is \$224,980.



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**Emerging Solutions in Pain: Awareness Building Initiatives**  
***Proposed Budget***  
July 5, 2007

<b>Cost Summary</b>	
<i>The Beacon e-Newsletter Series</i>	
Approximate Total, Direct Expenses	\$ 1,000
Total, Indirect Expenses	\$ 85,320
Subtotal, The Beacon e-Newsletter Series	\$ 86,320
<i>ESP Scholarship Fund</i>	
Approximate Total, Direct Expenses	\$ 20,500
Total, Indirect Expenses	\$ 13,960
Subtotal, ESP Scholarship Fund	\$ 34,460
<i>Awareness Campaign</i>	
Approximate Total, Direct Expenses	\$ 65,250
Total, Indirect Expenses	\$ 38,950
Subtotal, Awareness Campaign	\$ 104,200
<b>2008 ESP Awareness Building Initiatives</b>	<b>\$ 224,980</b>



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**Emerging Solutions in Pain: Awareness Building Initiatives**  
**Proposed Budget**  
July 5, 2007

<b>Detailed Budget Itemization: The Beacon e-Newsletter Series</b>	
<i>Direct Expenses, Approximate</i>	
Miscellaneous (phone, fax, non-fulfillment Fed Ex)	\$ 1,000
<b>Approximate Total, Direct Expenses</b>	<b>\$ 1,000</b>
<i>Indirect Expenses</i>	
<b>Project management</b>	
Review and maintenance of newsletter subscription lists	\$ 2,700
Coordination with internal teams	\$ 5,400
Preparation and coordination of status meetings/updates	\$ 900
<b>Content development</b>	
Review of new ESP web-based content posted in last quarter	\$ 6,400
Selection of highlights for newsletter posting	\$ 7,440
Editing for newsletter posting	\$ 9,600
<b>Graphic development for 4 quarterly electronic newsletters</b>	\$ 21,300
<b>Programming of 4 quarterly electronic newsletters</b>	\$ 31,500
<b>Administrative and accounting fees</b>	\$ 80
<b>Total, Indirect Expenses</b>	<b>\$ 85,320</b>



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**Emerging Solutions in Pain: Awareness Building Initiatives**  
**Proposed Budget**  
July 5, 2007

<b>Detailed Budget Itemization: ESP Scholarship Fund</b>	
<b>Direct Expenses, Approximate</b>	
<b>ESP clinician scholarship, quantity: four</b>	\$ 20,000
Includes registration, travel and stipend for selected clinician to one national association meeting/congress	
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$ 500
<b>Approximate Total, Direct Expenses</b>	<b>\$ 20,500</b>
<b>Indirect Expenses</b>	
<b>Project management</b>	
Coordination of scholarship application campaign	\$ 4,800
Selection of scholarship awardees	\$ 3,600
Coordination with scholarship awardees	\$ 1,800
Coordination with internal teams	\$ 750
Preparation and coordination of status meetings/updates	\$ 450
<b>Medical/scientific services</b>	
Creation of verbiage announcing scholarship fund, press releases other associated text	\$ 600
Review and edit to abstracts submitted by scholarship winners	\$ 800
<b>Data management</b>	\$ 750
<b>Administrative and accounting fees</b>	\$ 410
<b>Total, Indirect Expenses</b>	<b>\$ 13,960</b>





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**Emerging Solutions in Pain: Awareness Building Initiatives**  
**Proposed Budget**  
July 5, 2007

<b>Detailed Budget Itemization: Awareness Campaign</b>	
<i>Direct Expenses, Approximate</i>	
<b>Journal advertisements</b>	\$ 47,000
<b>Banner advertisements</b>	\$ 17,500
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$ 750
<b>Approximate Total, Direct Expenses</b>	\$ 65,250
<i>Indirect Expenses</i>	
<b>Project management</b>	
Coordination with internal teams	\$ 2,250
Coordination with third-party vendors	\$ 16,500
Preparation and coordination of status meetings/updates	\$ 1,500
<b>Graphic design / production services</b>	
Creation and subsequent adaptation of print advertisements	\$ 6,075
Creation and subsequent adaptation of banner advertisements	\$ 1,625
Programming of Flash-animations of banner advertisements	\$ 1,500
<b>Medical / scientific services</b>	\$ 8,750
<b>Administrative and accounting fees</b>	\$ 750
<b>Total, Indirect Expenses</b>	\$ 38,950



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## ***Program Summary: Print-Based Tactics***

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### **Program Title**

The Emerging Solutions in Pain Accredited Monograph Series

### **Program Overview**

Medical Learning Solutions is proposing to extend the success of the Emerging Solutions in Pain Accredited Monograph Series by developing and producing an accredited series of four, 8-page monographs, directed toward physicians, pharmacists, nurses and other health care professionals involved in the care of patients with chronic pain. This series of accredited monographs will initially be published in the *Practical Pain Management Journal*; all monographs will be available for credit online at the Emerging Solutions in Pain web site, as well.

### **CE Provider**

Based on the need to educate clinicians in the assessment and treatment of chronic pain patients who may be at risk for abuse, addiction and diversion, the The Emerging Solutions in Pain Accredited Monograph Series will be accredited by a third party CE vendor.

All articles in the Accredited Monograph Series will be accredited for:

- CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each activity will be approved for a maximum of one hour of category 1 credit toward the AMA Physician's Recognition Award.
- CPE credit for pharmacists by the Accreditation Council for Pharmacy Education. Each activity will be approved for a maximum of 1.0 credit hour (0.1 CEU) for Continuing Pharmacy Education
- CNE credit for nurses. Each activity will be approved for a maximum of 1.0 Contact Hours.

### **Intended Audience**

The primary audience of The Emerging Solutions in Pain Accredited Monograph Series includes physicians, pharmacists, nurses and other health care professionals who provide care to patients with pain.

### **Program Objectives**

The purpose of The Emerging Solutions in Pain Accredited Monograph Series is to educate clinicians on key topics relating to the Emerging Solutions in Pain initiatives. The next meeting of the Emerging Solutions in Pain Advisory Board will determine the topics and content areas of the four 2008 monographs; these topics may include, but are not limited to, the following:

- (1) A comparison of the currently available risk assessment tools, focusing on specificity, sensitivity and validity of each
- (2) Proactive documentation strategies for patients with chronic pain who are prescribed opioids
- (3) The medical ethics challenges associated with treating patients at the interface of pain and addiction
- (4) The neurobiology of addiction



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## ***Program Summary: Print-Based Tactics***

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- (5) The role of electronic prescription monitoring systems in identifying patients who are misusing their opioid medications
- (6) Medical residents' beliefs and concerns about using opioids to treat chronic cancer and noncancer pain
- (7) Understanding how opioids contribute to reward and analgesia
- (8) Opioid dependence and addiction during opioid treatment of chronic pain
- (9) Addiction and chronic pain: diagnostic and treatment dilemmas

### **Format**

A series of four, eight-page accredited monographs in the *Practical Pain Management Journal*

### **Post-Activity Feedback**

Course evaluation forms will be required of all participants who seek to receive continuing education credit. Medical Learning Solutions will work with the third party CE vendor to summarize the information collected from these forms in a formal report to evaluate program effectiveness.

Participants will evaluate the following as excellent, good, fair or poor:

- (1) Overall content
- (2) Faculty teaching effectiveness
- (3) Format

Participants will also respond to the following questions:

- (1) How well did the program achieve its educational objectives?
- (2) Do you feel the program material was useful and practice-oriented?
- (3) Do you feel that the information provided in this educational activity will aid in improving patient care in your practice?
- (4) Do you feel that fair balance was maintained for all therapeutic options?
- (5) Would you participate in future educational activities?

### **Distribution**

Medical Learning Solutions and the third party CE vendor will announce and promote The Emerging Solutions in Pain Accredited Monograph Series primarily through advertisement at the Emerging Solutions in Pain web site.

### **Request for Sponsor Support**

As a supplement to these primary methods, Medical Learning Solutions and the third party CE vendor may request the assistance of Cephalon, Inc. sales representatives in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.

### **Total Budget**

The total budget to fund this activity is \$226,548.



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## Emerging Solutions in Pain: Print-Based Tactics

### 2008 PPMJ Accredited Monograph Series

#### *Proposed Budget*

July 5, 2007

<i>Cost Summary</i>	
Approximate Total, Direct Expenses	\$ 170,600
Total, Indirect Expenses	\$ 55,948
<b>2008 PPMJ Accredited Monograph Series</b>	<b>\$ 226,548</b>



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## Emerging Solutions in Pain: Print-Based Tactics

### 2008 PPMJ Accredited Monograph Series

#### Proposed Budget

July 5, 2007

<b>Detailed Budget Itemization: PPMJ Monograph Series, Four Monographs Total</b>	
<b>Direct Expenses, Approximate</b>	
Clinical expert honoraria	\$ 20,000
Insert page charges, <i>Practical Pain Management Journal</i> Eight-page article printed on matte cover stock as journal insert	\$ 92,800
References	\$ 1,800
Accreditation of program for CME, CPE, CNE	\$ 32,000
Continuing Education participant certificates (estimate 750 certificates per program)	\$ 24,000
<b>Approximate Total, Direct Expenses</b>	<b>\$ 170,600</b>
<b>Indirect Expenses</b>	
<b>Project management</b>	
Coordination with faculty	\$ 1,800
Coordination with internal teams, PPMJ staff, accreditor	\$ 1,800
Preparation and coordination of status meetings/updates	\$ 300
<b>Medical services</b>	
Topic/author identification/research	\$ 4,800
Transcript review	\$ 2,400
Outline creation	\$ 3,200
Creation of monographs based on transcription, review with faculty	\$ 12,350
Development of supporting verbiage (needs assessment, objectives, etc.) and self-assessment	\$ 2,400
Incorporation of revisions	\$ 4,800
Proofreading	\$ 3,000
Fact-checking	\$ 8,000
<b>Production services</b>	
Layout and typesetting of articles	\$ 1,750
Creation of supporting web pages for online posting	\$ 250
Programming of finished video for Web-posting, archiving	\$ 3,800
Data management	\$ 2,000
Administrative and accounting fees	\$ 3,298
<b>Total, Indirect Expenses</b>	<b>\$ 55,948</b>



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## ***Program Summary: Print-Based Tactics***

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### **Program Title**

The Emerging Solutions in Pain 2007 Monograph Collection

### **Program Overview**

Medical Learning Solutions is proposing to collect and reaccredit the series of 4 monographs developed during 2007, and release the collection as a single print printed document.

### **CE Provider**

Based on the need to educate clinicians in the assessment and treatment of chronic pain patients who may be at risk for abuse, addiction and diversion, the The Emerging Solutions in Pain 2007 Accredited Monograph Series will be accredited by a third party CE vendor.

All monographs in the collection will be accredited for:

- CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each activity will be approved for a maximum of one hour of category 1 credit toward the AMA Physician's Recognition Award.
- CPE credit for pharmacists by the Accreditation Council for Pharmacy Education. Each activity will be approved for a maximum of 1.0 credit hour (0.1 CEU) for Continuing Pharmacy Education
- CNE credit for nurses. Each activity will be approved for a maximum of 1.0 Contact Hours.

### **Intended Audience**

The primary audience of The Emerging Solutions in Pain 2007 Accredited Monograph Collection includes physicians, pharmacists, nurses and other health care professionals who provide care to patients with pain.

### **Program Objectives**

The purpose of The Emerging Solutions in Pain 2007 Accredited Monograph Collection is to educate clinicians on key topics relating to the Emerging Solutions in Pain initiatives. The topics that will be included in the collection are:

- 1) *Treating Chronic Pain in the Shadow of Addiction* by Penelope Ziegler, MD, FASAM
- 2) *Patient and Clinician: Mutual Shareholders in the Treatment of Chronic Pain* by April Hazard-Vallerand, PhD, RN, FAAN
- 3) *Mapping the Interface of Pain and Addiction* by David Schlyer, MD
- 4) *Prescription Monitoring / Role of the Pharmacist in Chronic Pain (exact topic to be confirmed)* by David Brushwood, RPh, JD



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## ***Program Summary: Print-Based Tactics***

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### **Post-Activity Feedback**

Course evaluation forms will be required of all participants who seek to receive continuing education credit. Medical Learning Solutions will work with the third party CE vendor to summarize the information collected from these forms in a formal report to evaluate program effectiveness.

Participants will evaluate the following as excellent, good, fair or poor:

- (1) Overall content
- (2) Faculty teaching effectiveness
- (3) Format

Participants will also respond to the following questions:

- (1) How well did the program achieve its educational objectives?
- (2) Do you feel the program material was useful and practice-oriented?
- (3) Do you feel that the information provided in this educational activity will aid in improving patient care in your practice?
- (4) Do you feel that fair balance was maintained for all therapeutic options?
- (5) Would you participate in future educational activities?

### **Distribution**

Medical Learning Solutions and the third party CE vendor will announce and promote The Emerging Solutions in Pain 2007 Accredited Monograph Collection primarily as a giveaway at the Emerging Solutions in Pain exhibit booth.

### **Request for Sponsor Support**

As a supplement to these primary methods, Medical Learning Solutions and the third party CE vendor may request the assistance of Cephalon, Inc. sales representatives in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely be as a supplement to MLS' primary methods of announcement and promotion.

### **Total Budget**

The total budget to fund this activity is \$49,259.





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## Emerging Solutions in Pain: Print-Based Tactics

### 2007 Accredited Monograph Collection

#### *Proposed Budget*

July 5, 2007

<b><i>Cost Summary</i></b>	
Approximate Total, Direct Expenses	\$ 38,350
Total, Indirect Expenses	\$ 10,909
<b><i>2007 Accredited Monograph Collection</i></b>	<b>\$ 49,259</b>



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## Emerging Solutions in Pain: Print-Based Tactics

### 2007 Accredited Monograph Collection

#### *Proposed Budget*

July 5, 2007

<b>Detailed Budget Itemization: 2007 Monograph Collection</b>	
<i>Direct Expenses, Approximate</i>	
<b>Printing, quantity 2,000</b>	\$ 25,000
Includes printing of 40-page saddle-stitched booklet, reproducing all 2006 PPMJ monographs	
<b>Accreditation of program for CME, CPE, CNE</b>	\$ 5,000
<b>Continuing Education participant certificates (estimate 750 certificates per program)</b>	\$ 8,000
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$ 350
<b>Approximate Total, Direct Expenses</b>	<b>\$ 38,350</b>
<i>Indirect Expenses</i>	
<b>Project management</b>	
Coordination with internal teams, accreditor	\$ 2,400
Preparation and coordination of status meetings/updates	\$ 600
<b>Medical/scientific services</b>	
Editing review	\$ 1,400
Creation of supporting documents for individual accredited self-study programs	\$ 800
Proofreading	\$ 1,000
<b>Graphic design</b>	
Typesetting, layout	\$ 3,125
Coordination with print vendor	\$ 625
<b>Administrative and accounting fees</b>	\$ 959
<b>Total, Indirect Expenses</b>	<b>\$ 10,909</b>



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## ***Program Summary: Exhibition Booth Series***

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### **Program Title**

The Emerging Solutions in Pain Meet the Expert Exhibit Booth

### **Program Overview**

Medical Learning Solutions is proposing to continue utilizing the Meet the Experts Booth as an informational and interactive display for educating clinicians in the Emerging Solutions in Pain initiatives at national congresses and association meetings. MLS is also proposing to continue the cost effective and efficient tactic of tailoring the size and activities of the Meet the Expert Booth to reflect the attendance and specific purpose of the congress or association. Thus, at larger meetings, the full Meet the Expert Booth will be utilized, while a smaller Emerging Solutions in Pain Booth will be displayed at smaller congress and association meetings.

In 2008, MLS will update both the graphic imagery and multimedia displays to reflect current information in the fields of pain management and addiction medicine, as well as the tools, resources and activities available through ESP at the time of each meeting. Functionality for the full-size Meet the Expert Booth will include a seating area for meeting attendees to interact with Emerging Solutions in Pain clinical experts; computer terminals featuring interactive displays highlighting the Emerging Solutions in Pain initiatives, membership registration for the Emerging Solutions in Pain Web Site, and the Emerging Solutions in Pain Tool Kit. The smaller Emerging Solutions in Pain Booth will focus on interactive displays of the Tool Kit and video highlights of previous Meet the Expert presentations; membership registration; and distribution of the Emerging Solutions in Pain Tool Kit.

### **Intended Audience**

The primary audience of the Emerging Solutions in Pain Meet the Experts Booth will be physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain and who attend selected national association meetings and congresses. MLS is proposing to utilize the full-size exhibit booth at three national association meetings, and the mini exhibit booth at four national association meetings in 2007; each association conference demographic profile and other scientific agenda, and public relations information and will be analyzed on a continuing basis throughout the year to determine the best audience reach and utilization of exhibit booth funds. Possible meetings for both options are listed in below.

#### **Potential Meetings, Full-Size (20' x 20' island) Exhibit Booth**

- American Academy of Pain Medicine
- American Pain Society
- American Academy of Pain Management
- American Academy of Physical Medicine and Rehabilitation

#### **Potential Meetings, Mini (10' x 20" in-line) Exhibit Booth**

- American Society for Addiction Medicine
- American Society for Pain Management Nurses
- International Conference on Pain and Chemical Dependency
- American Academy of Physician Assistants
- American Association for the Treatment of Opioid Dependence
- National Community Pharmacists Association
- American College of Clinical Pharmacy
- American Society of Regional Anesthesia and Pain Medicine



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## ***Program Summary: Exhibition Booth Series***

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### **Program Objectives**

The purpose of the Emerging Solutions in Pain Meet the Expert Booth is to disseminate information concerning the Emerging Solutions in Pain initiative to clinicians practicing in the field of pain management, and to educate those clinicians on the assessment and monitoring of pain patients, and on good practice management techniques. Clinicians visiting the booth will have opportunities to:

- (1) Interact with Emerging Solutions in Pain clinical experts in small discussion groups, focusing on tools and strategies that will contribute to a proper balance of pain control and risk minimization (full-size Meet the Expert Booth only)
- (2) View multi-media, interactive programs highlighting the issues associated with minimization of misuse, abuse and addiction, the Emerging Solutions in Pain Tool Kit and associated case studies
- (3) Utilize interactive survey terminals to allow participants to earn one of the set of five faces of pain stress relievers giveaway
- (4) Receive copies of the Emerging Solutions in Pain Tool Kit CD-ROM and other support materials, such as the ESP Patient Tool Kit materials and the ESP Accredited Monograph collection.
- (5) Gain exposure to the resources available at the Emerging Solutions in Pain Web Site, and register as a "member", thereby expediting their ability to access online resources

### **Format**

The format of the Emerging Solutions in Pain Exhibition Booth Series is an interactive meeting booth, to be presented at national association meetings and congresses. The full-size Meet the Expert Booth will feature live peer-to-peer interactions with Emerging Solutions in Pain clinical experts, as well as interactive, multimedia programs that highlight the Emerging Solutions in Pain initiatives. The smaller Emerging Solutions in Pain Booth will focus on educating clinicians in the availability of the Emerging Solutions in Pain initiatives.

### **Distribution**

The Emerging Solutions in Pain Meet the Expert Booth will be available at selected national association meetings and congresses; meetings identified to date include the AAPM, APS, ASPMN, ICPCD, AATOD, AMCP, AAPMgmt, AAPA, ASRA and ASAM. The announcement of the Booth will be made via direct mail to registered meeting attendees and members, and via journal and/or banner advertisements. Information at the Booth will be provided by Emerging Solutions in Pain clinical experts and by Medical Learning Solutions staff members.

### **Request for Sponsor Support**

Medical Learning Solutions is promoting the Emerging Solutions in Pain Meet the Experts Booth through a variety of methods, including direct mail, publication of a multimedia Mini-Disc, and journal and banner advertisements.

As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. sales representatives in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely as a supplement to MLS' primary methods of



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### ***Program Summary: Exhibition Booth Series***

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announcement and promotion. Content developed for this program may also be repurposed as a CE-accredited enduring material and published on the ESP website at a later date.

#### **Total Budget**

The total budget to fund these activities is \$717,038.



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**2008 Emerging Solutions in Pain Exhibition Booth Series**  
**Proposed Budget**  
July 5, 2007

<b>Program Parameters</b>	
<b>Number of Exhibitions of the Full-Size 20x20 ESP Booth</b>	<b>3</b>
<b>Number of Exhibitions of the Mini 10x20 ESP Booth</b>	<b>4</b>

<b>Cost Summary</b>		
	Per Meeting	Total
<i>One-Time Expenses</i>		
<b>Approximate Total, Direct Expenses</b>	\$ -	\$ 20,150
<b>Indirect Expenses</b>	\$ -	\$ 17,201
<b>Subtotal, One-Time Expenses</b>	\$ -	\$ 37,351
<i>Full-Size, 20x20 Exhibit Booth Series, 3 Meetings Total</i>		
<b>Approximate Total, Direct Expenses</b>	\$ 79,200	\$ 237,600
<b>Total, Indirect Expenses</b>	\$ 47,111	\$ 141,333
<b>Subtotal, Full-Size 20x20 Exhibit Booth Series, 4 Meetings Total</b>	\$ 126,311	\$ 378,933
<i>Mini 10x20 Exhibit Booth Series, 4 Meetings Total</i>		
<b>Approximate Total, Direct Expenses</b>	\$ 37,100	\$ 148,400
<b>Total, Indirect Expenses</b>	\$ 38,088	\$ 152,354
<b>Subtotal, Mini 10x20 Exhibit Booth Series, 4 Meetings Total</b>	\$ 75,188	\$ 300,754
<b>Total Cost of the 2008 ESP Exhibition Booth Series</b>	\$	<b>717,038</b>



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**2008 Emerging Solutions in Pain Exhibition Booth Series**  
***Proposed Budget***  
July 5, 2007

<b>Detailed Budget Itemization: One-Time Expenses, 2008 ESP Exhibition Booth Series</b>		
<b>Direct Expenses, Approximate</b>		
	Per Meeting	Total
Updates and maintenance to 20x20 booth		\$ 3,000
Updates and maintenance to 10x20 booth		\$ 3,000
Exhibit booth storage fee		\$ 3,400
Additional faces of pain giveaways, quantity: 1,000		\$ 10,750
<b>Subtotal, One-Time Approximate Direct Expenses</b>		<b>\$ 20,150</b>
<b>Indirect Expenses</b>		
	Per Meeting	Total
<b>Project management</b>		
Coordination with internal teams		\$ 3,500
Coordination with third-party booth vendor		\$ 2,500
Preparation and coordination of status meetings/updates		\$ 1,500
<b>Medical/scientific services</b>		
Creation of supporting text for exhibit program		\$ 3,800
Proofreading		\$ 1,000
<b>Graphic design</b>		
Graphic design for new booth graphics		\$ 3,500
Coordination with third-party vendors		\$ 1,000
<b>Administrative, accounting fees</b>		<b>\$ 401</b>
<b>Subtotal, One-Time Indirect Expenses</b>		<b>\$ 17,201</b>





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**2008 Emerging Solutions in Pain Exhibition Booth Series**  
**Proposed Budget**  
July 5, 2007

<b>Detailed Budget Itemization: Full-Size, 20x20 Exhibit Booth Series</b>		
<b>Direct Expenses, Approximate</b>		
	<b>Per Meeting</b>	<b>Total, 3 Meetings</b>
<b>Exhibit space plus liability insurance</b>	\$ 14,800	\$ 44,400
<b>Booth set-up/tear-down</b> Includes floor plan, shop prep, installation and dismantling including labor supervision, travel	\$ 20,000	\$ 60,000
<b>AV installation and supervision</b> Includes installation of all computer units, plasma screens, switcher units, audio needs, electrical, telecommunication links, etc.	\$ 3,600	\$ 10,800
<b>Booth supplies</b> Rental and purchase of booth supplies such as flowers, chairs, cleaning service, waste baskets, etc.	\$ 500	\$ 1,500
<b>Shipping of booth to meeting site</b>	\$ 8,800	\$ 26,400
<b>Shipping of supplies</b> Includes shipping of mini-discs, Tool Kits, etc. to meeting site and delivery to booth charges	\$ 2,100	\$ 6,300
<b>Interactive touch screen survey</b> Includes development and management of electronic survey program capturing attendee response to meeting specific questionnaire	\$ 1,000	\$ 3,000
<b>Booth advertisement</b> Advertisement in meeting catalog/publication (full page, 4/c)	\$ 3,000	\$ 9,000
Booth posters, printing	\$ 900	\$ 2,700
<b>KOL expenses: two KOL faculty</b>		
Honoraria	\$ 12,000	\$ 36,000
Travel: air, hotel, ground, OOP	\$ 4,300	\$ 12,900
Faculty registration	\$ 1,000	\$ 3,000
<b>ROI expenses: three ROI staff</b>		
Travel: air, hotel, ground, OOP	\$ 6,900	\$ 20,700
Exhibitor registration	\$ 300	\$ 900
<b>Approximate Total, Direct Expenses</b>	<b>\$ 79,200</b>	<b>\$ 237,600</b>



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**2008 Emerging Solutions in Pain Exhibition Booth Series**  
**Proposed Budget**  
July 5, 2007

<b>Detailed Budget Itemization: Full-Size, 20x20 Exhibit Booth Series (con't)</b>		
<b>Indirect Expenses</b>		
	<b>Per Meeting</b>	<b>Total, 3 Meetings</b>
<b>Project management</b>		
Coordination with conference vendors	\$ 1,800	\$ 5,400
Coordination with KOLs for The Doctor is In schedule	\$ 2,700	\$ 8,100
Coordination of pre-meeting processes	\$ 6,150	\$ 18,450
Coordination of booth advertising and other support materials	\$ 1,800	\$ 5,400
Coordination with internal teams	\$ 1,950	\$ 5,850
Preparation and coordination of status meetings/updates	\$ 600	\$ 1,800
<b>Medical / scientific services</b>		
Development of copy for meeting advertisements	\$ 450	\$ 1,350
Development of copy for plasma screen loop, other booth support materials	\$ 1,050	\$ 3,150
Proofreading	\$ 1,000	\$ 3,000
<b>Graphic design / production services</b>		
Adaptation of display graphics for plasma loop and all associated tickers	\$ 2,000	\$ 6,000
Typesetting and layout of booth posters	\$ 750	\$ 2,250
Typesetting and layout of advertisements (direct mail plus meeting catalog)	\$ 1,750	\$ 5,250
Coordination with third-party print vendors	\$ 500	\$ 1,500
<b>Conference management services</b>		
Management of pre-meeting booth set-up	\$ 3,000	\$ 9,000
Management of post-meeting booth tear-down	\$ 3,350	\$ 10,050
Staffing of booth during meeting	\$ 14,700	\$ 44,100
Coordination with KOLs during meeting	\$ 1,950	\$ 5,850
<b>Administrative and accounting fees</b>	\$ 1,611	\$ 4,833
<b>Total, Indirect Expenses</b>	<b>\$ 47,111</b>	<b>\$ 141,333</b>



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**2008 Emerging Solutions in Pain Exhibition Booth Series**  
**Proposed Budget**  
July 5, 2007

<b>Detailed Budget Itemization: Mini, 10x20 Exhibit Booth Series</b>		
<b>Direct Expenses, Approximate</b>		
	<b>Per Meeting</b>	<b>Total, 4 Meetings</b>
<b>Exhibit space plus liability insurance</b>	\$ 6,250	\$ 25,000
<b>Booth set-up/tear-down</b> Includes floor plan, shop prep, installation and dismantling including labor supervision, travel	\$ 8,000	\$ 32,000
<b>AV installation and supervision</b> Includes installation of all computer units, plasma screens, switcher units, audio needs, electrical, telecommunication links, etc.	\$ 3,600	\$ 14,400
<b>Booth supplies</b> Rental and purchase of booth supplies such as flowers, chairs, cleaning service, waste baskets, etc.	\$ 500	\$ 2,000
<b>Shipping of booth to meeting site</b>	\$ 8,000	\$ 32,000
<b>Shipping of supplies</b> Includes shipping of mini-discs, Tool Kits, etc. to meeting site and delivery to booth charges	\$ 2,200	\$ 8,800
<b>Booth advertisement</b> Advertisement in meeting catalog/publication (full page, 4/c)	\$ 3,000	\$ 12,000
Booth posters, printing	\$ 750	\$ 3,000
<b>ROI expenses: three ROI staff</b> Travel: air, hotel, ground, OOP	\$ 4,600	\$ 18,400
Exhibitor registration	\$ 200	\$ 800
<b>Approximate Total, Direct Expenses</b>	<b>\$ 37,100</b>	<b>\$ 148,400</b>



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**2008 Emerging Solutions in Pain Exhibition Booth Series**  
**Proposed Budget**  
July 5, 2007

<b>Detailed Budget Itemization: Mini, 10x20 Exhibit Booth Series (con't)</b>		
<b>Indirect Expenses</b>		
	<b>Per Meeting</b>	<b>Total, 4 Meetings</b>
<b>Project management</b>		
Coordination with conference vendors	\$ 1,500	\$ 6,000
Coordination of pre-meeting processes	\$ 5,700	\$ 22,800
Coordination of booth advertising and other support materials	\$ 1,750	\$ 7,000
Coordination with internal teams	\$ 1,950	\$ 7,800
Preparation and coordination of status meetings/updates	\$ 600	\$ 2,400
<b>Medical / scientific services</b>		
Development of copy for meeting advertisements	\$ 450	\$ 1,800
Development of copy for plasma screen loop, other booth support materials	\$ 1,050	\$ 4,200
Proofreading	\$ 1,000	\$ 4,000
<b>Graphic design / production services</b>		
Adaptation of display graphics for plasma loop and all associated tickers	\$ 2,000	\$ 8,000
Typesetting and layout of booth posters	\$ 750	\$ 3,000
Typesetting and layout of advertisements (direct mail plus meeting catalog)	\$ 1,750	\$ 7,000
Coordination with third-party print vendors	\$ 500	\$ 2,000
<b>Conference management services</b>		
Management of pre-meeting booth set-up	\$ 2,850	\$ 11,400
Management of post-meeting booth tear-down	\$ 3,000	\$ 12,000
Staffing of booth during meeting	\$ 12,400	\$ 49,600
<b>Administrative and accounting fees</b>	\$ 838	\$ 3,354
<b>Total, Indirect Expenses</b>	<b>\$ 38,088</b>	<b>\$ 152,354</b>

## Appendix A: Emerging Solutions in Pain Accredited Monograph Series, 2006 - 2007

## Evaluation Summary Data

## VIGIL by David Brushwood, PharmD, JD

	Overall content		Format		State the goals of the VIGIL process		Define and describe the five-step VIGIL process		Contrast the differences and similarities of an opioid agreement and the VIGIL process		Identify responsibilities related to prescriber, dispenser, and patient when applying the VIGIL process		Do you feel the activity was useful to you in your practice setting?	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Yes	Percent
Excellent	68	56.2%	65	54.6%	81	67%	88	73%	65	54%	71	59%	114	95%
Good	49	40.5%	53	44.5%	38	31%	31	26%	51	42%	47	39%	No	
Fair	4	3.3%	1	0.8%	2	2%	2	2%	5	4%	2	2%	6	5%
Poor	0	0.0%	0	0.0%	0	0%	0	0%	0	0%	0	0%		
Totals	121	100%	119	100%	121	100%	121	100%	121	100%	120	100%	120	

## Relating Central Sensitization and Hyperalgesia to Opioid Pain Management and Preemptive Analgesia by Jeffrey Gudin, MD

	Overall content		Format		Differentiate central sensitization from peripheral sensitization		Recognize the role of microreceptor agonists in the development of hyperalgesia		Identify pharmacotherapeutic options demonstrated to improve patient management		Do you feel the activity was useful to you in your practice setting?	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Yes	Percent
Excellent	105	45.3%	98	43.6%	123	53%	103	44%	95	41%	227	97%
Good	121	52.2%	118	52.4%	99	42%	111	48%	118	51%	No	
Fair	6	2.6%	9	4.0%	11	5%	19	8%	18	8%	6	3%
Poor	0	0.0%	0	0.0%	0	0%	0	0%	0	0%		
Totals	232	100%	225	100%	233	100%	233	100%	231	100%	233	

## What Role Does Age Play in the Management of Chronic Pain in Adult Patients? By Bill H. McCarberg, MD

	Recognize why it is important to understand unique traits that characterize different populations		Identify differences between the health status of older and younger adult chronic pain patients		Identify the components of a pain management program that are particularly beneficial for older adults		Recognize the importance of assessing and monitoring for potential opioid abuse in all populations of chronic pain patients		Do you feel the activity was useful to you in your practice setting?	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Yes	Percent
Excellent	63	58.3%	55	50.9%	53	49%	20	48%	101	95%
Good	40	37.0%	48	44.4%	46	43%	21	50%	No	
Fair	5	4.6%	3	2.8%	9	8%	1	2%	5	5%
Poor	0	0.0%	2	1.9%	0	0%	0	0%		
Totals	108	100%	108	100%	108	100%	42	100%	106	

## Pain Patients at Risk of Abuse and Those with Comorbid Psychopathology: A Guide to Identification and Treatment by Rafael Miguel, MD

	Overall content		Format		Identify which comorbidities are associated with chronic pain and indicate their order of frequency		Contrast and compare the impact associated with inadequate treatment of pain or a comorbid condition		Identify three assessment tools that should help determine the option of referral		Recognize signs and symptoms of a chronic pain patient presenting with psychopathology or at risk for controlled substance misuse or addiction		Do you feel the activity was useful to you in your practice setting?	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Yes	Percent
Excellent	238	59.2%	228	57.9%	243	60%	215	54%	235	59%	36	64%	392	99%
Good	162	40.3%	165	41.9%	158	39%	178	44%	160	40%	19	34%	No	
Fair	2	0.5%	1	0.3%	3	1%	8	2%	4	1%	0	0%	4	1%
Poor	0	0.0%	0	0%	0	0%	0	0%	0	0%	1	2%		
Totals	402	100%	394	100%	402	100%	401	100%	399	100%	56	100%	396	

## Appendix A: Emerging Solutions in Pain Accredited Monograph Series, 2006 - 2007

## Evaluation Summary Data

Case Studies in Pain Management A Spectrum of Abuse and Addiction by Michael H. Moskowitz, MD,MPH															
	Overall content		Format		Identify and distinguish the clinical differences between addiction, tolerance, and physical dependence		Describe how the use of informed consent documentation and other techniques may be effectively used with patients who are prescribed opioids.			Describe assessment and monitoring tools and techniques that support the identification of a patient who may be displaying the signs of aberrant behavior		Summarize pharmacologic approaches to analgesia that may be used in a chronic pain patient with an increased risk for abuse, addiction or diversion of opioids		Do you feel the activity was useful to you in your practice setting?	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Percent	Number	Percent	Number	Percent	Yes	Percent
Excellent	15	50.0%	15	50.0%	14	47%	15	50%	50%	11	37%	13	43%	29	97%
Good	14	46.7%	13	43.3%	15	50%	12	40%	40%	15	50%	14	47%	No	
Fair	1	3.3%	2	6.7%	1	3%	3	10%	10%	4	13%	3	10%	1	3%
Poor	0	0.0%	0	0.0%	0	0%	0	0%	0%	0	0%	0	0%		
Totals	30	100%	30	100%	30	100%	30	100%	100%	30	100%	30	100%	30	

The Connection Between Cigarette Smoking and Aberrant Drug-Taking Behavior in Opioid Therapy for Chronic Pain by Steve Passik, PhD and Lara Dilling, PhD												
	Overall content		Format		To identify linkages between smoking and aberrant drug-taking behavior in patients with chronic pain		To examine multiple etiologies for the association between smoking and aberrant drug-taking behavior in patients with chronic pain		To critically evaluate the significance of smoking in the assessment of the chronic pain patient		Do you feel the activity was useful to you in your practice setting?	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Yes	Percent
Excellent	38	44.2%	34	42.0%	42	49%	40	47%	38	44%	86	100%
Good	45	52.3%	45	55.6%	43	50%	45	52%	47	55%	No	
Fair	3	3.5%	2	2.5%	1	1%	1	1%	1	1%	0	0%
Poor	0	0.0%	0	0.0%	0	0%	0	0%	0	0%		
Totals	86	100%	81	100%	86	100%	86	100%	86	100%	86	

Evaluating Interdisciplinary and Multidisciplinary Approaches to Chronic Pain Management by Steven Stanos, DO												
	Overall content		Format		Differentiate multidisciplinary vs. interdisciplinary therapeutic models for patients in chronic pain		Identify common features to both multidisciplinary and interdisciplinary care		Recognize clinical and economic outcomes derived from applying each type of care model		Do you feel the activity was useful to you in your practice setting?	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Yes	Percent
Excellent	56	45.5%	59	48.4%	78	62%	76	61%	61	49%	114	91%
Good	56	45.5%	49	40.2%	39	31%	39	31%	54	43%	No	
Fair	11	8.9%	9	7.4%	8	6%	9	7%	10	8%	11	9%
Poor	0	0.0%	5	4.1%	0	0%	0	0%	0	0%		
Totals	123	100%	122	100%	125	100%	124	100%	125	100%	125	

A Closer Look at Racial/Ethnic Disparities in Pain Management by April Hazard Vallerand, PhD, RN												
	Overall content		Format		Evaluate critical evidence of existing racial/ethnic disparities in pain management in the US		Summarize potential contributors to health disparities, including patient related and physician-related factors		Communicate strategies to reduce, and eventually eliminate, health disparities in pain management		Do you feel the activity was useful to you in your practice setting?	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Yes	Percent
Excellent	53	38.4%	62	44.9%	72	52%	64	46%	66	48%	122	90%
Good	80	58.0%	66	47.8%	61	44%	69	50%	64	46%	No	
Fair	4	2.9%	10	7.2%	5	4%	4	3%	7	5%	14	10%
Poor	1	0.7%	0	0.0%	0	0%	1	1%	1	1%		
Totals	138	100%	138	100%	138	100%	138	100%	138	100%	136	

Determining the Risk of Opioid Abuse by Lynn R. Webster, MD														
	Overall content		Format		Identify the risk factors most supported by the scientific literature for abusing the opioids prescribed for chronic pain		Summarize the importance of assessing patients for abuse risk prior to beginning chronic opioid pain therapy		Compare and contrast the various characteristics, advantages, and limitations of available assessment tools, with a special emphasis on newer, brief, opioid-specific tools		Outline the monitoring techniques proportionate to the individual patient's risk for abuse		Do you feel the activity was useful to you in your practice setting?	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Yes	Percent
Excellent	32	76.2%	27	65.9%	30	73%	28	68%	23	56%	25	61%	41	100%
Good	9	21.4%	13	31.7%	10	24%	12	29%	15	37%	12	29%	No	
Fair	1	2.4%	1	2.4%	1	2%	1	2%	3	7%	4	10%	0	0%
Poor	0	0.0%	0	0.0%	0	0%	0	0%	0	0%	0	0%		
Totals	42	100%	41	100%	41	100%	41	100%	41	100%	41	100%	41	



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## ***Appendix B: Medical Learning Solutions Faculty Advisory Board***

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**David B. Brushwood, RPh, JD**

Professor, Department of Pharmacy Health Care Administration  
University of Florida  
Gainesville, Florida

**Jennifer Bolen, JD**

Founder, The Legal Side of Pain  
A Division of the J. Bolen Group, LLC  
Knoxville, Tennessee

**Doug Gourlay, MD, FRCPC, FASAM**

Director, Pain and Chemical Dependency  
Wasser Pain Management Centre  
Mount Sinai Hospital  
Toronto, Ontario, Canada

**Howard A. Heit, MD, FACP, FASAM**

Board Certified in Internal Medicine and Gastroenterology/Hepatology  
Certified in Addiction Medicine and as a Medical Review Officer  
Chronic Pain Specialist  
Assistant Clinical Professor  
Georgetown University

**Steven Passik, PhD**

Associate Attending Psychologist, Memorial Sloan-Kettering Cancer Center  
Associate Professor of Psychiatry, Weill College of Cornell Medical Center,  
New York, New York

**Joseph Shurman, MD**

Chairman, Pain Management  
Scripps Memorial Hospital  
La Jolla, California

**Jennifer M. Strickland, PharmD, BCPS**

Pain Management and Palliative Care Specialist  
Lakeland Regional Medical Center  
Lakeland, Florida  
Assistant Clinical Professor  
University of Florida College of Pharmacy  
Gainesville, Florida

**April Hazard Vallerand, PhD, RN, FAAN**

Associate Professor  
College of Nursing  
Wayne State University  
Detroit, Michigan

**Lynn R. Webster, MD, FACPM, FASAM**

Medical Director  
Lifetree Clinical Research and Pain Clinic  
Salt Lake City, Utah





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## ***Appendix C: Medical Learning Solutions Disclosure Policy***

### **Purpose of the MLS Disclosure Policy**

The policy on disclosure exists to provide guidance for staff, faculty and joint/co-sponsors of the requirement to disclose specific information to participants in order to comply with the following standards for all activities sponsored by Medical Learning Solutions.

- ACCME's 2004 Updated Standards for Commercial Support
- ACPE's Criteria for Quality and Interpretive Guidelines
- California Board of Registered Nursing Standards and Guidelines

This disclosure policy includes identification and disclosure of the following:

- Sponsor financial relationships
- Faculty and family/significant others financial relationships
- Discussion of unlabeled or unapproved uses of drugs and devices

As a joint sponsor of continuing education programs, Medical Learning Solutions is required to collect information from individuals who have an opportunity to affect the CE content about products or services of a commercial interest with which he/she has a financial relationship to allow a determination to be made as to whether that relationship may constitute a conflict of interest that must be resolved.

### **The Medical Learning Solutions Disclosure Policy**

1. Disclosure documents must be completed by anyone involved in planning or presenting educational content at CE programs approved for CME/CPE/CNE inclusive of the MLS advisory committee members, clinical content reviewers and identified faculty members.
2. Medical Learning Solutions requires all those in a position to control content to provide specific information to CE participants.
3. Medical Learning Solutions requires faculty to provide specific information to CE participants. Disclosure is required in two areas:
  - **Financial Relationships**  
Faculty must disclose any significant relationship between themselves/significant others and (a) the commercial supporter(s) of the program, and (b) the manufacturer of any product discussed in the CE program or related to the topic of the event. Information reported shall include financial relationships in place over the preceding twelve-month period. If the faculty has nothing to report, that information must be indicated.
  - **Discussion of Unlabeled Use**  
Faculty must disclose in writing and communicate in writing through course materials, that a product is not labeled for the use under discussion or that the product is still investigational and not approved for use in the United States.
4. Faculty members are required to complete the Faculty Disclosure Forms, and Attestation Forms as required by the accredited provider of each activity, prior to the program development process.
  - Required forms attached as provided by MLS' accrediting partner, MediCom Worldwide, Inc.
5. Disclosure Forms must be completed and returned to MLS prior to content development. Faculty refusing to disclose may not participate as a speaker for program in which disclosure was not obtained.



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### ***Appendix C: Medical Learning Solutions Disclosure Policy***

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6. Potential conflicts of interest disclosed will be reviewed by MLS and must be resolved prior to the educational activity.
7. Once a conflict is identified, a content validation process is initiated to ensure that the content or format of the CE activity and related materials will promote improvements or quality in health care and not promote a specific proprietary business interest of a commercial interest.
8. MLS conducts an unbiased review of all planned content for activities certified for credit to resolve any actual or perceived conflict of interest that exists.
9. Faculty must disclose to participants prior to the start of the educational activity the existence of significant situations where a direct commercial support relationship exists with the educational activity.
10. MLS discloses the following information to learners: 1) the name of the individual, 2) the name of the commercial interest(s), and 3) the nature of the relationship the individual has with the commercial interest. MLS also discloses to learners the name(s) of commercial interests supporting each CE activity.
11. Faculty disclosures will be documented and available to all participants via written participant handout information i.e.; syllabi, introductory slides, workbooks.
  - Disclosure will be made available to audience at the start of each activity.
12. Faculty must also disclose prior to the start of the educational activity if no significant financial relationships exist.
13. If faculty members present at multiple independent educational activities, a separate disclosure form is required for each activity.
14. Implementation:
 

All internal content review staff and outside external expert reviewers and faculty will complete a *Financial Disclosure Form* that contains the following information:

  - The form shall note the title and date of the activity, as well as the name(s) of the commercial supporter(s) associated with the activity.
  - The form shall solicit information about the financial relationship(s) of the reviewer, faculty member, his/her immediate family member or significant other has with any commercial supporter, as well as manufacturers of products associated with the activity or related to the topic of the activity.
  - If no relationship exists, there shall be a box to check to that effect.
  - The form shall solicit information from the faculty member as to plan to address off-label discussion or investigational use of a drug in his/her presentation.
15. Timeline for disclosure of financial relationships:
  - Internal reviewer will complete the disclosure form upon employment.
  - External experts will complete the disclosure form at the time a relationship with MLS has been identified.
  - Presenting faculty will be asked to sign a disclosure form at the time of invitation to participate in a planned program.

## FACULTY DISCLOSURE FORM



As a CE provider accredited by the Accreditation Council for Continuing Medical Education (ACCME) and approved by the Accreditation Council for Pharmacy Education (ACPE), and the California Board of Registered Nursing, MediCom Worldwide, Inc. must ensure balance, independence, transparency, objectivity, and scientific rigor in all sponsored educational activities. Faculty participating in a sponsored activity are expected to (1) disclose to the audience any financial relationship with the manufacturer(s) of any commercial product(s) and/or provider(s) of commercial services, and/or with any commercial supporters of the activity and (2) assist in resolving any conflict of interest that may arise from the relationship. The intent of this disclosure is not to prevent a presenter with a financial or other relationship from making a presentation, but rather to provide learners with information on which they can make their own judgments. It remains for the audience to determine whether the speakers' interests or relationships may influence the presentation. In addition, MediCom Worldwide, Inc. presenters must make a meaningful disclosure to the audience of their discussions of unlabeled or unapproved drugs or devices. All MediCom Worldwide, Inc. faculty are required to provide disclosure as a condition of participation.

**Title of Presentation:**

**Faculty Member's Name:**

**Check all that apply:**

- ☐ I have no relationship(s) to disclose
- ☐ I, the undersigned, have a financial arrangement or affiliation with a corporate organization offering financial support or grant monies for, or related to, this activity
- ☐ I, the undersigned, have a financial relationship with a manufacturer of a product or device discussed in my presentation at this continuing education activity
- ☐ I have a spouse or partner who has a financial relationship with a corporate organization offering financial support or grant monies, and/or with a manufacturer of a product or device

*\* It is not a requirement to disclose honoraria received for a participation in a CE activity \**

Commercial Interest	*Nature of Relevant Financial Relationship		Suggestions for Resolving Conflicts of Interest
	What was received?	For what role?	

(Please attach a separate sheet of necessary)

**Example terminology:**

**What was received:** Salary, royalty, intellectual property rights, consulting fee, non-CE activity honoraria, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit.

**Role(s):** Employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities (please specify).

**Suggestions for resolving conflicts of interest (COI):** In addition to the MediCom Worldwide, Inc. peer review process for resolving COI, other examples include altering the control of the content of a CE activity by (1) choosing someone else to control that part of the content; (2) change the focus of the CE activity; (3) change the content of the person's assignment; (4) limit the content to a report without recommendations; and (5) limit the source for recommendations. \*There is no set dollar amount for a financial relationship to be significant. Inherent in any amount received is the incentive to maintain or increase the value of the relationship with a commercial entity or manufacturer of a product or device. Therefore, **any** amount received within the past 12 months must be disclosed.

- ☐ I intend to reference **unlabeled** uses of drugs or products in my presentation, and will disclose this to the audience (specify drug(s) or product(s)):

- ☐ I intend to reference **investigational/unapproved** uses of drugs or products in my presentation, and will disclose this to the audience (specify drug(s) or product(s)):

- ☐ I agree to the Terms and Conditions

Signature \_\_\_\_\_ Date \_\_\_\_\_

## TERMS AND CONDITIONS

By signing this form, the undersigned speaker/author understands and accepts the following rules as required by MediCom Worldwide, Inc., the *Essential Areas and Policies* of the ACCME, and the rules of the American Medical Association:

1. **Disclosure.** Speakers/authors must complete and submit a Faculty Disclosure Form prior to the presentation, and that Faculty Disclosure Form shall be complete and truthful to the best of the speakers' knowledge. Speakers/authors are required to disclose any financial relationship they may have with any product or class of products they discuss in an educational activity. The resolution of conflict of interest will assist the learners in assessing the potential for influence in information that is presented.
2. **Fair-Balance.** Speakers/authors are required to prepare fair and balanced presentations, which are *objective and scientifically rigorous*.
3. **Transparency.** Speakers/authors are required to disclose any financial relationship that will assist the learners in assessing the potential for influence in information that is presented.
4. **Unlabeled and Unapproved Uses.** Presentations that provide information in whole or in part related to non-FDA approved uses for drug products and/or devices must clearly acknowledge the unlabeled indications or the investigative nature of their proposed uses to the audience. Speakers who plan to discuss non-FDA approved uses for commercial products and/or devices must advise MediCom Worldwide, Inc. of their intent.
5. **Use of Generic versus Trade Names.** Presenters should use scientific or generic names in referring to products in their lectures or enduring materials. Should it be necessary to use a trade name, then *the trade names of all similar products or those within a class should be used*.
6. **Commercial Supporter Influence.** Faculty are not permitted to receive any direct remuneration or gifts from the commercial supporter(s) of this activity, nor should they be subject to direct input from a commercial supporter regarding the content of their presentation.







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## ***Appendix D: Medical Learning Solutions Policy Concerning Content Without Commercial Bias***

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### **Purpose of the MLS Policy Concerning Content Without Commercial Bias**

The policy on Content Without Commercial Bias exists to establish criteria, policy and process of implementation of content standards of CE activities in accordance with the ACCME Standard for Commercial Support; Content and Format without Commercial Bias, and the content requirements of the ACPE and California Board of Registered Nursing.

### **The Medical Learning Solutions Policy Concerning Content Without Commercial Bias**

1. Medical Learning Solutions must review the planned content of a CE activity to be certified by MediCom Worldwide, Inc., or other third party accredited provider, and demonstrate in documentation that the content or format of a CE activity adheres to the following criteria:
  - a. Presentations and/or its related materials must promote improvements or quality in health care and not a specific proprietary business interest of a commercial interest.
  - b. Presentations and/or its related materials must give a balanced view of therapeutic options.
  - c. Use of generic names within the body of the presentation or its related materials is required.
    - 1) Related presentation materials may contain trade names for all generic products contained within the presentation that are from several companies, as available.
2. All content from CE activities will undergo content validation process.
  - Content must conform to the generally accepted standards of experimental design, data collection and analysis.
  - Faculty must attest to MLS that the presentation content or content of its related materials promote improvement or quality in health care and not a specific proprietary business interest of a commercial interest.
  - Faculty must attest to MLS that the presentation gives a balanced view of therapeutic options.
  - MLS' internal and external reviewers must evaluate and attest that faculty presentation and its related materials promote improvements or quality in health care and not a specific proprietary business interest of a commercial interest.
  - Internal and external content reviewers must evaluate and attest that the presentation gives a balanced view of therapeutic options.
3. Activities are not eligible for certification if the content and/or format promote recommendations, treatments or manners of practicing medicine that are not within the definition of CME or are known to have risks or dangers that outweigh the benefits or are known to be ineffective in the treatment of patients. Activities that offer recommendation, treatments or practice manners outside of the definition of continuing pharmacy or nursing education, or that have risks or dangers that outweigh the benefits or are known to be ineffective are not eligible for certification.
4. CE activities must be developed and presented utilizing the principles of adult learning, which includes thorough assessment of learners' needs and focus on participant involvement in the learning process.
5. Faculty selected to participate must be demonstrated thought leaders in the topic of the CE activity and must have demonstrated skill in providing education to adult learners. Faculty should hold advanced degrees in their area of specialty, and should be active in research or patient care within



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### ***Appendix D: Medical Learning Solutions Policy Concerning Content Without Commercial Bias***

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an academic or clinical setting. Faculty may not be employees of the commercial supporter of an educational activity, regardless of qualification. Faculty will be asked to provide their qualifications and educational background to activity planners for review. Faculty will be advised of content requirements in their faculty letters.

6. MLS may solicit the review by an expert reviewer; members of the Medical Learning Solutions advisory committee provide oversight of MLS' program planning and design. A member of the advisory committee may be asked to provide content review for selected MLS activities. Whenever possible, advisory committee members are asked to review activities that fall within their area of clinical expertise.
7. The clinical pharmacy consultant provides oversight and review of program planning, design and in-depth content review of each activity, and verifies that the proposed amounts of pharmacology hours and content are appropriate for pharmacy credit.
8. The executive director will give final approval for the activity content and appropriate credit/contact hour designation, indicating that the content is deemed valid and within the criteria as stated in this policy. This form will be signed by the executive director. This is contained in the CE planning document.
9. Evidence of valid content will be placed in the activity file under planning.





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## ***Appendix E: Medical Learning Solutions Policy on Faculty and Speaker Selection***

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### **Purpose of the MLS Policy on Faculty and Speaker Selection**

The policy on Faculty and Speaker Selection exists to establish guidelines for the determination of qualitative and quantitative considerations in the faculty selection process.

### **The Medical Learning Solutions Policy on Faculty and Speaker Selection**

#### ***Qualitative Considerations***

Faculty selected to participate must be demonstrated thought leaders in the topic of the CE activity and must have demonstrated skill in providing education to adult learners. Faculty should hold advanced degrees in their area of specialty, and should be active in research or patient care within an academic or clinical setting. Faculty may not be employees of the commercial supporter of an educational activity, regardless of qualifications. Faculty will be asked to provide their qualifications and educational background to MLS for review. Faculty will be advised of content requirements in their faculty letters sent by MLS.

1. Faculty must attest to MLS that the presentation content or content of its related materials promote improvement or quality in healthcare and not a specific proprietary business interest of a commercial interest.
  - Faculty must attest to MLS that the presentation gives a balanced view of therapeutic options.
  - MLS' internal and external reviewers must evaluate and attest that faculty presentation and its related materials promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.
  - CE activities must be developed and presented utilizing the principles of adult learning, which includes thorough assessment of learners' needs and focus on participant involvement in the learning process.
2. Upon selection and approval of the faculty, a letter of guidance is written to the faculty outlining the expectations.
3. Each faculty member must submit a CV for review.
4. Each faculty member must complete and sign a disclosure form and attestation form.
5. Those faculty members who do not complete required disclosure information will not be permitted to participate in the activity as planned.
6. The executive director or designee will communicate directly with faculty, providing each faculty member with written information related to objectives of the program.
7. The executive director or designee will provide technical assistance necessary to prepare materials for presentation.

#### ***Determination of Number of Faculty Required Per Planned Activity***

1. An appropriate number of qualified faculty members shall be utilized for each continuing education program
2. The executive director will be responsible for determination of number of faculty required for each program. Determination will be based on number of topics, depth of subject matter and



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## ***Appendix E: Medical Learning Solutions Policy on Faculty and Speaker Selection***

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anticipated duration of  
the program.

3. MLS will strive to maintain a ratio of at least one faculty member per every one hour of formal didactic lecture.

### ***Program Evaluation***

1. A program evaluation form is developed for each activity, which is intended to solicit participant's assessment of faculty effectiveness.
2. Evaluation forms are distributed to participants at the end of each activity. Each participant is required to complete the form as designed, as well as provide any written feedback or comments regarding program.
3. A formal summary report is completed following each program or program series. This report compiles the results of the evaluation form as well as narrative comments from participants.
4. A designated member of the CE staff will directly monitor each educational activity.



## Exhibit B

## ACTIQ Risk Management Program

Provider is aware that ACTIQ® (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- ACTIQ is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- ACTIQ is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.
- ACTIQ is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.



www.cephalon.com

## FENTORA Risk Management Program

Cephalon, Inc.  
 41 Moores Road  
 P.O. Box 4011  
 Frazer, PA 19355  
 Phone 610-344-0200  
 Fax 610-344-0065

Provider is aware that FENTORA™ (fentanyl buccal tablet) [C-II] was approved subject to a Risk Minimization Action Plan (RiskMAP). The RiskMAP includes key safety messages that are essential to the safe use of this product. They are:

- FENTORA is indicated for the management of breakthrough pain in patients with cancer who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.*
- FENTORA is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- No misuse of FENTORA should occur.
- Unintended (accidental) exposure to FENTORA should not occur.
- Patients considered opioid tolerant are those who are taking at least 60 mg oral morphine/day, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that FENTORA can be fatal to a child. Keep all units away from children and discard properly.
- FENTORA is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

G0013648

**INDEPENDENT EDUCATIONAL PROGRAM GRANT AGREEMENT**

This Agreement is entered into as of this 25<sup>th</sup> day of January, 2008, by and between Cephalon ("Cephalon"), located at 41 Moores Road, Post Office Box 4011, Frazer, PA 19355, and Medical Learning Solutions ("Provider") located at 101 Washington Street, Morrisville, PA 19067.

WHEREAS, Cephalon has reviewed Provider's grant request to support a medical education program ("Program"); and

WHEREAS, Cephalon has determined that the Program has the potential to significantly further medical knowledge and improve patient care; and

WHEREAS, it is the intent of the parties to ensure that the Program will be independent, objective, balanced and scientifically rigorous so that it will not be viewed by the United States Food and Drug Administration ("FDA") as promotional and that Cephalon will not be viewed as responsible for its content; and

WHEREAS, Cephalon agrees to provide funding for the Program under the conditions set forth below.

NOW THEREFORE, Provider and Cephalon agree to the following terms under this Agreement:

1. Title of Program. The Educational Program is entitled "*Emerging Solutions in Pain* Meet the Experts Exhibit Booth at IASP 2008", and a copy of the grant request for the Program is attached hereto as Exhibit A.
2. Type of Program. The Program is:  
  
An independent program where CE credits will not be offered.
3. Educational Partner. The Provider shall not use a third party that will provide assistance in support of the Program ("Educational Partner").



4. Educational Components. The expected components of the Program (e.g., number of live meetings, CD ROM, web-based, etc.) are as follows:
  - (a) *Emerging Solutions in Pain* Meet the Experts Interactive Exhibit Booth at IASP 2008.
5. Program Purpose. The Program is for scientific and educational purposes only and is not intended to promote a Cephalon product, directly or indirectly. The Program is not a repeat performance of a prior program.
6. Grant Amount Funding Arrangements.
  - (a) Cephalon will provide support for the Program by means of an educational grant in the total amount of \$182,506. If the Program is canceled or terminated prior to completion, Provider shall return the grant, or any unused portion thereof, to Cephalon within thirty (30) days of such termination or cancellation. Provider shall have full responsibility for all funding arrangements of the Program, including any funding to be provided to its Educational Partner. Payment of the grant shall be made in accordance with a schedule agreed to by the parties. All payments due hereunder shall be made by Cephalon within forty-five (45) days of its receipt of an invoice for same, provided Provider is in compliance with the terms of this Agreement..
  - (b) Within ninety (90) days of completion of the Program, Provider shall provide Cephalon with a detailed reconciliation of actual expenses incurred, and to the extent Cephalon has overpaid Provider for same, Provider shall provide a refund to Cephalon within thirty (30) days thereafter. Such detailed reconciliation shall be forwarded to Cephalon at the address above to the attention of Bhaval Shah Bell, Ph.D., Sr. Manager, Medical Education.
  - (c) Provider may not use funds provided by Cephalon to pay travel, lodging, honoraria or personal expenses for non-faculty attendees. Grant funds may be used to reduce the overall registration fees for attendees. Grant funds may not be used to purchase capital equipment or to provide general operational support for an institution. Funds for hospitality shall not be provided, except that funds may be used for modest meals or receptions that are held as part of the Program, but such events shall not compete with, nor take precedence over, educational events. The appropriateness of any reception shall be at the sole discretion of the Provider, and Provider shall have final decision-making authority in connection with any such activities.
  - (d) Funds may be used by the Provider to permit medical students, residents, fellows or other health care professionals in training to travel to and attend the Program; provided, however, that the selection of such students, residents or fellows who receive funds is made by either the academic or training institution, or, if by the Provider, such selection shall be made with the full concurrence of the academic or training institution.



7. Objectivity and Balance. Provider shall retain full responsibility for control of the content of the Program and shall ensure that the following requirements are met:

- (a) The Program material/information will be objective, balanced and free from commercial bias. All topics shall be treated in an impartial, unbiased manner. All discussions shall include a range of views about each class of drug and disease treatment options. Information shall not unfairly represent a spectrum of views favoring a product or class of products marketed by Cephalon or any other company. The title of the Program will fairly and accurately represent the scope of the presentation.
- (b) Provider agrees that neither Cephalon nor its agents shall control the content of the Program. Provider agrees that there will be no scripting, targeting of points for emphasis, or other activities by Cephalon or its agents that are designed to influence the content of the Program. Cephalon personnel will not attend content development meetings unless requested in writing by the Provider or the Medical Education Communications Company to make presentations of disease data and/or Cephalon product data to faculty. In this instance, Cephalon personnel may stay only for this portion of the meeting, and the accredited provider must be in attendance.
- (c) If requested, in writing, by the Provider or Educational Partner, Cephalon personnel from Scientific Communications may also provide written material on a Cephalon product or compound in development, such as *specific product data, manuscripts, posters, product labels and other scientific material* (not in slide format) in accordance with internal corporate guidelines based on the level of information that is acceptable to disclose.
- (d) If a product marketed by Cephalon is the subject of discussion, the data will be objectively selected and presented, with an accurate reflection of favorable and unfavorable information about the product and shall also include a balanced discussion of prevailing information on alternative products and /or therapies.
- (e) Any suggestions of superiority of one product or treatment over another will be supported by the body of available data and will not result from selective presentation or emphasis on data favorable to a particular treatment.
- (f) Provider represents that neither it nor the Educational Partner (if any) has either an open complaint or decision from the Accreditation Council for Continuing Medical Education ("ACCME") or the FDA that a program provided by the Provider or the Educational Partner failed to meet standards of independence, balance, objectivity, or scientific rigor.





8. Risk Minimization Action Plan. Cephalon provides the following Risk Minimization Action Plan ("RiskMAP") information to all Providers. Neither Cephalon nor its agents shall influence or control whether a product marketed by Cephalon is the subject of discussion. A RiskMAP is a strategic safety program designed to meet specific goals and objectives in minimizing known risks of a product while preserving its benefits. Any product marketed by Cephalon that is approved with a RiskMAP, and the key safety-related health outcomes outlined in that RiskMAP, are listed in Exhibit B. Provider agrees that it is aware of the RiskMAP(s) and the key safety messages.
9. Faculty Selection. Provider shall retain full responsibility for the selection of the presenters, authors, moderators, and/or other faculty (hereinafter referred to collectively as "Faculty").
10. Disclosures. Provider will ensure meaningful disclosure of limitations of data (e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion). Provider will require that Faculty disclose when a product is not approved in the United States for the use under discussion.
11. Question and Answer Session. To the extent the Program is a presentation, Provider will ensure meaningful opportunities for questioning by the audience.
12. Financial Relationships. Provider will ensure meaningful disclosure to the audience of Cephalon funding and any significant relationship between individual Faculty and Cephalon. All meaningful disclosure(s) shall also be made in any written materials, including, but not limited to, announcements, brochures, syllabi and enduring material. Disclosures shall not mention product trade names.
13. Metrics/Copies of Program Material.
  - (a) Provider and/or Educational Partner shall provide certain outcome measurements and metrics to Cephalon as requested by the Scientific Communications Department. Such metrics shall be provided either after the conclusion of a single live event or monthly for a year-long accredited Program and may, at Cephalon's request, include the number of Program participants, number of certifications, assessment of the Program and Faculty, and demonstration of learning by Program participants.
  - (b) After the Program has occurred, Provider shall provide Cephalon with one (1) copy of all Program materials in CD ROM or electronic format and fifty (50) copies in print format.
14. Representations and Warranties. Provider represents that:
  - (a) Neither it nor the Educational Partner, if any, provides marketing, advertising, public relations, market research, medical education services or other consulting services (e.g., support for advisory boards) to any other department within Cephalon ("Marketing Activities");



- (b) If Provider or the Educational Partner has an affiliated company that provides Marketing Activities to Cephalon, Provider has instituted appropriate controls and safeguards to ensure the Program (i) remains independent, objective, balanced and scientifically rigorous, (ii) is not intended to promote a Cephalon product, directly or indirectly, and (iii) is not in any way biased due to the affiliated company's relationship with Cephalon;
  - (c) Provider has determined that it is appropriate to use the Educational Partner in light of the requirements under this Agreement; and
  - (d) If Provider or its Educational Partner employs a former Cephalon employee who worked at Cephalon at anytime during the most recent year and who had marketing responsibility in the therapeutic area that will be covered by the Program, then that former employee will not have any role in the planning, development or delivery of the Program.
- 15. Invitations/Enduring Materials. The Program audience will be selected by the Provider. The Provider shall be responsible for distributing materials about the Program, including invitations, reminder notices, and business reply cards that can be used by third parties to obtain any enduring Program material from the Provider. Notwithstanding the foregoing, Provider hereby authorizes Cephalon to distribute a subset of Program invitations/reminder notices that have been prepared or approved by the Provider.
- 16. Ancillary Promotional Activities. To the extent the Program is a live presentation, no promotional activities or product advertisements will be permitted in the same room as, or in an oblique path to, the Program. If the Program is a teleconference or webcast, no product advertisements or promotional activities will be permitted immediately prior to, during, or immediately after the delivery of the Program. If the Program is in print format, no product advertisements or promotional materials will be interleaved within the pages of the Program. If the Program is made available electronically, no product advertisements or promotional materials will appear within the Program material or interleaved between computer windows or screens of the Program
- 17. Compliance with Guidelines. Provider represents that the Program, including development of the Program and Program materials, shall conform to the American Medical Association ("AMA") Guidelines on Gifts to Physicians, the AMA Ethical Opinion on Continuing Medical Education, the ACCME Standards for Commercial Support, the FDA December 3, 1997 Final Guidance for Industry-Supported Scientific and Educational Activities, and the Pharmaceutical Research and Manufacturers Association ("PhRMA") Code on Interactions with Healthcare Professionals.
- 18. Logistical Status Reports. Provider and/or Educational Partner shall provide periodic reports to Cephalon regarding the management and logistics of Program components.



19. Miscellaneous.

- (a) No party shall use the other party's or its affiliates' name or trademarks for publicity or advertising purposes, except with the prior written consent of the other party.
- (b) Provider agrees to obtain all consents, authorizations, approvals and releases that may be necessary for the production of the Program and of any written materials prepared in connection therewith. Provider agrees to indemnify Cephalon with respect to any claims, actions or demands, including reasonable attorneys' fees that may arise in any manner out of Provider's failure to secure such consents, authorizations, approvals or releases.
- (c) No term, condition or other provision of any attachment or addendum to this Agreement shall supersede any term, condition or other provision of this Agreement, and with respect to any inconsistency or ambiguity, the Agreement shall control.



IN WITNESS WHEREOF, the parties, by their duly authorized representatives,  
agree to comply with all the terms and conditions of this Agreement.

**MEDICAL LEARNING SOLUTIONS**

By: *[Signature]*  
Name: Sheri C. Gavinski  
Title: President

The above signatory is a duly authorized  
corporate officer of the IEP Provider.

Date: 2-6-08  
Tax ID #: 90-0135153

**CEPHALON, INC.**

By: *[Signature]*  
Name: Lesley Russell, MB, Ch.B., MRCP  
Title: Executive Vice President  
Worldwide Med & Reg Operations

Date: 2/4/08





Exhibit A

Copy of Grant Request



101 Washington Street  
Morrisville, Pennsylvania 19067  
Phone 215.337.6103  
Fax 215.337.0960

***The Emerging Solutions in Pain Meet the Experts Exhibit Booth Attendance at the 12<sup>th</sup> World Congress on Pain***

***Grant Request  
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 Phone 215.337.6103  
 Fax 215.337.0960

January 21, 2008

Bhaval Shah-Bell, PhD  
 Cephalon, Inc.  
 41 Moores Road  
 Frazer, PA 19355

Dear Dr. Shah-Bell,

Medical Learning Solutions, Inc. has recently completed a comprehensive needs assessment to identify the educational needs of international clinicians who provide care to patients with chronic pain. This needs assessment was compiled from the following sources:

- Clinical advisory review
- Surveys of international clinicians as reported by leading international and world health organizations
- Literature search

Based on the identified educational need, Medical Learning Solutions is requesting an educational grant from Cephalon, Inc. to expand the knowledge and awareness of *Emerging Solutions in Pain* initiatives among international clinicians who provide care to patients with chronic pain. This will involve the distribution of educational materials and information at the 12<sup>th</sup> World Congress on Pain, held by the International Association for the Study of Pain, via the *Emerging Solutions in Pain* Meet the Experts Exhibit Booth. Through this distribution of education, tools and resources, the **ESP** initiatives will support the ongoing international clinical need to provide adequate analgesia to patients with chronic pain, with the global need to monitor for potential issues of abuse, addiction and diversion of controlled substances.

The budget to fund these activities is approximately \$182,506. Please refer to the detailed budget section of this proposal for the complete grant funding proposal. This scientific event will comply with all ACCME, FDA, AMA, and ACPE regulations for industry-supported professional continuing education.

Thank you in advance for your consideration of this request.

Respectfully,

A handwritten signature in cursive script, reading "Sheri L. Gavinski".

Sheri L. Gavinski  
 President  
 Medical Learning Solutions, Inc.





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***Educational Needs Assessment***

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**Pain is Undertreated Worldwide**

Effective and safe treatment of pain is a human right, but currently the best available global evidence indicates a major gap between an increasingly sophisticated understanding of the pathophysiology of pain and the continued widespread inadequacy of its treatment, evidenced by the following statements.<sup>1</sup>

*The United States of America*

According to the National Center for Health Statistics 2006 Health Survey, one in four adult Americans reported suffering a day-long bout of pain in the previous month, and 10% reported that the pain had lasted a year or more.<sup>2</sup>

*Europe*

*Pain in Europe* survey results indicated that 40% of all respondents had not achieved effective pain control.<sup>3</sup>

*Australia*

An estimated one in five Australians of working age suffers from relentless and often disabling pain, but as few as 10% of those affected are getting adequate treatment.<sup>4</sup>

*Asia*

Chronic neuropathic and inflammatory pain are often underdiagnosed and mismanaged in the Asia Pacific region, leading to prolonged patient suffering and additional strain on the health care system.<sup>5</sup>

*Africa*

A recent review of palliative care in Sub-Saharan Africa found a chronic lack of African-relevant evidence on outcomes in palliative care despite a wealth of practitioner experience.<sup>6</sup>

**Universal Barriers to Effective Therapeutic Management**

Barriers to effective pain treatment are many, including cultural, medical, financial, and religious issues.<sup>7</sup> It is, however, political and legal impediments that most discourage adequate pain management. While opioids remain the drugs of first choice for the treatment of moderate-to-severe pain, regardless of etiology, fears of opioid abuse, misuse and diversion continue to shape policies related to medical-use opioids. This modulation of opioid policy begins with the opioid importation and manufacture, continues with distribution and prescribing, and ends with patient use or misuse and administration.<sup>8</sup>

Opioids, as controlled substances, are subject to international, national, and local (eg, International Narcotics Control Board (INCB), US state-level Drug Enforcement Administration (DEA) and state medical board) control. Many countries have inefficient systems for procurement, manufacture, and distribution of opioids<sup>9</sup> or impose limits on their prescription. Morphine consumption is especially low in most developing countries. In 2004 data published by the International Narcotics Control Board (INCB), six nations accounted for 79% of medical morphine consumption, and 120 consumed little or none.<sup>10</sup> In some countries, opioids cannot be prescribed for cancer pain, yet are available for postoperative pain, and in other countries they cannot be prescribed for children, but are available to adults. In other countries, only immediate-release preparations of morphine tablets are available.<sup>11</sup> Overly stringent regulations also discourage the medical use of controlled drugs. Some practitioners are fearful of the legal and regulatory climate and choose not to prescribe opioids at all. Others are not fully aware of the laws and regulations pertaining to the prescribing of controlled substances, and are vulnerable to regulatory and legal scrutiny



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and prosecution. Finally, disparity in health care exists worldwide for both treatment of pain and addiction. Care is not equally available or provided to those who are at greatest risk and to those who are typically exhibiting greatest need (eg, the mentally ill, HIV-AIDS patients, and those living in poverty).<sup>12</sup>

These very limitations and conditions can create an environment ripe for patient self-medication. Patients in pain, left untreated, seek drugs from nonmedical sources and use other methods of illegal analgesic procurement with the sole intent of pain relief. Pain patients without a medical source of effective pain management often display aberrant behaviors (pseudoaddiction) until their pain is effectively controlled. These patient behaviors tend to reinforce the uninformed clinician's preconceived notions about opioid prescribing.<sup>13</sup>

Additionally, the governmental restrictions and added risk of legal provocation create an environment of fear ("opiophobia") for both patient and prescribing practitioner.<sup>1,8</sup> First, there is considerable concern about opioid addiction, tolerance and hyperalgesia,<sup>1,14-15</sup> including dose escalation and dependence. It is estimated that 10% of patients prescribed opioid analgesics may become addicted, however, of these, 10%-25% had no history of substance abuse or addiction.<sup>1,16</sup> This information may be interpreted to mean that comprehensive and risk-contained patient management may need to include not only the patient, but family members or those who reside with or support the health care of the patient. It may also be interpreted that some patients may be ineffectively treated and are seeking drugs from other sources to alleviate pain. Either scenario suggests that prescribers and patients need to be better informed to recognize aberrant behaviors, improve communications and pain assessment, and increase knowledge and application of appropriate and effective pharmacotherapies.

Many physicians and patients worry about precipitating adverse side effects, believing that opioids should be reserved for the palliative cancer pain care. There is also an unfounded assumption among physicians and patients that chronic opioid treatment impairs health-related quality of life. Patients may believe that opioids can only be administered parenterally, while physicians may believe that opioid analgesia may delay accurate initial diagnosis of a change in patient condition. Others believe that at least some pain is inevitable and that opioid administration must be related to the severity of the disease rather than the intensity of the pain.<sup>1,17-19</sup>

"Opiophobia" among health care providers is compounded by a certain level of ignorance.<sup>8</sup> Repeatedly, survey respondents acknowledge that they have received insufficient training in, or exposure to, pain management.<sup>1,19-22</sup> These attitudes toward opioid analgesia spring from inadequate education.<sup>1,19-22</sup> Among patients and families, higher levels of concern about opioids are associated with advancing age, lower levels of education, and lower incomes.<sup>1,23</sup> Such concerns appear to be cross-cultural; studies in Puerto Rico,<sup>1,24</sup> Taiwan,<sup>1,25</sup> and the United States<sup>1,23</sup> found similar concerns about the use of opioid medication.

**Demonstrated Global Need for Continuing Education in Pain Management**

- The following is an excerpt from a report given to the United Nations Economic and Social Council by the President of the INCB at the 58<sup>th</sup> World Health Assembly Meeting, Dr. P. Emafo, on July 25, 2007.<sup>26</sup>

*"The low licit consumption of opiate analgesics for the management of pain is an area on which the Board has been active in the recent past. Also, at the request of the Council and the World*



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*Health Assembly, the Board and the World Health Organization examined the feasibility of a possible assistance mechanism that would facilitate the management of pain using opioid analgesics. A Framework for the Access to Controlled Medications Program has jointly been produced by the Board and the World Health Organization. The report was presented to the Commission on Narcotic Drugs in March 2007 and the World Health Assembly in May 2007. The Access to Controlled Medications Program will be implemented by the World Health Organization and with the support of the Board as far as the mandate of the Board allows us."*

- *The 7<sup>th</sup> International Conference on Pain and Chemical Dependency was held in New York City, June 21-24, 2007. The entire conference was devoted to educating clinicians about improved pain management practice methodologies designed to contain risk for their patients, for themselves and for their practice related to the prescribing and use of opioids. The following is a quote from the Chairman of the 2007 conference, Dr. Russell Portenoy<sup>27</sup>:*

*"It is a challenging era-increasing recognition of the potential benefits of opioid therapy for chronic pain, but great concern about the rising toll of prescription drug abuse; increasing fear about the intrusion of regulators and law enforcement into clinical practice, but more willingness to seek balance between medicine and drug control policies for the public good; and increasing complexity of both pain medicine and addiction medicine, but efforts in each field to reach out to the other.*

*"In such an era, a timely conference devoted to best practices and evidence at the interface between pain and chemical dependency is of great utility to clinicians of every type."*

- *Excerpt from the 2004 Annual Report of the International Narcotics Control Board Focuses on Relationship between Drug Abuse, Crime and Violence at Community Level<sup>28</sup>*

*In keeping with its task of monitoring and ensuring that an adequate supply of narcotic drugs exists for licit medical purposes, the INCB warns that the availability and consumption of some essential narcotic drugs, particularly opioids, which are used for pain treatment, including palliative care, remains extremely low in many countries worldwide.*

*The Board has identified that the low availability of certain types of medicine can be related to at least three different factors.*

- *First, unnecessarily strict rules and regulations have created an impediment for providing adequate access of populations to certain controlled drugs in some countries.*
- *Second, the negative perception about controlled drugs among medical professionals and patients in many countries has limited their rational use.*
- *Third, lack of economic means and insufficient resources for health care has resulted in inadequate medical treatment, including the use of narcotic drugs.*

**Literature Search Supports a Need for Education**

An extensive and recently conducted PubMed medical literature search revealed the following publications in support of furthering education in the following areas:



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1. Safe and effective treatment of pain as a human right; including assessment, risk containment, appropriate treatment selection, and monitoring. <sup>1,3,12-15,26,30-38</sup>
2. Promotion of risk-containment strategies and methodologies. <sup>1,16,39-45</sup>
3. Provision of guidance to clinicians who prescribe opioid analgesics to patients in pain. <sup>1,9,10,17,46-55</sup>

***The Emerging Solutions in Pain Educational Initiative: Fulfilling an Educational Need***

***The Emerging Solutions in Pain Mission Statement***

*Emerging Solutions in Pain* (ESP) is an ongoing educational initiative developed to address some of today's most critical issues in pain management. These issues involve balancing fundamental rights of patients and clinicians with the challenge of risk containment for opioid misuse, abuse and addiction associated with medical prescribing and use of controlled substances. Through evidence-based scientific data, validated tools, and the expertise of a cadre of leading pain and addiction medicine experts, the ESP program provides clinicians with guidance in the implementation of best practice management techniques. Site features and programs emphasize favorable interaction with regulatory and law enforcement agencies, as well as effective assessment, monitoring and documentation strategies; all of which contribute to the overall goal of optimizing outcomes for patients in pain.

***Global Educational Objectives***

In 2008, *Emerging Solutions in Pain* will continue to create educational tools, resources and activities that support the goals and objectives outlined by the ESP Mission Statement. These global objectives are designed to fulfill the educational needs of clinicians, worldwide, who provide care to patients with chronic pain, and include the following:

- (1) Educate clinicians on practices, techniques and tools that support safe and effective prescribing of opioids
- (2) Increase clinician understanding of best practices associated with minimization of the risk of opioid misuse, abuse and addiction
- (3) Develop educational tools and resources that support appropriate risk assessment, effective ongoing monitoring programs and documentation strategies for patients who are prescribed opioids

***Intended Audience and the Ongoing Need for Awareness Building Activities***

*The Emerging Solutions in Pain* initiatives were launched in 2005 with the goal of providing education, tools and resources to clinicians that support safe and effective prescribing of opioids while minimizing the risk potential of opioid misuse, abuse and addiction. These goals, as outlined above, are applicable to clinicians worldwide. While clinicians in the United States have access to a plethora of pharmacologic agents for treating chronic pain and are able to select from an extensive and diverse array of educational tools and resources that support safe and effective prescribing of these agents, this is clearly not the case with clinicians in many areas of the world. Thus, the data detailed above supports the critical need for the provision of educational tools and resources to an audience of international clinicians; these groups include, but are not limited to, the following:



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- (1) International pain specialists, addictionologists and other physicians who are not yet members of the ESP website
- (2) Non-physician members of the international pain management community, eg, nurses, physician assistants, pharmacists
- (3) International residents and fellows who have an interest in treating pain as part of their studies

**Educational Resources Available to Clinicians Through the *Emerging Solutions in Pain* Initiatives**

The *Emerging Solutions in Pain* initiatives are designed to be a broad-based series of programs, tools and resources that support safe and effective prescribing of opioids. Included in this series are the following:

- The *Emerging Solutions in Pain* Tool Kit, which includes practical clinical tools for assessing, monitoring and documenting patients with chronic pain who are prescribed opioids
- The *Emerging Solutions in Pain* Website, which is a repository for all programs and information produced through the ESP initiatives
- The *Emerging Solutions in Pain* Accredited Monograph Series, which have addressed diverse topics in pain management and addiction medicine
- The *Emerging Solutions in Pain* Meet the Experts Exhibit Booth, which has been a key feature of the *Emerging Solutions in Pain* initiatives since the series was launched in February 2005

**The *Emerging Solutions in Pain* Meet the Experts Exhibit Booth Series**

Since its launch in 2005, the ESP Booth has been exhibited at 18 national association meetings and congresses to date, with total exposure to more than 21,000 clinicians across all events, as measured by total meeting attendance. The Booth has thus been a key point of education concerning the mission, tools and resources of the ESP initiatives, and has been instrumental in recruiting more than 3,000 members to the ESP website. In addition, more than 2,700 ESP Tool Kits and more than 3,000 ESP monographs have been distributed to clinicians through the deployment of the Meet the Experts Booth.

In addition to its function as a distribution point for key *Emerging Solutions in Pain* information and programs, the ESP Meet the Experts Booth is also a fundamental component in developing an interactive community among clinicians involved in the fields of pain management and/or addiction medicine, through "The Doctor Is In" function of the Booth. Through "The Doctor Is In," ESP faculty members are present at scheduled times during exhibition hours, with the sole function of interacting with attendees of the meeting in an informal, one-on-one session. More than 17 ESP faculty members have successfully participated in this activity since the initial deployment of the Booth in February 2005.

As these figures demonstrate, the *Emerging Solutions in Pain* Exhibit Booth has been consistently successful as a key point of resources and information distribution for clinicians who provide care to patients with chronic pain, and who require education concerning safe and effective prescribing of opioids. The attendance of the ESP Meet the Experts Booth at the 12<sup>th</sup> World Congress on Pain will be an important step in the campaign to increase awareness among international clinicians of the tools and resources available through the *Emerging Solutions in Pain* initiatives, with the ultimate goal of supporting safe and effective use of opioids for the treatment of chronic pain.





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**Summary**

There is a need for continuing medical education to change and improve practice behaviors of clinicians working in pain management and it is recognized and recommended by leading health organizations, expert thought leaders in pain medicine, and governing agencies around the world. An opportunity exists to fill this obvious need by further educating clinicians with information and supplying them with tools to help maximize performance improvements for patient care in the accurate and safe assessment of pain and risk of addiction, accurate diagnosis of pain, re-visit monitoring, appropriate and safe analgesic prescribing for effective, safe and comprehensive therapeutic management offering potential for improved patient outcomes. *Emerging Solutions in Pain* has successfully developed, produced and implemented a significant number of educational activities, tools and resources for clinicians who treat chronic pain. Medical Learning Solutions is proposing, in this grant, to present these critical resources, and thereby support the need to maximize treatment compliance, contain risk, improve care and affect therapeutic outcomes to an international audience of clinicians who treat patients with chronic pain.

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**Program Summary: The Emerging Solutions in Pain Meet the Experts Exhibit Booth  
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## Program Overview

As detailed in the Needs Assessment section (pages 3 – 10), pain represents a significant international health care crisis, and many international clinicians require education in the safe, effective and appropriate use of opioid medications, and in tools, resources and information, which will minimize misuse, abuse and addiction of these agents. In addition, significant concern exists in the international medical community concerning the addictive potential of opioids, which in many countries deters use of these agents. Medical Learning Solutions is therefore proposing to utilize the *Emerging Solutions in Pain Meet the Experts Booth* as an informational and interactive display for educating clinicians who are attending the 12<sup>th</sup> World Congress on Pain, to be held August 17 – 22, 2008 in Glasgow, Scotland. This meeting, which is the triennial meeting of the International Association for the Study of Pain (IASP), will be attended by more than 5,000 pain specialists from around the world who share a common interest in the appropriate understanding, assessment and treatment of pain. The *Emerging Solutions in Pain Meet the Experts Booth* will represent a new, and much-needed, resource for many international clinicians who provide care to patients with chronic pain, or who require education and information in the field of addiction medicine as it relates to the safe and effective use of opioids.

The ESP Meet the Experts Booth will feature an array of interactive resources for clinicians who provide care to patients with chronic pain. The Meet the Experts Booth will include, but will not be limited to, the following educational activities:

- A seating area for meeting attendees to interact with *Emerging Solutions in Pain* clinical experts
- A distribution center for *Emerging Solutions in Pain* tools, resources and activities, including:
  - The *Emerging Solutions in Pain* Tool Kit
  - The *Emerging Solutions in Pain* Patient Education Companion Tool Kit
  - Accredited monographs in the *Emerging Solutions in Pain* Monograph Series
- Kiosks with interactive, multimedia displays
  - Touch-screen access to the Frequently Asked Questions Video Library
  - Full display of the *Emerging Solutions in Pain* Tool Kit and Patient Education Companion Tool Kit
  - Immediate membership registration to *Emerging Solutions in Pain*
  - Touch-screen access to select video-based clips from the *Emerging Solutions in Pain* website
    - Ask the Expert questions
    - Video or audio clinical commentaries
  - Download stations for *Emerging Solutions in Pain* Podcasts
- Graphic imagery and multimedia displays that reflect current information in the fields of pain management and addiction medicine
  - Lighted graphic panels
  - A plasma screen highlighting important features of the *Emerging Solutions in Pain* initiatives
  - Scrolling tickers with headlines from current pain- and addiction-related news stories
  - A video wall highlighting the history, key objectives and resources available through the *Emerging Solutions in Pain* initiatives



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**Program Summary: The Emerging Solutions in Pain Meet the Experts Exhibit Booth  
Attendance at the 12<sup>th</sup> World Congress on Pain**

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### **Intended Audience**

The primary audience of the *Emerging Solutions in Pain Meet the Experts Booth* will be international physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain and who will attend the 12<sup>th</sup> World Congress on Pain to be held August 17 – 22, 2008 in Glasgow, Scotland.

### **Program Objectives**

The purpose of the *Emerging Solutions in Pain Meet the Experts Booth* is to disseminate information concerning the *Emerging Solutions in Pain* initiative to clinicians practicing in the field of pain management, and to educate those clinicians on the assessment and monitoring of pain patients, and on good practice management techniques. Clinicians visiting the booth will have opportunities to:

- (1) Interact with *Emerging Solutions in Pain* clinical experts in small discussion groups, focusing on tools and strategies that will contribute to a proper balance of pain control and risk minimization
- (2) View multimedia, interactive programs highlighting the issues associated with minimization of misuse, abuse and addiction, the *Emerging Solutions in Pain Tool Kit* and associated case studies
- (3) Utilize interactive survey terminals to allow participants to earn one of the set of five faces of pain stress relievers giveaway
- (4) Receive copies of the *Emerging Solutions in Pain Tool Kit* CD-ROM and other support materials, such as the ESP Patient Tool Kit materials and the ESP Accredited Monograph collection
- (5) Gain exposure to the resources available at the *Emerging Solutions in Pain Website*, and register as a "member," thereby expediting their ability to access online resources

### **Format**

The format of the *Emerging Solutions in Pain Exhibition Booth Series* is an interactive meeting booth, to be presented at the 12<sup>th</sup> World Congress on Pain. The Meet the Experts Booth will feature live peer-to-peer interactions with *Emerging Solutions in Pain* clinical experts, as well as interactive, multimedia programs that highlight the *Emerging Solutions in Pain* initiatives.

### **Distribution**

Announcement of the *Emerging Solutions in Pain Meet the Experts Booth* at the 12<sup>th</sup> World Congress on Pain will be made via direct mail and/or blast email communications to registered meeting attendees and members, and via journal and/or banner advertisements. *Emerging Solutions in Pain* clinical experts and Medical Learning Solutions staff members will provide all information at the Booth.



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***Program Summary: The Emerging Solutions in Pain Meet the Experts Exhibit Booth  
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**Request for Sponsor Support**

Medical Learning Solutions is promoting the *Emerging Solutions in Pain Meet the Experts Booth* through a variety of methods, including direct mail, publication of a multimedia mini-disc, and journal and banner advertisements.

As a supplement to these primary methods, Medical Learning Solutions may request the assistance of Cephalon, Inc. sales representatives in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of Medical Learning Solutions, and any such distribution will solely as a supplement to MLS' primary methods of announcement and promotion. Content developed for this program may also be repurposed as a CE-accredited enduring material and published on the ESP website at a later date.

**Total Budget**

The total budget to fund these activities is \$202,006.



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**Emerging Solutions in Pain Exhibit Booth**  
**IASP Glasgow, Scotland 2008**  
***Proposed Budget***

<b><i>Program Parameters</i></b>
<b>20'x 20' Ask the Experts Booth</b> <b>Scottish Exhibition &amp; Conference Centre - Glasgow, Scotland (August 16 - 22, 2008)</b>
<b>Show Hours:</b> August 16, 9:00 am - 8:00 pm (Exhibit Installation) August 17, 9:00 am - 8:00 pm (Exhibit Installation) August 18, 8:30 am - 5:30 pm August 19, 8:30 am - 5:30 pm August 20, 8:30 am - 5:30 pm August 21, 8:30 am - 5:30 pm August 22, 8:30 am - 2:30 pm August 22, 3:00 pm - 10:30 pm (Exhibit Dismantle)

<b><i>Cost Summary</i></b>	
<b><i>One-Time Expenses</i></b>	
<b>Approximate Total, Direct Expenses</b>	\$ 5,300
<b>Total Indirect Expenses</b>	\$ -
<b>Subtotal, One-Time Expenses</b>	\$ 5,300
<b><i>Meeting Expenses</i></b>	
<b>Approximate Total, Direct Expenses</b>	\$ 129,975
<b>Total, Indirect Expenses</b>	\$ 47,231
<b>Subtotal, Meeting Costs</b>	\$ 177,206
<b>Total Cost of the 2008 IASP Meeting</b>	<b>\$ 182,506</b>



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**Emerging Solutions in Pain Exhibit Booth  
IASP Glasgow, Scotland 2008  
Proposed Budget**

<b>Detailed Budget Itemization: One-Time Expenses</b>	
<i>Direct Expenses, Approximate</i>	
European Electrical Updates	\$ 2,000
Graphic Update	\$ 800
Production of new graphic to meet ceiling guidelines of convention hall	
Video IPODs for giveaways (one per day, five total)	\$ 1,500
Additional faces of pain giveaways	\$ 1,000
<b>Subtotal, One-Time Approximate Direct Expenses</b>	<b>\$ 5,300</b>

<b>Detailed Budget Itemization: IASP 20x20 Exhibit</b>	
<i>Direct Expenses, Approximate</i>	
Exhibit space plus liability insurance	\$ 29,675
Booth set-up/tear-down	\$ 24,900
Includes floor plan, shop prep, installation and dismantling including labor supervision, travel	
AV rental	\$ 3,000
Includes rental of 2 computer units, 1 plasma screen, 2 touch screens monitors and all necessary cabling	
AV installation and supervision	\$ 4,600
Includes installation of all computer units, plasma screens, switcher units, video wall, audio needs, electrical, telecommunication links, etc.	
Booth supplies	\$ 800
Rental and purchase of booth supplies such as flowers, chairs, cleaning service, waste baskets, etc.	
Shipping of booth to meeting site	\$ 34,500
Includes shipping of 20'x20' exhibit property from NJ to Glasgow via ocean container freight and ground carrier to include all foreign duties, taxes and customs fees	
Shipping of supplies	\$ 4,300
Includes shipping of mini-discs, Tool Kits, giveaways, etc. to meeting site and delivery to booth charges	
Interactive touch screen survey	\$ -
Includes development and management of meeting specific electronic survey program, capturing attendee response to meeting specific questionnaire	
Booth advertisement	
Advertisement in meeting catalog/publication (full page, 4/c)	\$ 3,000
Booth posters, printing	\$ 900
KOL expenses: two KOL faculty	
Travel: air, hotel, ground, OOP	\$ -
Honoraria	\$ 3,000
MLS expenses: three MLS staff	
Travel: air, hotel, ground, OOP	\$ 18,500
Exhibitor registration	\$ 300
Miscellaneous	\$ 2,500
<b>Approximate Total, Direct Expenses</b>	<b>\$ 129,975</b>



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**Emerging Solutions in Pain Exhibit Booth  
IASP Glasgow, Scotland 2008  
Proposed Budget**

<b>Detailed Budget Itemization: IASP 20x20 Exhibit (con't)</b>	
<b>Indirect Expenses</b>	
<b>Project management</b>	
Coordination with conference vendors	\$ 1,800
Coordination with KOLs for The Doctor is In schedule	\$ 2,700
Coordination of pre-meeting processes	\$ 6,150
Coordination of booth advertising and other support materials	\$ 1,800
Coordination with internal teams	\$ 1,950
Preparation and coordination of status meetings/updates	\$ 600
<b>Medical / scientific services</b>	
Development of copy for meeting advertisements	\$ 450
Development of copy for plasma screen loop, other booth support materials	\$ 1,050
Proofreading	\$ 1,000
<b>Graphic design / production services</b>	
Adaptation of display graphics for plasma loop and all associated tickers	\$ 2,000
Typesetting and layout of booth flyers (Doctor Is In, iPod giveaway, survey)	\$ 750
Typesetting and layout of booth lightbox, wing panels	\$ 750
Typesetting and layout of advertisements (direct mail plus meeting catalog)	\$ 1,000
Coordination with third-party print vendors	\$ 500
<b>Conference management services</b>	
Management of pre-meeting booth set-up	\$ 3,000
Management of post-meeting booth tear-down	\$ 2,250
Staffing of booth during meeting	\$ 14,490
Coordination with KOLs during meeting	\$ 1,950
<b>Administrative and accounting fees</b>	\$ 3,041
<b>Total, Indirect Expenses</b>	<b>\$ 47,231</b>





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***Appendix A: Medical Learning Solutions Faculty Advisory Board***

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**David B. Brushwood, RPh, JD**

Professor, Department of Pharmacy Health Care Administration  
University of Florida  
Gainesville, Florida

**Jennifer Bolen, JD**

Founder, The Legal Side of Pain  
A Division of the J. Bolen Group, LLC  
Knoxville, Tennessee

**Doug Gourlay, MD, FRCPC, FASAM**

Director, Pain and Chemical Dependency  
Wasser Pain Management Centre  
Mount Sinai Hospital  
Toronto, Ontario, Canada

**Howard A. Heit, MD, FACP, FASAM**

Board Certified in Internal Medicine and Gastroenterology/Hepatology  
Certified in Addiction Medicine and as a Medical Review Officer  
Chronic Pain Specialist  
Assistant Clinical Professor  
Georgetown University

**Steven Passik, PhD**

Associate Attending Psychologist, Memorial Sloan-Kettering Cancer Center  
Associate Professor of Psychiatry, Weill College of Cornell Medical Center,  
New York, New York

**Joseph Shurman, MD**

Chairman, Pain Management  
Scripps Memorial Hospital  
La Jolla, California

**Jennifer M. Strickland, PharmD, BCPS**

Pain Management and Palliative Care Specialist  
Lakeland Regional Medical Center  
Lakeland, Florida  
Assistant Clinical Professor  
University of Florida College of Pharmacy  
Gainesville, Florida

**April Hazard Vallerand, PhD, RN, FAAN**

Associate Professor  
College of Nursing  
Wayne State University  
Detroit, Michigan

**Lynn R. Webster, MD, FACPM, FASAM**

Medical Director  
Lifetree Clinical Research and Pain Clinic  
Salt Lake City, Utah



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## ***Appendix B: Medical Learning Solutions Disclosure Policy***

### **Purpose of the MLS Disclosure Policy**

The policy on disclosure exists to provide guidance for staff, faculty and joint/co-sponsors of the requirement to disclose specific information to participants in order to comply with the following standards for all activities sponsored by Medical Learning Solutions.

- ACCME's 2004 Updated Standards for Commercial Support
- ACPE's Criteria for Quality and Interpretive Guidelines
- California Board of Registered Nursing Standards and Guidelines

This disclosure policy includes identification and disclosure of the following:

- Sponsor financial relationships
- Faculty and family/significant others financial relationships
- Discussion of unlabeled or unapproved uses of drugs and devices

As a joint sponsor of continuing education programs, Medical Learning Solutions is required to collect information from individuals who have an opportunity to affect the CE content about products or services of a commercial interest with which he/she has a financial relationship to allow a determination to be made as to whether that relationship may constitute a conflict of interest that must be resolved.

### **The Medical Learning Solutions Disclosure Policy**

1. Disclosure documents must be completed by anyone involved in planning or presenting educational content at CE programs approved for CME/CPE/CNE inclusive of the MLS advisory committee members, clinical content reviewers and identified faculty members.
2. Medical Learning Solutions requires all those in a position to control content to provide specific information to CE participants.
3. Medical Learning Solutions requires faculty to provide specific information to CE participants. Disclosure is required in two areas:
  - **Financial Relationships**  
Faculty must disclose any significant relationship between themselves/significant others and (a) the commercial supporter(s) of the program, and (b) the manufacturer of any product discussed in the CE program or related to the topic of the event. Information reported shall include financial relationships in place over the preceding twelve-month period. If the faculty has nothing to report, that information must be indicated.
  - **Discussion of Unlabeled Use**  
Faculty must disclose in writing and communicate in writing through course materials, that a product is not labeled for the use under discussion or that the product is still investigational and not approved for use in the United States.
4. Faculty members are required to complete the Faculty Disclosure Forms, and Attestation Forms as required by the accredited provider of each activity, prior to the program development process.
  - Required forms attached as provided by MLS' accrediting partner, MediCom Worldwide, Inc.
5. Disclosure Forms must be completed and returned to MLS prior to content development. Faculty refusing to disclose may not participate as a speaker for program in which disclosure was not obtained.



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### ***Appendix B: Medical Learning Solutions Disclosure Policy***

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6. Potential conflicts of interest disclosed will be reviewed by MLS and must be resolved prior to the educational activity.
7. Once a conflict is identified, a content validation process is initiated to ensure that the content or format of the CE activity and related materials will promote improvements or quality in health care and not promote a specific proprietary business interest of a commercial interest.
8. MLS conducts an unbiased review of all planned content for activities certified for credit to resolve any actual or perceived conflict of interest that exists.
9. Faculty must disclose to participants prior to the start of the educational activity the existence of significant situations where a direct commercial support relationship exists with the educational activity.
10. MLS discloses the following information to learners: 1) the name of the individual, 2) the name of the commercial interest(s), and 3) the nature of the relationship the individual has with the commercial interest. MLS also discloses to learners the name(s) of commercial interests supporting each CE activity.
11. Faculty disclosures will be documented and available to all participants via written participant handout information i.e.; syllabi, introductory slides, workbooks.
  - Disclosure will be made available to audience at the start of each activity.
12. Faculty must also disclose prior to the start of the educational activity if no significant financial relationships exist.
13. If faculty members present at multiple independent educational activities, a separate disclosure form is required for each activity.
14. Implementation:
 

All internal content review staff and outside external expert reviewers and faculty will complete a Financial Disclosure Form that contains the following information:

  - The form shall note the title and date of the activity, as well as the name(s) of the commercial supporter(s) associated with the activity.
  - The form shall solicit information about the financial relationship(s) of the reviewer, faculty member, his/her immediate family member or significant other has with any commercial supporter, as well as manufacturers of products associated with the activity or related to the topic of the activity.
  - If no relationship exists, there shall be a box to check to that effect.
  - The form shall solicit information from the faculty member as to plan to address off-label discussion or investigational use of a drug in his/her presentation.
15. Timeline for disclosure of financial relationships:
  - Internal reviewer will complete the disclosure form upon employment.
  - External experts will complete the disclosure form at the time a relationship with MLS has been identified.
  - Presenting faculty will be asked to sign a disclosure form at the time of invitation to participate in a planned program.

## FACULTY DISCLOSURE FORM



As a CE provider accredited by the Accreditation Council for Continuing Medical Education (ACCME) and approved by the Accreditation Council for Pharmacy Education (ACPE), and the California Board of Registered Nursing, MediCom Worldwide, Inc. must ensure balance, independence, transparency, objectivity, and scientific rigor in all sponsored educational activities. Faculty participating in a sponsored activity are expected to **(1)** disclose to the audience any financial relationship with the manufacturer(s) of any commercial product(s) and/or provider(s) of commercial services, and/or with any commercial supporters of the activity and **(2)** assist in resolving any conflict of interest that may arise from the relationship. The intent of this disclosure is not to prevent a presenter with a financial or other relationship from making a presentation, but rather to provide learners with information on which they can make their own judgments. It remains for the audience to determine whether the speakers' interests or relationships may influence the presentation. In addition, MediCom Worldwide, Inc. presenters must make a meaningful disclosure to the audience of their discussions of unlabeled or unapproved drugs or devices. All MediCom Worldwide, Inc. faculty are required to provide disclosure as a condition of participation.

**Title of Presentation:**

**Faculty Member's Name:**

**Check all that apply:**

- ☐ I have no relationship(s) to disclose
- ☐ I, the undersigned, have a financial arrangement or affiliation with a corporate organization offering financial support or grant monies for, or related to, this activity
- ☐ I, the undersigned, have a financial relationship with a manufacturer of a product or device discussed in my presentation at this continuing education activity
- ☐ I have a spouse or partner who has a financial relationship with a corporate organization offering financial support or grant monies, and/or with a manufacturer of a product or device

**\* It is not a requirement to disclose honoraria received for a participation in a CE activity \***

Commercial Interest	*Nature of Relevant Financial Relationship		Suggestions for Resolving Conflicts of Interest
	What was received?	For what role?	

(Please attach a separate sheet of necessary)

**Example terminology:**

**What was received:** Salary, royalty, intellectual property rights, consulting fee, non-CE activity honoraria, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit.

**Role(s):** Employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities (please specify).

**Suggestions for resolving conflicts of interest (COI):** In addition to the MediCom Worldwide, Inc. peer review process for resolving COI, other examples include altering the control of the content of a CE activity by (1) choosing someone else to control that part of the content; (2) change the focus of the CE activity; (3) change the content of the person's assignment; (4) limit the content to a report without recommendations; and (5) limit the source for recommendations. \*There is no set dollar amount for a financial relationship to be significant. Inherent in any amount received is the incentive to maintain or increase the value of the relationship with a commercial entity or manufacturer of a product or device. Therefore, any amount received within the past 12 months must be disclosed.

- ☐ I intend to reference **unlabeled** uses of drugs or products in my presentation, and will disclose this to the audience (specify drug(s) or product(s)):

\_\_\_\_\_

- ☐ I intend to reference **investigational/unapproved** uses of drugs or products in my presentation, and will disclose this to the audience (specify drug(s) or product(s)):

\_\_\_\_\_

- ☐ I agree to the Terms and Conditions

Signature \_\_\_\_\_ Date \_\_\_\_\_

## TERMS AND CONDITIONS

By signing this form, the undersigned speaker/author understands and accepts the following rules as required by MediCom Worldwide, Inc., the *Essential Areas and Policies* of the ACCME, and the rules of the American Medical Association:

1. **Disclosure.** Speakers/authors must complete and submit a Faculty Disclosure Form prior to the presentation, and that Faculty Disclosure Form shall be complete and truthful to the best of the speakers' knowledge. Speakers/authors are required to disclose any financial relationship they may have with any product or class of products they discuss in an educational activity. The resolution of conflict of interest will assist the learners in assessing the potential for influence in information that is presented.
2. **Fair-Balance.** Speakers/authors are required to prepare fair and balanced presentations, which are objective and scientifically rigorous.
3. **Transparency.** Speakers/authors are required to disclose any financial relationship that will assist the learners in assessing the potential for influence in information that is presented.
4. **Unlabeled and Unapproved Uses.** Presentations that provide information in whole or in part related to non-FDA approved uses for drug products and/or devices must clearly acknowledge the unlabeled indications or the investigative nature of their proposed uses to the audience. Speakers who plan to discuss non-FDA approved uses for commercial products and/or devices must advise MediCom Worldwide, Inc. of their intent.
5. **Use of Generic versus Trade Names.** Presenters should use scientific or generic names in referring to products in their lectures or enduring materials. Should it be necessary to use a trade name, then the trade names of all similar products or those within a class should be used.
6. **Commercial Supporter Influence.** Faculty are not permitted to receive any direct remuneration or gifts from the commercial supporter(s) of this activity, nor should they be subject to direct input from a commercial supporter regarding the content of their presentation.

## DISCLOSURE

Please indicate your understanding of and willingness to comply with each statement below. If you have any questions regarding your ability to comply, please contact the activity coordinator as soon as possible.

**Agree      Disagree**

<input type="checkbox"/>	<input type="checkbox"/>	I have disclosed to MediCom Worldwide, Inc. all relevant financial relationships, and I will disclose this information to learners verbally (for live activities) and in print.
<input type="checkbox"/>	<input type="checkbox"/>	The content and/or presentation of the information with which I am involved will promote quality or improvements in health care and will not promote a specific proprietary business interest or a commercial interest. Content for this activity, including any presentation of therapeutic options, will be well-balanced, evidence-based and unbiased.
<input type="checkbox"/>	<input type="checkbox"/>	I have not and will not accept any honoraria, additional payments or reimbursements beyond that which has been agreed upon directly with MediCom Worldwide, Inc.
<input type="checkbox"/>	<input type="checkbox"/>	I understand that MediCom Worldwide, Inc. will need to review my presentation and/or content prior to the activity, and I will provide educational content and resources in advance as requested.

**Agree      Disagree      N/A**

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If I am presenting at a live event, I understand that a CE monitor will be attending the event to ensure that my presentation is educational, and not promotional, in nature.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If I am providing recommendations involving clinical medicine, they will be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients. All scientific research referred to, reported or used in CE in support of justification of a patient care recommendation will conform to the generally accepted standards of experimental design, data collection and analysis.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If I am discussing specific health care products or services, I will use generic names to the extent possible. If I need to use trade names, I will use trade names from several companies when available, and not just trade names from any single company.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If I am discussing any product use that is off label, I will disclose that the use or indication in question is not currently approved by the FDA for labeling or advertising.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If I have been trained or utilized by a commercial entity or its agent as a speaker (e.g., speaker's bureau) for any commercial interest, the promotional aspects of that presentation will not be included in any way with this activity.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If I am presenting research funded by a commercial company, the information presented will be based on generally accepted scientific principles and methods, and will not promote the commercial interest of the funding company.

**I have carefully read and considered each item in this form, and have completed it to the best of my ability.**

Signature \_\_\_\_\_

Date \_\_\_\_\_

Please return these three pages to Christine Mettelle via fax at **215-337-0959**, or mail to her attention at MediCom Worldwide, Inc., 101 Washington Street, Morrisville, PA 19067. Please call Christine with any questions at 215-337-9991 or via email at [cmettelle@medicaled.com](mailto:cmettelle@medicaled.com).

Revised 06/2006

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### ***Appendix C: Medical Learning Solutions Policy Concerning Content Without Commercial Bias***

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#### **Purpose of the MLS Policy Concerning Content Without Commercial Bias**

The policy on Content Without Commercial Bias exists to establish criteria, policy and process of implementation of content standards of CE activities in accordance with the ACCME Standard for Commercial Support; Content and Format without Commercial Bias, and the content requirements of the ACPE and California Board of Registered Nursing.

#### **The Medical Learning Solutions Policy Concerning Content Without Commercial Bias**

1. Medical Learning Solutions must review the planned content of a CE activity to be certified by MediCom Worldwide, Inc., or other third party accredited provider, and demonstrate in documentation that the content or format of a CE activity adheres to the following criteria:
  - a. Presentations and/or its related materials must promote improvements or quality in health care and not a specific proprietary business interest of a commercial interest.
  - b. Presentations and/or its related materials must give a balanced view of therapeutic options.
  - c. Use of generic names within the body of the presentation or its related materials is required.
    - 1) Related presentation materials may contain trade names for all generic products contained within the presentation that are from several companies, as available.
2. All content from CE activities will undergo content validation process.
  - Content must conform to the generally accepted standards of experimental design, data collection and analysis.
  - Faculty must attest to MLS that the presentation content or content of its related materials promote improvement or quality in health care and not a specific proprietary business interest of a commercial interest.
  - Faculty must attest to MLS that the presentation gives a balanced view of therapeutic options.
  - MLS' internal and external reviewers must evaluate and attest that faculty presentation and its related materials promote improvements or quality in health care and not a specific proprietary business interest of a commercial interest.
  - Internal and external content reviewers must evaluate and attest that the presentation gives a balanced view of therapeutic options.
3. Activities are not eligible for certification if the content and/or format promote recommendations, treatments or manners of practicing medicine that are not within the definition of CME or are known to have risks or dangers that outweigh the benefits or are known to be ineffective in the treatment of patients. Activities that offer recommendation, treatments or practice manners outside of the definition of continuing pharmacy or nursing education, or that have risks or dangers that outweigh the benefits or are known to be ineffective are not eligible for certification.
4. CE activities must be developed and presented utilizing the principles of adult learning, which includes thorough assessment of learners' needs and focus on participant involvement in the learning process.
5. Faculty selected to participate must be demonstrated thought leaders in the topic of the CE activity and must have demonstrated skill in providing education to adult learners. Faculty should hold advanced degrees in their area of specialty, and should be active in research or patient care within an academic or clinical setting. Faculty may not be employees of the commercial supporter of an





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***Appendix C: Medical Learning Solutions  
Policy Concerning Content Without Commercial Bias***

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educational activity, regardless of qualification. Faculty will be asked to provide their qualifications and educational background to activity planners for review. Faculty will be advised of content requirements in their faculty letters.

6. MLS may solicit the review by an expert reviewer; members of the Medical Learning Solutions advisory committee provide oversight of MLS' program planning and design. A member of the advisory committee may be asked to provide content review for selected MLS activities. Whenever possible, advisory committee members are asked to review activities that fall within their area of clinical expertise.
7. The clinical pharmacy consultant provides oversight and review of program planning, design and in-depth content review of each activity, and verifies that the proposed amounts of pharmacology hours and content are appropriate for pharmacy credit.
8. The executive director will give final approval for the activity content and appropriate credit/contact hour designation, indicating that the content is deemed valid and within the criteria as stated in this policy. This form will be signed by the executive director. This is contained in the CE planning document.
9. Evidence of valid content will be placed in the activity file under planning.



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## ***Appendix D: Medical Learning Solutions Policy on Faculty and Speaker Selection***

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### **Purpose of the MLS Policy on Faculty and Speaker Selection**

The policy on Faculty and Speaker Selection exists to establish guidelines for the determination of qualitative and quantitative considerations in the faculty selection process.

### **The Medical Learning Solutions Policy on Faculty and Speaker Selection**

#### ***Qualitative Considerations***

Faculty selected to participate must be demonstrated thought leaders in the topic of the CE activity and must have demonstrated skill in providing education to adult learners. Faculty should hold advanced degrees in their area of specialty, and should be active in research or patient care within an academic or clinical setting. Faculty may not be employees of the commercial supporter of an educational activity, regardless of qualifications. Faculty will be asked to provide their qualifications and educational background to MLS for review. Faculty will be advised of content requirements in their faculty letters sent by MLS.

1. Faculty must attest to MLS that the presentation content or content of its related materials promote improvement or quality in healthcare and not a specific proprietary business interest of a commercial interest.
  - Faculty must attest to MLS that the presentation gives a balanced view of therapeutic options.
  - MLS' internal and external reviewers must evaluate and attest that faculty presentation and its related materials promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.
  - CE activities must be developed and presented utilizing the principles of adult learning, which includes thorough assessment of learners' needs and focus on participant involvement in the learning process.
2. Upon selection and approval of the faculty, a letter of guidance is written to the faculty outlining the expectations.
3. Each faculty member must submit a CV for review.
4. Each faculty member must complete and sign a disclosure form and attestation form.
5. Those faculty members who do not complete required disclosure information will not be permitted to participate in the activity as planned.
6. The executive director or designee will communicate directly with faculty, providing each faculty member with written information related to objectives of the program.
7. The executive director or designee will provide technical assistance necessary to prepare materials for presentation.

#### ***Determination of Number of Faculty Required Per Planned Activity***

1. An appropriate number of qualified faculty members shall be utilized for each continuing education program
2. The executive director will be responsible for determination of number of faculty required for each program. Determination will be based on number of topics, depth of subject matter and



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#### ***Appendix D: Medical Learning Solutions Policy on Faculty and Speaker Selection***

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anticipated duration of  
the program.

3. MLS will strive to maintain a ratio of at least one faculty member per every one hour of formal didactic lecture.

#### ***Program Evaluation***

1. A program evaluation form is developed for each activity, which is intended to solicit participant's assessment of faculty effectiveness.
2. Evaluation forms are distributed to participants at the end of each activity. Each participant is required to complete the form as designed, as well as provide any written feedback or comments regarding program.
3. A formal summary report is completed following each program or program series. This report compiles the results of the evaluation form as well as narrative comments from participants.
4. A designated member of the CE staff will directly monitor each educational activity.



**Exhibit B**

**Fentora/ACTIQ RiskMAP**



### FENTORA Risk Management Program

Provider is aware that FENTORA™ (fentanyl buccal tablet) [C-II] was approved subject to a Risk Minimization Action Plan (RiskMAP). The RiskMAP includes key safety messages that are essential to the safe use of this product. They are:

- FENTORA is indicated for the management of breakthrough pain in patients with cancer who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- FENTORA is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- No misuse of FENTORA should occur.
- Unintended (accidental) exposure to FENTORA should not occur.
- Patients considered opioid tolerant are those who are taking at least 60 mg oral morphine/day, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that FENTORA can be fatal to a child. Keep all units away from children and discard properly.
- FENTORA is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

### ACTIQ Risk Management Program

Provider is aware that ACTIQ® (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- ACTIQ is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- ACTIQ is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.
- ACTIQ is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

**INDEPENDENT EDUCATIONAL PROGRAM GRANT AGREEMENT**

This Agreement is entered into as of this 2<sup>nd</sup> day of May, 2008, by and between Cephalon ("Cephalon"), located at 41 Moores Road, Post Office Box 4011, Frazer, PA 19355, and MediCom Worldwide, Inc. ("Provider") located at 101 Washington Street, Morrisville, PA 19067 and Medical Learning Solutions ("Educational Partner") located at 101 Washington Street, Morrisville, PA 19067.

WHEREAS, Cephalon has reviewed Provider's grant request to support a medical education program ("Program"); and

WHEREAS, Cephalon has determined that the Program has the potential to address educational gaps and improve patient care; and

WHEREAS, it is the intent of the parties to ensure that the Program will be independent, objective, balanced, scientifically rigorous, and have reasonable expectations of meeting its educational objectives so that it will not be viewed by the United States Food and Drug Administration ("FDA") as promotional and that Cephalon will not be viewed as responsible for its content; and

WHEREAS, Cephalon agrees to provide funding for the Program under the conditions set forth below.

NOW THEREFORE, Provider and Cephalon agree to the following terms under this Agreement:

1. Title of Program. The Educational Program is entitled "2008 Emerging Solutions in Pain Lecture in Conjunction with AAPM 2008", and a copy of the grant request for the Program is attached hereto as Exhibit A.
2. Type of Program. The Program is:
  - ☒ accredited (e.g., continuing medical education or "CME"); or
  - ☐ an independent program where CE credits will not be offered.
3. Educational Partner. The Provider ☒ shall ☐ shall not use a third party that will provide assistance in support of the Program ("Educational Partner"). The name of the Educational Partner is Medical Learning Solutions.
4. Educational Components. The expected components of the Program (e.g., number of live meetings, CD ROM, web-based, etc.) are as follows:
  - (a) Live Symposium;
  - (b) Streaming Video Enduring Material Adaptation;

5. Program Purpose. The Program is for scientific and educational purposes only, and is based on established bona fide and independently verifiable patient and/or practitioner needs or gaps in healthcare performance, and is not intended to promote a Cephalon product, directly or indirectly. The Program is not a repeat performance of a prior program.
6. Grant Amount Funding Arrangements.
  - (a) Cephalon will provide support for the Program by means of an educational grant in the total amount of \$350,423, as set forth in the budget attached hereto, or a pro rata amount based on the actual work performed and expenses incurred by Provider in accordance with the Budget. If the Program is canceled or terminated prior to completion, Provider shall return the grant, or any unused portion thereof, to Cephalon within thirty (30) days of such termination or cancellation. Provider shall have full responsibility for all funding arrangements of the Program, including any funding to be provided to its Educational Partner. Payment terms of the grant shall be made in accordance with any schedule/criteria provided in the Budget.
  - (b) Within ninety (90) days of completion of the Program, Provider shall provide Cephalon with a detailed reconciliation of actual expenses incurred, and to the extent Cephalon has overpaid Provider for same, Provider shall provide a refund to Cephalon within thirty (30) days thereafter. Such detailed reconciliation shall be forwarded to Cephalon at the address above to the attention of Bhaval Shah Bell, Associate Director, Medical Education.
  - (c) Provider may not use funds provided by Cephalon to pay travel, lodging, honoraria or personal expenses for non-faculty attendees. Grant funds may be used to reduce the overall registration fees for attendees. Grant funds may not be used to purchase capital equipment or to provide general operational support for an institution. Funds for hospitality shall not be provided, except that funds may be used for modest meals or receptions that are held as part of the Program, but such events shall not compete with, nor take precedence over, educational events. The appropriateness of any reception shall be at the sole discretion of the Provider, and Provider shall have final decision-making authority in connection with any such activities.
  - (d) Funds may be used by the Provider to permit medical students, residents, fellows or other health care professionals in training to travel to and attend the Program; provided, however, that the selection of such students, residents or fellows who receive funds is made by either the academic or training institution, or, if by the Provider, such selection shall be made with the full concurrence of the academic or training institution.



7. Objectivity and Balance. Provider shall retain full responsibility for control of the content of the Program and shall ensure that the following requirements are met:

- (a) The Program material/information will be objective, balanced and free from commercial bias. All topics shall be treated in an impartial, unbiased manner. All discussions shall include a range of views about each class of drug and disease treatment options. Information shall not unfairly represent a spectrum of views favoring a product or class of products marketed by Cephalon or any other company. The title of the Program will fairly and accurately represent the scope of the presentation.
- (b) Provider agrees that neither Cephalon nor its agents shall control the content of the Program. Provider agrees that there will be no scripting, targeting of points for emphasis, or other activities by Cephalon or its agents that are designed to influence the content of the Program. Cephalon personnel will not attend content development meetings unless requested in writing by the Provider or the Educational Partner make presentations of disease data and/or Cephalon product data to faculty. In this instance, Cephalon personnel may stay only for this portion of the meeting, and the accredited provider must be in attendance.
- (c) If requested, in writing, by the Provider or Educational Partner, Cephalon Medical personnel may also provide written material on a Cephalon product or compound in development, such as *specific product data, manuscripts, posters, product labels and other scientific material* (not in slide format) in accordance with internal corporate guidelines based on the level of information that is acceptable to disclose.
- (d) Cephalon shall not review the Program for medical accuracy or completeness and the Provider and/or Educational Partner (if any) agree that they will not make such a request of Cephalon.
- (e) If a product marketed by Cephalon is the subject of discussion, the data will be objectively selected and presented, with an accurate reflection of favorable and unfavorable information about the product and shall also include a balanced discussion of prevailing information on alternative products and /or therapies.
- (f) Any suggestions of superiority of one product or treatment over another will be supported by the body of available data and will not result from selective presentation or emphasis on data favorable to a particular treatment.
- (g) Provider represents that neither it nor the Educational Partner (if any) has either an open complaint or decision from the Accreditation Council for Continuing Medical Education ("ACCME") or the FDA that a program provided by the Provider or the Educational Partner failed to meet standards of independence, balance, objectivity, or scientific rigor.

8. Risk Minimization Action Plan. Cephalon provides the following Risk Minimization Action Plan ("RiskMAP") information to all Providers. Neither Cephalon nor its agents shall influence or control whether a product marketed by Cephalon is the subject of discussion. A RiskMAP is a strategic safety program designed to meet specific goals and objectives in minimizing known risks of a product while preserving its benefits. Any product marketed by Cephalon that is approved with a RiskMAP, and the key safety-related health outcomes outlined in that RiskMAP, are listed in Exhibit B. Provider agrees that it is aware of the RiskMAP(s) and the key safety messages.
9. No Faculty Selection. Provider shall retain full responsibility for the selection of the presenters, authors, moderators, and/or other faculty (hereinafter referred to collectively as "Faculty"). Provider and/or Educational Partner (if any) shall not request recommendations for Faculty from Cephalon
10. Disclosures. Provider will ensure meaningful disclosure of limitations of data (e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion). Provider will require that Faculty disclose when a product is not approved in the United States for the use under discussion.
11. Question and Answer Session. To the extent the Program is a presentation, Provider will ensure meaningful opportunities for questioning by the audience.
12. Financial Relationships. Provider will ensure meaningful disclosure to the audience of Cephalon funding and any significant relationship between individual Faculty and Cephalon. All meaningful disclosure(s) shall also be made in any written materials, including, but not limited to, announcements, brochures, syllabi and enduring material. Disclosures shall not mention product trade names.
13. Representations and Warranties. Provider represents that:
  - (a) Neither it nor the Educational Partner, if any, provides marketing, advertising, public relations, market research, medical education services or other consulting services (e.g., support for advisory boards) to any other department within Cephalon ("Marketing Activities");
  - (b) If Provider or the Educational Partner has an affiliated company that provides Marketing Activities to Cephalon, Provider has instituted appropriate controls and safeguards to ensure the Program (i) remains independent, objective, balanced and scientifically rigorous, (ii) is not intended to promote a Cephalon product, directly or indirectly, and (iii) is not in any way biased due to the affiliated company's relationship with Cephalon;
  - (c) Provider has determined that it is appropriate to use the Educational Partner in light of the requirements under this Agreement; and
  - (d) If Provider or its Educational Partner employs a former Cephalon employee who worked at Cephalon at anytime during the most recent

year and who had marketing responsibility in the therapeutic area that will be covered by the Program, then that former employee will not have any role in the planning, development or delivery of the Program.

14. Invitations/Enduring Materials. The Program audience will be selected by the Provider. The Provider shall be responsible for distributing materials about the Program, including invitations, reminder notices, and business reply cards that can be used by third parties to obtain any enduring Program material from the Provider.
15. Ancillary Promotional Activities. To the extent the Program is a live presentation, no promotional activities or product advertisements will be permitted in the same room as, or in an oblique path to, the Program. If the Program is a teleconference or webcast, no product advertisements or promotional activities will be permitted immediately prior to, during, or immediately after the delivery of the Program. If the Program is in print format, no product advertisements or promotional materials will be interleaved within the pages of the Program. If the Program is made available electronically, no product advertisements or promotional materials will appear within the Program material or interleaved between computer windows or screens of the Program, all as stipulated in ACCME Guidelines.
16. Compliance with Guidelines. Provider represents that the Program, including development of the Program and Program materials, shall conform to the American Medical Association ("AMA") Guidelines on Gifts to Physicians, the AMA Ethical Opinion on Continuing Medical Education, the ACCME Standards for Commercial Support, the FDA December 3, 1997 Final Guidance for Industry-Supported Scientific and Educational Activities, and the Pharmaceutical Research and Manufacturers Association ("PhRMA") Code on Interactions with Healthcare Professionals.
17. Logistical Status Reports. Provider and/or Educational Partner shall provide periodic reports to Cephalon regarding the management and logistics of Program components.
18. Miscellaneous.
  - (a) No party shall use the other party's or its affiliates' name or trademarks for publicity or advertising purposes, except with the prior written consent of the other party.
  - (b) Provider agrees to obtain all consents, authorizations, approvals and releases that may be necessary for the production of the Program and of any written materials prepared in connection therewith.
  - (c) No term, condition or other provision of any attachment or addendum to this Agreement shall supersede any term, condition or other provision of this Agreement, and with respect to any inconsistency or ambiguity, the Agreement shall control.

IN WITNESS WHEREOF, the parties, by their duly authorized representatives, agree to comply with all the terms and conditions of this Agreement.

**CEPHALON, INC.**

By: [Signature]  
 Name: Lesley Russell, MB, Ch.B., MRCP  
 Title: Executive Vice President  
 Worldwide Med. & Reg. Operations

Date: 5/2/08

**MEDICOM WORLDWIDE, INC.**

By: [Signature]  
 Name: JOAN MEYER  
 Title: PRESIDENT

The above signatory is a duly authorized corporate officer of the IEP Provider.

Date: 5-17-08  
 Tax ID #: 23 306 3738

**MEDICAL LEARNING SOLUTIONS**

By: [Signature]  
 Name: Shari L. Gavinski  
 Title: President

The above signatory is a duly authorized corporate officer of the Educational Partner.

Date: 5-19-08  
 Tax ID #: 90-135153

**Exhibit A**  
**Copy of Grant Request**



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 Morrisville, Pennsylvania 19067  
**Phone** 215.337.9991  
 800.408.4242  
**Fax** 800.679.0959  
**Website** www.MedicalEd.com

## ***2008 Emerging Solutions in Pain Lecture Grant Request Table of Contents***

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February 26, 2008



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February 26, 2008

Bhaval Shah-Bell, PhD  
Cephalon, Inc.  
41 Moores Road  
Frazer, PA 19355

Dear Dr. Shah-Bell:

MediCom Worldwide, Inc., in partnership with Medical Learning Solutions, Inc., has recently completed a comprehensive needs assessment to identify the educational needs of clinicians who provide care to patients with chronic pain. This needs assessment was compiled from the following sources:

- Evaluation summaries of completed and ongoing 2007 Emerging Solutions in Pain programs and activities
- Clinical advisory review
- Survey of health care professionals, including participants in completed and ongoing 2007 Emerging Solutions in Pain programs
- Literature search

Based on the identified educational need, Medical Learning Solutions is requesting an educational grant from Cephalon, Inc. to support a live symposium that will support the continuation and further development of the **Emerging Solutions in Pain**, or **ESP**, initiatives. This lecture will be held as a full-day plenary session symposium in conjunction with the scientific program of the 2008 American Academy of Pain Management. The **2008 Emerging Solutions in Pain Lecture** will focus on balancing the clinical need to provide adequate analgesia to patients with chronic pain with the legal and societal need to monitor for potential issues of abuse, addiction and diversion of controlled substances. Following the live symposium, Medical Learning Solutions is proposing to adapt the educational material as a three-part accredited streaming video series on [EmergingSolutionsinPain.com](http://EmergingSolutionsinPain.com), as well as an accredited print monograph, to be released as an insert into *Practical Pain Management Journal*, as well as an online monograph at [EmergingSolutionsinPain.com](http://EmergingSolutionsinPain.com)

The budget to fund the live symposium activities is approximately \$234,583; the budgets for the streaming video and print monograph are \$115,840 and \$98,674, respectively. Please refer to the detailed budget section of this proposal for complete grant funding proposals. These scientific events will comply with all ACCME, FDA, AMA, and ACPE regulations for industry-supported professional continuing education.

MediCom Worldwide is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians and is approved by the Accreditation Council for Pharmacy Education to provide pharmacy continuing education, as well as an





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approved provider of nursing continuing education through the California State Board of Registered Nursing.

Thank you in advance for your consideration of this request.

Respectfully,

A handwritten signature in cursive script, appearing to read 'Joan Meyer'.

Joan Meyer  
President,  
MediCom Worldwide, Inc.

A handwritten signature in cursive script, appearing to read 'Sheri L. Gavinski'.

Sheri L. Gavinski  
President,  
Medical Learning Solutions, Inc.



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**2008 Emerging Solutions in Pain Lecture Grant Request  
 American Academy of Pain Management Symposium**

***Educational Needs Assessment***

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***Learning Objectives***

1. Outline the clinical challenges that are commonly associated with the treatment of chronic pain, and summarize clinical and pharmacological strategies that will support improved patient outcomes for individuals with chronic pain
2. Describe and differentiate various multimodal therapies, including complementary and alternative treatments, that may be prescribed and applied for the management of chronic pain in an interdisciplinary approach to care
3. Identify the risks of addiction related to chronic opioid therapy prescribed for chronic pain, and outline how clinicians should differentiate tolerance, physical dependence, and pseudoaddiction from addiction
4. Summarize regulatory issues surrounding controlled substance prescribing and identify practical methods clinicians may use to contain risk.

***The Challenges and Complexities of Treating Chronic Pain***

Chronic pain presents a significant and complex challenge for the patient, the patient's family, friends and caregivers, as well as for the practitioner who is managing the patient's care. Many factors support the depth and breadth of chronic pain as a complex and challenging clinical problem: there are no objective tests, for example, that may be applied to an individual to determine if he or she is suffering from chronic pain, or to determine the relative level of pain the individual is experiencing. Furthermore, chronic pain is neither unidimensional, nor is it symptomatic; it is instead widely regarded as a progressive, debilitating, multifactorial, circumstantial, and personal syndrome of conditions that may stem from a variety of etiologies, some of which remain unknown today, despite years of intensive research and investigation. Treatment of chronic pain is similarly complex and challenging, as every individual experiences pain in a unique way, and chronic pain is widely believed to be based on the bio-genetics, perceptions and experiences of the individual affected.<sup>1-3</sup> Finally, complicating clinical assessment, diagnosis and treatment even further, chronic pain is commonly associated with comorbid conditions, such as depression, anxiety, sleep dysfunction, and substance misuse, all of which must be assessed and treated for any significant improvement in the patient's functioning and outcomes.

The challenges associated with chronic pain as a multifactorial and complex problem are thus significant and diverse. It is not surprising, therefore, that therapeutic options for treating chronic pain span an equally broad spectrum of diverse pharmacological and nonpharmacological options. There is simply no one clinical option which will work for all patients who suffer from chronic pain, due to the infinite diversity of individual responses to both pain and its treatment. Clinicians cannot, therefore, take a "one size fits all" approach to treatment of chronic pain, but



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**2008 Emerging Solutions in Pain Lecture Grant Request  
American Academy of Pain Management Symposium**

***Educational Needs Assessment***

must, instead, understand appropriate and specific techniques for assessment and diagnosis, as well as the best uses, benefits and risks of a range of available treatment options.

Treatment for chronic pain can, and should, include options that address the spectrum of pain's bio-psycho-social impact. Many patients who suffer with chronic pain may, for example, respond to adjuvant nonpharmacologic therapies, including complementary and alternative medicine (CAM), as these treatments are designed to improve the status of the various health domains affected. These solutions are not meant to "cure," but to assist with pain management and the patient's return to function. High-quality randomized controlled trials indicate that multidisciplinary pain programs<sup>a</sup> represent the best therapeutic option for the management of patients with complaints associated with complex chronic pain.<sup>2</sup>

The majority of patients with chronic pain, however, will undergo at least one trial of pharmacologic therapy, and the spectrum of choices here is diverse. One class of drugs, the opioid analgesics, is frequently prescribed to patients with chronic pain when the pain does not respond to other treatment options. Opioids, like any other medication, have a risk-benefit ratio that must be examined within the context of the specific patient and his or her unique pain experience. Unlike many other medications, however, the analysis of an opioid's risk-benefit ratio must balance the ability of opioids to deliver analgesia across a wide a spectrum of pain syndromes with the potential of these agents to contribute to addiction, on a personal, familial, and societal level.

This ratio can, unfortunately, be challenging to define, as addiction is as individualized as pain itself. A recent review of the literature indicates that the prevalence of addiction in chronic pain patients prescribed opioid therapy reportedly varied from 0% up to 50%, and from 0% to 7.7% in cancer patients, depending of the subpopulation studied and the criteria used. This variance, however, does not mitigate the fact that both practitioner and patient must fully appreciate the risk-benefit ratio of opioid treatment, on an individualized basis, to appropriately support the safe and effective customized treatment and management of pain.<sup>1,2</sup>

When treating patients with chronic pain with opioids, therefore, it is essential that clinicians be educated and aware of techniques for managing the risk of opioid misuse, abuse, and addiction. Clinicians must be able to understand and differentiate, on a practical, clinical level, the terms addiction, tolerance and physical dependency. In order to accurately assess, monitor, and optimally treat patients prescribed opioid therapy, clinicians must understand the fine differences in patient presentation, and how to treat patients differentially, depending upon their relative risk of addiction.

<sup>a</sup> Per the NIH Roadmap Initiative, a multidisciplinary approach brings together numerous experts from diverse disciplines to collectively address a complex problem, with each expert addressing the issues from the perspective of his or her own discipline. In contrast, an interdisciplinary approach is what results from the melding of two or more disciplines to create a new (interdisciplinary) science. Biophysics, biostatistics, bioinformatics, bioengineering, social neuroscience, and psychoneuroimmunology are just a few examples of existing interdisciplinary sciences.<sup>15</sup>



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**2008 Emerging Solutions in Pain Lecture Grant Request  
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***Educational Needs Assessment***

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***Maximizing Benefit, Minimizing Risk: Understanding Addiction***

By far, the greatest challenge to the treatment of chronic pain is the looming threat of addiction, misuse, and diversion. Unfortunately, the risk of addiction affects clinical decision making, often leading to "opiophobia" by either the clinician or the patient, hampering treatment. However, all chronic pain patients are entitled to receive adequate analgesia, regardless of a history of substance abuse.<sup>4</sup> Opioids have tremendous clinical utility in the treatment of pain, and are the mainstay of treatment for chronic somatic and neuropathic pain refractory to other analgesics. However, while this class of medications carries the greatest potential for palliation, it also carries the greatest potential for abuse.

Several clinical tools are available that are designed to alert clinicians to the signs of drug abuse and predict which patients are most at risk of misuse.<sup>5,6</sup> Use of a controlled substance abuse agreement has been shown to reduce prescription opioid abuse by 50%, from 17.8% to 9%.<sup>7</sup> Similarly, the combination of adherence monitoring and random urine testing has been shown to reduce illicit drug abuse in chronic pain patients from 22% to 16%.<sup>8,9</sup> However, pain assessment and management models are changing, and the misuse of medically prescribed opioids is on the rise. Most chronic pain patients do not experience tolerance once their pain is adequately controlled with a stable dose. In most cases, diminished response over time indicates worsening of the underlying condition causing the pain, rather than tolerance.

Unfortunately, the prevalence of medically prescribed opioid misuse and diversion in the US has risen dramatically during the last decade, in concert with an increase of 542% in the prevalence of addiction to prescribed opioids during the period spanning 1992 to 2003.<sup>10</sup> These activities have created a serious public health problem, as the number of Americans abusing prescription drugs increased by 94%, and prescription drug abuse by teens 12-17 years old increased by 212%. During this same period, the number of prescriptions for controlled drugs increased by 154%, prescriptions for opioids increased by 222% (see Figure 1), and prescriptions for oxycodone increased by 380%.<sup>10</sup> At present, 56% more Americans abuse opioid prescription drugs than abuse cocaine, heroin, hallucinogens, and inhalants combined.<sup>11</sup> Among chronic pain patients receiving opioids, approximately 1 in 5 abuse prescription controlled substances. The problem has gotten so bad that almost a quarter of a trillion dollars of the US annual health care bill funds substance abuse and addiction.<sup>12</sup> This shifting pattern of abuse has been attributed to changes in medication prescribing practices, drug formulations, and easy access over the Internet. The most common sources for obtaining pain relievers nonmedically are a friend or relative (59.8%) or a physician (16.8%).<sup>10</sup>

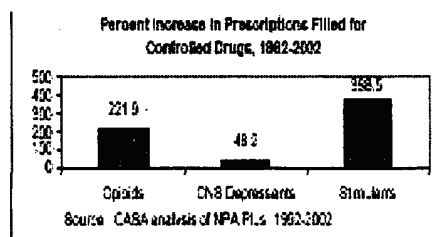


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**2008 Emerging Solutions in Pain Lecture Grant Request  
American Academy of Pain Management Symposium**

**Educational Needs Assessment**

**Figure 1: Percent increase in prescriptions filled for controlled drugs, 1992-2002.<sup>10</sup>**



To help physicians, further education is required. There is a fine balance between identifying patients who exhibit drug-seeking behavior because their pain is not being adequately controlled (pseudoaddiction), and mistaking them for patients with aberrant behaviors indicative of substance abuse who were not forthcoming with their history.<sup>13,14</sup> A physician survey conducted by the Center on Addiction and Substance Abuse (CASA) showed detriments in this regard, demonstrating that 94% of physicians failed to identify the symptoms of alcohol abuse or addiction.<sup>10</sup> Nearly half of physicians have difficulty discussing prescription drug abuse with their patients, and only 54% question patients about prescription drug abuse when taking their history. Despite recommendations to the contrary, only 55% of physicians usually call or obtain records from the patient's previous physician prior to prescribing controlled drugs on a long-term basis. These lapses are further reinforced by pharmacists, 28% of whom do not regularly validate the prescribing physician's DEA number when dispensing controlled drugs. Other pharmacists admit to dispensing a controlled drug without sufficient information (a completed *written* prescription). Both the prescriber and pharmacist communities would benefit from education addressing the importance of adhering to protocol when prescribing, and the recognition and prevention of abuse and diversion.

CASA's survey results reveal several ways that diversion can occur at the clinical level, the primary reason being lack of training.<sup>10</sup> CASA cites poor communication between physicians and pharmacists as impeding the prevention of prescription drug abuse, finding that pharmacists are reluctant to report physicians they suspect are actively involved in diversion. Pharmacists with advanced training in substance abuse and addiction are less reluctant to report.<sup>10</sup> As described by Theodore Perran Jr., MD, Associate Clinical Professor of Addiction Medicine at Case Western Reserve University, some of the CME training has hindered development of skills necessary to deliver optimal pain management. As he explains, the emphasis of training might best be shifted:

"This emphasis on rapport-building techniques to the virtual exclusion of limit-setting helps to create the current clinical reality in which physicians feel acutely uncomfortable with conflict and interpersonal confrontation."<sup>10</sup>



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## ***2008 Emerging Solutions in Pain Lecture Grant Request American Academy of Pain Management Symposium***

### ***Educational Needs Assessment***

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#### ***The Role of Regulations in Chronic Pain***

Clinician understanding of, and confidence in, techniques for assessing, identifying and minimizing opioid misuse, abuse, addiction and diversion is thus a critical component in the ability to provide care that involves opioids to patients with chronic pain. Safe and effective prescribing of opioids not only benefits the patient, in support of improved outcomes; it is also required by law. Clinicians who prescribe opioids must be educated in federal and state regulations pertaining to controlled substances, in support of minimizing the potential for misuse, abuse, addiction and diversion while simultaneously supporting the use of opioids for legitimate medical care; this is, in fact, the directive of the Drug Enforcement Agency, or DEA. While necessary and required, these regulations only add to the layers of complexities associated with caring for chronic pain patients, by virtue of increased scrutiny and strict requirements for regulatory compliance in the prescribing and dispensing of controlled substances.

Given the complexities associated with chronic pain, with treatments for chronic pain, and with safe and effective pharmacologic management that maximizes benefits while minimizing risk, no single health care professional, regardless of level of competency and/or expertise, can adequately address the multitude of secondary conditions or domains (physical, cognitive, psycho-social, emotional, and cultural) impacted by the effects of chronic pain. **An educational need, therefore, exists for health care professionals to better understand the complex nature of chronic pain and the need for multidisciplinary care in the management of chronic pain. Practitioners need to identify how this multidisciplinary care model will best serve their patients by improving outcomes and how it will also provide risk containment support to the patient, the entire pain management team and to their medical practices.**

#### ***Literature Search***

An extensive and recently conducted PubMed medical literature search (2006-2008) revealed the following publications in support of furthering education in the following areas:

1. Safe and effective treatment of pain as a human right; including assessment, risk containment, appropriate treatment and patient selection, and monitoring.<sup>1-3,15-34</sup>
2. Provision of guidance to clinicians who prescribe opioid analgesics to patients in pain.<sup>23,32-39</sup>
3. Multidisciplinary, multimodal, CAM treatment approach.<sup>40-43</sup>

Additionally, results from a recently published VA Health System study concluded that users of prescribed opioids had higher rates of opioid and nonopioid abuse problems compared with nonusers of prescribed opioids, but these higher rates appear to be partially mediated by depressive and anxiety disorders. **In patients receiving prescribed opioids, clinicians need to be alert to drug abuse problems and potentially mediating mental health disorders.**<sup>4</sup>





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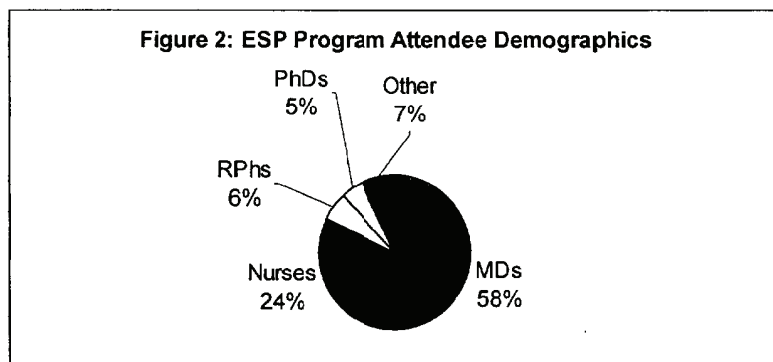
## 2008 Emerging Solutions in Pain Lecture Grant Request American Academy of Pain Management Symposium

### Educational Needs Assessment

#### Professional Surveys

Surveys of practicing health care professionals consistently support the need for education surrounding safe and effective prescribing of opioids. For example, a recently published survey study critically examined subjective factors that influence the prescribing practices of advanced practice registered nurses (APRNs) for patients with chronic nonmalignant pain. Data were collected through semistructured interviews with participating APRNs. Critical analysis of the data revealed that prescribing decisions for patients with chronic pain were characterized by a conflict of interest in which the patients' best interests were given a low priority. This conflict, which is socially and politically created and maintained, renders nurses unlikely to fulfill their ethical responsibility to patients.<sup>45</sup> **Teaching basic pain management as an ethical responsibility of practice is a first step toward ending the conflict and ensuring that the patients' best interests are addressed.**

To ensure that the educational needs identified through the *Emerging Solutions in Pain* initiatives are consistent with the results of published studies, ESP has endeavored to collect and analyze data from registered members of *Emerging Solutions in Pain*, and from participants in ESP-sponsored programs. Figure 2 represents the demographics of 209 clinicians who attended ESP live symposia in 2007; all of these health care professionals identified themselves as active in the treatment of patients with pain and/or addiction issues.<sup>46</sup>



Following the live symposia, the attendees were asked to identify and rate topics and factors that are important to them in their practice setting; these ratings are provided in Table 1.<sup>46</sup> As can be seen from the responses, the top three topics that were identified as the "most important" were the interface of pain and addiction, federal regulations pertaining to controlled substances, and assessment and diagnosis issues. These three topics alone were cited by a combined total of 61% of the attendees as "most important."<sup>46</sup>





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**Table 1: Topics Identified as "Most Important" in Clinical Practice<sup>46</sup>**

<b>Topic</b>	<b>Percentage of Attendees Citing Topic As "Most Important" in Their Clinical Practice Setting</b>
Interface of Pain & Addiction	28%
Federal Regulations	17%
Assessment/Diagnosis	16%
Pharmacology	11%
Urine Drug Testing	8%
Universal Precautions	8%
Non-Medication Treatment Approaches	6%
Neurobiology	5%
Epidemiology	1%

These health care professionals were also asked to identify their planned usage of a spectrum of assessment and monitoring tools, as a measure of their understanding of these important components of a comprehensive and proactive pain management treatment plan. These responses are provided in Table 2.<sup>46</sup>

**Table 2: Planned Implementation of Assessment/Monitoring Tools<sup>46</sup>**

	<i>Plan to implement using new information learned</i>	<i>Need further education for implementation</i>	<i>Currently use in practice</i>
Opioid Risk Tool (ORT)	43%	28%	29%
CAGE questionnaire	32%	15%	50%
Physical Disability Index (PDI)	32%	37%	31%
Pre-and post-therapy physical functioning assessment	28%	17%	56%
4 A's	24%	21%	54%
Differential pain assessment (intermittent & breakthrough)	31%	7%	72%
Abilities of daily living (ADL)	17%	14%	69%
Urine drug testing	13%	6%	81%
Treatment/Opioid Agreement	9%	4%	87%
Patient informed consent	8%	3%	87%
Numeric rating scale	7%	3%	89%



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As can be seen in Table 2, the top two tools clinicians planned on using involved risk assessment; significant percentages of other clinicians in the same group also identified a need for these two tools, but felt they required further education on them prior to implementation. Out of the top five tools that were identified as tools for implementation post-program activity, it is significant that, in this group of health care professionals who provide care to patients with pain, three of the five involved risk assessment or monitoring. This data underscores the significant need in the pain management community for information, tools and resources that support safe and effective prescribing of opioids.<sup>46</sup>

This group of 209 health care professionals was also prolific in their requests for additional information. Topics for future educational activities that were identified on the post-program evaluation form included a range of topics on pharmacologic and non-pharmacologic treatment of pain, as well as common comorbid conditions. A significant minority (23%) of the suggested topics focused on assessing and monitoring for opioid misuse, abuse and addiction.<sup>46</sup> Representative comments included:

- Universal precautions, addiction/abuse screening
- Please increase time spent on practical tools for prevention of opioid misuse and abuse
- Include a lecture on urine testing including methods, interpretation, false positives/negatives, etc.

Questions that were submitted and/or asked during the actual symposia were also recorded and analyzed. More than 85 pertinent questions were submitted on question cards; subsequent analysis allocated each of these 85 questions into a single topic category. This analysis is provided in Table 3, and a representative sample of questions is provided in Table 4.

**Table 3: Topic Distribution of Submitted Questions<sup>46</sup>**

Topic	Questions Submitted
Pharmacology	27
Interface of Pain and Addiction	26
Federal Regulations	13
Neurology	7
Urine Drug Testing	6
Non-medication Approaches to Treatment	5
Epidemiology	2



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**Table 4: Representative Sample of Submitted Questions<sup>46</sup>**

Topic	Representative Questions
Pharmacology	Can we give short-acting pain medication in four hours continuously for months or years for chronic pain?
	What is the best way to manage opioid-induced constipation? What percentages of patients don't respond to typical treatments? What do you think about peripheral opioid antagonists for constipation?
	Any pharmacologic rationale for using hydrocodone and benzodiazepines concurrently?
Interface of Pain and Addiction	If you underdose a patient with history of opioid dependency (in recovery), are you putting that patient at risk for relapse?
	Is it true combining two different opioids helps reduce chance of addiction?
	How do you detoxify patients with addiction, ie, the high dose overlapping fentanyl patches or high levels MSER? Do you suggest an inpatient or outpatient protocol?
Federal Regulations	Can we split a Schedule II script for economic reasons?
	What should one do if one finds out that a prescription has been stolen and the pharmacy faxes a copy and it's not the doctor's writing. How do you protect yourself?
	Are there combinations of pain medications that are being prescribed by physicians that are "red flagged" to regulatory agencies, such as Schedule III drugs and benzodiazepines?
Neurology	Are opioid tolerance and opioid-induced hyperalgesia really the same thing? If not, how do they differ?
	Would short-acting opioids be more likely to cause a decrease in the opioid receptor and the change to excitatory response than a long-acting opioid?
	Hyperalgesia perpetuates increased pain or decreased pain tolerance – can withdrawal symptoms produce death in a patient who is asked to reduce opioids usage?
Urine Drug Testing	Can you describe your routine protocol regarding urine drug testing? How do you change that protocol if the UDT results come back abnormal for that patient? If the UDT results come back abnormal for a second time, how do you approach that afterwards?
	If a patient routinely fails your tox screens, then what do you do? Do they still get their prescription?
	How many days after a patient stops taking opioids does the urine screen test become negative?



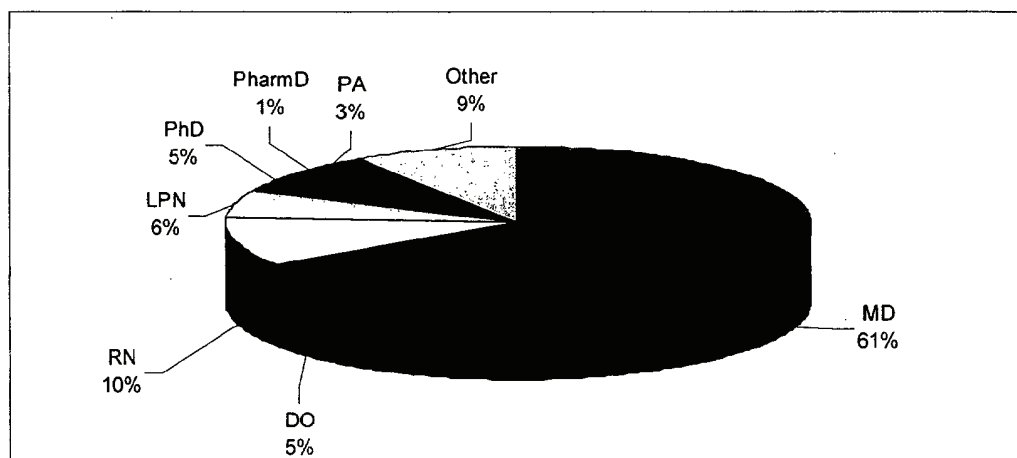
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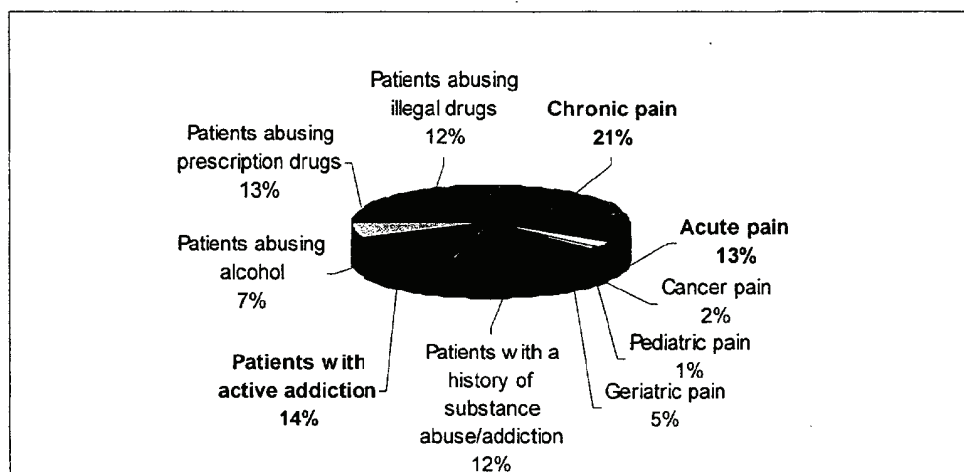
### Educational Needs Assessment

In addition to surveying participants in live symposia sponsored by *Emerging Solutions in Pain*, ESP proactively surveys members of the ESP website ([www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com)). The 1,257 members of the ESP website represent a diverse cross section of practicing health care professionals who provide care to patients with chronic pain and/or addiction. Demographics for 514 members of the ESP website who responded to these surveys are provided in Figures 3 and 4.<sup>47</sup>

**Figure 3: Degree Distribution of ESP Members**



**Figure 4: Top Three Types of Pain Patients in Your Practice**





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These members were asked to provide information concerning their self-identified areas of educational need, and barriers they perceived in their practice to appropriate pain management. As can be seen in Figure 5, assessment tools for identifying risk potential of abuse, and/or diversion, pharmacologic and nonpharmacologic treatment of pain, and interdisciplinary approaches to pain management were clear areas of educational need for these health care professionals.<sup>47</sup>

**Figure 5: Top Three Areas of Educational Need**

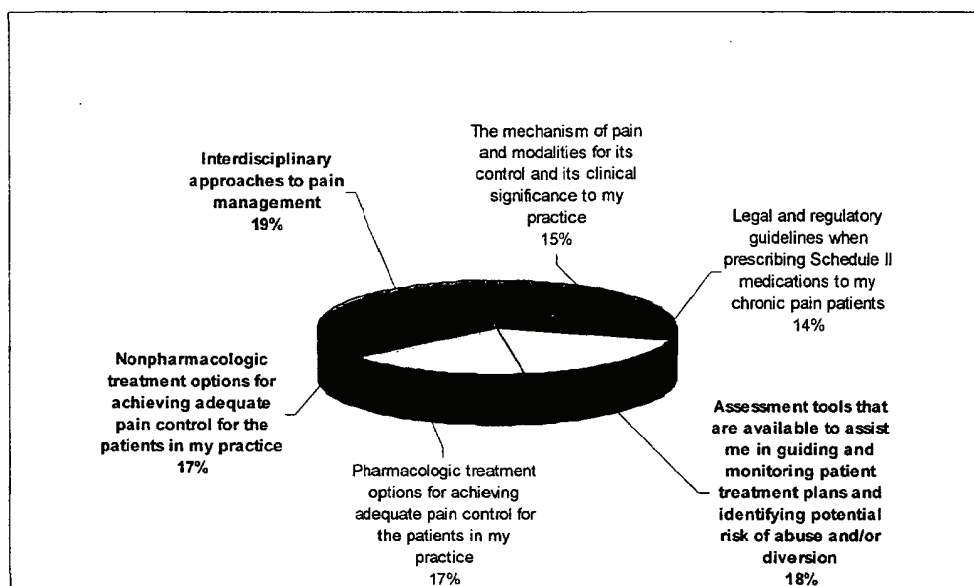


Figure 6 below depicts the results of these health care professionals' self-reported barriers to adequate pain relief. While patient-based issues (lack of compliance and poor self-reporting) were obvious barriers, other identified areas were clearly areas in which these clinicians would benefit from additional educational information and activities. These included assessment and monitoring tools, patient-clinician communication barriers and a reluctance to prescribe opioids.<sup>47</sup>

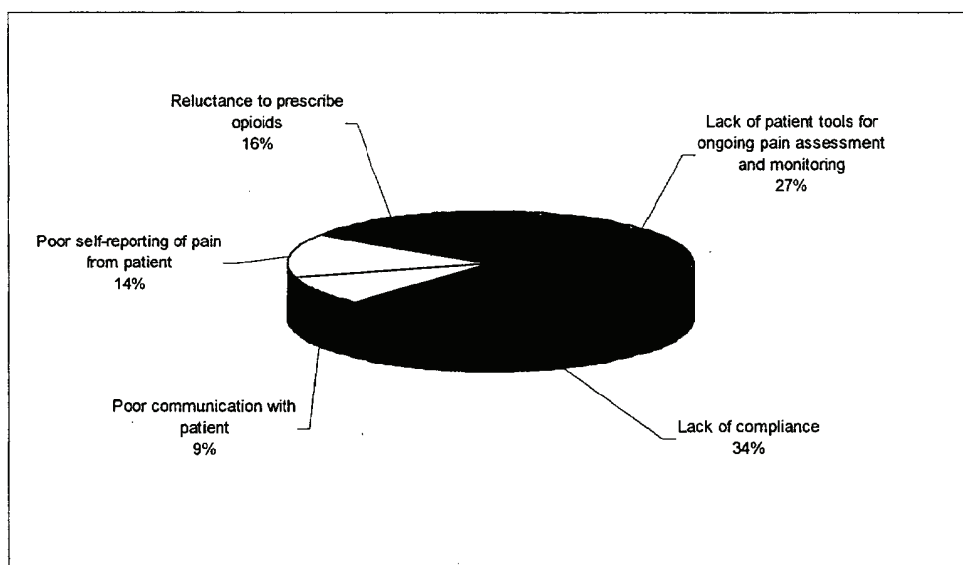


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**Figure 6: Barriers to Adequate Pain Relief in My Practice**



Finally, these health care professionals were asked to identify 10 topics that would help them to meet professional challenges and improve their personal practices. The results of the top 23 topics are provided in Table 5.<sup>47</sup>



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**Table 5: Identified Educational Topics<sup>47</sup>**

<b>Topic</b>	<b>Number of Respondents</b>
Anxiety and Pain/Addiction	149
Addiction Treatment	146
Acute Pain	119
Complementary and Alternative Pain Management	117
Behavior Modification Therapies	104
Basic Science of Pain and Addiction	95
Acupuncture	94
Breakthrough Pain	93
Arthritis Pain	88
Craving	84
Abstinence Syndrome	78
Clinical Research Update/New Drug Pipeline	76
Depression and Pain/Addiction	66
Methadone Contraindications	62
Opioids and Pregnancy	59
Chronic Opioid Therapy and Sleep Disorder	57
Pain Management in Addicts	50
Methadone Guidelines	47
Low Back Pain	46
Adolescents	44
Cancer Pain	43
Neuropathic Pain	41
Opioid Mechanisms	38

Clearly, the data presented in the tables and graphs above attest to the need for more information about risk screening and assessment of patients treated with opioids to determine risk of abuse, misuse, addiction and diversion of prescribed medications or other substances for conditions of chronic pain, as well as a need for additional information on Federal Regulations for controlled substance prescribing.<sup>46,47</sup>





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***Expert Opinion***

Managing pain presents a complex clinical challenge. Here are some thoughts from leading experts in the therapeutic areas of pain and addiction management regarding the increased need for education to improve professional practice behaviors.

- Nora Volkow, MD, director of the National Institute of Drug Abuse spoke at the 2007 National Institutes of Health Drug Abuse Conference on Pain, Opioids, and Addiction:

*"The abuse of opiate analgesics is an urgent issue. But the fact that these medications have the potential to produce addiction in no way decreases their value. The challenge comes in terms of understanding better the risks for becoming addicted ... and minimizing these risks."*<sup>48</sup>

- Patricia Berry, NP, a nursing faculty member at the University of Utah, Berry is a doctorally prepared researcher who has analyzed state regulations governing controlled substance prescribing by nurse practitioners. She provided the following quote to ADVANCE for Nurse Practitioners, 2007:

*"The one thing that really impedes prescriptive authority change, particularly around controlled substances, is all the myths about pain and pain management, we get addiction, physical dependence and tolerance all mixed up. We make all these assumptions based on erroneous beliefs about opioid analgesics and addiction, side effects, respiratory depression, those kinds of things."*<sup>49</sup>

- Kathryn Weiner, PhD, director of the American Academy of Pain Management discusses multidisciplinary teams as an effective approach to treating pain:

*"Because pain is a complex puzzle, no single health care profession holds the puzzle piece that solves this puzzle; rather, each health care profession holds a critical piece that contributes to the completion of the puzzle. Pain practitioners are trained to see their patients as multifaceted, whole systems requiring a multidisciplinary viewpoint."*<sup>50</sup>

- Martha Illige, MD of Rose Family Medicine Residency at the University of Colorado at Denver Health Science Center echoes the desire to work within a collaborative care model for treating chronic pain (December 1, 2007):

*"Management of chronic pain is a common concern among physicians. In training programs, office meetings, informal networks, we worry about undertreatment versus overtreatment, drug regulations, and professional interactions. We look for help and*



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*clarification for our patients and ourselves. The underlying concept, buried in the phrase "group visits," is that multidisciplinary management is best for chronic diseases. We need support for sharing responsibilities with our teams, including the patients, staff, behavioral health specialists, and physicians."*<sup>51</sup>

In October of 2007, testimony by experts before a subcommittee of the US House of Representatives in the areas of epidemiology and pain medicine exemplified the prevalent views of the need for continuing education in the area of pain and addiction.

- Leonard J. Paulozzi, MD, MPH, a medical epidemiologist from the Center for Disease Control, testified about the increasing rates of unintended deaths attributed to opioid medications. He proposed that one mechanism for reducing the problem would be:

*"Educating physicians and pharmacists to more closely monitor patients who are taking opioid painkillers on a long-term basis."*<sup>52</sup>

- Andrea Trescot, MD, president of the American Society of Interventional Pain Physicians (ASIPP), remarked that:

*"We in ASIPP also feel that since less than 40% of physicians receive any training regarding pain evaluation in medical school, the White House should organize events to facilitate dissemination of pain and addiction information to the general medical community...We also feel that controlled substance education should be mandated in medical schools, residency training, and supported by continuing education programs every year."*<sup>53</sup>

- AAPM President, Todd Sitzman, MD, MPH, was interviewed in February 2007 and stated the following when asked: *What do you see as the most important issue in pain medicine?*

*"[The patient's] understanding is that a pain medicine specialist will establish an appropriate diagnosis and treatment based on their specific needs. For successful treatment of chronic pain, the majority of which results from degenerative conditions, therapy will require a multimodal, long-term approach."*<sup>54</sup>

### **Conclusion**

When the results of literature searches, clinician surveys and expert opinion are combined, it is clear that additional curriculum and training are required to help provide information on the delivery of pain relief and dependency issues. The goal of such programs must be to support



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clinicians in improving patient care while reducing the potential for abuse, addiction, diversion, and medical regulatory/malpractice liability exposures arising from poor pain management practices.

To prepare clinicians to treat chronic pain appropriately, this educational activity will focus on several topics at the interface of chronic pain and risk of abuse, misuse, and addiction. All topics are based upon the educational needs outlined in this assessment, and include the role of patient assessment and monitoring in a proactive pain management treatment plan, and how appropriate use of these tools and tactics can contribute to improved outcomes. Emphasis will be placed on increasing clinicians' abilities to differentiate between the clinical conditions of tolerance, drug dependency and addiction, to support improved triage and outcomes. Risk containment is an essential consideration in managing chronic pain patients, and time will also be devoted to providing information on various methods to improve this process, so as to contribute to reduced undesirable consequences. This will lead to improved, safe and efficacious therapy for the patient, as well as improved practitioner and medical practice compliance. Finally, as a sound basis for safe and effective prescribing of opioids, the program will also engage the attendee clinicians in interactive and case-based forums for discussing legal and regulatory issues associated with the prescribing of controlled substances.

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**Program Title** *An Emerging Solutions in Pain Lecture*  
 The Right Patient, The Right Therapy, The Best Outcomes: Understanding the Interface of Pain and addiction

**Program Overview** In 2006, Medical Learning Solutions developed a clinically relevant, scientifically rigorous educational activity that was disseminated as a full-day symposium held in conjunction with the annual meeting of the American Academy of Pain Management. This annual lecture, which was presented again in 2007 as a plenary session in the AAPM's scientific program, has now educated more than 400 practicing health care professionals in issues and challenges associated with opioid misuse, abuse and addiction. In 2008, Medical Learning Solutions is proposing to build upon the educational foundation created in the 2006 and 2007 lectures, through expanding and updating the information presented, and by utilizing a lecture format that incorporates audience participation and interaction throughout the symposium.

One of the key issues in pain management today is the challenge of appropriately assessing the patient. This assessment must focus on tests that elucidate the physical disease or disorder, so that appropriate therapy may be initiated. For those patients who may be prescribed opioid analgesics, however, this assessment must include a proactive and thorough assessment of risk potential for opioid misuse, abuse and addiction, as well. Through a thoughtful and proactive combination of these two assessment processes, clinicians may be more informed concerning the type, duration and dosage of therapy that will be most likely to contribute to positive outcomes. For many patients with chronic pain, this therapy will include a trial of an opioid; however, not every patient is an appropriate candidate for opioid analgesics, and one of the goals of this assessment process is to determine the most appropriate therapeutic regimen for the individual patient.

The tactics of a thoughtful and thorough assessment, followed by ongoing monitoring, are not only good medical practices that will support improved outcomes, however. These are also processes that are required when any controlled substance is prescribed. In today's clinical environment, clinicians are scrutinized by legal and regulatory authorities with regard to their prescribing of controlled substances, and the media is increasingly focusing on issues surrounding illicit use of prescription medications. Together, these factors make it imperative that clinicians must have a thorough understanding of the following:

- The complex challenges of treating pain, addiction and the interface of these two areas
- Rational pharmacotherapy of pain, including non-opioid analgesics, opioids and complementary and alternative treatments
- The imperative of being able to clinically differentiate between addiction, physical dependency, tolerance and pseudo-addiction





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## **2008 Emerging Solutions in Pain Lecture Grant Request Program Summary**

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- Legal and regulatory issues surrounding the appropriate prescription of controlled substances
- Clinical strategies for creating individualized treatment plans that maximize the potential for improved outcomes and minimize the potential for opioid misuse, abuse, addiction and diversion

Due to the increasing focus on safe and effective prescribing of opioids that effectively minimizes possible negative consequences of opioid misuse, this symposium will begin with an interactive segment in which the issues surrounding appropriate prescribing will be portrayed to the symposium attendees through a mock "trial". In this "trial", various faculty members will act as the judge, the defendant and the prosecutor; the audience will play the role of the jury, and the moderator will circulate through the audience, capturing comments from attendees. This style of information presentation will ensure that the audience will be relate to, and understand on a personal level, the imperative of the issues and topics presented.

Following the mock "trial" that establishes the need and relevancy of the information, a series of focused didactic lectures will reinforce the most appropriate approaches to patient assessment, pharmacotherapy and risk minimization. Each of these focused lectures will be followed by a question and answer session that encourages frequent audience interaction with faculty. The symposium will conclude with a series of case-based presentations that summarize the "best practices" information presented throughout the day.

<b>Proposed Agenda</b>	7:25 – 7:30 AM	Welcome and Introductions
	7:30 – 8:00 AM	The Interface of Pain and Addiction: the Challenges of Safe and Effective Treatment That Maximizes Positive Outcomes
	8:00 – 9:30 AM	Why You Need To Understand the Synergy of Pain and Addiction: A Mock Trial
	9:30 – 9:55 AM	Break
	9:55 – 10:25 AM	Rational Pharmacotherapy: Opioids, Non-opioids and Adjuvant Therapies
	10:25 – 10:40 AM	Q&A
	10:40 – 11:10 AM	Assessment Strategies That Support Identification of the Best Therapy for the Individual Patient
	11:10 – 11:25 AM	Q&A



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11:25 – 11:55 AM	Practical Approaches to Successful Monitoring: Differentiating Between Addiction, Tolerance, Physical Dependence and Pseudo-addiction
11:55 AM – 12:05 PM	Q&A
12:05 – 1:25 PM	Lunch
1:25 – 1:55 PM	Case #1: Focus on the Issues of Tolerance and Hyperalgesia
1:55 – 2:10 PM	Panel Discussion
2:10 – 2:20 PM	Q&A
2:20 – 2:40 PM	Case #2: Focus on the Patient with Comorbid Illnesses
2:40 – 2:55 PM	Panel Discussion
2:55 – 3:05 PM	Q&A
3:05 – 3:30 PM	Break
3:30 – 3:50 PM	Case #3: Focus on the Multidisciplinary Team Approach to Pain Management
3:50 – 4:10 PM	Panel Discussion
4:10 – 4:20 PM	Q&A
4:20 – 4:30 PM	Conclusion

### **Proposed Faculty**

The core group of proposed faculty includes:

- Howard Heit, MD, FACP, FASAM (moderator)
- Douglas Gourlay, MD, MSc, FRCPC
- Steven Passik, PhD
- Jennnifer Bolen, JD
- Peggy Compton, RN, PhD
- Steven Stanos, DO

### **CE Provider**

Based on the need to educate clinicians in the assessment and treatment of chronic pain patients who may be at risk for abuse, addiction and diversion, the 2008 Emerging Solutions in Pain Lecture will be accredited by MediCom Worldwide, Inc



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## **2008 Emerging Solutions in Pain Lecture Grant Request Program Summary**

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- CME credit for physicians by the Accreditation Council for Continuing Medical Education. This full-day activity will be approved for a maximum of 6 hours of category 1 credit toward the AMA Physician's Recognition Award.
- CPE credit for pharmacists by the Accreditation Council for Pharmacy Education. This full-day activity will be approved for a maximum of 6 credit hours (0.6 CEU) for Continuing Pharmacy Education.
- CNE credit for nurses. This single full-day activity will be approved for a maximum of 6 Contact Hours.

**Intended Audience** The primary audience of includes physicians, pharmacists, nurses and other health care professionals who provide care to patients with pain.

**Program Objectives** The purpose of this activity is to educate clinicians on key topics relating to the Emerging Solutions in Pain initiatives; specific learning objectives will include the following:

- Outline the clinical challenges that are commonly associated with the treatment of chronic pain, and summarize clinical and pharmacological strategies that will support improved patient outcomes for individuals with chronic pain
- Describe and differentiate various multimodal therapies, including complementary and alternative treatments, that may be prescribed and applied for the management of chronic pain in an interdisciplinary approach to care
- Identify the risks of addiction related to chronic opioid therapy prescribed for chronic pain, and outline how clinicians should differentiate tolerance, physical dependence, and pseudoaddiction from addiction
- Summarize regulatory issues surrounding controlled substance prescribing and identify practical methods clinicians may use to contain risk

**Live Program  
Format**

This full-day meeting will be presented as part of the plenary session of the scientific program of the American Academy of Pain Management national meeting. This program will be comprised of a mock "trial", didactic lectures, case study presentations utilizing both faculty presented case based presentations as



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## 2008 Emerging Solutions in Pain Lecture Grant Request Program Summary

well as live interactive patient interview techniques, interactive panel discussions  
and question/answer sessions will be included in the overall agenda

### Enduring Material Options

Format	Description	Expected Reach
Symposium adaptation: online accredited <b>streaming video program</b> based on the presentation of the mock trial and didactic presentations	Symposium filmed and edited into accredited streaming video posted on EmergingSolutionsinPain.com	Reach: 1,800 (views)  CE certificates: 250
Symposium adaptation: Print monograph based on a summary of case presentations presented during live activity	CME accredited monograph based on the three case studies presented. Each case to be individually summarized and distributed via EmergingSolutionsinPain.com as well as via journal supplement in <i>Practical Pain Management Journal (PPMJ)</i>	Reach: 39,000 (print) + 600 (views)  CE certificates: 550 (online + print)

### Distribution/ Invitation Process

#### Live Event

The live symposium will be announced and promoted through the use of approximately 5,200 printed invitations via direct mail to identified target audience related to the scientific conference. In addition, the activity will be advertised in the promotional literature generated for the American Academy of Pain Management conference. Finally, Medical Learning Solutions and MediCom Worldwide, Inc. will announce and promote the 2008 Emerging Solutions in Pain Lecture through the Emerging Solutions in Pain web site. The live meetings will also be highlighted in the ESP e-mail blasts, the ESP electronic newsletters, and the ESP exhibit booth.

#### Enduring Material

*Online Adaptation:* The online adaptation will be released following the live symposium as a series of accredited modules based on the mock trial and didactic presentation video captured and edited from the live event. Activity will



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## **2008 Emerging Solutions in Pain Lecture Grant Request Program Summary**

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launch via EmergingSolutinsinPain.com no less than 90 days post-live event and will maintain accreditation throughout a 12-month hosting period. Distributions reach to approximately 1,800.

Target Launch Date: December 2008

*Journal Distribution:* The case based presentations will be summarized for print monograph and distributed via the journal of practical pain management within four months of the live event. Distribution reach is approximately 39,000 readers. Target Distribution Date: March 2009

### **Post-Activity Feedback**

Course evaluation forms will be required of all participants who seek to receive continuing education credit. MediCom Worldwide, Inc will summarize the information collected from these forms in a formal report to evaluate program effectiveness.

Participants will evaluate the following as excellent, good, fair or poor:

- (1) Overall content
- (2) Faculty teaching effectiveness
- (3) Format

Participants will also respond to the following questions:

- (1) How well did the program achieve its educational objectives?
- (2) Do you feel the program material was useful and practice-oriented?
- (3) Do you feel that the information provided in this educational activity will aid in improving patient care in your practice?
- (4) Do you feel that fair balance was maintained for all therapeutic options?
- (5) Would you participate in future educational activities?

### **Request for Sponsor Support**

As a supplement to these primary methods, Medical Learning Solutions and MediCom Worldwide, Inc may request the assistance of the Cephalon, Inc. sales force in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of MediCom Worldwide, Inc and any such distribution will solely be as a supplement to any primary methods of announcement and promotion.



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## 2008 Emerging Solutions in Pain Lecture Grant Request Program Summary

### Budget Summary Overview

#### AAPM Accredited Plenary Symposium plus Enduring Material Options Proposal Overview

Tactic	Description	Expected Outcome	Proposed Budget	
Full day plenary session at 2008 AAPM conference	Six-speaker accredited live symposium	300 AAPM conference attendees	Direct Costs	\$181,052
			Indirect Costs	\$53,532
			<b>Total</b>	<b>\$234,583</b>
Symposium adaptation: Print monograph based on case study presentations	Distributed as a journal supplement in <i>PPMJ</i> as well as available online via EmergingSolutionsinPain.com	Reach: 39,000 (print) + 600 (views)  CE certificates: 550 (online + print)	Direct Costs	\$55,800
			Indirect Costs	\$42,874
			<b>Total</b>	<b>\$98,674</b>
Symposium adaptation: online accredited streaming video program	Symposium filmed and edited into accredited streaming video posted on EmergingSolutionsinPain.com	Reach: 1,800 (views)  CE certificates: 250	Direct Costs	\$79,650
			Indirect Costs	\$36,190
			<b>Total</b>	<b>\$115,840</b>



101 Washington St, Suite 110  
Morrisville, PA 19067

Proposal Number: 07-056a

Date: February 21, 2008

**The Right Patient, The Right Therapy, The Best Outcomes:  
Understanding the Interface of Pain and Addiction  
A Full-Day Plenary Session Symposium Held in Conjunction with the American Academy of Pain  
Management: Projected Budget Estimate**

<b>Program Parameters</b>	
Number of accredited symposia	1
Number of credit hours	7
Number of direct mail program announcements	5,200
Faculty presenters per symposia	6
Approximate number, health care professional attendees per meeting	300

<b>Cost Summary</b>	
Approximate Total, Direct Expenses	\$ 181,052
Total, Indirect Expenses	\$ 53,532
<b>Cost of the 2008 AAPM Full-Day Plenary Session Symposium</b>	<b>\$ 234,583</b>





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**The Right Patient, The Right Therapy, The Best Outcomes:  
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Management: Projected Budget Estimate**

*Detailed Budget Itemization*

**Direct Expenses, Approximate**

<b>Association Fee</b>	\$ 30,000
<b>Speaker honoraria</b>	
Chairman (1)	\$ 3,500
Faculty (5)	\$ 12,500
<b>Graphic design and print materials</b>	
Graphic design of look/feel	\$ 2,900
Typesetting, layout of direct mail program announcement	\$ 1,000
Direct mail program announcements, mailed to AAPM membership. Four-color process printing on gloss stock, 5.5" x 8.5", double-sided, prepped for mailing. Quantity 5,200	\$ 2,625
Postage for direct mail. Quantity 5,200	\$ 2,153
Slide creation	\$ 9,500
Handout binders, includes binder shell plus all internal sheets; binders to include accreditation information, speaker biographical and disclosure information, agenda, reference materials and presentation slides	\$ 18,725
Typesetting, layout of handout binders	\$ 2,500
CDs of presentations	\$ 325
Set design: staging	\$ 5,000
Set design pieces: banners	\$ 2,000
Set design pieces: signage	\$ 1,800
Program book advertisements	\$ 3,000
Typesetting, layout of program advertisements	\$ 1,000
Typesetting, layout of signage	\$ 1,500
Typesetting, layout of set design pieces	\$ 1,000
<b>Speaker travel (air, OOP, hotel)</b>	
Speaker air	\$ 3,000
Speaker hotel	\$ 4,200
Speaker OOP	\$ 600
Speaker ground transportation	\$ 1,200
MediCom air	\$ 3,000
MediCom hotel	\$ 4,200
MediCom OOP	\$ 600
MediCom ground transportation	\$ 600
<b>Travel, site visit</b>	\$ 2,000
<b>Catering</b>	
Morning Break, quantity 350	\$ 4,665
Box Lunch, quantity 350	\$ 14,928
Afternoon Break, quantity 350	\$ 5,831
<b>Audio/visual services</b>	\$ 30,000
<b>Reference purchase</b>	\$ 1,200
<b>Stock photo purchase</b>	\$ 1,500
<b>Shipping/Fed Ex</b>	\$ 1,500
<b>Miscellaneous</b>	\$ 1,000
<b>Approximate Total, Direct Expenses</b>	
	\$ 181,052



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*A Full-Day Plenary Session Symposium Held in Conjunction with the American Academy of Pain  
Management: Projected Budget Estimate*

*Detailed Budget Itemization*

<b>Indirect Expenses</b>	
<b>Project management</b>	
Negotiation with association	\$ 300
Coordination with vendors	\$ 1,800
Coordination with faculty	\$ 2,400
Coordination with internal teams	\$ 1,800
Preparation and coordination of status meetings/updates	\$ 500
<b>Medical services</b>	
Development of agenda, objectives, program outline	\$ 800
Identification of faculty	\$ 400
Development of needs assessment	\$ 3,200
Development of supporting materials	\$ 1,200
Development of copy for posters, advertisements, set design	\$ 600
Proofreading	\$ 1,500
Fact-checking	\$ 1,500
<b>Site visit (1 staff member)</b>	\$ 1,350
<b>Accreditation of program for CME, CPE, CNE</b>	\$ 15,000
<b>Continuing Education participant certificates (est. 200)</b>	\$ 3,000
<b>Onsite CME coordination</b>	\$ 1,350
<b>Meeting management</b>	
Venue coordination	\$ 2,000
Travel coordination for faculty and staff	\$ 2,000
Coordination of associated meeting logistics	\$ 1,500
<b>Onsite management (4 staff members)</b>	\$ 5,400
<b>Registration database development/management (includes online reg)</b>	\$ 500
<b>Administrative and accounting fees</b>	\$ 5,432
<b>Total, Indirect Expenses</b>	<b>\$ 53,532</b>



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Proposal Number: 07-056a  
Date: February 21, 2008

**The Right Patient, The Right Therapy, The Best Outcomes:  
Understanding the Interface of Pain and Addiction**

*An Accredited Self-Study Series of Three Streaming Video Modules Based on the Morning Plenary  
Session Symposium Held in Conjunction with the American Academy of Pain Management*

**Projected Budget Estimate**

<b>Cost Summary</b>	
Approximate Total, Direct Expenses	\$ 79,650
Total, Indirect Expenses	\$ 36,190
<b><i>The Interface of Pain and Addiction Streaming Video Accredited Self-Study Series</i></b>	<b>\$ 115,840</b>

**Detailed Budget Itemization**

<b>Direct Expenses, Approximate</b>	
<b>Transcription</b>	\$ 750
<b>Program announcement/advertisement</b>	
Adaptation of symposium design for direct mail, journal & banner advertisements	\$ 1,000
Blast email campaign: 8 separate email blasts to target list of ESP members	\$ 3,600
<b>Enduring material production</b>	
Digitizing, Edit decision list and logging of footage	\$ 1,520
Digital Capture Station	\$ 6,000
Editing of all video and audio	\$ 6,750
Authoring of Final Content for Web Delivery	\$ 3,240
Adaptation of presentation slides to video format	\$ 2,000
Creation of animations, highlights, lower thirds, additional graphics	\$ 1,250
Adaptation of symposium program material design for Internet program and Render of all files	\$ 2,000
<b>Posting on EmergingSolutionsinPain.com</b>	
Infrastructure programming	\$ 5,000
Creation and posting of supportive text	\$ 3,500
Creation of graphic user interface PHP and SDK	\$ 2,520
140 minutes Encoding to Stream server	\$ 2,800
Streaming Server Programming	\$ 8,820
Streaming Minutes, Hosting, Maintenance and Troubleshooting	\$ 24,000
<b>Travel (film crew)</b>	\$ 3,900
<b>Stock photo/footage purchase</b>	\$ 1,000
<b>Approximate Total, Direct Expenses</b>	<b>\$ 79,650</b>



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Proposal Number: 07-056a

Date: February 21, 2008

**The Right Patient, The Right Therapy, The Best Outcomes:  
Understanding the Interface of Pain and Addiction**

**An Accredited Self-Study Series of Three Streaming Video Modules Based on the Morning Plenary  
Session Symposium Held in Conjunction with the American Academy of Pain Management**

**Projected Budget Estimate**

**Detailed Budget Itemization**

<b>Indirect Expenses</b>	
<b>Project management</b>	
Review of footage for editing direction	\$ 2,100
Coordination with internal teams	\$ 1,200
Digital Media direction and coordination of all media	\$ 2,700
Preparation and coordination of status meetings/updates	\$ 1,200
<b>Medical/scientific services</b>	
Editing review	\$ 1,400
Creation of additional self-assessment questions	\$ 1,200
Creation of supporting documents for individual accredited self-study programs	\$ 500
Proofreading	\$ 1,500
<b>Accreditation of program for CME, CPE, CNE</b>	\$ 7,500
<b>Continuing Education participant certificates</b>	
650 CE certificates; additional certificates to be charged at \$15 each	\$ 9,750
<b>Data management</b>	
Management of participant database	\$ 1,000
Data analysis and reporting	\$ 2,250
<b>Shipping, Blank Media, phone and fax</b>	\$ 1,500
<b>Administrative and accounting fees</b>	\$ 2,390
<b>Total, Indirect Expenses</b>	<b>\$ 36,190</b>



101 Washington St, Suite 110  
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Proposal Number: 07-056a

Date: February 26, 2008

**The Right Patient, The Right Therapy, The Best Outcomes:  
Understanding the Interface of Pain and Addiction**

**An Accredited Self-Study Monograph Based on the Afternoon Case-based Plenary Session  
Symposium Held in Conjunction with the American Academy of Pain Management**

**Projected Budget Estimate**

<b>Cost Summary</b>	
Approximate Total, Direct Expenses	\$ 55,800
Total, Indirect Expenses	\$ 42,874
<b>The Interface of Pain and Addiction Accredited Self-Study Monograph</b>	<b>\$ 98,674</b>

**Detailed Budget Itemization**

<b>Direct Expenses, Approximate</b>	
Transcription	\$ 750
Insert page charges, <i>Practical Pain Management Journal</i> 12-page article printed on matte cover stock as journal insert	\$ 34,800
Blast email campaign	\$ 3,600
Enduring material production	
Layout and typesetting	\$ 5,000
Creation of supporting web pages for online posting	\$ 1,000
Proofreading	\$ 6,000
Programming of monographs, archiving	\$ 900
Travel (medical writer)	\$ 1,950
References	\$ 1,800
<b>Approximate Total, Direct Expenses</b>	<b>\$ 55,800</b>



101 Washington St, Suite 110  
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Proposal Number: 07-056a

Date: February 26, 2008

**The Right Patient, The Right Therapy, The Best Outcomes:  
Understanding the Interface of Pain and Addiction**

***An Accredited Self-Study Monograph Based on the Afternoon Case-based Plenary Session  
Symposium Held in Conjunction with the American Academy of Pain Management***

***Projected Budget Estimate***

***Detailed Budget Itemization***

<b><i>Indirect Expenses</i></b>	
<b>Project management</b>	
Coordination with internal teams, PPMJ staff	\$ 1,800
Preparation and coordination of status meetings/updates	\$ 900
<b>Medical services</b>	
Transcript review	\$ 2,400
Outline creation	\$ 1,600
Creation of monograph based on transcription, review with faculty	\$ 8,000
Development of supporting verbiage (needs assessment, objectives, etc.) and self-assessment	\$ 1,600
Incorporation of revisions	\$ 2,400
Fact-checking	\$ 2,000
<b>Accreditation of program for CME, CPE, CNE</b>	\$ 7,500
<b>Continuing Education participant certificates</b>	
650 CE certificates; additional certificates to be charged at \$15 each	\$ 9,750
<b>Data management</b>	
Management of participant database	\$ 1,000
Data analysis and reporting	\$ 2,250
<b>Administrative and accounting fees</b>	\$ 1,674
<b>Total, Indirect Expenses</b>	<b>\$ 42,874</b>

**Disclosure**

It is the policy of MediCom Worldwide, Inc. to plan and implement educational activities in accordance with ACCME, ACPE and CA Board of Nursing. As a provider it is the policy of MediCom Worldwide, Inc. to ensure balance, independence, objectivity and scientific rigor in all its sponsored educational activities.

All program planners, faculty, and providers are required to disclose any relevant financial relationships they may have or have had within the last 12 months with commercial supporter or the manufacturer(s) of any commercial device(s) discussed in this educational activity. Faculty have been asked to disclose this information to the CME audience verbally and on introductory slides at the beginning of their presentations.

**Conflict of Interest****Resolution Statement**

MediCom Worldwide, Inc. has established policies in place that will identify and resolve conflicts of interest prior to this educational activity. When individuals in a position to control content have reported financial relationships with one or more commercial interests, MediCom Worldwide, Inc. works with them to resolve such conflicts to ensure that the content presented is free of commercial bias.



## Exhibit B

### FENTORA Risk Management Program

Provider is aware that FENTORA™ (fentanyl buccal tablet) [C-II] was approved subject to a Risk Minimization Action Plan (RiskMAP). The RiskMAP includes key safety messages that are essential to the safe use of this product. They are:

- FENTORA is indicated for the management of breakthrough pain in patients with cancer who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- FENTORA is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- No misuse of FENTORA should occur.
- Unintended (accidental) exposure to FENTORA should not occur.
- Patients considered opioid tolerant are those who are taking at least 60 mg oral morphine/day, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that FENTORA can be fatal to a child. Keep all units away from children and discard properly.
- FENTORA is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

### ACTIQ Risk Management Program

Provider is aware that ACTIQ® (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- ACTIQ is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- ACTIQ is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.
- ACTIQ is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

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www.cephalon.com

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Fax: 910-344-0065

May 28, 2008

Ms. Joan Meyer  
President  
MediCom Worldwide, Inc.  
101 Washington Street  
Morrisville, PA 19067

AND

Ms. Jerrie Lynn Kind  
Executive Director  
American Society for Pain Management Nursing  
18000 West 105<sup>th</sup> Street  
Olathe, KS 66061

Re: Amendment No. 1 to "American Society for Pain Medicine Nursing  
Satellite Symposium and Enduring Materials" Agreement

Dear Joan and Jerrie Lynn:

This letter is to confirm our understanding concerning an amendment to be made with respect to the "American Society for Pain Medicine Nursing Satellite Symposium and Enduring Materials" Agreement dated as of July 27, 2007, (the "Agreement"), between Cephalon, Inc. ("Cephalon") and MediCom Worldwide, Inc. ("IEP Provider") and American Society for Pain Management Nursing ("Educational Partner"). All terms not otherwise defined herein are used as defined in the Agreement.

The purpose of this Amendment is to authorize the IEP Provider and the Educational Partner to modify the terms of the project under the Agreement.

The Agreement is hereby amended as follows:

1. The modified project is described in the attached **Exhibit A-1**, which shall replace **Exhibit A** for purposes of the Agreement.
2. The project cost, payment schedule and project schedule for the modified project are also described in the attached **Exhibit A-1**.
3. Except as amended hereby, the Agreement remains in full force and effect.

#### Exhibit A-1

Copy of Grant Request

If the foregoing accurately reflects your understanding as to these matters, please indicate your agreement in the space provided below, and return one fully-executed original to me.

Very truly yours,

*Lesley Russell*  
Lesley Russell, MB, Ch.B., MRCP  
Executive Vice President  
Worldwide Med and Reg Operations

Approved as  
to me

*JRM*



Acknowledged and agreed to by:

**MEDICOM WORLDWIDE INC.**

By: *Joan Meyer*  
Name: Joan Meyer  
Title: President

Date: *6-4-08*

AND

**AMERICAN SOCIETY FOR PAIN MANAGEMENT NURSING**

By: *Jerrie Lynn Kind*  
Name: Jerrie Lynn Kind  
Title: Executive Director

Date: *6/6/08*

MediCom Worldwide, Inc.

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March 12, 2008

Bhava! Shah-Bell, PhD  
Cephalon, Inc.  
41 Moores Road  
Frazer, PA 19355

Dear Dr. Shah-Bell:

The following educational grant request is submitted as an addendum to the previously submitted grant request for the American Society of Pain Management Nurses. As a result of review and identified educational need we have expanded the scope of our program and designed the program to allow for live as well as video based assessment and interview challenges.

Based on the identified educational need, MediCom is requesting an educational grant from Cephalon, Inc to support the development of a live symposium in conjunction with the American Society of Pain Management Nurses scheduled to be held in September of 2008 in Tucson, Arizona. In addition to the live program MediCom is requesting additional funding to provide enduring material support initiatives resulting from the content developed for the live meeting in order to maximize the reach to nurses throughout the United States. The activities described in this proposal include:

1. Live symposium
2. Internet based activity hosted by Medscape as well as EmergingSolutionsinPain

The total grant request to fund these activities is \$388,206; please refer to the detailed budget section of this proposal for complete grant funding details of the individual educational initiatives.

These scientific events will comply with all OIG, PhRAM, FDA, and ANCC regulations for industry-supported professional continuing education.

Thank you in advance, for your consideration of this request.

Respectfully,

Joan Meyer  
Executive Director, Continuing Education

MediCom Worldwide, Inc.  
101 Washington Street • Morrisville, PA 19067 • 215-337-9991

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**Program Objectives**

Upon completion of this activity, participants should be able to:

1. Describe communications techniques and screening tools used to measure pain and explain why they are necessary for the effective management of patients with chronic pain
2. Indicate two reasons why risk assessment is necessary in the effective management of patients with chronic pain
3. Identify three types of screening tools used to assess patients with chronic pain for the risk of abuse, misuse, addiction and/or diversion of prescribed opioid medications and why their use contributes to a reduction in practitioner liability
4. Summarize the importance assessment results interpretation to developing an effective treatment strategy

**Target Audience**

Nursing participants attending the American Society of Pain Management Nurses Conference  
Target participation: 500 attendees

**Program Format**

Live symposium held in Tucson, Arizona in conjunction with the American Society of Pain Management Nurses Conference. The symposium will be based on interactive case based presentations as well as the inclusion of didactic presentations by the multidisciplinary faculty on the topics of effective assessment tools for evaluating/treating patients with chronic pain. The focus will be on the valuable participation of nurses in the overall evaluation and management of patient care.

To encourage active learning and participation, MediCom will utilize a blend of prerecorded videotaped patient-clinician assessment techniques as performed by a nurse and physician as well as live case-based assessment interactions. Cases will be designed with specific real life problems, patient presentations and complaints that will demand learners to utilize analytic skills and determine appropriate course of action and treatment. This activity is designed to offer a strong instructional foundation to meet the learning objectives of acquiring knowledge, skills and influencing attitudes and behaviors. Each segment and case study will be led by a clinical expert to help guide the process and facilitate the best course of action.

**Agenda****Presentation 1:**

**Assessment and Communication Tools and Techniques Designed to Guide Your Treatment**

- Multidimensional pain assessment tools
- Techniques to optimize communication
- Importance of obtaining an accurate baseline pain assessment
- Are we hearing what our patients are really telling us

**Proposed Faculty:** Christine Miaskowski, RN, PhD, FAAN

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MediCom Worldwide, Inc.

Program Summary

**Program Title**

**Refining the Art of Assessment in the Patient with Chronic Pain:  
The Key to Minimizing Risk and Improved Outcomes**

**Program Overview**

According to a recent survey, 80 million Americans experience pain and is the third leading physical impairment in the United States following cancer and heart disease. Despite the prevalence of pain disorders among Americans, the number of patients reporting adequate pain relief is less than optimal. According to a survey conducted by the American Pain Society, only 40% of people suffering from moderate to severe pain have experienced relief.

Assessment of the patient experiencing pain is the cornerstone to optimal pain management. However, the quality and utility of any assessment tool is only as effective as the clinician's ability to thoroughly focus on the patient.

One of the key issues in pain management today is the challenge of appropriately assessing the patient. This assessment must focus on tests that elucidate the physical disease or disorder, so that appropriate therapy may be initiated. For those patients who may be prescribed opioid analgesics, however, this assessment must include a proactive and thorough assessment of risk potential for opioid misuse, abuse and addiction, as well. Through a thoughtful and proactive combination of these two assessment processes, clinicians may be more informed concerning the type, duration and dosage of therapy that will be most likely to contribute to positive outcomes. For many patients with chronic pain, this therapy will include a trial of an opioid; however, not every patient is an appropriate candidate for opioid analgesics, and one of the goals of this assessment process is to determine the most appropriate therapeutic regimen for the individual patient.

The tactics of a thoughtful and thorough assessment, followed by ongoing monitoring, are not only good medical practices that will support improved outcomes, however. These are also processes that are required when any controlled substance is prescribed. In today's clinical environment, clinicians are scrutinized by legal and regulatory authorities with regard to their prescribing of controlled substances, and the media is increasingly focusing on issues surrounding illicit use of prescription medications.

Due to the increasing focus on safe and effective prescribing of opioids that effectively minimizes possible negative consequences of opioid misuse, this symposium will be designed to incorporate a blend of didactic presentations, prerecorded video case vignettes as well as live interview scenarios based on a series of case studies designed to provide the attendees with insights and interviewing techniques to assure a thorough assessment in which to make the most appropriate diagnosis and subsequent treatment plan.

Each of segments will be followed by a question and answer session that encourages frequent audience interaction with faculty. The symposium will conclude with a review of cases as presented and a summary "best practices" information presented.

Professor and Associate Dean for Academic Affairs  
Department of Physiological Nursing  
University of California, San Francisco

**Presentation 2:**

**Moment of Truth: Tools and Techniques Needed To Manage the Patient with Chronic Pain**

- Identify effective clinical strategies and treatment options which demonstrate how appropriate assessments and tools may be incorporated into the clinical setting
- Assessing aberrant behaviors and how they may be managed effectively
- Key clinical indicators in determining diagnosis based on assessment
  - a. Guidelines in managing treatment
  - b. Understand myths and misconceptions to remove barriers to effective treatment

Steven D. Passik, PhD  
Associate Attending Psychologist  
Memorial Sloan-Kettering Cancer Center  
New York, New York

**Case-Based Interviews: What Is Your Diagnosis?**

- Cases will be designed to address real life clinical practice and patient presentations based on key challenges of patients presenting as chemical copers, pseudoaddiction, opioid tolerant, drug seekers
- Video and live interview segments guided by the clinical experts
- ARS used to poll audience on their diagnosis
- Panel discussion of audience results and rationale

**Presentation 3:**

**Wrap Up: Understanding Why Objective Assessment Results Improve the Patient-Practitioner Relationship**

- Importance of reduction of risk coupled with appropriate use of medications
- Awareness of risk potential – using the right medication with the right patient
- Based on pain characteristics and type identify pharmacologic and nonpharmacologic treatment decisions driving plan of care

Steven Stanos, DO  
Medical Director  
Chronic Pain Care Center  
Rehabilitation Institute of Chicago  
Chicago, IL

**Panel Discussion / Q&A**

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**Invitation/Distribution Process:****Live Event**

The live symposium will be announced and promoted through the use of approximately 4,000 printed invitations via direct mail to identified target audience related to the scientific conference.

**Enduring Material**

**Online Adaptation:** The internet adaptation will be released following the live symposium as video adaptation. Online posting will be available to participants one year from the original posting date.

Activity will launch via Medscape.com as well as Emergingsolutionsinpain.com no less than 90 days post-live event and will maintain accreditation throughout a 12-month hosting period. Average CNE completion goal of 500 completed activities per Medscape hosting site per month and additional 150 completions per month hosted by ESP.

**Target Launch Date:** ESP: October 2008  
Medscape: December 2008

**Request for Sponsor Support Live Event**

As a supplement to these primary methods, MediCom Worldwide, Inc. may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of MediCom and any such distribution will solely be as a supplement to MediCom's primary methods of announcement and promotion.

**CE Provider**

The symposium will be accredited by MediCom Worldwide, Inc. in joint sponsorship with the American Society of Pain Management Nurses. Each activity will be approved for 1.0 contact hours.

**Needs Assessment**

Every day, nurses in all clinical settings work closely with patients who are experiencing various types and intensities of pain. Advances in pain management have given present patients and their families a variety of options that allow them a renewed dimension to the quality of their lives. Because of this it is important that nurses keep up to date on basic principles of assessment, pain management/treatment options and current pharmacologic and nonpharmacologic approaches.

To better understand the potential educational needs, MediCom Worldwide, Inc has utilized the following sources of information:

- 2006-2007 MediCom Needs Assessment Survey
- 2007 Survey of Participants at the ASPMN Symposium
- Consultation with Nursing Advisors in the Field of Pain Management
- Environmental Scan
  - o Literature Review
  - o Pain Management Core Competency Guide for Nurses
  - o Therapeutic Research Review
  - o Pain Management Nurses: Scope and Standards of Practice
  - o ANCC Pain Management Credentialing Requirements for Ongoing Education
  - o APS Survey Publications

**Current Environment and Standard of Care Barriers to Effective Pain Management**

Optimal treatment of chronic pain may be assisted by three paradigms:

- Adequate model of assessment
- Treatment focused on pathophysiology (whether physical, psychosocial, or some combination of these)
- Frequent reassessment of total social function

Using these approaches, contribution to drug abuse, diversion, and life deterioration can be largely avoided.<sup>1</sup>

**Poor Assessment of Pain: a barrier to effective pain management**

Effective pain management begins with comprehensive and accurate assessment of the patient experiencing pain and is considered the cornerstone to optimal pain management. However, even with the assortment of validated and simple assessment tools available for use (i.e., numerical ratings scale, Baker-Wong Faces scale), unidimensional metrics tend to fall short, unless the practitioner possesses the ability to focus on the patient and engage in clear and open dialogue.<sup>2-4</sup> Pain assessment is a

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multifaceted process. Numeric indicators cannot measure disability, coping skills or mood<sup>5</sup>. The fifth vital sign, pain, remains totally subjective, unlike objective blood pressure measurement or diagnostic tests, and as a result, patient self report remains the mainstay of pain assessment<sup>6</sup>. Healthcare providers are challenged to develop more precise and objective measures of pain. Until something better comes along, the time-honored bedside skills of listening, observing and interpreting are the most reliable tools for effective pain assessment<sup>6</sup>. This method of communication means *inviting* the patient to open-up and communicate the necessary information needed to assess pain and its effects properly. The clinician must ask the patient open-ended questions in order to get at the root of the problem. Asking the patient if he has pain will not provide an adequate answer to the clinician. A patient stating that she is in pain will not offer enough information to the clinician for development of a therapeutic solution. Instead, clinicians need to ask the patient what the pain is like; ask for a description.

It means *listening with empathy*, using heart and mind to believe what the patient is stating and to legitimize or advocate the patient's pain while understanding what the patient is trying to say and imagining the patient's pain experience. Listening means not talking, and no thinking about the next question or conjuring a response. After truly listening to the patient, the practitioner needs to *summarize* what is believed to have been heard back to the patient for confirmation. If a patient states that her pain becomes intense after standing on her feet all day at work, the clinician may summarize by saying: "So, your pain worsens in the evening hours, after you arrive home from work." This three-step method of communication: invite, listen and summarize on behalf of the clinician confirms to the patient that there is genuine interest in the patient as a person, and that he/she is not merely representative of a disease or condition. Other factors may also affect the discussion surrounding assessment. Stereotypes, fear, bias and preconceived notions may color practitioner-patient communications and interfere with effective pain patient assessment and management.<sup>7</sup>

Validated multidimensional pain assessment tools exist and are designed to facilitate these discussions. The Short Form McGill Questionnaire is an excellent example of a tool that includes information to assess both sensory and affective domains. The long McGill form provides sufficient questions to assess not only sensory and affective components of pain, but evaluative components as well. Equally important is the ability of the patient in pain to verbalize the pain experience to the clinician. The patient must express in terms that will instill compassion yet provide verbal triggers essential to the practitioner in order to gain a clear clinical picture of the patient's current health. Clinically, pain is whatever the person says he or she is experiencing whenever he or she says it occurs. With this in mind, patients need to be clear with their health care providers. Type of pain, location, onset, duration, frequency, and intensity are essential to proper assessment. A discussion related to factors that either alleviate or aggravate the pain will also help determine course of therapy. Too often patients may be reluctant to admit to their health care providers that they have pain and may attempt to minimize its frequency or severity. Patients may feel they must suffer in pain not realizing they can expect pain relief, and may be concerned about taking pain medications for fear of associated side effects and the attached stigma of "drug-user". Both the patient's level of knowledge and belief system regarding pain will play heavily against if and how the

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dialogue with practitioner will begin. The clinician's role is to act as advocate or provide a contact for advocacy to the patient and help them optimize their expression of pain for improved communications and care outcomes. Patient advocacy supports the patient with the essentials needed to more clearly communicate with the healthcare provider at time of assessment<sup>8</sup>.

**Screening for Risk: preamble to effective pain management**

A multidimensional pain assessment will include the following domains: Pain, function, mood or affect, coping skills, and social support network. It is the clinician's responsibility to initiate assessment conversation and employ multidimensional assessment tools that encourage patients to feel safe and allow them the freedom to communicate without judgment. Controlled substances may be abused, misused or diverted. Results from a recent study indicate that users of prescribed opioids had higher rates of opioid and nonopioid abuse problems compared with nonusers of prescribed opioids, but these higher rates appeared to be partially mediated by depressive and anxiety disorders.<sup>10</sup>

In patients receiving prescribed opioids, clinicians need to be alert to drug abuse problems and potentially mediating mental health disorders. To improve practice performance when prescribing controlled substances for pain, a comprehensive assessment should include screening the patient for risk of drug misuse, abuse and addiction. Use of the Opioid Risk Tool (ORT), CAGE-AID, Screener and Opioid Assessment for Patients in Pain (SOAPP<sup>TM</sup>), or alternate drug misuse screener helps to identify patients who will require further assessment to determine if a more rigorous structure of treatment plan is needed to contain risk for patient, practitioner and practice. Mental health assessment, especially for anxiety, depression and sleep disorders, common comorbid conditions, is also suggested. Short form assessments, mentioned previously, serve to screen the patient to determine if further assessment by a mental health specialist is necessary.

Although patient self-report often correlates with problematic behaviors, it may also lead to erroneous information, especially if the patient is an addict or drug-seeker. Addicts and people with criminal intent lie in order to gain what they want. Use of assessment tools helps the clinician gain an objective measure of risk. An addict or drug seeker is not easily recognized. These types of patient do not always look or act a certain way. The clinician's own value judgments and prejudices may also affect therapeutic decision making. Screening tools provide objective metrics to temper subjective assumptions that may impede effective therapy. Results from screening do not equate to a diagnosis. Results simply stratify the patient at low to high risk of abuse, misuse, addiction or diversion. Patients who score moderate-to-high risk require additional and advanced assessment. All patients in pain, whether assessed at high or low risk of drug abuse, misuse, or addiction have a right to obtain effective pain relief. Patients who obtain prescription drugs for resale and profit are criminals and clinicians must report known illegal activities to the proper authorities.

Use of formal screening instruments also provides the clinician and medical practice with documentation. Should a question arise, the patient's medical record will demonstrate the assessment results and therapeutic actions taken as a result of their interpretation.

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## Documented Need for Improved Communications and Assessment

During assessment of pain the data provided by the patient to practitioner must be interpreted accurately to navigate a meaningful next-step question. Appropriate assessment of the patient in pain takes into consideration source, onset, severity, pattern, subtype, and cause of pain. These clinical cues may be interpreted by referring to evidence-based guidance from the American Pain Society, the American Geriatric Society, and the World Health Organization (WHO Analgesic Ladder). All of which offer formal guidance to the clinician to help navigate therapeutic decision-making based on assessment results.<sup>11,12</sup>

Patients who suffer with chronic pain may wish to be pain-free but attaining that goal is not always possible. Basing therapeutic goals on reducing pain to a level that permits the patient to engage in functions they either enjoy or must do is practical and more frequently achievable. Appropriate and successful treatment is important because under-diagnosed or under-treated pain has a profound impact on the patient's quality of life, as well as cost of health care.

Undertreated pain may cause the patient to exhibit signs of aberrant drug-related behaviors. The patient whose pain is undertreated may request additional analgesia, may self-medicate, or may use other substances to alleviate the pain (i.e., alcohol). This condition is termed pseudoaddiction. Both pain assessment and risk assessment results will help the clinician determine if pseudoaddiction is the problem. In this subset of patients, when analgesia is adjusted to provide increased and effective pain relief, the aberrant behaviors resolve.

Patients who have been prescribed chronic opioid therapy may become tolerant or they may experience hyperalgesia as a direct effect from the drug. Drugs that once afforded these patients effective pain relief now appear to have no analgesic effect or may actually induce pain. Re-assessment for monitoring purposes is needed. Cellular receptors may become desensitized from chronic opioid administration. In these patients, opioid rotation is suggested. Weaning the patient from the original drug and titrating to an alternate analgesic often solves this problem. Chronic opioid administration may also cause hypersensitization of receptors. When this occurs, the analgesic drug causes pain rather than alleviating it. In this case, by lowering the dose in small increments, the analgesic effect is often restored.

Very little attention has been given to chronic nonmalignant pain in the nursing literature. Although there has been increasing debate concerning prescribing practices among physicians for patients with chronic nonmalignant pain, little, if any, understanding exists about advanced practice registered nurses (APRNs) in this context.<sup>13</sup>

Although the focus of pain assessment has shifted in recent years to examine the disparity of assessing pain in the non-verbal patient, there still exists need within the nursing community to improve pain assessment in the verbally-competent pain patient. A common assumption is that all nurses have the same baseline knowledge about pain, a potentially erroneous assumption that influences clinical practice. Nurses have varied

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obtaining this test before prescribing opioids and only 15.0% performing urine toxicology tests on patients already prescribed opioids.<sup>18</sup>

Another recent study examined clinicians' evaluation and management of co-existing mental health, substance abuse, and chronic pain conditions in patients with prolonged critical illness in the intensive care environment. Results indicated several barriers to care which included limited history taking and assessment of substance abuse and chronic pain conditions and the use of cognitive shortcuts. Consequences included nonintegration of substance abuse and chronic pain medications and diagnoses, episodic pharmacologic responses to psychobehavioral symptoms, and clinician-patient interpersonal tension. Contextual factors involved ambiguous psychobehavioral symptomatology, patients' critical illness and inability to speak, and competing clinical goals. The study resulted in this conclusion: The explicit evaluation and management of substance abuse and chronic pain conditions was highly variable and inconsistent across cases. Findings suggest that substance abuse and chronic pain conditions require monitoring and management similar to that required for other chronic conditions. Multidisciplinary, individual-level, and system-level responses are warranted to address the complex interplay of barriers, consequences, and context.<sup>19</sup>

A final study examined the International Classification of Functioning Disability and Health (ICF) Core Sets for chronic low back pain. The investigators examined if the questions asked were reflective of the patient's greatest concerns. It was reported that two questions (one related to recreation and leisure functioning and the second related to the ability to care for household objects) which were of greatest concern and most meaningful to the patient were not included in the brief core score used in assessment of functionality related to pain. These results demonstrate the assessment-disconnect between healthcare providers and their patients, and suggest that improved patient-focused questioning is needed.<sup>20</sup> New reports suggest that functional assessment (pinch, grip, range of motion) is also being added to comprehensive pain assessment for patients with rheumatoid arthritis to detect level of pain related to function in disabled patients who have learned to compensate.<sup>21</sup> These new forms of pain assessment related to functionality have yet to be adopted as routine in the clinical environment. Discussion and assessment of function relative to pain is recommended as an essential element of multidimensional pain assessment.

As mentioned, the gold-standard for pain screening and assessment is the patient report<sup>22</sup>. It is essential that the healthcare clinician who is with the patient at intake performing the initial assessment and subsequent re-assessments provides an accurate portrayal of the patient's report. Achieving optimal and safe pain-management practices is only possible if the assessment report is genuine. Several studies have recently been published to reflect the need for improved assessment of pain.<sup>23,24</sup>

Research supports and also suggests that maladaptive beliefs on behalf of the patient about chronic pain can have a negative impact on adherence and treatment response.<sup>24-29</sup>

It is up to the clinician to encourage the patient to reveal her beliefs about her pain experience. Some areas of exploration include: denial that mood affects pain, denial that pain affects mood, perception of blame, inadequate support, disability entitlement, desire

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experiences in education and pain management. In a study conducted by Michaels, et al, results demonstrated that nurses who received one educational activity about documentation of pain, patient satisfaction scores, and pain knowledge was not adequate to improve pain assessment and care. The authors suggest that pain education needs to be ongoing to change practice and affect overall pain management. Additionally, the authors recommend that efforts in pain assessment move beyond the basics to include assessment and communications that are safe, opportune, evidence-based, and interdisciplinary.<sup>34</sup> Another recent study of nursing perceptions related to chronic pain management demonstrated the following areas of concern: pain assessment (lack of recognition of pain, uncertainty about the accuracy of pain assessment and diagnosis) and treatment (reluctance to use opioids, working to individualize pain treatments, issues relating to physician trust of the nurse on prescribing patterns).<sup>15</sup>

A third study examined pain assessment in the geriatric verbal chronic pain patient and the investigators reported the following: Epidemiologic studies show a very high prevalence of persistent pain, often exceeding 50% of community-dwelling older persons and up to 80% of nursing home residents. Recently, there has been a major push to develop age-appropriate pain assessment tools, including several observer-rated scales of behavioral pain indicators for use in those with dementia. There has also been the release of several comprehensive guidelines for the assessment and management of pain in older persons, although the current evidence-base used to guide clinical practice is extremely limited. Unfortunately, despite these advances, pain remains grossly under treated in older persons, regardless of the healthcare setting.<sup>35</sup>

In another study, nursing students in Louisiana were surveyed regarding their level of knowledge in pain management. These survey results, published in 2006, reported that this population of nursing students collectively scored poorly (mean score of 64%) and these results indicate an inadequate level of knowledge, especially in regard to pain assessment, analgesic dosing and side effect management, and an unfounded fear related to pain patient addiction. Answers in response to a case study revealed that students frequently substituted their judgment for the patient's subjective judgment of pain. The survey investigators recommended that knowledge and attitudes about pain management in this nursing population were in need of improvement. Despite the fact that these results originated from nursing students, students graduate to practice in the clinical environment. It is clear that improved communications in pain assessment and management are needed, in addition to an improved competency and attitude towards opioid prescribing.<sup>17</sup>

A fifth survey examined clinician's practice behaviors related to opioid prescribing to patients with chronic pain. Concerns regarding opioid therapy included prescription drug abuse (84.2%), addiction (74.9%), adverse effects (68%), tolerance (60.7%), and medication interaction (32%). The survey found that the majority of the respondents were comfortable in prescribing narcotics to patients with terminal cancer. However, they were less comfortable prescribing narcotics to patients with low back pain and persons with a current or past history of drug or alcohol abuse. Physician management practices suggested that urine toxicology tests were under-utilized with only 6.9% reporting

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for medical breakthrough, skepticism of multidisciplinary approach, and conviction of hopelessness.<sup>36</sup> The usual problems encountered in providing coherent and effective treatment for any chronic medical illness are compounded in painful conditions by time, society's choices, and the cultural role of the patient. Effective treatment strategies for these patients depend on the persistence of and accurate interpretation of the assessment results by the nurse clinician to the prescribing physician.<sup>30</sup>

The HealthCare Foundation of California published an extensive document, entitled, *Helping Patients Manage their Chronic Conditions* in June, 2005. The authors stress the importance of self-management support for patients with chronic conditions in order to encourage daily decisions that improve health-related behaviors and clinical outcomes. The executive summary underscores the importance of collaborative decision making through information exchange exemplified through various dialogue styles between care providers and patients. The report stresses the importance of care teams who are assigned established roles within the program and learn to effectively cross-communicate. Many sample dialogues are provided throughout the report and are meant to demonstrate effective communication styles through a series of questions and answers. The authors recommend self-management support as a means to inform and motivate patients with chronic conditions, leading to improved compliance and outcomes. This state-wide initiative was developed out of a need for improved performance and exemplifies the educational need of nurses and other primary care providers to improve patient communications techniques, especially in patients who require care for chronic conditions.<sup>31</sup>

In 2006, the American Medical Association published a voluminous report entitled: *Improving Communication: Improving Care, an Ethical Force Program™ Consensus Report*. The goal of the report was to help health care organizations communicate better and promote patient-centered communications as a formal performance improvement initiative. The Ethical Force Program uses a three stage process for developing performance improvement measures. It selects a specific domain of ethics for performance measure development, works an iterative process to develop a framework and expectations for assessing the domain, and presents a consensus on steps for healthcare organizations to use to assess and improve their performance in that domain. This process is needs-based, as a thorough review of the literature and current performance in the selected area is assessed. It is clear from the amount of effort, cost and energy expended by this ethical task force that communications between patient and healthcare providers, including both physicians and nurse, is in need of improvement.<sup>32</sup>

## The Physician-Nursing Relationship

Two important and recent communications will significantly impact the physician-nurse relationship in the sector of chronic pain management.

The first is a ruling released by the Louisiana State Court regarding a lawsuit *Spine Diagnostics Center of Baton Rouge, Inc., versus Louisiana State Board of Nursing*. The ruling states that chronic pain management is not within the traditional scope of practice of a nurse anesthetist.<sup>33</sup> Other states may soon follow suit and as a result

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pain management practice by advanced practice nurses may be curtailed or altered in some way. Alternately, the onus is being fully placed on nurses to ensure reduction of preventable complications associated with chronic conditions, with reimbursement hinging on outcomes (pay for performance), as indicated by the second communication, the FY2008 Inpatient Prospective Payment System (IPPS) ruling.<sup>34</sup> These changes in scope of practice and responsibility underscore the need for nurses and physicians to communicate more closely and work as an integrated team to reduce error and improve outcomes in their shared patients. Documentation of assessments and dual interpretation of the assessment results will provide a confirmatory model of care. It is critical that both nurse and doctor are educated in the art and science of assessment for use in improving outcomes in chronic pain management.

#### Pain Management Team and Patient Relationship

Assessment is an on-going and dynamic process. By involving the patient in his own care from the beginning of his healthcare journey, setting reasonable and achievable function-related therapeutic goals, educating the patient about the management and not the cure of her pain, using a multimodal approach, discontinuing or not selecting an opioid analgesic when the patient is not a candidate for opioid therapy, and assessing and monitoring the patient's pain, risk of misuse, abuse, addiction and diversion, and therapeutic progress, effective outcomes can be attained.<sup>37</sup> Therapeutic compliance leads to effective and safe pain relief. Education is a key component of this paradigm, not only for the healthcare team, but also for the patient.

#### Surveys

##### National Survey Results Indicate Need for Improved Communications

Recently published (2007) national survey results of nurses, physicians, and hospital executives regarding the impact of the nursing shortage report that most respondents found agreement in the shortage of nurses negatively impacting communications, patient-centered care and nurse-patient relationships. An additional area identified was reduced time for team collaboration. In response to these findings, it is clear that efficient and effective communication is sorely needed<sup>38</sup>.

One study in particular surveyed nursing students in Louisiana regarding their level of knowledge in pain management. These survey results, published in 2006, reported that this population of nursing students collectively scored poorly (mean score of 64%) and these results indicate an inadequate level of knowledge, especially in regard to pain assessment, analgesic dosing and side effect management, and an unfounded fear related to pain patient addiction. Answers in response to a case study revealed that students frequently substituted their judgment for the patient's subjective judgment of pain. The survey investigators recommended that knowledge and attitudes about pain management in this nursing population were in need of improvement. Despite the fact that these results originated from nursing students, students graduate to practice in the clinical environment. It is clear that improved communications in pain assessment and management are needed, in addition to an improved competency and attitude towards opioid prescribing<sup>39</sup>.

##### Standards and Guidelines Reinforce Need and Requirement to Address Pain Management

Because pain is so important to the provision of health care today, many organizations have developed standards by which those who provide health care can measure their practice. Two such organizations are the Joint Commission on Accreditation of Healthcare Organizations and the American Academy of Pediatrics. These standards indicate how seriously these national organizations view the reduction of pain and the provision of comfort for people of all ages. As stated previously, pain cannot be objectively measured in the same way, as for example, measuring the results of a blood test. Only the person who is suffering knows how the experience feels. The American Pain Society states that it is 'not the responsibility of the clients to prove they are in pain; it is the nurses/physician's responsibility to accept the patient's report of pain'.

##### Pain Management Nursing: Scope and Standards of Practice Addresses Ongoing Requirement for Credentialing

In a joint collaboration between the American Society of Pain Management Nursing and the ANCC the first national pain management nurse certification examination took place in 2005. Ongoing certification in this field requires pain management nurses to obtain a minimum of 30 hours of continuing education in a three year period. The examination covers several domains of practices relative to ongoing educational needs. Following are the top three core elements:

- 29% of the examination focuses on pain assessment

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- 16% of the examination focuses on intervention
- 17% of the examination focuses on patient and family education

#### Attitude, Barriers and Knowledge Gaps

- There have been several practice guidelines and regulatory guidelines put in place over the last several years which have made an impact on healthcare clinicians' awareness of the prevalence of pain, and that physicians and nurses need to take a patient's statement of pain seriously. On the other hand there is still along way to go in changing people's stereotypes and really changing the culture.
- Medical Schools and Nursing Schools spend little time on pain management despite the priority. Pain is not addressed in post graduate training or adequately in the nursing curriculum.
- There still exists a "mystic" around chronic pain and a "fear" of prescribing opioids.
- Educational gaps in understanding chronic pain syndromes. Differences in presentation and treatment

#### Needs Assessment Survey/Past Participant Evaluation Outcome

To further define the educational needs of clinicians, MediCom conducted a review of 305 nursing professionals perceived continuing educational needs surveyed via email post activity at the 2007 ASPMN nursing conference. The survey provided data regarding clinicians' top interest, preferred method of learning and other details regarding continuing education. The following results demonstrate topics that the respondents view to be the top 10 highest interests in ongoing education in the field of pain management and ranked by priority of need.

Educational Assessment of Needs	High Priority	Moderate Priority	Low Priority	NA
Assessment of pain	X	X		
General Pharmacology	X			
Communication	X			
Co morbidities associated with pain		X		
Shared goal setting		X		
Opioids	X			
Psychiatry		X		
Abuse and Addiction Issues	X			
Sleep Disorders		X		

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Mechanisms of Pain

X

Specific topics of interest related to pain are evaluated on an ongoing basis. The following information is a summary of completed survey reports from 2006 through 2007, year to date. Total number of evaluations completed were 600, of those returned approximately 34% were from a health care professional in the field of nursing i.e.: RN, LPN, NP

Topics of Interest	No Interest	Some Interest	High Interest
Acute Pain Management	5%	35%	60%
Chronic Pain Management	6%	18%	76%
Research and Scientific Application	20%	35%	45%
Pharmacological Advances in Pain Management	3%	15%	76%
Addiction, Abuse	16%	31%	75%

#### Need for Continuing Education

Pain can alter the quality of life more than any other health-related problem. It interferes with sleep, mobility, nutrition, cognition and overall emotional well-being. Even though pain is such an important obstacle to comfort, it is one of the least understood, most under-treated and often discounted problems of health care providers and their patients. Because of multiple barriers to adequate pain management, all patients are at risk for under treatment of pain. Since pain is identified and reported primarily through patient self-reporting, difficulty in communicating increases the patient's risk for under-treatment.

Effective pain management by nurses requires them to have an understanding of the biological basis of the pain interventions which may be used to control pain. In addition an emphasis on a complete and ongoing pain assessment is paramount to developing a comprehensive treatment plan. Based on a review of the literature, needs assessment surveys as well as input from clinical experts there is a continued need to provide a platform for nurses to gain the most up to date information relative to unrelieved pain in chronic pain states.

#### Key Areas of Need

- Adopting communication methodologies to improve assessment of pain
- Recognizing what questions to ask the patient and when and how to ask them
- Identifying and differentiating pain based on the patient's self-report
- Improved accuracy related to interpretation of assessment results to improve therapeutic strategy and treatment planning
  - Various pain expressions indicative of specific types of pain
  - Various types of pain indicative of condition-appropriate and evidence-based treatments
- Improved risk assessment leading to improved risk containment

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### Conclusions

Based on review of the literature, feedback from clinical experts, needs assessment data received from practicing pain management nurses and current standards and guidelines there is an ongoing need to provide knowledge and practice-based programs for nurses relative to the assessment and management of pain in everyday practice.

The incidence of chronic pain and abuse of prescription opioid analgesics continues to increase. Using assessment measures, effective and thoughtful patient-centered communication, and shared decision making, effective pain management can be realized.

All patients in pain deserve effective pain relief treatment. Learning to stratify patients from low to high risk of drug abuse, misuse, addition and diversion by using on-going assessment and monitoring helps the clinician achieve safe and effective pain management. Compliance by both patient and healthcare team helps to contain risk for all concerned, including the society at large. Education is a key component and is emphasized as essential by numerous experts in healthcare and chronic pain management.

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### MediCom Worldwide, Inc. Program Overview

#### Enduring Material Options

Format	Description	Expected Reach
Symposium adaptation: online accredited streaming video program hosted on Medscape	Symposium filmed and edited into accredited streaming video posted at Medscape.com. Program to be active and available online for one year from posting date	Medscape nursing eNewsletter subscribers: 270,000 nurses; 600 completions
Symposium adaptation: online accredited streaming video hosted on <a href="http://emerging-solutions.inpain.com">emerging-solutions.inpain.com</a>	Symposium filmed and edited into accredited streaming video posted at <a href="http://emerging-solutions.inpain.com">emerging-solutions.inpain.com</a> . Program to be active and available online for one year from posting date	Expected reach: 500 nursing completions

#### Conflict of Interest Identification and Resolution

MediCom Worldwide, Inc. is in full compliance with all rules and regulations put forth by the ACCME in the revised Standards for Commercial Support. MediCom has defined all those in position to control content as faculty, authors, presenters, planning committee members and all those internal staff who are in position to write, alter or impact the content of a CME activity.

All members identified in the planning process must provide signed disclosures to MediCom prior to the planning of the activity.

When individuals in a position to control content have reported Financial Relationships with one or more commercial interests, MediCom works with them to resolve such conflicts to ensure that the content presented is free of commercial bias. The following mechanisms have been identified in which to resolve conflicts as identified:

- Peer review of content by external reviewer
- Content validation by external topic expert and internal MediCom clinical editorial staff

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**Post-Activity Feedback**

Course evaluation forms will be required for all participants who seek to receive continuing education credit. MediCom will summarize the information collected in a formal report to evaluate program effectiveness and participant learning.

Participants will evaluate the following components:

1. Overall content
2. Faculty teaching effectiveness
3. Format
4. Usefulness of information
5. Relevance to practice setting
6. Fair balance
7. Impact to the care of the patient experiencing pain

In addition to rating scales participants will be asked to participate in pre/post testing scenarios as a measurement of learning. Learning will be analyzed based on self-reported changes in knowledge or perceptions by the participants as a result of this activity and how well he or she will be able to apply learning to a specific practice setting. Three months post activity, participants will be reassessed based on retention and incorporation

**Budget Summary Overview****ASPMN Accredited Satellite Symposium Plus Enduring Material Options  
Proposal Overview**

Tactic	Description	Expected Outcome	Proposed Budget	
			Direct Costs	Indirect Costs
Satellite symposium at 2008 ASPMN national conference	Three-speaker accredited live symposium	500 ASPMN members	\$103,910	
				\$ 71,700
			<b>Total</b>	<b>\$175,610</b>
Symposium adaptation: accredited online adaptation hosted on emerging solutions in pain.com	Symposium filmed and edited into accredited streaming video posted on emerging solutions in pain.com	Expected reach: 500 nursing completions	\$ 54,365	
				\$ 25,581
			<b>Total</b>	<b>\$ 79,946</b>
Symposium adaptation: online accredited streaming video program	Symposium filmed and edited into accredited streaming video posted at Medscape.com	Medscape nursing eNewsletter subscribers: 270,000 nurses	\$ 6,400	
				\$105,000
			<b>Total</b>	<b>\$ 21,250</b>
			<b>Total</b>	<b>\$132,050</b>

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**Budget:**

Live Activity:	\$175,610
ESP Hosting	\$ 79,946
Medscape Web Hosting	\$132,650
<b>Total Budget:</b>	<b>\$388,206</b>

**Budget Reporting and Reconciliation:****Appropriate Use of Commercial Support:**

- a. Funds should be in the form of an educational grant made payable to MediCom Worldwide, Inc.
- b. No other funds from Cephalon, Inc. will be paid to the program director, faculty, or others involved with the CE activity (additional honoraria, extra social events, etc).
- c. MediCom Worldwide, Inc. will furnish the commercial interest with documentation detailing the receipt and expenditure of the commercial support within 90 days of activity completion.
- d. In the event of program cancellation and or providers inability to complete the activity as designed, provider agrees to return all unused grant funds to Cephalon. Provider will furnish Cephalon with documentation detailing any and all receipts of expenditures related to expense incurred up to program cancellation.

**Payment Structure:**

50% due upon signing of agreement:	\$194,103
Final 50% due Sept 1, 2008:	\$194,103

Should proposal be accepted all Letters of Agreement shall be signed by the following representatives:

Joan Meyer  
President  
MediCom Worldwide, Inc

Jerrie Lynn Kind  
Executive Director  
American Society for Pain Management Nursing

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MediCom Worldwide, Inc.  
101 Washington Street  
Morrisville, Pennsylvania 19067

**Online Adaptation from Live Symposium  
Hosted as Internet Activity on Medscape  
Proposed Budget  
ASPMN**

**Program Description**

This proposal is for a video adaptation of a live symposium and accredited for self-study. The self-study program will include: all graphic images used in the presentations, including animations of graphs and charts; content to be posted on line via Medscape

Cost Summary	
Approximate Total, Direct Expenses	\$ 111,400
Total, Indirect Expenses	\$ 21,250
<b>Cost of One Self-Study Multi-Media Online Program Adapted from Live Symposium</b>	<b>\$ 132,650</b>

Detailed Budget Itemization	
Direct Expenses, Approximate	
Video capture station; editing	\$ 3,400
Speaker honoraria; post-symposium	\$ 3,000
Medscape Hosting Fee	\$ 105,000
<b>Approximate Total, Direct Expenses</b>	<b>\$ 111,800</b>

Indirect Expenses	
Program Development	\$ 10,000
Includes creation of graphic user interface; coordination with speakers for adaptation; coordination with speaker for final review; coordination with medscape	
Program Editing	
Authoring of Final Content for Web Delivery	\$ 1,700
Adaptation of symposium program material design for Internet program and Render of all files	\$ 800
Editing of all video and audio	\$ 1,000
Accreditation of program for CNE	\$ 3,000
Data management	\$ 750
Includes management of participant database, data analysis, quarterly reports, final summary report	
Project management	\$ 4,000
<b>Total, Indirect Expenses</b>	<b>\$ 21,250</b>

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101 Washington Street  
Morrisville, Pennsylvania 19067

**2008 American Society of Pain Management Nursing**  
**Job #M00633**

Program Parameters			
	Accreditation Hours		2
	Faculty		3
	Symposium Attendees		525
	Direct mail invitations to health care professionals		4,000
Cost Summary			
	Approximate Total, Direct Expenses	\$	103,910
	Total, Indirect Expenses	\$	71,700
<b>Cost of 2008 American Society of Nursing Management</b>		<b>\$</b>	<b>175,610</b>



MediCom Worldwide, Inc.  
101 Washington Street  
Morrisville, Pennsylvania 19067

**2008 American Society of Pain Management Nursing**

Direct Expenses; Approximate	
ASPMN Fee to include:	\$ 40,000
Catering up to approx 500 guests; provider needs to assume additional coverage	
Brochure announcement	
Basic AV set up; one screen; one podium mic; AV tech	
Joint accreditation fee and ASPMN advisory review and approval	
Venue Rental	
Mailing List Rental	
Direct mail invitations	
Direct mail invitations, mailed to registered meeting attendees; includes printing; development of database	
email homepage for registration	\$ 4,000
Direct mail list purchase	No charge
Mail Services, postage, phone, fax, email registration	\$ 1,560
Includes assembly, mail services and postage. Follow up recruitment per phone, fax, email	
Invitation door-drop/advertisement fee	\$ 5,000
Participant handouts	\$ 11,500
Includes printing of participant workbook; will include accreditation information, speaker biographical and disclosure information, agenda, and symposium graphics; total quantity 525 color copy	
Posters advertisement materials	\$ 2,400
Faculty expenses	
Honoraria:	
Nursing Experts (2)	\$ 3,000
MD Expert (1)	\$ 2,500
Travel (3 faculty members)	\$ 1,800
Accommodations (assumed one night stay)	\$ 1,500
Meal expense faculty	\$ 300
Ground transportation	\$ 525
Room Rental	No charge
Catering provided by ASPMN up to 500 attendees; assumed overage amount of 50 attendees	\$ 3,500
Audience Response System	\$ 6,000
Onsite equipment rental	\$ 5,000
Audio/visual services: Basic AV provided by ASPMN; upcharge related to additional AV requirements	\$ 5,000
MediCom expenses	
Air travel	\$ 1,500
Accommodations	\$ 1,600
Meals	\$ 300
Ground transportation	\$ 350
CCP	\$ 75
Travel/expense firm crew; production	\$ 5,000
Shipping/Fed Ex	\$ 1,500
<b>Approximate Total, Meeting Management Direct Expenses</b>	<b>\$ 103,910</b>



MediCom Worldwide, Inc.  
101 Washington Street  
Morrisville, Pennsylvania 19067

**2008 American Society of Pain Management Nursing**

Indirect Expenses	
MediCom pre-meeting coordination and Development of Video Case Study	\$ 25,000
Includes faculty recruitment, agenda coordination, coordination with association, coordination with venue, participant recruitment, coordination of filming of patient video case study	
Scripting of patient interviews (3 scenarios)	
Medical Advisory review of content	
Development of needs assessment	
Equipment rental; actor/studio rental; filming; editing; production of video case presentation	\$ 15,000
Onsite filming of entire live event; includes interview segments with presenters	\$ 10,000
Development Editorial	\$ 3,000
Includes presentation slides x3 faculty approx 125 slides; editorial content review; reference and fact checking; design and format	
MediCom on-site symposium coordination; 3 MediCom staff	\$ 3,200
Graphic design	\$ 2,500
Accreditation of program for CNE coordinated in conjunction with ASPMN	\$ 3,000
Project management	\$ 10,000
<b>Total, Indirect Expenses</b>	<b>\$ 71,700</b>

50016924



www.cephalon.com

Cephalon, Inc.  
41 Moores Road  
P.O. Box 4011  
Frazer, PA 19355  
Phone 610-344-0200  
Fax 610-344-0065

### INDEPENDENT EDUCATIONAL PROGRAM GRANT AGREEMENT

This Agreement is entered into as of this 20<sup>th</sup> day of August, 2008, by and between Cephalon ("Cephalon"), located at 41 Moores Road, Post Office Box 4011, Frazer, PA 19355, and MediCom Worldwide, Inc. ("Provider") located at 101 Washington Street, Morrisville, PA 19067.

WHEREAS, Cephalon has reviewed Provider's grant request to support a medical education program ("Program"); and

WHEREAS, Cephalon has determined that the Program has the potential to address educational gaps and improve patient care; and

WHEREAS, it is the intent of the parties to ensure that the Program will be independent, objective, balanced, scientifically rigorous, and have reasonable expectations of meeting its educational objectives so that it will not be viewed by the United States Food and Drug Administration ("FDA") as promotional and that Cephalon will not be viewed as responsible for its content; and

WHEREAS, Cephalon agrees to provide funding for the Program under the conditions set forth below.

NOW THEREFORE, Provider and Cephalon agree to the following terms under this Agreement:

1. Title of Program. The Educational Program is entitled "Minimizing Risk and Improving Outcomes in Chronic Pain: A Focus on the Challenge of Communication and Interviewing Skills in Assessing Pain Patients," and a copy of the grant request for the Program is attached hereto as Exhibit A.
2. Type of Program. The Program is:
  - ☒ accredited (e.g., continuing medical education or "CME"); or
  - ☐ an independent program where CE credits will not be offered.
3. Educational Partner. The Provider ☐ shall ☒ shall not use a third party that will provide assistance in support of the Program ("Educational Partner").
4. Educational Components. The expected components of the Program (e.g., number of live meetings, CD ROM, web-based, etc.) are as follows:
  - (a) ICPCD Symposium;
  - (b) ESP Website;

5. Program Purpose. The Program is for scientific and educational purposes only, and is based on established bona fide and independently verifiable patient and/or practitioner needs or gaps in healthcare performance, and is not intended to promote a Cephalon product, directly or indirectly. The Program is not a repeat performance of a prior program.
6. Grant Amount Funding Arrangements.
  - (a) Cephalon will provide support for the Program by means of an educational grant in the total amount of \$252,121, as set forth in the budget attached hereto, or a pro rata amount based on the actual work performed and expenses incurred by Provider in accordance with the Budget. If the Program is canceled or terminated prior to completion, Provider shall return the grant, or any unused portion thereof, to Cephalon within thirty (30) days of such termination or cancellation. Provider shall have full responsibility for all funding arrangements of the Program, including any funding to be provided to its Educational Partner. Payment terms of the grant shall be made in accordance with any schedule/criteria provided in the Budget.
  - (b) Within ninety (90) days of completion of the Program, Provider shall provide Cephalon with a detailed reconciliation of actual expenses incurred, and to the extent Cephalon has overpaid Provider for same, Provider shall provide a refund to Cephalon within thirty (30) days thereafter. Such detailed reconciliation shall be forwarded to Cephalon at the address above to the attention of Bhaval Shah Bell, Ph.D., Associate Director.
  - (c) Provider may not use funds provided by Cephalon to pay travel, lodging, honoraria or personal expenses for non-faculty attendees. Grant funds may be used to reduce the overall registration fees for attendees. Grant funds may not be used to purchase capital equipment or to provide general operational support for an institution. Funds for hospitality shall not be provided, except that funds may be used for modest meals or receptions that are held as part of the Program, but such events shall not compete with, nor take precedence over, educational events. The appropriateness of any reception shall be at the sole discretion of the Provider, and Provider shall have final decision-making authority in connection with any such activities.
  - (d) Funds may be used by the Provider to permit medical students, residents, fellows or other health care professionals in training to travel to and attend the Program; provided, however, that the selection of such students, residents or fellows who receive funds is made by either the academic or training institution, or, if by the Provider, such selection shall be made with the full concurrence of the academic or training institution.

7. Objectivity and Balance. Provider shall retain full responsibility for control of the content of the Program and shall ensure that the following requirements are met:
- (a) The Program material/information will be objective, balanced and free from commercial bias. All topics shall be treated in an impartial, unbiased manner. All discussions shall include a range of views about each class of drug and disease treatment options. Information shall not unfairly represent a spectrum of views favoring a product or class of products marketed by Cephalon or any other company. The title of the Program will fairly and accurately represent the scope of the presentation.
  - (b) Provider agrees that neither Cephalon nor its agents shall control the content of the Program. Provider agrees that there will be no scripting, targeting of points for emphasis, or other activities by Cephalon or its agents that are designed to influence the content of the Program. Cephalon personnel will not attend content development meetings unless requested in writing by the Provider or the Educational Partner make presentations of disease data and/or Cephalon product data to faculty. In this instance, Cephalon personnel may stay only for this portion of the meeting, and the accredited provider must be in attendance.
  - (c) If requested, in writing, by the Provider or Educational Partner, Cephalon Medical personnel may also provide written material on a Cephalon product or compound in development, such as *specific product data, manuscripts, posters, product labels and other scientific material* (not in slide format) in accordance with internal corporate guidelines based on the level of information that is acceptable to disclose.
  - (d) Cephalon shall not review the Program for medical accuracy or completeness and the Provider and/or Educational Partner (if any) agree that they will not make such a request of Cephalon.
  - (e) If a product marketed by Cephalon is the subject of discussion, the data will be objectively selected and presented, with an accurate reflection of favorable and unfavorable information about the product and shall also include a balanced discussion of prevailing information on alternative products and /or therapies.
  - (f) Any suggestions of superiority of one product or treatment over another will be supported by the body of available data and will not result from selective presentation or emphasis on data favorable to a particular treatment.
  - (g) Provider represents that neither it nor the Educational Partner (if any) has either an open complaint or decision from the Accreditation Council for Continuing Medical Education ("ACCME") or the FDA that a program provided by the Provider or the Educational Partner failed to meet standards of independence, balance, objectivity, or scientific rigor.

8. Risk Minimization Action Plan. Cephalon provides the following Risk Minimization Action Plan ("RiskMAP") information to all Providers. Neither Cephalon nor its agents shall influence or control whether a product marketed by Cephalon is the subject of discussion. A RiskMAP is a strategic safety program designed to meet specific goals and objectives in minimizing known risks of a product while preserving its benefits. Any product marketed by Cephalon that is approved with a RiskMAP, and the key safety-related health outcomes outlined in that RiskMAP, are listed in Exhibit B. Provider agrees that it is aware of the RiskMAP(s) and the key safety messages.
9. No Faculty Selection. Provider shall retain full responsibility for the selection of the presenters, authors, moderators, and/or other faculty (hereinafter referred to collectively as "Faculty"). Provider and/or Educational Partner (if any) shall not request recommendations for Faculty from Cephalon
10. Disclosures. Provider will ensure meaningful disclosure of limitations of data (e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion). Provider will require that Faculty disclose when a product is not approved in the United States for the use under discussion.
11. Question and Answer Session. To the extent the Program is a presentation, Provider will ensure meaningful opportunities for questioning by the audience.
12. Financial Relationships. Provider will ensure meaningful disclosure to the audience of Cephalon funding and any significant relationship between individual Faculty and Cephalon. All meaningful disclosure(s) shall also be made in any written materials, including, but not limited to, announcements, brochures, syllabi and enduring material. Disclosures shall not mention product trade names.
13. Representations and Warranties. Provider represents that:
  - (a) Neither it nor the Educational Partner, if any, provides marketing, advertising, public relations, market research, medical education services or other consulting services (e.g., support for advisory boards) to any other department within Cephalon ("Marketing Activities");
  - (b) If Provider or the Educational Partner has an affiliated company that provides Marketing Activities to Cephalon, Provider has instituted appropriate controls and safeguards to ensure the Program (i) remains independent, objective, balanced and scientifically rigorous, (ii) is not intended to promote a Cephalon product, directly or indirectly, and (iii) is not in any way biased due to the affiliated company's relationship with Cephalon;
  - (c) Provider has determined that it is appropriate to use the Educational Partner in light of the requirements under this Agreement; and

- (d) If Provider or its Educational Partner employs a former Cephalon employee who worked at Cephalon at anytime during the most recent year and who had marketing responsibility in the therapeutic area that will be covered by the Program, then that former employee will not have any role in the planning, development or delivery of the Program.

14. Invitations/Enduring Materials. The Program audience will be selected by the Provider. The Provider shall be responsible for distributing materials about the Program, including invitations, reminder notices, and business reply cards that can be used by third parties to obtain any enduring Program material from the Provider.
  
15. Ancillary Promotional Activities. To the extent the Program is a live presentation, no promotional activities or product advertisements will be permitted in the same room as, or in an obligate path to, the Program. If the Program is a teleconference or webcast, no product advertisements or promotional activities will be permitted immediately prior to, during, or immediately after the delivery of the Program. If the Program is in print format, no product advertisements or promotional materials will be interleaved within the pages of the Program. If the Program is made available electronically, no product advertisements or promotional materials will appear within the Program material or interleaved between computer windows or screens of the Program, all as stipulated in ACCME Guidelines.



16. Compliance with Guidelines. Provider represents that the Program, including development of the Program and Program materials, shall conform to the American Medical Association ("AMA") Guidelines on Gifts to Physicians, the AMA Ethical Opinion on Continuing Medical Education, the ACCME Standards for Commercial Support, the FDA December 3, 1997 Final Guidance for Industry-Supported Scientific and Educational Activities, and the Pharmaceutical Research and Manufacturers Association ("PhRMA") Code on Interactions with Healthcare Professionals.
17. Logistical Status Reports. Provider and/or Educational Partner shall provide periodic reports to Cephalon regarding the management and logistics of Program components.
18. Miscellaneous.
  - (a) No party shall use the other party's or its affiliates' name or trademarks for publicity or advertising purposes, except with the prior written consent of the other party.
  - (b) Provider agrees to obtain all consents, authorizations, approvals and releases that may be necessary for the production of the Program and of any written materials prepared in connection therewith.

(c) No term, condition or other provision of any attachment or addendum to this Agreement shall supersede any term, condition or other provision of this Agreement, and with respect to any inconsistency or ambiguity, the Agreement shall control.

IN WITNESS WHEREOF, the parties, by their duly authorized representatives, agree to comply with all the terms and conditions of this Agreement.

CEPHALON, INC.

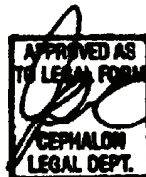
By: [Signature]  
Name: JOAN MEYER  
Title: President Medilum Worldwide, INC

The above signatory is a duly authorized corporate officer of the IEP Provider.

Date: 8-27-08  
Tax ID #: 23-306

By: [Signature]  
Name: Robert Kaper, MD  
Title: Vice President, Medical Affairs

Date: 08-26-08



*Exhibit A*  
*Copy of Grant Request*

MediCom Worldwide, Inc.

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June 12, 2008

Bhaval Shah-Bell, PhD  
Cephalon, Inc.  
41 Moores Road  
Frazer, PA 19355

Dear Dr. Shah-Bell:

Based on the identified educational need in pain management, MediCom is requesting an educational grant from Cephalon, Inc. to support the development of a live symposium in conjunction with the following educational conference:

- International Pain and Chemical Dependency Conference (ICPCD) scheduled to be held October 30 – November 1, 2008 in Philadelphia, Pennsylvania

In addition to the live program MediCom is requesting additional funding to provide enduring material support initiatives resulting from the content developed for the live meeting in order to maximize the reach to healthcare professionals throughout the United States. The activities described in this proposal include:

1. Live symposium held at ICPCD
2. Online adaptation via streaming video hosted on [www.emergingsolutionsinpain.com](http://www.emergingsolutionsinpain.com)

The total grant request to fund these activities is \$ 252,121; please refer to the detailed budget section of this proposal for complete grant funding details of the individual educational initiatives.

These scientific events will comply with all OIG, PhRAM, FDA, and ANCC regulations for industry-supported professional continuing education. In so doing MediCom Worldwide, Inc will be solely responsible for the identification of educational need, development and control of content to be presented as well as faculty selection for each date and venue.

Thank you in advance, for your consideration of this request.

Respectfully,

A handwritten signature in cursive script, appearing to read 'Joan Meyer'.

Joan Meyer  
Executive Director, Continuing Education

MediCom Worldwide, Inc.  
101 Washington Street • Morrisville, PA 19067 • 215-337-9991

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MediCom Worldwide, Inc.

Program Summary



**Program Title**

*Minimizing Risk and Improving Outcomes in Chronic Pain: A Focus on the Challenges of Communication and Interviewing Skills in Assessing Pain Patients*

**Program Overview**

According to a recent survey, 80 million Americans experience pain and is the third leading physical impairment in the United States following cancer and heart disease. Despite the prevalence of pain disorders among Americans, the number of patients reporting adequate pain relief is less than optimal. According to a survey conducted by the American Pain Society, only 40% of people suffering from moderate to severe pain have experienced relief.

Assessment of the patient experiencing pain is the cornerstone to optimal pain management. However, the quality and utility of any assessment tool is only as effective as the clinician's ability to thoroughly focus on the patient.

One of the key issues in pain management today is the challenge of appropriately assessing the patient. This assessment must focus on tests that elucidate the physical disease or disorder, so that appropriate therapy may be initiated. For those patients who may be prescribed opioid analgesics, however, this assessment must include a proactive and thorough assessment of risk potential for opioid misuse, abuse and addiction, as well. Through a thoughtful and proactive combination of these two assessment processes, clinicians may be more informed concerning the type, duration and dosage of therapy that will be most likely to contribute to positive outcomes. For many patients with chronic pain, this therapy will include a trial of an opioid; however, not every patient is an appropriate candidate for opioid analgesics, and one of the goals of this assessment process is to determine the most appropriate therapeutic regimen for the individual patient.

The tactics of a thoughtful and thorough assessment, followed by ongoing monitoring, are not only good medical practices that will support improved outcomes, however. These are also processes that are required when any controlled substance is prescribed. In today's clinical environment, clinicians are scrutinized by legal and regulatory authorities with regard to their prescribing of controlled substances, and the media is increasingly focusing on issues surrounding illicit use of prescription medications.

Due to the increasing focus on safe and effective prescribing of opioids that effectively minimizes possible negative consequences of opioid misuse, this symposium will be designed to incorporate a blend of didactic presentations, prerecorded challenging video case vignettes as well as live interview scenarios based on a series of case studies designed to provide the attendees with insights and interviewing techniques to assure a

thorough assessment in which to make the most appropriate diagnosis and subsequent treatment plan.

Each of segments will be followed by a question and answer session that encourages frequent audience interaction with faculty. The symposium will conclude with a review of cases as presented and a summary "best practices" information presented.

#### **Program Learning Objectives**

Upon completion of this activity, participants should be able to:

1. Describe communications techniques and screening tools used to measure pain and explain why they are necessary for the effective management of patients with chronic pain
2. Indicate two reasons why risk assessment is necessary in the effective management of patients with chronic pain and demonstrate how to apply these assessments in the clinical setting
3. Identify three types of screening tools used to assess patients with chronic pain for the risk of abuse, misuse, addiction and/or diversion of prescribed opioid medications and how their use contributes to a reduction in practitioner liability
4. Summarize the importance assessment results interpretation to developing an effective treatment strategy and apply this to individual practice setting.

#### **Target Audience**

Nurses, Physicians, Pharmacists, Allied Health Professionals participating in the ICPCD Conference.

#### **Program Format**

The symposium will be driven by case examples and will provide attendees with a range of interview and interaction techniques and approaches. Presenters will have specific clinical expertise and special skills in communication and will facilitate interactive case based presentations as well as the inclusion of didactic presentations.

To encourage active learning and participation, MediCom will utilize a blend of prerecorded videotaped patient-clinician assessment techniques as performed by a nurse and physician as well as live case-based assessment interactions. Cases will be designed with specific real life problems, patient presentations and complaints that will demand learners to utilize analytic skills and determine appropriate course of action and treatment. This activity is designed to offer a strong instructional foundation to meet the learning objectives of acquiring knowledge, skills and influencing attitudes and behaviors. Each segment and case study will be led by a clinical expert to help guide the process and facilitate the best course of action.



## **Agenda**

### **Presentation 1:**

#### ***Assessment and Communication Tools and Techniques Designed to Guide Your Treatment***

- Multidimensional pain assessment tools
- Techniques to optimize communication
- Importance of obtaining an accurate baseline pain assessment
- Are we hearing what our patients are really telling us

### **Presentation 2:**

#### ***The Chronic Pain Patient Identified At Risk***

- Identify effective clinical strategies and treatment options which demonstrate how appropriate assessments and tools may be incorporated into the clinical setting
- Assessing aberrant behaviors and how they may be managed effectively
- Key clinical indicators in determining diagnosis based on assessment
  - a. Understand myths and misconceptions to remove barriers to effective assessment and treatment
  - b. Demonstrating challenges and variable patient responses

### **Case-Based Interviews: Test your Interviewing skills and techniques**

- Cases will be designed to address real life clinical practice and patient presentations based on key challenges of patients presenting as chemical copers, pseudoaddiction, opioid tolerant, drug seekers, chronic pain pt. with substance abuse disorder
- Video and live interview segments guided by the clinical experts
- ARS used to poll audience on their diagnosis
- Panel discussion of audience results and rationale

### **Presentation 3:**

#### ***Wrap Up: Understanding Why Objective Assessment Results Improve the Patient-Practitioner Relationship and Minimize Risk***

- Importance of reduction of risk coupled with appropriate use of medications
- Awareness of risk potential – using the right medication with the right patient
- Based on pain characteristics and type identify pharmacologic and nonpharmacologic treatment decisions driving plan of care

### **Panel Discussion / Q&A**

**Proposed Faculty**

Steven D. Passik, PhD

Micke Brown, RN  
American Pain Foundation

Howard Heit, MD

**Invitation/Distribution Process:****Live Event**

The live symposium will be announced and promoted through the use of direct mail printed invitations to identified target audience related to the scientific conference.

**Enduring Material****Online Adaptation:**

Video adaptation to website will occur following the live event held in October.

Online posting will be available to participants one year from the original posting date.

Activity will launch via Emergingsolutionsinpain.com (ESP) within 30 days post-live event and will maintain accreditation throughout a 12-month hosting period. Average completions of approximately 300 per hosting period.

**Target Launch Date:** November 2008

**Request for Sponsor Support Live Event**

As a supplement to these primary methods, MediCom Worldwide, Inc. may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of MediCom and any such distribution will solely be as a supplement to MediCom's primary methods of announcement and promotion.

**Accreditation**

CME credit for physicians by the Accreditation Council for Continuing Medical Education. This activity will be approved for a maximum of 1.5 hours of category 1 credit toward the AMA Physician's Recognition Award.

CPE credit for pharmacists by the Accreditation Council for Pharmacy Education. This full-day activity will be approved for a maximum of 1.5 credit hours (0.15 CEU) for Continuing Pharmacy Education.

CNE credit for nurses. This activity will be approved for a maximum of 1.5 Contact Hours.

## MediCom Worldwide, Inc.

### Needs Assessment



#### Overview

Every day, clinicians in all clinical settings work closely with patients who are experiencing various types and intensities of pain. Advances in pain management have given present patients and their families a variety of options that allow them a renewed dimension to the quality of their lives. Because of this it is important that healthcare practitioners keep up to date on basic principles of assessment, pain management/treatment options and current pharmacologic and nonpharmacologic approaches.

To better understand the potential educational needs, MediCom Worldwide, Inc. has utilized the following sources of information:

- 2006-2007 MediCom Needs Assessment Survey
- 2007 Survey of Participants at the ICPCD Symposium
- Environmental Scan
  - Literature Review
  - Therapeutic Research Review
  - Scope and Standards of Practice
  - APS Survey Publications

#### **Current Environment and Standard of Care**

##### ***Barriers to Effective Pain Management***

Optimal treatment of chronic pain may be assisted by three paradigms:

- Adequate model of assessment
- Treatment focused on pathophysiology (whether physical, psychosocial, or some combination of these)
- Frequent reassessment of total social function

Using these approaches, contribution to drug abuse, diversion, and life deterioration can be largely avoided.<sup>1</sup>

#### **Poor Assessment of Pain: a barrier to effective pain management**

Effective pain management begins with comprehensive and accurate assessment of the patient experiencing pain and is considered the cornerstone to optimal pain management. However, even with the assortment of validated and simple assessment tools available for use (i.e., numerical ratings scale, Wong-Baker FACES scale), unidimensional metrics tend to fall short, unless the practitioner possesses the ability to focus on the patient and engage in clear and open dialogue.<sup>2-4</sup> Pain assessment is a multifaceted process. Numeric indicators cannot measure disability, coping skills or mood<sup>5</sup>. The fifth vital sign, pain, remains totally subjective, unlike objective blood pressure measurement or diagnostic tests, and as a result, patient self report remains the mainstay of pain assessment.<sup>6</sup> Healthcare providers are challenged to develop more precise and objective measures of pain. Until something better comes along, the time-

honored bedside skills of listening, observing and interpreting are the most reliable tools for effective pain assessment.<sup>6</sup> This method of communication means *inviting* the patient to open-up and communicate the necessary information needed to assess pain and its effects properly. The clinician must ask the patient open-ended questions in order to get at the root of the problem. Asking the patient if he has pain will not provide an adequate answer to the clinician. A patient stating that she is in pain will not offer enough information to the clinician for development of a therapeutic solution. Instead, clinicians need to ask the patient what the pain is like; ask for a description.

It means *listening* with empathy, using heart and mind to believe what the patient is stating and to legitimize or advocate the patient's pain while understanding what the patient is trying to say and imagining the patient's pain experience. Listening means no talking, and no thinking about the next question or conjuring a response. After truly listening to the patient, the practitioner needs to *summarize* what is believed to have been heard back to the patient for confirmation. If a patient states that her pain becomes intense after standing on her feet all day at work, the clinician may summarize by saying: "So: your pain worsens in the evening hours, after you arrive home from work." This third communications step reduces the likelihood of miscommunication or assumption. This three-step method of communication: invite, listen and summarize on behalf of the clinician confirms to the patient that there is genuine interest in the patient as a person, and that he/she is not merely representative of a disease or condition. Other factors may also affect the discussion surrounding assessment. Stereotypes, fear, bias and preconceived notions may color practitioner-patient communications and interfere with effective pain patient assessment and management.<sup>7</sup>

Validated multidimensional pain assessment tools exist and are designed to facilitate these discussions. The Short Form McGill Questionnaire is an excellent example of a tool that includes information to assess both sensory and affective domains. The long McGill form provides sufficient questions to assess not only sensory and affective components of pain, but evaluative components as well. Equally important is the ability of the patient in pain to verbalize the pain experience to the clinician. The patient must express in terms that will instill compassion yet provide verbal triggers essential to the practitioner in order to gain a clear clinical picture of the patient's current health. Clinically, pain is whatever the person says he or she is experiencing whenever he or she says it occurs. With this in mind, patients need to be clear with their health care providers. Type of pain, location, onset, duration, frequency, and intensity are essential to proper assessment. A discussion related to factors that either alleviate or aggravate the pain will also help determine course of therapy. Too often patients may be reluctant to admit to their health care providers that they have pain and may attempt to minimize its frequency or severity. Patients may feel they must suffer in pain not realizing they can expect pain relief, and may be concerned about taking pain medications for fear of associated side effects and the attached stigma of "drug-user". Both the patient's level of knowledge and belief system regarding pain will play heavily against if and how the dialogue with practitioner will begin. The clinician's role is to act as advocate or provide a contact for advocacy to the patient and help them optimize their expression of pain for improved communications and care outcomes. Patient advocacy supports the patient with the essentials needed to more clearly communicate with the healthcare provider at time of assessment.<sup>8,9</sup>

### **Screening for Risk: preamble to effective pain management**

A multidimensional pain assessment will include the following domains: Pain, function, mood or affect, coping skills, and social support network. It is the clinician's responsibility to initiate assessment conversation and employ multidimensional assessment tools that encourage patients to feel safe and allow them the freedom to communicate without judgment. Controlled substances may be abused, misused or diverted. Results from a recent study indicate that users of prescribed opioids had higher rates of opioid and nonopioid abuse problems compared with nonusers of prescribed opioids, but these higher rates appeared to be partially mediated by depressive and anxiety disorders.<sup>10</sup>

In patients receiving prescribed opioids, clinicians need to be alert to drug abuse problems and potentially mediating mental health disorders. To improve practice performance when prescribing controlled substances for pain, a comprehensive assessment should include screening the patient for risk of drug misuse, abuse and addiction. Use of the Opioid Risk Tool (ORT), CAGE-AID, Screener and Opioid Assessment for Patients in Pain (SOAPP™), or alternate drug misuse screener helps to identify patients who will require further assessment to determine if a more rigorous structure of treatment plan is needed to contain risk for patient, practitioner and practice. Mental health assessment, especially for anxiety, depression and sleep disorders, common comorbid conditions, is also suggested. Short form assessments, mentioned previously, serve to screen the patient to determine if further assessment by a mental health specialist is necessary.

Although patient self-report often correlates with problematic behaviors, it may also lead to erroneous information, especially if the patient is an addict or drug-seeker. Addicts and people with criminal intent lie in order to gain what they want. Use of assessment tools helps the clinician gain an objective measure of risk. An addict or drug seeker is not easily recognized. These types of patient do not always look or act a certain way. The clinician's own value judgments and prejudices may also affect therapeutic decision making. Screening tools provide objective metrics to temper subjective assumptions that may impede effective therapy. Results from screening do not equate to a diagnosis. Results simply stratify the patient at low to high risk of abuse, misuse, addiction or diversion. Patients who score moderate-to-high risk require additional and advanced assessment. All patients in pain, whether assessed at high or low risk of drug abuse, misuse, or addiction have a right to obtain effective pain relief. Patients who obtain prescription drugs for resale and profit are criminals and clinicians must report known illegal activities to the proper authorities.

Use of formal screening instruments also provides the clinician and medical practice with documentation. Should a question arise, the patient's medical record will demonstrate the assessment results and therapeutic actions taken as a result of their interpretation.

### **Documented Need for Improved Communications and Assessment**

During assessment of pain the data provided by the patient to practitioner must be interpreted accurately to navigate a meaningful next-step question.

Appropriate assessment of the patient in pain takes into consideration source, onset, severity, pattern, subtype, and cause of pain. These clinical cues may be interpreted by referring to evidence-based guidance from the American Pain Society, the American Geriatric Society, and the World Health Organization (WHO Analgesic Ladder). All of which offer formal guidance to the clinician to help navigate therapeutic decision-making based on assessment results.<sup>11,12</sup>

Patients who suffer with chronic pain may wish to be pain-free but attaining that goal is not always possible. Basing therapeutic goals on reducing pain to a level that permits the patient to engage in functions they either enjoy or must do is practical and more frequently achievable. Appropriate and successful treatment is important because under-diagnosed or under-treated pain has a profound impact on the patient's quality of life, as well as cost of health care.

Undertreated pain may cause the patient to exhibit signs of aberrant drug-related behaviors. The patient whose pain is undertreated may request additional analgesia, may self-medicate, or may use other substances to alleviate the pain (i.e., alcohol). This condition is termed pseudoaddiction. Both pain assessment and risk assessment results will help the clinician determine if pseudoaddiction is the problem. In this subset of patients, when analgesia is adjusted to provide increased and effective pain relief, the aberrant behaviors resolve.

Patients who have been prescribed chronic opioid therapy may become tolerant or they may experience hyperalgesia as a direct effect from the drug. Drugs that once afforded these patients effective pain relief now appear to have no analgesic effect or may actually induce pain. Re-assessment for monitoring purposes is needed. Cellular receptors may become desensitized from chronic opioid administration. In these patients, opioid rotation is suggested. Weaning the patient from the original drug and titrating to an alternate analgesic often solves this problem. Chronic opioid administration may also cause hypersensitization of receptors. When this occurs, the analgesic drug causes pain rather than alleviating it. In this case, by lowering the dose in small increments, the analgesic effect is often restored.

Very little attention has been given to chronic nonmalignant pain in the nursing literature. Although there has been increasing debate concerning prescribing practices among physicians for patients with chronic nonmalignant pain, little, if any, understanding exists about advanced practice registered nurses (APRNs) in this context.<sup>13</sup>

Although the focus of pain assessment has shifted in recent years to examine the disparity of assessing pain in the non-verbal patient, there still exists need within the nursing community to improve pain assessment in the verbally-competent pain patient. A common assumption is that all nurses have the same baseline knowledge about pain, a potentially erroneous assumption that influences clinical practice. Nurses have varied experiences in education and pain management. In a study conducted by



Michaels, et al, results demonstrated that nurses who received one educational activity about documentation of pain, patient satisfaction scores, and pain knowledge was not adequate to improve pain assessment and care. The authors suggest that pain education *needs to be ongoing to change practice and affect overall pain management*. Additionally, the authors recommend that efforts in pain assessment move beyond the basics to include assessment and communications that are safe, opportune, evidence-based, and interdisciplinary.<sup>14</sup> Another recent study of nursing perceptions related to chronic pain management demonstrated the following areas of concern: *pain assessment (lack of recognition of pain, uncertainty about the accuracy of pain assessment and diagnosis) and treatment (reluctance to use opioids, working to individualize pain treatments, issues relating to physician trust of the nurse on prescribing patterns)*.<sup>15</sup>

A third study examined pain assessment in the geriatric verbal chronic pain patient and the investigators reported the following: Epidemiologic studies show a very high prevalence of persistent pain, often exceeding 50% of community-dwelling older persons and up to 80% of nursing home residents. *Recently, there has been a major push to develop age-appropriate pain assessment tools, including several observer-rated scales of behavioral pain indicators for use in those with dementia. There has also been the release of several comprehensive guidelines for the assessment and management of pain in older persons, although the current evidence-base used to guide clinical practice is extremely limited. Unfortunately, despite these advances, pain remains grossly under treated in older persons, regardless of the healthcare setting.*<sup>16</sup>

In another study, nursing students in Louisiana were surveyed regarding their level of knowledge in pain management. These survey results, published in 2006, reported that this population of nursing students collectively scored poorly (mean score of 64%) and these results indicate an inadequate level of knowledge, especially in regard to pain assessment, analgesic dosing and side effect management, and an unfounded fear related to pain patient addiction. Answers in response to a case study revealed that students frequently substituted their judgment for the patient's subjective judgment of pain. The survey investigators recommended that knowledge and attitudes about pain management in this nursing population were in need of improvement. Despite the fact that these results originated from nursing students, students graduate to practice in the clinical environment. It is clear that improved communications in pain assessment and management are needed, in addition to an improved competency and attitude towards opioid prescribing.<sup>17</sup>

A fifth survey examined clinician's practice behaviors related to opioid prescribing to patients with chronic pain. Concerns regarding opioid therapy included prescription drug abuse (84.2%), addiction (74.9%), adverse effects (68%), tolerance (60.7%), and medication interaction (32%). The survey found that the majority of the respondents were comfortable in prescribing narcotics to patients with terminal cancer. However, they were less comfortable prescribing narcotics to patients with low back pain and persons with a current or past history of drug or alcohol abuse. Physician management practices suggested that urine toxicology tests were under-utilized with only 6.9% reporting obtaining this test before prescribing opioids and only 15.0% performing urine toxicology tests on patients already prescribed opioids.<sup>18</sup>

Another recent study examined clinicians' evaluation and management of co-existing mental health, substance abuse, and chronic pain conditions in patients with prolonged critical illness in the intensive care environment. Results indicated several barriers to care which included limited history taking and assessment of substance abuse and chronic pain conditions and the use of cognitive shortcuts. Consequences included nonintegration of substance abuse and chronic pain medications and diagnoses, episodic pharmacologic responses to psychobehavioral symptoms, and clinician-patient interpersonal tension. Contextual factors involved ambiguous psychobehavioral symptomatology, patients' critical illness and inability to speak, and competing clinical goals. The study resulted in this conclusion: The explicit evaluation and management of substance abuse and chronic pain conditions was highly variable and inconsistent across cases. Findings suggest that substance abuse and chronic pain conditions require monitoring and management similar to that required for other chronic conditions. Multidisciplinary, individual-level, and system-level responses are warranted to address the complex interplay of barriers, consequences, and context.<sup>19</sup>

A final study examined the International Classification of Functioning Disability and Health (ICF) Core Sets for chronic low back pain. The investigators examined if the questions asked were reflective of the patient's greatest concerns. It was reported that two questions (one related to recreation and leisure functioning and the second related to the ability to care for household objects) which were of greatest concern and most meaningful to the patient were not included in the brief core score used in assessment of functionality related to pain. **These results demonstrate the assessment-disconnect between healthcare providers and their patients, and suggest that improved patient-focused questioning is needed.**<sup>20</sup> New reports suggest that functional assessment (pinch, grip, range of motion) is also being added to comprehensive pain assessment for patients with rheumatoid arthritis to detect level of pain related to function in disabled patients who have learned to compensate.<sup>21</sup> These new forms of pain assessment related to functionality have yet to be adopted as routine in the clinical environment. **Discussion and assessment of function relative to pain is recommended as an essential element of multidimensional pain assessment.**

As mentioned, the gold-standard for pain screening and assessment is the patient report<sup>22</sup>. It is essential that the healthcare clinician who is with the patient at intake performing the initial assessment and subsequent re-assessments provides an accurate portrayal of the patient's report. Achieving optimal and safe pain-management practices is only possible if the assessment report is genuine. **Several studies have recently been published to reflect the need for improved assessment of pain.**<sup>23,24</sup>

Research supports and also suggests that maladaptive beliefs on behalf of the patient about chronic pain can have a negative impact on adherence and treatment response.<sup>24-29</sup> It is up to the clinician to encourage the patient to reveal her beliefs about her pain experience. Some areas of exploration include: denial that mood affects pain, denial that pain affects mood, perception of blame, inadequate support, disability entitlement, desire for medical breakthrough, skepticism of multidisciplinary approach, and conviction of hopelessness.<sup>26</sup> The usual problems encountered in providing coherent and effective treatment for any chronic medical illness are compounded in painful conditions by time,

society's choices, and the cultural role of the patient. **Effective treatment strategies for these patients depend on the persistence of and accurate interpretation of the assessment results by the nurse clinician to the prescribing physician.**<sup>30</sup>

The HealthCare Foundation of California published an extensive document, entitled, *Helping Patients Manage their Chronic Conditions* in June, 2005. The authors stress the importance of self-management support for patients with chronic conditions in order to encourage daily decisions that improve health-related behaviors and clinical outcomes. The executive summary underscores the importance of collaborative decision making through information exchange exemplified through various dialogue styles between care providers and patients. The report stresses the importance of care teams who are assigned established roles within the program and learn to effectively cross-communicate. Many sample dialogues are provided through-out the report and are meant to demonstrate effective communication styles through a series of questions and answers. The authors recommend self-management support as a means to inform and motivate patients with chronic conditions, leading to improved compliance and outcomes. **This state-wide initiative was developed out of a need for improved performance and exemplifies the educational need of nurses and other primary care providers to improve patient communications techniques, especially in patients who require care for chronic conditions.**<sup>31</sup>

In 2006, the American Medical Association published a voluminous report entitled: *Improving Communication- Improving Care; an Ethical Force Program™ Consensus Report*. The goal of the report was to help health care organizations communicate better and promote patient-centered communications as a formal performance improvement initiative. The Ethical Force Program uses a three stage process for developing performance improvement measures. It selects a specific domain of ethics for performance measure development, works an iterative process to develop a framework and expectations for assessing the domain, and presents a consensus on steps for healthcare organizations to use to assess and improve their performance in that domain. This process is needs-based, as a thorough review of the literature and current performance in the selected area is assessed. **It is clear from the amount of effort, cost and energy expended by this ethical task force that communications between patient and healthcare providers, including both physicians and nurse, is in need of improvement.**<sup>32</sup>

### **The Physician-Nursing Relationship**

Two important and recent communications will significantly impact the physician-nurse relationship in the sector of chronic pain management.

The first is a ruling released by the Louisiana State Court regarding a lawsuit *Spine Diagnostics Center of Baton Rouge, Inc., versus Louisiana State Board of Nursing*. **The ruling states that chronic pain management is not within the traditional scope of practice of a nurse anesthetist.**<sup>33</sup> Other states may soon follow suit, and as a result pain management practice by advanced practice nurses may be curtailed or altered in some way. **Alternately, the onus is being fully placed on nurses to ensure reduction of preventable complications associated with chronic conditions, with**

**reimbursement hinging on outcomes** (pay for performance), as indicated by the second communication, the *FY2008 Inpatient Prospective Payment System (IPPS)* ruling.<sup>34</sup> These changes in scope of practice and responsibility underscore the need for nurses and physicians to communicate more closely and work as an integrated team to reduce error and improve outcomes in their shared patients. Documentation of assessments and dual interpretation of the assessment results will provide a confirmatory model of care. **It is critical that both nurse and doctor are educated in the art and science of assessment for use in improving outcomes in chronic pain management.**

#### **Pain Management Team and Patient Relationship**

Assessment is an on-going and dynamic process. By involving the patient in his own care from the beginning of his healthcare journey, setting reasonable and achievable function-related therapeutic goals, educating the patient about the management and not the cure of her pain, using a multimodal approach, discontinuing or not selecting an opioid analgesic when the patient is not a candidate for opioid therapy, and assessing and monitoring the patient's pain, risk of misuse, abuse, addiction and diversion, and therapeutic progress; effective outcomes can be attained.<sup>37</sup> **Therapeutic compliance leads to effective and safe pain relief. Education is a key component of this paradigm, not only for the healthcare team, but also for the patient.**

## **Surveys**

### **National Survey Results Indicate Need for Improved Communications**

Recently published (2007) national survey shows results of nurses, physicians, and hospital executives regarding the impact of the nursing shortage report that most respondents found agreement in the shortage of nurses negatively impacting communications, patient-centered care and nurse-patient relationships. An additional area identified was reduced time for team collaboration. In response to these findings, it is clear that efficient and effective communication is sorely needed.<sup>36</sup>

One study in particular surveyed nursing students in Louisiana regarding their level of knowledge in pain management. These survey results, published in 2006, reported that this population of nursing students collectively scored poorly (mean score of 64%) and these results indicate an inadequate level of knowledge, especially in regard to pain assessment, analgesic dosing and side effect management, and an unfounded fear related to pain patient addiction. Answers in response to a case study revealed that students frequently substituted their judgment for the patient's subjective judgment of pain. The survey investigators recommended that knowledge and attitudes about pain management in this nursing population were in need of improvement. Despite the fact that these results originated from nursing students, students graduate to practice in the clinical environment. It is clear that improved communications in pain assessment and management are needed, in addition to an improved competency and attitude towards opioid prescribing.<sup>37</sup>

### ***Standards and Guidelines Reinforce Need and Requirement to Address Pain Management***

Because pain is so important to the provision of health care today, many organizations have developed standards by which those who provide health care can measure their practice. Two such organizations are the Joint Commission on Accreditation of Healthcare Organizations and the American Academy of Pediatrics. These standards indicate how seriously these national organizations view the reduction of pain and the provision of comfort for people of all ages. As stated previously, pain cannot be objectively measured in the same way, as for example, measuring the results of a blood test. Only the person who is suffering knows how the experience feels. The American Pain Society states that it is "not the responsibility of the clients to prove they are in pain; it is the nurses/physician's responsibility to accept the patient's report of pain".

### ***Attitude, Barriers and Knowledge Gaps***

- There have been several practice guidelines and regulatory guidelines put in place over the last several years which have made an impact on healthcare clinicians' awareness of the prevalence of pain, and that physicians and nurses need to take a patient's statement of pain seriously. On the other hand there is still along way to go in changing people's stereotypes and really changing the culture.
- Medical Schools and Nursing Schools spend little time on pain management despite the priority. Pain is not addressed in post graduate training or adequately in the nursing curriculum.

- There still exists a "mystic" around chronic pain and a "fear" of prescribing opioids.
- Educational gaps in understanding chronic pain syndromes. Differences in presentation and treatment

***Needs Assessment Survey/Past Participant Evaluation Outcome***

To further define the educational needs of clinicians, MediCom conducted a review of 305 healthcare professionals perceived continuing educational needs surveyed via email. The survey provided data regarding clinicians' top interest, preferred method of learning and other details regarding continuing education. The following results demonstrate topics that the respondents view to be the top 10 highest interests in ongoing education in the field of pain management and ranked by priority of need.

<b>Educational Assessment of Needs</b>	<b>High Priority</b>	<b>Moderate Priority</b>	<b>Low Priority</b>	<b>NA</b>
Assessment of pain	X	X		
General Pharmacology	X			
Communication	X			
Co morbidities associated with pain		X		
Shared goal setting		X		
Opioids	X			
Psychiatry		X		
Abuse and Addiction Issues	X			
Sleep Disorders		X		
Mechanisms of Pain	X			



Specific topics of interest related to pain are evaluated on an ongoing basis. The following information is a summary of completed survey reports from 2006 through 2007, year to date. Total number of evaluations completed were 800.

Topics of Interest	No Interest	Some Interest	High Interest
Acute Pain Management	5%	35%	60%
Chronic Pain Management	6%	18%	76%
Research and Scientific Application	20%	35%	45%
Pharmacological Advances in Pain Management	3%	15%	76%
Addiction, Abuse	16%	31%	75%

#### ***Need for Continuing Education***

Pain can alter the quality of life more than any other health-related problem. It interferes with sleep, mobility, nutrition, cognition and overall emotional well-being. Even though pain is such an important obstacle to comfort, it is one of the least understood, most under-treated and often discounted problems of health care providers and their patients. Because of multiple barriers to adequate pain management, all patients are at risk for under treatment of pain. Since pain is identified and reported primarily through patient self-reporting, difficulty in communicating increases the patient's risk for under-treatment.

Effective pain management by nurses requires them to have an understanding of the biological basis of the pain interventions which may be used to control pain. In addition an emphasis on a complete and ongoing pain assessment is paramount to developing a comprehensive treatment plan. Based on a review of the literature, needs assessment surveys as well as input from clinical experts there is a continued need to provide a platform for nurses to gain the most up to date information relative to unrelieved pain in chronic pain states.

#### ***Key Areas of Need***

- Adopting communication methodologies to improve assessment of pain
- Recognizing what questions to ask the patient and when and how to ask them
- Identifying and differentiating pain based on the patient's self-report
- Improved accuracy related to interpretation of assessment results to improve therapeutic strategy and treatment planning
  - Various pain expressions indicative of specific types of pain
  - Various types of pain indicative of condition-appropriate and evidence-based treatments
- Improved risk assessment leading to improved risk containment



**Conclusions**

Based on review of the literature, feedback from clinical experts, needs assessment data received from practicing pain management specialists and current standards and guidelines there is an ongoing need to provide knowledge and practice-based programs for nurses relative to the assessment and management of pain in everyday practice.

The incidence of chronic pain and abuse of prescription opioid analgesics continues to increase. Using assessment measures, effective and thoughtful patient-centered communication, and shared decision making, effective pain management can be realized.

All patients in pain deserve effective pain relief treatment. Learning to stratify patients from low to high risk of drug abuse, misuse, addition and diversion by using on-going assessment and monitoring helps the clinician achieve safe and effective pain management. Compliance by both patient and healthcare team helps to contain risk for all concerned, including the society at large. **Education is a key component and is emphasized as essential by numerous experts in healthcare and chronic pain management.**

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## MediCom Worldwide, Inc.

### Program Overview



#### ***Conflict of Interest Identification and Resolution***

MediCom Worldwide, Inc. is in full compliance with all rules and regulations put forth by the ACCME in the revised Standards for Commercial Support. MediCom has defined all those in position to control content as faculty, authors, presenters, planning committee members and all those internal staff who are in position to write, alter or impact the content of a CME activity.

All members identified in the planning process must provide signed disclosures to MediCom prior to the planning of the activity.

When individuals in a position to control content have reported Financial Relationships with one or more commercial interests, MediCom works with them to resolve such conflicts to ensure that the content presented is free of commercial bias. The following mechanisms have been identified in which to resolve conflicts as identified:

- Peer review of content by external reviewer
- Content validation by external topic expert and internal MediCom clinical editorial staff

#### **Disclosure Policy**

MediCom discloses the following information to learners: 1) the name of the individual, 2) the name of the commercial interest(s), and 3) the nature of the relationship the individual has with the commercial interest. MediCom also discloses to learners the name(s) of commercial interests supporting each CE activity.

Faculty disclosures will be documented and available to all participants via written participant handout information i.e.; syllabi, introductory slides, workbooks. Disclosure will be made available to audience at the start of each activity.

#### ***Post-Activity Evaluation and Feedback***

Course evaluation forms will be required for all participants who seek to receive continuing education credit. MediCom will summarize the information collected in a formal report to evaluate program effectiveness and participant learning.

Participants will evaluate the following components:

1. Overall content
2. Faculty teaching effectiveness
3. Format
4. Usefulness of information
5. Relevance to practice setting
6. Fair balance
7. Impact to the care of the patient experiencing pain

In addition to rating scales participants will be asked to participate in pre/post testing scenarios as a measurement of learning. Learning will be analyzed based on self-reported changes in knowledge or perceptions by the participants as a result of this activity and how well he or she will be able to apply learning to a specific practice setting. Three months post activity; participants will be reassessed based on retention and incorporation of behavior changes within their specific practice setting.

### ICPCD Activity Timeline

2008

	May 2008	June 2008	July 2008	August 2008	September 2008	October 2008	November 2008	December 2008	January 2009	February 2009	March 2009	April 2009	May 2009	June 2009	July 2009	August 2009	September 2009	October 2009	November 2009	December 2009
Faculty Confirmed for ICPCD	★																			
Invitations Distributed Via Direct Mail for ICPCD			■																	
Live Event ICPCD					★															
ESP Posting							✱	✱	✱	✱	✱	✱	✱	✱	✱	✱	✱	✱	✱	✱
Metrics and eval data from ICPCD live event							☎													
Metrics from online activity								📶												

★	Faculty Confirmed for ICPCD May 1, 2008
■	Invitations Distributed Via Direct Mail for ICPCD July-August 2008
★	Live Event ICPCD
✱	ESP Posting
☎	Metrics and Eval Data from ICPCD Live Event
📶	Metrics from Online Activity

MediCom Worldwide, Inc.

## Budget Summary and Options



## Budget Summary Live Activities

**ICPCD Accredited Satellite Symposium  
Proposal Overview**

Tactic	Description	Expected Outcome	Proposed Budget	
Satellite symposium at 2008 ICPCD international conference	Three-speaker accredited live symposium	Expected reach: 250 ICPCD participants onsite;	Direct Costs	\$118,800
			Indirect Costs	\$53,375
			<b>Total Costs</b>	<b>\$172,175</b>
Symposium adaptation: online accredited streaming video hosted on <a href="http://emergingsolutionsinpain.com">emergingsolutionsinpain.com</a>	Symposium filmed and edited into accredited streaming video posted at <a href="http://emergingsolutionsinpain.com">emergingsolutionsinpain.com</a>  Program to be active and available online for one year from posting date	Expected reach: 300 completions	Direct Costs	\$54,365
			Indirect Costs	\$25, 581
			<b>Total Costs</b>	<b>\$79, 946</b>



MediCom Worldwide, Inc.  
101 Washington Street  
Morrisville, Pennsylvania 19067

**Satellite Symposium in conjunction with the 8th International Pain and  
Chemical Dependency Conference**

<i><b>Program Parameters</b></i>	<i><b>Planned</b></i>
Accreditation Hours	1.5
Faculty	3
Symposium Attendees	250
Direct mail invitations to health care professionals	4,000
<i><b>Cost Summary</b></i>	<i><b>Budget</b></i>
Approximate Total, Direct Expenses	\$ 118,800
Total, Indirect Expenses	\$ 53,375
<b>ICPCD Satellite Symposium</b>	<b>\$ 172,175</b>

<i><b>Direct Expenses; Approximate</b></i>	<i><b>Budget</b></i>
<b>IPCD Admin Fee</b>	\$ 20,000
<b>Direct mail invitations</b>	
Direct mail invitations, mailed to registered meeting attendees; includes printing; development of database e-mail home page for registration	\$ 5,750
Graphic Design and formatting; typesetting of invitation and handouts	\$ 3,550
<b>Direct mail list purchase</b>	No charge
<b>Mail Services, postage, phone, fax, e-mail registration</b>	\$ 3,200
Includes assembly, mail services and postage. Follow up recruitment per phone, fax, e-mail	
<b>Invitation door-drop/advertisement fee</b>	\$ 5,000
<b>Participant handouts</b>	\$ 7,250
Includes printing of participant workbook; will include accreditation information, speaker biographical and disclosure information, agenda, and symposium graphics; total quantity 225 color copy; actual quantity printed 350	
<b>Posters advertisement materials</b>	\$ 2,400
<b>Faculty expenses</b>	
Honoraria: X 3	\$ 7,500
Meal expense faculty	\$ 300
Ground transportation	\$ 300
Room Rental	\$ 1,000
<b>Catering 250 X \$100 pp;</b>	\$ 25,000
<b>Audio/visual services: Including digital audio record</b>	\$ 18,000
<b>Filming; equipment, onsite management; film crew (x2)</b>	\$ 15,000

Confidential

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<b>MediCom expenses</b>	
Accommodations 2 staff x 2 nights	\$ 1,200
Meals	\$ 150
Ground transportation	\$ 125
Shipping/Fed Ex	\$ 75
Interview/talent	\$3,000
<b>Approximate Total, Meeting Management Direct Expenses</b>	<b>\$ 118,800</b>

<b>Indirect Expenses</b>	<b>Budget</b>
<b>MediCom pre-meeting coordination and development</b>	\$ 25,000
Includes faculty recruitment, agenda coordination, coordination with association; coordination with venue; participant recruitment; coordination of filming of patient video case study; equipment rental	
Medical/script writing	\$10,000
<b>Development Editorial</b>	\$ 2,500
Includes presentation slides x2 faculty approx. 90 slides; editorial content review; reference and fact checking; design and format	
<b>MediCom on-site symposium coordination; 2 MediCom staff</b>	\$ 1,600
<b>Accreditation of program for CME; includes distribution of CE certificates</b>	\$ 10,000
<b>Database development; record tracking</b>	\$ 775
<b>Project management</b>	\$ 3,500
<b>Total, Indirect Expenses</b>	<b>\$ 53,375</b>



101 Washington Street  
Morrisville, PA 19067

## Streaming Video Adaptation of a Live Satellite Symposium Held in Conjunction with the 2008 ICPCD

### Projected Budget Estimate

<b>Cost Summary</b>	
Approximate Total, Direct Expenses	\$ 54,365
Total, Indirect Expenses	\$ 25,581
<b>Streaming Video Adaptation of the 2008 ICPCD Satellite Symposium to ESP</b>	<b>\$ 79,946</b>

### Detailed Budget Itemization

<b>Direct Expenses, Approximate</b>	
<b>Transcription</b>	\$ 375
<b>Program announcement/advertisement</b>	
Adaptation of symposium design for direct mail, journal & banner advertisements	\$ 1,000
Blast email campaign: 4 separate e-mail blasts to target list of ESP members	\$ 1,800
<b>Enduring material production</b>	
Digitizing, Edit decision list and logging of footage	\$ 760
Digital Capture Station	\$ 3,000
Editing of all video and audio	\$ 4,050
Authoring of Final Content for Web Delivery	\$ 2,160
Adaptation of presentation slides to video format	\$ 1,250
Creation of animations, highlights, lower thirds, additional graphics	\$ 1,000
Adaptation of symposium program material design for Internet program and Render of all files	\$ 2,000
<b>Posting on EmergingSolutionsinPain.com</b>	
Infrastructure programming	\$ 3,750
Creation and posting of supportive text	\$ 2,500
Creation of graphic user interface PHP and SDK	\$ 2,520
80 minutes Encoding to Stream server	\$ 1,600
Streaming Server Programming	\$ 4,200
Streaming Minutes, Hosting, Maintenance and Troubleshooting	\$ 18,000
<b>Travel (film crew)</b>	\$ 3,900
<b>Stock photo/footage purchase</b>	\$ 500
<b>Approximate Total, Direct Expenses</b>	<b>\$ 54,365</b>

**Detailed Budget Itemization**

<b>Indirect Expenses</b>	
<b>Project management</b>	
Review of footage for editing direction	\$ 1,200
Coordination with internal teams	\$ 600
Digital Media direction and coordination of all media	\$ 1,800
Preparation and coordination of status meetings/updates	\$ 600
<b>Medical/scientific services</b>	
Editing review	\$ 600
Creation of additional self-assessment questions	\$ 400
Creation of supporting documents for individual accredited self-study programs	\$ 500
Proofreading	\$ 1,250
<b>Accreditation of program for CME, CPE, CNE</b>	\$ 7,500
<b>Continuing Education participant certificates</b>	
500 CE certificates; additional certificates to be charged at \$15 each	\$ 7,500
<b>Data management</b>	
Management of participant database	\$ 500
Data analysis and reporting	\$ 1,000
<b>Shipping, Blank Media, phone and fax</b>	\$ 500
<b>Administrative and accounting fees</b>	\$ 1,631
<b>Total, Indirect Expenses</b>	<b>\$ 25,581</b>

**Budget:**

Live Symposium	\$172,175
ESP Website Hosting	\$ 79,946
<b>Total Budget:</b>	<b>\$252,121</b>

**Budget Reporting and Reconciliation:****Appropriate Use of Commercial Support:**

- a. Funds should be in the form of an educational grant made payable to MediCom Worldwide, Inc.
- b. No other funds from Cephalon, Inc. will be paid to the program director, faculty, or others involved with the CE activity (additional honoraria, extra social events, etc).
- c. MediCom Worldwide, Inc. will furnish the commercial interest with documentation detailing the receipt and expenditure of the commercial support within 90 days of activity completion.
- d. In the event of program cancellation and or providers inability to complete the activity as designed, provider agrees to return all unused grant funds to Cephalon. Provider will furnish Cephalon with documentation detailing any and all receipts of expenditures related to expense incurred up to program cancellation.

**Signatures Required****for Grant Acceptance:**

Joan Meyer  
 President, MediCom Worldwide, Inc  
 101 Washington Street  
 Morrisville, PA 19067

**Payment Structure:**

50% due upon signing of agreement:	\$126,060.50
Final 50% due October 1, 2008:	\$126,060.50

### Exhibit B ACTIQ Risk Management Program

Provider is aware that ACTIQ® (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- ACTIQ is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- ACTIQ is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.
- ACTIQ is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

### FENTORA Risk Management Program

Provider is aware that FENTORA™ (fentanyl buccal tablet) [C-II] was approved subject to a Risk Minimization Action Plan (RiskMAP). The RiskMAP includes key safety messages that are essential to the safe use of this product. They are:

- FENTORA is indicated for the management of breakthrough pain in patients with cancer who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- FENTORA is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- No misuse of FENTORA should occur.
- Unintended (accidental) exposure to FENTORA should not occur.
- Patients considered opioid tolerant are those who are taking at least 60 mg oral morphine/day, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that FENTORA can be fatal to a child. Keep all units away from children and discard properly.
- FENTORA is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.



www.cephalon.com

Cephalon, Inc.  
41 Moores Road  
P.O. Box 4011  
Frazer, PA 19355  
Phone 610-344-0200  
Fax 610-344-0065

## INDEPENDENT EDUCATIONAL PROGRAM GRANT AGREEMENT

This Agreement is entered into as of this 6th day of November 2008, by and between Cephalon ("Cephalon"), located at 41 Moores Road, Post Office Box 4011, Frazer, PA 19355, and MediCom Worldwide, Inc. ("Provider") located at 101 Washington Street, Morrisville, PA 19053

WHEREAS, Cephalon has reviewed Provider's grant request to support a medical education program ("Program"); and

WHEREAS, Cephalon has determined that the Program has the potential to address educational gaps and improve patient care; and

WHEREAS, it is the intent of the parties to ensure that the Program will be independent, objective, balanced, scientifically rigorous, and have reasonable expectations of meeting its educational objectives so that it will not be viewed by the United States Food and Drug Administration ("FDA") as promotional and that Cephalon will not be viewed as responsible for its content; and

WHEREAS, Cephalon agrees to provide funding for the Program under the conditions set forth below.

NOW THEREFORE, Provider and Cephalon agree to the following terms under this Agreement:

1. Title of Program. The Educational Program is entitled "Emerging Solutions in Pain Meet the Experts Booth", and a copy of the grant request for the Program is attached hereto as Exhibit A.
2. Type of Program. The Program is:
  - ☐ accredited (e.g., continuing medical education or "CME"); or
  - ☒ an independent program where CE credits will not be offered.
3. Educational Partner. The Provider ☐ shall ☒ shall not use a third party that will provide assistance in support of the Program ("Educational Partner").
4. Educational Components. The expected components of the Program (e.g., number of live meetings, CD ROM, web-based, etc.) are as follows:
  - a. interactive meeting booth to be presented at the 25<sup>th</sup> annual meeting of the American Academy of Pain Medicine (AAPM).  
(ESP Exhibition Booth Meet-the-Expert)
5. Program Purpose. The Program is for scientific and educational purposes only, and is based on established bona fide and independently verifiable patient and/or

8/11/2008 10:00 AM

practitioner needs or gaps in healthcare performance, and is not intended to promote a Cephalon product, directly or indirectly. The Program is not a repeat performance of a prior program.

6. Grant Amount Funding Arrangements.

- (a) Cephalon will provide support for the Program by means of an educational grant in the total amount of \$150,635.00, as set forth in the budget attached hereto, or a pro rata amount based on the actual work performed and expenses incurred by Provider in accordance with the Budget. If the Program is canceled or terminated prior to completion, Provider shall return the grant, or any unused portion thereof, to Cephalon within thirty (30) days of such termination or cancellation. Provider shall have full responsibility for all funding arrangements of the Program, including any funding to be provided to its Educational Partner. Payment terms of the grant shall be made in accordance with any schedule/criteria provided in the Budget.
- (b) Within ninety (90) days of completion of the Program, Provider shall provide Cephalon with a detailed reconciliation of actual expenses incurred, and to the extent Cephalon has overpaid Provider for same, Provider shall provide a refund to Cephalon within thirty (30) days thereafter. Such detailed reconciliation shall be forwarded to Cephalon at the address above to the attention of Bhaval Shah Bell, PhD.
- (c) Provider may not use funds provided by Cephalon to pay travel, lodging, honoraria or personal expenses for non-faculty attendees. Grant funds may be used to reduce the overall registration fees for attendees. Grant funds may not be used to purchase capital equipment or to provide general operational support for an institution. Funds for hospitality shall not be provided, except that funds may be used for modest meals or receptions that are held as part of the Program, but such events shall not compete with, nor take precedence over, educational events. The appropriateness of any reception shall be at the sole discretion of the Provider, and Provider shall have final decision-making authority in connection with any such activities.
- (d) Funds may be used by the Provider to permit medical students, residents, fellows or other health care professionals in training to travel to and attend the Program; provided, however, that the selection of such students, residents or fellows who receive funds is made by either the academic or training institution, or, if by the Provider, such selection shall be made with the full concurrence of the academic or training institution.

7. Objectivity and Balance. Provider shall retain full responsibility for control of the content of the Program and shall ensure that the following requirements are met:



- (a) The Program material/information will be objective, balanced and free from commercial bias. All topics shall be treated in an impartial, unbiased manner. All discussions shall include a range of views about each class of drug and disease treatment options. Information shall not unfairly represent a spectrum of views favoring a product or class of products marketed by Cephalon or any other company. The title of the Program will fairly and accurately represent the scope of the presentation.
  - (b) Provider agrees that neither Cephalon nor its agents shall control the content of the Program. Provider agrees that there will be no scripting, targeting of points for emphasis, or other activities by Cephalon or its agents that are designed to influence the content of the Program. Cephalon personnel will not attend content development meetings unless requested in writing by the Provider or the Educational Partner make presentations of disease data and/or Cephalon product data to faculty. In this instance, Cephalon personnel may stay only for this portion of the meeting, and the accredited provider must be in attendance.
  - (c) If requested, in writing, by the Provider or Educational Partner, Cephalon Medical personnel may also provide written material on a Cephalon product or compound in development, such as *specific product data, manuscripts, posters, product labels and other scientific material* (not in slide format) in accordance with internal corporate guidelines based on the level of information that is acceptable to disclose.
  - (d) Cephalon shall not review the Program for medical accuracy or completeness and the Provider and/or Educational Partner (if any) agree that they will not make such a request of Cephalon.
  - (e) If a product marketed by Cephalon is the subject of discussion, the data will be objectively selected and presented, with an accurate reflection of favorable and unfavorable information about the product and shall also include a balanced discussion of prevailing information on alternative products and /or therapies.
  - (f) Any suggestions of superiority of one product or treatment over another will be supported by the body of available data and will not result from selective presentation or emphasis on data favorable to a particular treatment.
  - (g) Provider represents that neither it nor the Educational Partner (if any) has either an open complaint or decision from the Accreditation Council for Continuing Medical Education ("ACCME") or the FDA that a program provided by the Provider or the Educational Partner failed to meet standards of independence, balance, objectivity, or scientific rigor.
8. Risk Minimization Action Plan. Cephalon provides the following Risk Minimization Action Plan ("RiskMAP") information to all Providers. Neither

Cephalon nor its agents shall influence or control whether a product marketed by Cephalon is the subject of discussion. A RiskMAP is a strategic safety program designed to meet specific goals and objectives in minimizing known risks of a product while preserving its benefits. Any product marketed by Cephalon that is approved with a RiskMAP, and the key safety-related health outcomes outlined in that RiskMAP, are listed in Exhibit B. Provider agrees that it is aware of the RiskMAP(s) and the key safety messages.

9. No Faculty Selection. Provider shall retain full responsibility for the selection of the presenters, authors, moderators, and/or other faculty (hereinafter referred to collectively as "Faculty"). Provider and/or Educational Partner (if any) shall not request recommendations for Faculty from Cephalon
10. Disclosures. Provider will ensure meaningful disclosure of limitations of data (e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion). Provider will require that Faculty disclose when a product is not approved in the United States for the use under discussion.
11. Question and Answer Session. To the extent the Program is a presentation, Provider will ensure meaningful opportunities for questioning by the audience.
12. Financial Relationships. Provider will ensure meaningful disclosure to the audience of Cephalon funding and any significant relationship between individual Faculty and Cephalon. All meaningful disclosure(s) shall also be made in any written materials, including, but not limited to, announcements, brochures, syllabi and enduring material. Disclosures shall not mention product trade names.
13. Representations and Warranties. Provider represents that:
  - (a) Neither it nor the Educational Partner, if any, provides marketing, advertising, public relations, market research, medical education services or other consulting services (e.g., support for advisory boards) to any other department within Cephalon ("Marketing Activities");
  - (b) If Provider or the Educational Partner has an affiliated company that provides Marketing Activities to Cephalon, Provider has instituted appropriate controls and safeguards to ensure the Program (i) remains independent, objective, balanced and scientifically rigorous, (ii) is not intended to promote a Cephalon product, directly or indirectly, and (iii) is not in any way biased due to the affiliated company's relationship with Cephalon;
  - (c) Provider has determined that it is appropriate to use the Educational Partner in light of the requirements under this Agreement; and
  - (d) If Provider or its Educational Partner employs a former Cephalon employee who worked at Cephalon at anytime during the most recent year and who had marketing responsibility in the therapeutic area that will

be covered by the Program, then that former employee will not have any role in the planning, development or delivery of the Program.

14. Invitations/Enduring Materials. The Program audience will be selected by the Provider. The Provider shall be responsible for distributing materials about the Program, including invitations, reminder notices, and business reply cards that can be used by third parties to obtain any enduring Program material from the Provider.

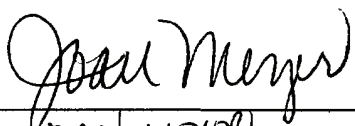
Notwithstanding the foregoing, Provider hereby authorizes Cephalon to distribute a subset of Program invitations/reminder notices that have been prepared or approved by the Provider.

15. Ancillary Promotional Activities. To the extent the Program is a live presentation, no promotional activities or product advertisements will be permitted in the same room as, or in an obligate path to, the Program. If the Program is a teleconference or webcast, no product advertisements or promotional activities will be permitted immediately prior to, during, or immediately after the delivery of the Program. If the Program is in print format, no product advertisements or promotional materials will be interleaved within the pages of the Program. If the Program is made available electronically, no product advertisements or promotional materials will appear within the Program material or interleaved between computer windows or screens of the Program, all as stipulated in ACCME Guidelines.

16. Compliance with Guidelines. Provider represents that the Program, including development of the Program and Program materials, shall conform to the American Medical Association ("AMA") Guidelines on Gifts to Physicians, the AMA Ethical Opinion on Continuing Medical Education, the ACCME Standards for Commercial Support, the FDA December 3, 1997 Final Guidance for Industry-Supported Scientific and Educational Activities, and the Pharmaceutical Research and Manufacturers Association ("PhRMA") Code on Interactions with Healthcare Professionals.
17. Logistical Status Reports. Provider and/or Educational Partner shall provide periodic reports to Cephalon regarding the management and logistics of Program components.
18. Miscellaneous.
- (a) No party shall use the other party's or its affiliates' name or trademarks for publicity or advertising purposes, except with the prior written consent of the other party.
  - (b) Provider agrees to obtain all consents, authorizations, approvals and releases that may be necessary for the production of the Program and of any written materials prepared in connection therewith.

- (c) No term, condition or other provision of any attachment or addendum to this Agreement shall supersede any term, condition or other provision of this Agreement, and with respect to any inconsistency or ambiguity, the Agreement shall control.

IN WITNESS WHEREOF, the parties, by their duly authorized representatives, agree to comply with all the terms and conditions of this Agreement.

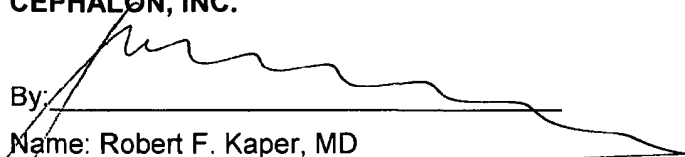
By:   
Name: JOAN MEYER  
Title: President

The above signatory is a duly authorized corporate officer of the IEP Provider.

Date: 11-19-08

Tax ID #: Redaction - Personal Information

**CEPHALON, INC.**

By:   
Name: Robert F. Kaper, MD  
Title: VP, Medical Affairs

Date: November 6, 2008

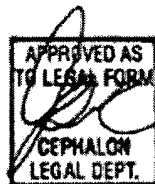


Exhibit A  
Copy of Grant Request

**Exhibit B**  
**ACTIQ Risk Management Program**

Provider is aware that ACTIQ® (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- ACTIQ is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- ACTIQ is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.
- ACTIQ is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

**FENTORA Risk Management Program**

Provider is aware that FENTORA™ (fentanyl buccal tablet) [C-II] was approved subject to a Risk Minimization Action Plan (RiskMAP). The RiskMAP includes key safety messages that are essential to the safe use of this product. They are:

- FENTORA is indicated for the management of breakthrough pain in patients with cancer who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- FENTORA is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- No misuse of FENTORA should occur.
- Unintended (accidental) exposure to FENTORA should not occur.
- Patients considered opioid tolerant are those who are taking at least 60 mg oral morphine/day, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that FENTORA can be fatal to a child. Keep all units away from children and discard properly.
- FENTORA is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.





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Phone 215.337.9991  
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## ***American Academy of Pain Medicine: ESP Exhibition Booth Meet-the-Expert***

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### **Program Title**

The Emerging Solutions in Pain Meet the Expert Exhibit Booth

### **Program Overview**

MediCom Worldwide, Inc. is proposing to utilize the Meet the Experts Booth as an informational and interactive display for educating clinicians at the 25<sup>th</sup> Annual Meeting of the American Academy of Pain Medicine (AAPM), to be held January 27 - 31, 2009 in Honolulu, Hawaii. The 25<sup>th</sup> Annual Meeting will include an international array of distinguished speakers from Australia, China, Canada, and the United States.

MediCom is also proposing to continue the cost effective and efficient tactic of tailoring the size and activities of the Meet the Expert Booth to reflect the attendance and specific purpose of the congress or association. In keeping with this and the ESP mission of focusing on emerging solutions in pain management to address the most critical and current issues, this meeting will include meet-the-expert sessions from the following options:

<b>Speaker</b>
Perry Fine, MD Professor of Anesthesiology University of Utah School of Medicine
Howard Heit, MD, FACP, FASAM Assistant Clinical Professor Georgetown School of Medicine
Rollin M Gallagher, MD, MPH Clinical Professor of Psychiatry and Anesthesiology University of Pennsylvania
Michael Cousins, MD, DSc, FANZCA, FRCA, FACHPM (RACP), FFPMANZCA University of Sydney

In 2009, MediCom will continue to update both the graphic imagery and multimedia displays to reflect current information in the fields of pain management and addiction medicine, as well as the tools, resources and activities available through ESP at the time of each meeting. Functionality for the full-size Meet the Expert Booth will include a seating area for meeting attendees to interact with the ESP clinical experts; computer terminals featuring interactive displays highlighting the Emerging Solutions in Pain initiatives, membership registration for the Emerging Solutions in Pain Web Site, and the Emerging Solutions in Pain Tool Kit Volume II.

### **Intended Audience**

The American Academy of Pain Medicine (AAPM) is the medical specialty society representing physicians practicing in the field of pain medicine. The practice of pain medicine is multi-disciplinary in approach, incorporating modalities from various specialties to ensure the comprehensive evaluation and treatment of the pain patient. AAPM represents the diverse scope of the field through membership from a variety of origins, therefore, the primary audience of the Emerging Solutions in Pain Meet the Experts Booth will be



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## **American Academy of Pain Medicine: ESP Exhibition Booth Meet-the-Expert**

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specialties such as anesthesiology, internal medicine, neurology, neurological surgery, orthopedic surgery, psychiatry, and psychiatry.

### **Program Objectives**

The purpose of the Emerging Solutions in Pain Meet the Expert Booth is to disseminate information concerning the Emerging Solutions in Pain Initiative to clinicians practicing in the field of pain management, and to educate those clinicians on the appropriate selection of the right therapy for the right patient, continual assessment and monitoring of pain patients, and on good practice management techniques. Clinicians visiting the booth will have opportunities to:

- (1) Interact with Emerging Solutions in Pain clinical experts in small discussion groups, focusing on discussions on the most critical and current issues in pain management today
- (2) View multi-media, interactive programs highlighting the Issues associated with minimization of misuse, abuse and addiction, the Emerging Solutions in Pain Tool Kit Volume II and associated case studies
- (3) Utilize interactive surveys via touch screen terminals and forms to review the key pain management attitudes and challenges facing diverse array of participants
- (4) Receive copies of the Emerging Solutions in Pain Tool Kit Volume II and other support materials, such as the ESP Patient Tool Kit materials and the ESP Accredited Monograph collection.
- (5) Gain exposure to the resources available at the Emerging Solutions in Pain Web Site, and register as a "member", thereby continuing to provide participants with ongoing education and support

### **Format**

The format of the *Emerging Solutions in Pain* Exhibition Booth Series is an interactive meeting booth, to be presented at the 25<sup>th</sup> Annual Meeting of the American Academy of Pain Medicine (AAPM). The Meet the Experts Booth will feature live peer-to-peer interactions with *Emerging Solutions in Pain* clinical experts, as well as interactive, multimedia programs that highlight the *Emerging Solutions in Pain* initiatives.

### **Awareness**

Announcement of the *Emerging Solutions in Pain* Meet the Experts Booth at the 25<sup>th</sup> Annual Meeting of the American Academy of Pain Medicine will be made via direct mail and/or blast email communications to registered meeting attendees and members, and via journal and/or banner advertisements. *Emerging Solutions in Pain* clinical experts and MediCom Worldwide staff members will provide all information at the Booth.



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## ***American Academy of Pain Medicine: ESP Exhibition Booth Meet-the-Expert***

### **Booth Surveys**

To maximize the information collection capabilities of the Emerging Solutions in Pain Meet the Experts Booth, and to identify in as much detail as possible, the educational needs of those clinicians who provide care to patients with chronic pain, the ESP Booth will support several diverse surveys and needs assessment campaigns during the three days of the AAPM Meeting. As part of ESP's ongoing campaign to elucidate the level of understanding of clinicians regarding the issue of tolerance and opioid prescription and use, ESP will utilize an electronic needs assessment survey focused on these topics. On the second and third days of the meeting, additional surveys will be conducted to identify clinician attitudes toward pain and opioids and key challenges to the effective treatment of pain.

<b>Date</b>	<b>Survey</b>
Wednesday, January 28 – Friday, January 30	Tolerance needs assessment
Thursday, January 29	Clinician attitudes toward pain and the use of opioid analgesics
Friday, January 30	Key challenges to effective pain treatment – phobia, cultural, medical, financial, legal/regulatory, religious, knowledge, resources

### **Request for Sponsor Support**

MediCom Worldwide is promoting the Emerging Solutions in Pain Meet the Experts Booth through a variety of methods, including direct mail, blast emails, and journal and banner advertisements.

As a supplement to these primary methods, MediCom may request the assistance of Cephalon, Inc. sales representatives in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of MediCom, and any such distribution will solely as a supplement to MediCom's primary methods of announcement and promotion.

### **Conflict of Interest Identification and Resolution**

MediCom Worldwide, Inc. is in full compliance with all rules and regulations put forth by the ACCME in the revised Standards for Commercial Support. MediCom has defined all those in position to control content as faculty, authors, presenters, planning committee members and all those internal staff who are in position to write, alter or impact the content of a CME activity.

All members identified in the planning process must provide signed disclosures to MediCom prior to the planning of the activity.

When individuals in a position to control content have reported Financial Relationships with one or more commercial interests, MediCom works with them to resolve such conflicts to ensure that the content presented is free of commercial bias. The following mechanisms have been identified in which to resolve conflicts as identified:

- Peer review of content by external reviewer
- Content validation by external topic expert and internal MediCom clinical editorial staff



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## ***American Academy of Pain Medicine: ESP Exhibition Booth Meet-the-Expert***

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### **Total Budget and Timeline**

The total budget to fund these activities is \$150,635.  
 100% of budget due at signing of grant.

Booth payment due:	November 1, 2008
Confirmation of faculty:	November 1, 2008
Booth Shipped:	December 1, 2008
Booth Activity:	January 27 – 31, 2009

### **Signatures Required for Grant Acceptance**

President MediCom Worldwide, Inc  
 Cephalon Representative

### **Budget Reporting and Reconciliation:**

#### *Appropriate Use of Commercial Support:*

- a. Funds should be in the form of an educational grant made payable to MediCom Worldwide, Inc.
- b. No other funds from Cephalon, Inc. will be paid to the program director, faculty, or others involved with the CE activity (additional honoraria, extra social events, etc).
- c. MediCom Worldwide, Inc. will furnish the commercial interest with documentation detailing the receipt and expenditure of the commercial support within 90 days of activity completion.
- d. In the event of program cancellation and or providers inability to complete the activity as designed, provider agrees to return all unused grant funds to Cephalon. Provider will furnish Cephalon with documentation detailing any and all receipts of expenditures related to expense incurred up to program cancellation.
- e. In order to successfully achieve the goals for this activity, 100% of requested grant funds will be required in order to implement grant.



www.cephalon.com

Cephalon, Inc.  
41 Moores Road  
P.O. Box 4011  
Frazer, PA 19355  
Phone 610-344-0200  
Fax 610-344-0065

## INDEPENDENT EDUCATIONAL PROGRAM GRANT AGREEMENT

This Agreement is entered into as of this 15th day of January, 2009, by and between Cephalon ("Cephalon"), located at 41 Moores Road, Post Office Box 4011, Frazer, PA 19355, and MediCom Worldwide, Inc. ("Provider") located at 101 Washington Street, Morrisville, PA 19053.

WHEREAS, Cephalon has reviewed Provider's grant request to support a medical education program ("Program"); and

WHEREAS, Cephalon has determined that the Program has the potential to address educational gaps and improve patient care; and

WHEREAS, it is the intent of the parties to ensure that the Program will be independent, objective, balanced, scientifically rigorous, and have reasonable expectations of meeting its educational objectives so that it will not be viewed by the United States Food and Drug Administration ("FDA") as promotional and that Cephalon will not be viewed as responsible for its content; and

WHEREAS, Cephalon agrees to provide funding for the Program under the conditions set forth below.

NOW THEREFORE, Provider and Cephalon agree to the following terms under this Agreement:

1. Title of Program. The Educational Program is entitled "Emerging Solutions in Pain," and a copy of the grant request for the Program is attached hereto as Exhibit A.
2. Type of Program. The Program is:  
☒ accredited (e.g., continuing medical education or "CME"); or  
☐ an independent program where CE credits will not be offered.
3. Educational Partner. The Provider ☐ shall ☒ shall not use a third party that will provide assistance in support of the Program ("Educational Partner").
4. Educational Components. The expected components of the Program (e.g., number of live meetings, CD ROM, web-based, etc.) are as follows:
  - (a) Four Live Meetings;
  - (b) One Emerging Solutions in Pain Website;
  - (c) One Print Supplements;
  - (d) Two DVD/VHS/CD-ROM's;

5. Program Purpose. The Program is for scientific and educational purposes only, and is based on established bona fide and independently verifiable patient and/or practitioner needs or gaps in healthcare performance, and is not intended to promote a Cephalon product, directly or indirectly. The Program is not a repeat performance of a prior program.
6. Grant Amount Funding Arrangements.
  - (a) Cephalon will provide support for the Program by means of an educational grant in the total amount of \$1,617,114, as set forth in the budget attached hereto, or a pro rata amount based on the actual work performed and expenses incurred by Provider in accordance with the Budget. If the Program is canceled or terminated prior to completion, Provider shall return the grant, or any unused portion thereof, to Cephalon within thirty (30) days of such termination or cancellation. Provider shall have full responsibility for all funding arrangements of the Program, including any funding to be provided to its Educational Partner. Payment terms of the grant shall be made in accordance with any schedule/criteria provided in the Budget.
  - (b) Within ninety (90) days of completion of the Program, Provider shall provide Cephalon with a detailed reconciliation of actual expenses incurred, and to the extent Cephalon has overpaid Provider for same, Provider shall provide a refund to Cephalon within thirty (30) days thereafter. Such detailed reconciliation shall be forwarded to Cephalon at the address above to the attention of Bhaval Shah Bell, PhD, Medical Affairs.
  - (c) Provider may not use funds provided by Cephalon to pay travel, lodging, honoraria or personal expenses for non-faculty attendees. Grant funds may be used to reduce the overall registration fees for attendees. Grant funds may not be used to purchase capital equipment or to provide general operational support for an institution. Funds for hospitality shall not be provided, except that funds may be used for modest meals or receptions that are held as part of the Program, but such events shall not compete with, nor take precedence over, educational events. The appropriateness of any reception shall be at the sole discretion of the Provider, and Provider shall have final decision-making authority in connection with any such activities.
  - (d) Funds may be used by the Provider to permit medical students, residents, fellows or other health care professionals in training to travel to and attend the Program; provided, however, that the selection of such students, residents or fellows who receive funds is made by either the academic or training institution, or, if by the Provider, such selection shall be made with the full concurrence of the academic or training institution.



7. Objectivity and Balance. Provider shall retain full responsibility for control of the content of the Program and shall ensure that the following requirements are met:
- (a) The Program material/information will be objective, balanced and free from commercial bias. All topics shall be treated in an impartial, unbiased manner. All discussions shall include a range of views about each class of drug and disease treatment options. Information shall not unfairly represent a spectrum of views favoring a product or class of products marketed by Cephalon or any other company. The title of the Program will fairly and accurately represent the scope of the presentation.
  - (b) Provider agrees that neither Cephalon nor its agents shall control the content of the Program. Provider agrees that there will be no scripting, targeting of points for emphasis, or other activities by Cephalon or its agents that are designed to influence the content of the Program. Cephalon personnel will not attend content development meetings unless requested in writing by the Provider or the Educational Partner make presentations of disease data and/or Cephalon product data to faculty. In this instance, Cephalon personnel may stay only for this portion of the meeting, and the accredited provider must be in attendance.
  - (c) If requested, in writing, by the Provider or Educational Partner, Cephalon Medical personnel may also provide written material on a Cephalon product or compound in development, such as *specific product data, manuscripts, posters, product labels and other scientific material* (not in slide format) in accordance with internal corporate guidelines based on the level of information that is acceptable to disclose.
  - (d) Cephalon shall not review the Program for medical accuracy or completeness and the Provider and/or Educational Partner (if any) agree that they will not make such a request of Cephalon.
  - (e) If a product marketed by Cephalon is the subject of discussion, the data will be objectively selected and presented, with an accurate reflection of favorable and unfavorable information about the product and shall also include a balanced discussion of prevailing information on alternative products and /or therapies.
  - (f) Any suggestions of superiority of one product or treatment over another will be supported by the body of available data and will not result from selective presentation or emphasis on data favorable to a particular treatment.
  - (g) Provider represents that neither it nor the Educational Partner (if any) has either an open complaint or decision from the Accreditation Council for Continuing Medical Education ("ACCME") or the FDA that a program provided by the Provider or the Educational Partner failed to meet standards of independence, balance, objectivity, or scientific rigor.



8. Risk Minimization Action Plan. Cephalon provides the following Risk Minimization Action Plan ("RiskMAP") information to all Providers. Neither Cephalon nor its agents shall influence or control whether a product marketed by Cephalon is the subject of discussion. A RiskMAP is a strategic safety program designed to meet specific goals and objectives in minimizing known risks of a product while preserving its benefits. Any product marketed by Cephalon that is approved with a RiskMAP, and the key safety-related health outcomes outlined in that RiskMAP, are listed in Exhibit B. Provider agrees that it is aware of the RiskMAP(s) and the key safety messages.
9. No Faculty Selection. Provider shall retain full responsibility for the selection of the presenters, authors, moderators, and/or other faculty (hereinafter referred to collectively as "Faculty"). Provider and/or Educational Partner (if any) shall not request recommendations for Faculty from Cephalon
10. Disclosures. Provider will ensure meaningful disclosure of limitations of data (e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion). Provider will require that Faculty disclose when a product is not approved in the United States for the use under discussion.
11. Question and Answer Session. To the extent the Program is a presentation, Provider will ensure meaningful opportunities for questioning by the audience.
12. Financial Relationships. Provider will ensure meaningful disclosure to the audience of Cephalon funding and any significant relationship between individual Faculty and Cephalon. All meaningful disclosure(s) shall also be made in any written materials, including, but not limited to, announcements, brochures, syllabi and enduring material. Disclosures shall not mention product trade names.
13. Representations and Warranties. Provider represents that:
  - (a) Neither it nor the Educational Partner, if any, provides marketing, advertising, public relations, market research, medical education services or other consulting services (e.g., support for advisory boards) to any other department within Cephalon ("Marketing Activities");
  - (b) If Provider or the Educational Partner has an affiliated company that provides Marketing Activities to Cephalon, Provider has instituted appropriate controls and safeguards to ensure the Program (i) remains independent, objective, balanced and scientifically rigorous, (ii) is not intended to promote a Cephalon product, directly or indirectly, and (iii) is not in any way biased due to the affiliated company's relationship with Cephalon;
  - (c) Provider has determined that it is appropriate to use the Educational Partner in light of the requirements under this Agreement; and

- (d) If Provider or its Educational Partner employs a former Cephalon employee who worked at Cephalon at anytime during the most recent year and who had marketing responsibility in the therapeutic area that will be covered by the Program, then that former employee will not have any role in the planning, development or delivery of the Program.

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Notwithstanding the foregoing, Provider hereby authorizes Cephalon to distribute a subset of Program invitations/reminder notices that have been prepared or approved by the Provider.

- 15. Ancillary Promotional Activities. To the extent the Program is a live presentation, no promotional activities or product advertisements will be permitted in the same room as, or in an obligate path to, the Program. If the Program is a teleconference or webcast, no product advertisements or promotional activities will be permitted immediately prior to, during, or immediately after the delivery of the Program. If the Program is in print format, no product advertisements or promotional materials will be interleaved within the pages of the Program. If the Program is made available electronically, no product advertisements or promotional materials will appear within the Program material or interleaved between computer windows or screens of the Program, all as stipulated in ACCME Guidelines.

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18. Miscellaneous.
- (a) No party shall use the other party's or its affiliates' name or trademarks for publicity or advertising purposes, except with the prior written consent of the other party.
  - (b) Provider agrees to obtain all consents, authorizations, approvals and releases that may be necessary for the production of the Program and of any written materials prepared in connection therewith.

- (c) No term, condition or other provision of any attachment or addendum to this Agreement shall supersede any term, condition or other provision of this Agreement, and with respect to any inconsistency or ambiguity, the Agreement shall control.

IN WITNESS WHEREOF, the parties, by their duly authorized representatives, agree to comply with all the terms and conditions of this Agreement.

**MEDICOM WORLDWIDE, INC**

By: Joan Meyer  
 Name: JOAN MEYER  
 Title: President

The above signatory is a duly authorized corporate officer of the IEP Provider.

Date: 2-1-09  
 Tax ID #: 23-3063738

**CEPHALON, INC.**

By: [Signature]  
 Name: Robert Kaper, MD  
 Title: Vice President, Medical Affairs

Date: 01-16-09

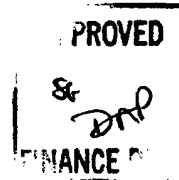


Exhibit A  
Copy of Grant Request



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## ***Emerging Solutions in Pain:***

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## ***Emerging Solutions in Pain:***

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## ***Emerging Solutions in Pain:***

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November 12, 2008

Bhaval Shah Bell, PhD  
 Associate Director, Medical Education  
 Cephalon, Inc.  
 41 Moores Road  
 Frazer, PA 19355

Dear Dr. Shah Bell:

MediCom Worldwide, Inc. is committed to continually identifying educational needs to develop programs and implement processes designed to address the identified gaps. A critical element of this process is the comprehensive multisourced needs assessment based upon current medical literature, expert opinion, member polls and health care provider surveys. The needs assessment to identify the educational disparities of clinicians who provide care to patients suffering chronic pain was amassed from reviewing the following data sources:

- *Emerging Solutions in Pain* (ESP) website member utilization
- ESP member polls
- Tolerance needs assessment questionnaire
- Advisory panel opinion
- Evaluation summaries of completed 2008 educational activities
- Association statements
- FDA requirements for RiskMAPs and REMs
- Current clinical practice guidelines
- Literature search

Based on the above identified educational needs, MediCom Worldwide, Inc. is requesting an educational grant from Cephalon, Inc. to support the continuation and further development of *Emerging Solutions in Pain*, or ESP, initiatives.

This foundation educational grant will include the continuation of the most valued ESP programs currently available on the website, as well as a faculty advisory board meeting, new identified educational programs, and the development and production of outcomes metrics to continually improve and provide the most current and relevant information and resources to clinicians in order to ultimately improve patient care.

All ESP initiatives will focus on identifying the right patient, the right therapy and the right outcomes thereby, balancing the clinical need to provide adequate analgesia to patients with chronic pain with monitoring for potential issues of abuse, addiction, and diversion of controlled substances.

These activities will be designed and planned as follows:

- The *Emerging Solutions in Pain* tactics includes:
  - ESP Foundation Initiatives:
    - ESP Peer review Panel and Expanded Clinical Advisors
    - 2009 Scientific and Clinical Expert Advisory Board
  - ESP Website Programming, Infrastructure and Maintenance of Content:
    - Website Migration to Joomla 1.5: Infrastructure Development and Site Programming
    - Knowledge Center
      - Clinical Expert Commentaries
      - In the Know Summaries



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- Knowledge Library FAQs
- ESP Multimedia
- Ask the Experts
- Resources
  - In the News
  - Web Resources and Links
  - Suggested Reading
- ESP Case Library
- ESP Interdisciplinary Content Integration
- Tools
  - Continual Update of Content and Tools
  - Online Distribution of the ESP Patient Tool Kit
- Emerging Solutions in Pain New Content, Tools and Resources Initiatives
  - ESP Patient Interview Decision Tree Algorithm
  - ESP Referral Tool
  - ESP Resource Learning Center
- Accredited Symposia
  - Live AAPM Symposia
  - Enduring Materials – Automated slides and audio
- Accredited Print
  - 2009 Monographs Series
  - 2008 Monograph Collection
- Exhibit Booth Program
  - Island Booth
  - Mini Booth
  - Booth Maintenance, Storage and General Support
- Outcomes Measurement Initiatives
  - Web-based Outcomes
  - Outcomes Study
- Targeted Specialist Recruitment and Awareness Campaign
  - Targeting Outreach and Awareness Program
  - The Beacon Weekly e-Newsletter
  - The ESP Scholarship Fund

The budget to fund these activities is approximately \$2,517,609. Please refer to the detailed budget section for complete grant funding proposals. These scientific events will comply with all ACCME, FDA, AMA, PhRMA code, OIG guidelines and ACPE regulations for industry-supported professional continuing education.

MediCom Worldwide, Inc. is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians and is accredited by the Accreditation Council for Pharmacy Education (ACPE) to provide continuing pharmacy education, as well as an approved provider of nursing continuing education through the California Board of Registered Nursing.

Thank you in advance for your consideration of this request.

Respectfully,

A handwritten signature in cursive script, appearing to read 'Joan Meyer'.

Joan Meyer  
 President, MediCom Worldwide, Inc.



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## ***Emerging Solutions in Pain:***

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#### **The Co-Occurring Epidemics of Undertreated Pain and Prescription Pain Abuse**

Pain continues to be a serious, undertreated public health problem in the United States. In testimony before an FDA advisory committee evaluating an opioid pain medication, Micke Brown, director of advocacy for the American Pain Foundation and a pain management nurse, spoke on the subject of the public health burden of undertreated pain.

"There is an epidemic of chronic pain in our nation. Though pain affects more than 76 million Americans it continues to be untreated, undertreated, or inappropriately treated. This continues to occur in spite of the knowledge that without timely, appropriately tailored care, pain can weaken the immune system and slow recovery from disease or injury. Persistent pain leads to needless suffering and lost productivity. Chronic pain is not only emotionally and physically debilitating for patients, it also places a tremendous burden on families and caregivers. The undertreatment of pain contributes to excessive health care costs and lost work productivity of approximately \$100 billion dollars every year. The pain crisis will become even more salient given increasing life expectancy and an aging baby boomer population."<sup>1</sup>

With increasing awareness of and responsibility for pain management, physicians have begun treating pain more aggressively, including using opioid pain medications. In January 2007, an article published in *JAMA* cited several other contributing reasons for the rise in opioid prescriptions.

- The importance of opioid analgesics in the treatment of persistent pain has been recognized by a number of organizations including the American Medical Association, the World Health Organization, American Geriatric Society, Veterans Health Affairs, and countless others.
- Advances in neuroscience have contributed to the understanding of physiologic responses to opioid actions, allowing physicians to understand pain and manage physical dependence.
- State and national agencies have adopted policies for use of opioids, providing reassurance to physicians. For example, the Federation of State Medical Boards has crafted a model policy, adopted by many states, on regulating the use of controlled substances. The policy emphasizes adequate pain control and that physicians should periodically monitor patients to prevent abuse.<sup>2</sup>

With rising patient and physician awareness of the need for and right to analgesics, opioid pain medications are among the most prescribed drugs in the United States. In the same FDA advisory committee meeting before which Ms. Brown testified, findings from the Treatment Episode Data Set (TEDS) was presented by Deborah Trunzo, Office of Applied Studies Substance Abuse and Mental Health Services Administration (SAMHSA).

TEDS tracks client-level information on treatment admissions collected by states and reported to SAMHSA. Estimated reporting coverage is 80%, representing 1.8 million admissions annually. Demographic variables are reported along with drug use history of top three substances of abuse at admission. All states report on "opiates other than heroin" as a group, and 16 states report specific brand names or formulations. *Ms. Trunzo reported that treatment admissions from opioid analgesics from 1996 – 2006 rose from 38,000 to 130,000.*<sup>3</sup>



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Both undertreatment of pain and abuse of prescription pain medicines result in significant public health burdens, and it is essential to address how to balance the unmet needs of patients living with inadequately treated pain with the potential for the very treatments for that pain to be diverted, misused, and abused.

What is less clear than the epidemiologic and surveillance data is precisely what educational activities and informational resources do practitioners need in meeting these challenges? There is no systematic approach to teaching pain management at any level of medical training. Mandates for pain education have led to fragmented educational initiatives that ignore the multidisciplinary nature of pain management.<sup>4</sup>

Having specialized in the pain and risk management setting for the past 15 years, MediCom Worldwide, Inc. has developed unique insights that are learned only with experience, enabling the development of high-impact, effective educational programs that are based directly on practitioner input, not inferences from secondary sources. *Emerging Solutions in Pain* (ESP) is one of those programs.

#### ***Emerging Solutions in Pain Generates Continuous, Real-World Needs Data***

In the past, needs assessments for ESP have been derived and deduced from expert opinion, continuing education program evaluations, and the published literature. The challenges of treating chronic pain conditions and the risks attached to those treatments are consistently well documented. From reports of undertreatment of a wide range of chronic painful conditions to the ever-rising safety, abuse, misuse, and diversion statistics related to opioid medications, the impact of these co-occurring societal health challenges is clear. Since 2004, ESP has supported multidisciplinary practitioners managing pain with information, education, and tools to optimize outcomes and minimize risks related to pain treatments. After four years of delivering the best-known evidence and proven practices, ESP has developed a loyal and growing group of users who have integrated the website resources into their armamentarium of practice supports.



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Exhibit 3.1: Membership Growth from 2005 to Date

Year	Members	Growth
2005	343	N/A
2006	1,507	+339.4%
2007	3,601	+139.0%
2008*	5,877	+63.2%

\* 2008 Data to 9<sup>th</sup> Nov 2008


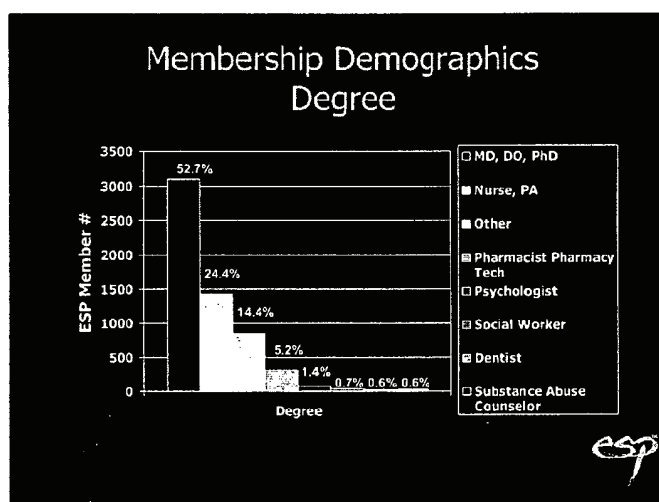


Exhibit 3.2: ESP Membership Demographics by Degree



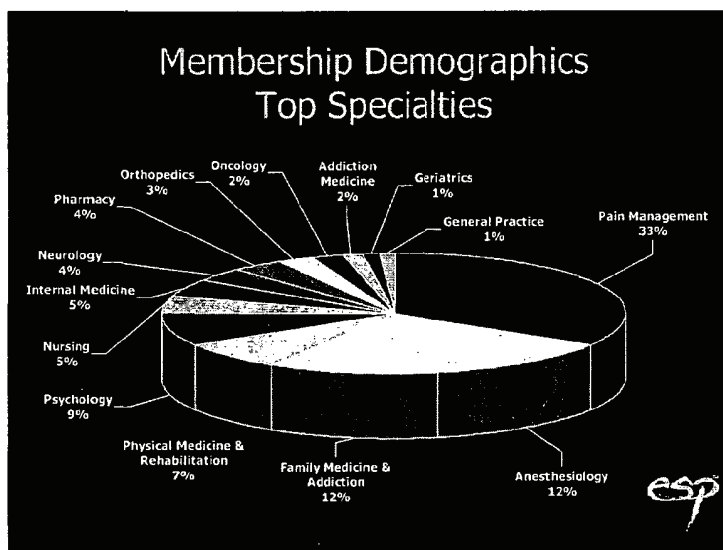


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***Exhibit 3.3: ESP Membership Demographics by Specialty***



The inherent ability to capture user sessions, traffic on individual pages, and downloads provides continuous educational and informational needs metrics that most other educational activities cannot approximate. Thus, primary research and data are the principle mechanisms used to determine the informational and educational needs of practitioners outlined in this grant request.

The specific content consumed on the ESP website provides primary metrics related to practitioner need. Current contents of the web resource are outlined in Section 7: ESP 2009 Grant Website Pages 52 to 64 and the following table shows the most frequently accessed information over the past year.



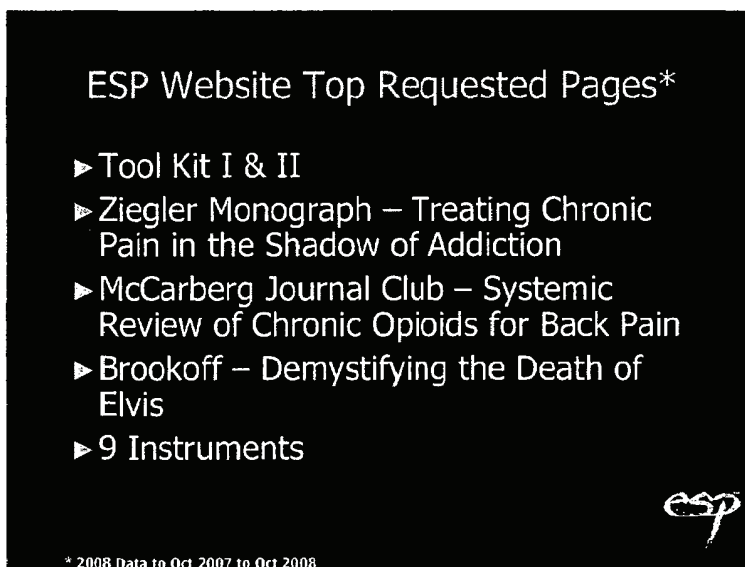


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***Exhibit 3.4: ESP Most Frequently Accessed Web Content***



Robust and relevant content delivered via innovative educational activities and programs has enhanced learning for steadily increasing numbers of practitioners. The average time spent on the ESP website is higher than any other pain/risk related practitioner site, see *Exhibit 3.5* for the user hits,<sup>\*</sup> sessions,<sup>†</sup> and average session length,<sup>‡</sup> attributed primarily to the broad and deep content that resides there.

<sup>\*</sup> A Hit is defined as a request for a file from the web server. The number of hits received by a website is a standard measure of a websites' popularity.

<sup>†</sup> A Session is defined as a series of requests from the same uniquely identified ESP member from log in to log out. A session contains multiple hits and page views.

<sup>‡</sup> Average Length of Session is defined as the amount of time that visitors spend on the site each time they visit. It usually represents a measure of user engagement.



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**Exhibit 3.5: ESP User Hits, Sessions and Average Length of Sessions**

ESP Website Usage Summary			
Metric	ESP Total	Date Range	Total
Hits	5,404,427*	2005	926,098
		2006	1,631,606
		2007	1,854,002
		2008*	1,841,852
Sessions	212,913*	2005	9,362
		2006	31,048
		2007	71,700
		2008*	108,383
Average Length of Session (minutes)	8:18*	2005	7:19
		2006	5:23
		2007	6:34
		2008*	10:22

\*2008 Data to 9<sup>th</sup> Nov 2008

**Exhibit 3.6: ESP User Average Length of Sessions versus the Main Pain Education Websites**

ESP: Comparative Statistics Average Session Length	
Site	Average Session Length* (minutes)
EmergingSolutionsinPain.com	16:21
PartnersAgainstPain.com	12:33
Medscape.com	6:40
NPECweb.org	6:33
Pain.com	5:56
StopPain.org	4:41
Pain-Topics.org	3:35
AmPainSoc.org	3:20
PainFoundation.org	3:07
PainEdu.org	1:58
PainBalance.org	1:45
PainKnowledge.org	1:26
ChronicPainNetwork.com	Insufficient data

Source: Compete.com (online activity data analysis group)  
\*Time Frame: October 2007 – October 2008



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Content is delivered by the optimal instructional design for the information to be communicated, then it is delivered through all appropriate media, recognizing the learning styles and preferences of practitioners. Content<sup>§</sup> has also been distributed quarterly via a series of 12 print monographs to a community of 45,000 multidisciplinary practitioners. The ESP exhibit booth program has reached over 19,000 people at leading conferences. See *Exhibit 3.7* for the complete booth metrics.

***Exhibit 3.7: ESP Exhibit Booth Metrics***

ESP Exhibit Booth Program	
Item	Number
Total Delegates	19,100
Faculty Sessions	14
Monographs Distributed	10,420
Tools Distributed	2,954
Awareness Items Distributed	4,608
Needs Assessments Completed	1,747
New ESP Members Enrolled	1,064

The ESP logo is a stylized, lowercase 'esp' in a script font.

#### **MediCom Worldwide, Inc. Primary Research in Pain Education Needs**

While ESP metrics are informative and definitive in and of themselves, providing fresh and relevant new content will result in an even higher reliance on and confidence in the ESP resources and ultimately improved practice outcomes, including minimized risk.

<sup>§</sup> Data to end December 2008



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In September 2008, MediCom Worldwide, Inc. fielded a number of surveys to various practitioner groups involved in the management of chronic pain. The results of these surveys identify what practitioners confront in daily practice and prioritize those topics in which more knowledge is sought.

*MediCom Worldwide, Inc. Pain Education Needs Survey.* This survey was distributed to the MediCom proprietary database of 13,905 practitioners in pain and addiction medicine who have participated in continuing education activities over recent years. More than 900 responded to the survey, with 782 (85.8%) currently involved in direct patient treatment. Those responses were used in the analysis. The targeted segments for the survey mirror those currently targeted for ESP activities and include physicians, nurses, physician assistants, and pharmacists. Results of the survey are summarized below.

#### *Demographics*

- Pain management specialists (32.2%) and addiction treatment specialists (20.6%) were the top two areas of full-time professional focus of responders, followed by physical medicine and rehabilitation, and psychology at 5.8% and 5.4% respectively.
- More than one-third (37.7%) of responders are MD/DO, 17.1% are MS/MA/MSW/MBAs, and 11.0% are RN/NP/MSNs. The current full-time work setting for most is office-based practice (26.8%), academic health centers (13.6%), and community hospital setting (13.1%).
- The number of years in practice were distributed somewhat evenly, with the largest group of responders in practice between 21-25 years (23.1%); 5-10 years and >25 years each registered 18.1%; 16.4% have practiced for 11-15 years.
- A cross-tabulation of the physician segment, 343 responders, was performed. The vast majority (43%) of responders classified themselves as pain management specialists, with physical medicine and rehabilitation and anesthesiology tied for second, with 13% each. IM/FP/GPs make up 8% of the responders. The majority work in an office-based practice (38%), and 45% have been in practice for 16-25 years.

#### *Practice Characteristics*

- More than one-quarter (28.2%) of all responders see <25 patients in an average week, and 25% see 26-50 per week. When asked the total seen with a pain complaint or condition, 44.7% reported that < 25 per week are seen.



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- The top three pain conditions managed are low back pain (68.5%), chronic non-cancer pain (40.4%), and neuropathic pain (32.3%). Fibromyalgia, acute pain, and headaches were each selected by approximately 20% of all responders.
- When asked what percentage of patients being treated for pain also had a history or active problem related to alcohol, illegal drugs, or opioid prescription drug abuse, about half (45-55%) of responders reported 0-10% of their patients fell into this category.
- However, the same number of responders reported that 31-40% of their patients presented with comorbidities related to psychiatric disorders such as depression or anxiety, or non-psychiatric conditions like diabetes or hypertension.
- In the physician analysis, the largest segment of these responders sees between 76-100 patients per week, seeing the same condition mix identified by all responders. When asked what percent of patients have a history or current problem with alcohol, prescription medicine, illicit drugs, or prescription opioid abuse or dependency, 57%-66% reported that fewer than 10% of patients fell into these categories. However, most responders manage substantial numbers of patients with psychiatric (82%) and non-psychiatric (73%) comorbidities.

#### ***Barriers to Optimal Outcomes***

- For patients who do not reach adequate pain relief, the most significant barriers were identified as limited access to multidisciplinary care providers (51.4%), patient concerns related to side-effects or addiction (20.7%), and reimbursement (19%). Physician concern related to addiction or side effects, and a lack of patient education tools for compliance were selected by approximately 16% of all responses. No substantial differences were noted in the physician demographic.

#### ***Knowledge Needed to Improve Practice***

- When asked "If you could expand your current level of knowledge of 10 topics that would help you meet professional challenges and improve your personal practice relative to the effective management of pain, which would you study?" the survey responders ranked the following topics as the top 25 of 55 choices. The numbers listed next to the topic represent the number of times the topic was included in a responders list of top 10 preferences.

1. Complementary and Alternative Pain Management	267
2. Basic Science of Pain and Addiction	253
3. Emerging Non-Opioid Pain Treatments	236
4. Behavior Modification Therapies	228
5. Comorbidities (Psychiatric)	224



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6. Chronic Non-Malignant Pain	216
7. Pain Management in Addicts	206
8. Personality Disorders, Pain and Addiction	177
9. Adjuvant Therapies	171
10. Pain and Sleep	157
11. Breakthrough Pain	154
12. Multidisciplinary Pain Management Approaches	152
13. Low Back Pain	149
14. Unrelieved Pain	145
15. Neuropathic Pain	137
16. Fibromyalgia	136
17. Physical vs. Emotional Pain	134
18. Adverse Drug Reactions	129
19. Agreements for Opioid Treatment	118
20. Dosing, Titration, Conversion between Opioids	116
21. Compliance Improvement Strategies	114
22. Hyperalgesia	114
23. Aberrant Behaviors	111
24. Dependence	109
25. Diversion Management	109

MediCom Worldwide, Inc. Primary Care Pain Survey 2008. Chronic non-cancer pain management is clearly a challenge in the primary care community; the Primary Care Education Network (PCEN), an accredited provider of education to primary care providers, reached out to MediCom to assist in understanding the educational needs of practitioners relative to chronic pain. The last week of August, an online survey was distributed to 39,378 PCPs in the PCEN database. After one week, 750 completed surveys were received. The survey was fielded to the mix of MDs, DOs, NPs, and PAs contained in the PCEN database who are representative of program participation. PCEN reports that their "typical audience is 65% MD/ DO, 26% NP, and 9% PA." Two cross-tabulations were performed to determine differences in educational need with length of time in practice and with patient volume. The differences measured are reported with each question. The following are the survey results.

- The overwhelming proportion (42%) of practitioners is in a primary care mixed provider practice. Nearly one-half of responders have been in practice more than 15 years and half fewer than 15 years. Nearly half of the responders (48%) see between 50–100 patients per week. Practitioners who see more than 100 patients per week equal 27%, with the lower-volume practitioners representing 26% of those who took the survey.
- More than one-third (38%) see between 25-50 patients per week with a pain complaint or disorder. 44% reported the number they see as 25 or fewer. Less than 20% see more than 50 patients per week. Adult medicine is the focus one-half to three-quarters of the time for nearly 70% of the PCPs responding. Geriatric practice is one-quarter or less for 48%, while 26% reported that geriatrics represents between 25-50% of their practice.



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- Lower back pain is a condition that more than two-thirds of PCPs are confronted with in their practice. Osteoarthritis, the second most often chosen condition, was cited by 26% fewer responders, emphasizing the significance of low back pain in primary care. Headache is seen with almost as much frequency as arthritis. Acute and post-acute pain management of abdominal and traumatic pain was selected by 31% and 23% of responders respectively. Additional musculoskeletal and neuropathic conditions were cited by approximately 20%.
- 20% reported that they do not usually refer patients to secondary care to manage their pain, indicating that the other 80% do refer, and 61% estimate they refer between 1 and 5 times in an average week.
- When asked, "If you could expand your current level of knowledge of 10 topics that would help you meet professional challenges and improve your personal practice relative to the effective management of pain, which would you study?" the results were conclusive. Survey responders overwhelmingly (58%) cited back pain as the #1 topic which they would like to learn about. It was chosen by 13% more responders than the second most frequently cited topic.
- The second tier of responses was chosen by about 300 of the surveyed group. Interestingly, they relate specifically to having command of effective pain management treatments -- complementary and alternative treatments, emerging therapies and optimal medication use all were topics 40-44% thought would improve personal practice relative to the effective management of pain.
- A larger and more diverse group of topics were selected by 30-39% of those surveyed, but they can be clustered into three main categories of topics:
  1. Pain types – neuropathic, chronic, acute, arthritis, fibromyalgia
  2. Pain and other conditions – depression, sleep, emotional vs. physical pain
  3. Practice strategies – multidisciplinary care approaches, practice management, legal/regulatory aspects of opioid treatments
- Ranked in the lowest 20% of responses were topics related to:
  1. Abuse and addiction risk, urine monitoring
  2. Pain and geriatrics, adolescents, pediatrics, and pregnant women
  3. Updates of clinical research and outcomes
  4. Cancer pain, breakthrough pain
  5. Hyperalgesia
  6. Acupuncture

American Pain Foundation 2007 Practitioner Survey of Attitudes, Perceptions, and Practices in Opioid Therapy for Chronic Non-Cancer Pain. October 2007, the American Pain Foundation completed an online survey to gain an in-depth understanding of provider prescribing patterns, attitudes and perceptions





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around opioid therapy for non-cancer chronic pain. Nearly 240 primary care physicians, pain specialists, nurse practitioners and physicians assistant responded. To qualify, respondents had to personally see/manage no less than 30 patients, of which at least 20 are prescribed Schedule II opioids (5 for PCPs, NPs, and PAs) in a typical month. The final sample consisted of 150 primary care physicians, 32 rheumatologists, 26 physiatrists, 26 nurse practitioners, and 4 physician assistants. 13% of the total respondents were board certified in pain management. The mean number of patients seen and/or managed by the total sample group per month was 413. The survey participants outlined that the mean percent of their patients who required pain medication was 52% and the mean number of non-cancer chronic patients prescribed Schedule II opioids was 49. A summary of their findings follows.

- Non-cancer pain is undertreated and misunderstood. 76% believe that moderate-to-severe non-cancer pain is undertreated in the United States. Interestingly, nurse practitioners and physician assistants were more likely than primary care physicians to believe pain is undertreated.
- Legal and regulatory issues have a dramatic impact on opioid utilization and the ability to provide optimal patient care. 77% say that today's drug control laws/policies impact their opioid prescribing practices. Only 9% are comfortable with their level of understanding about the current legal environment for opioid use. 27% of respondents said they could benefit from expanded guidance on monitoring patients on opioids for legal reasons.
- Fears and misunderstandings about addiction greatly hinder use of opioid therapy; these fears are compounded by patient and provider confusion over addiction, tolerance, and physical dependence. Nearly one-third (29%) of respondents' prescribing habits are affected by their fear of patient addiction. 77% of respondents say roughly one out of three of their patients face prejudices while filling their opioid prescription.
- Confusion about tolerance, dependence, and addiction is problematic. Less than one-quarter of respondents (23%) agree/completely agree that the clinical signs of tolerance and dependence are distinct enough from those of addiction. Most believe that physicians can differentiate between tolerance, dependence, and addiction in patients treated with opioids only some of the time (66%), or never (12%). Nearly half of those surveyed (46%) rely on psychological and behavioral insight into their patients to understand/determine the extent of addictive behavior as opposed to applying addictive medicine practices. 34% of respondents agree/completely agree that their patients often mistake tolerance for addiction.
- Non-clinical factors impact decisions to prescribe opioids. Nearly half of the respondents (45%) believe that most physicians today make their decision to prescribe opioids based on non-clinical considerations (societal and legal issues). "Risks of treating due to regulatory attention," "stigma of opioid choice," and "risks of non-treating due to societal pressure" are the most frequently cited non-clinical issues when determining whether or not to prescribe opioids.
- Managing patients using opioid therapy over time is a key challenge. In addition to fear of addiction and legalities, concerns of dose escalation (55%), and difficulty monitoring efficacy and



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usage (52%) were cited as top challenges regarding the use of opioids. Only 12% of respondents don't expect to treat patients with a succession of opioids and according to respondents, 90% of all chronic pain patients need modifications to their opioid treatment. Nearly half of respondents (45%) are concerned that drug-to-drug interactions limits their use of opioids for pain management; however, only 11% report that their treatment options have been limited due to drug-to-drug interaction.

- Lack of reimbursement/formulary support somehow hinders health care providers' ability to offer the ultimate care. 40% of respondents believe that it is important for them to have as many reimbursed opioid options as possible due to patient's non-responsiveness; however, less than half (45%) have all opioid treatment options reimbursed in the area where they practice.

#### **Summary of Needs Assessment Findings: Ongoing Challenges Associated with Optimizing Pain Treatment and Minimizing Risk**

Using the survey results in combination with ESP website intelligence, several areas of focus for educational activities emerge. While there are clearly differences in the practices of pain specialists and primary care providers, it is clear from the research that pain specialists and primary care providers have comparable pain conditions to manage, and both groups rate the most commonly encountered pain conditions at the top of their list of "more education needed" topics.

It is clear that the highest interest in managing chronic pain lies in alternative treatments, the participation of diverse specialties and disciplines in chronic pain care, improved patient education, and compliance strategies. This supports what the APF practitioner attitude survey measured – there are serious concerns related to the use of opioid medications in spite of demonstrated effectiveness in treating pain. Specific educational activities are needed that will support practitioners confidence in managing chronic pain, especially when opioid treatments may provide the optimal outcomes.

More education and tools are needed to address the:

- *Nature and rate of known risks versus benefits*
- *Types, magnitude, and frequency of risks and benefits*
- *Populations at greatest risk and/or those likely to derive the most benefit*
- *Reversibility of adverse events observed*
- *Using appropriate tools to minimize treatment risks while preserving treatment benefits*
- *Employing ongoing evaluation and reassessment approaches*
- *Making adjustments, as appropriate, to the treatment and risk minimization plans to further improve outcomes*



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Desire to better understand and manage the most commonly encountered conditions may also be driven by attitudes toward opioid use. Clinical topics the surveyed groups want to learn more about to improve their professional practices can be logically clustered.

- *Assessment of pain, stages of pain, and strategies for management*
  - *Diagnostic tools and approaches*
- *Pain types – chronic: low back pain, neuropathic, arthritis, fibromyalgia*
  - *Presentation, etiology, differential diagnosis, care plan, monitoring*
- *Pain types – post-acute: post-traumatic, post-operative*
  - *Presentation, etiology, differential diagnosis, care plan, monitoring*
- *Pain and other conditions – depression, sleep, anxiety, common comorbidities*
- *Effective pain treatments including complementary and alternative treatments, emerging therapies and optimal medication use, behavioral modification therapies*
- *Practice strategies – multidisciplinary care approaches, practice management, referral management, access to specialized supportive pain management resources*
- *Basic neurobiology and neuroscience of pain and addiction scored highly across surveys*

The pain specialist group and those PCPs who manage many chronic pain conditions with opioids have distinct interest in the broad array of opioid-related topics rated in the second tier of the MediCom pain survey:

- *Adverse Drug Reactions*
- *Agreements for Opioid Treatment*
- *Dosing, Titration, Conversion between Opioids*
- *Compliance Improvement Strategies*
- *Hyperalgesia*
- *Aberrant Behaviors*
- *Dependence*
- *Diversion Management*

A vast unmet need exists for effective management of chronic pain in spite of the availability of proven effective medications and the increasing incidence of abuse, misuse, and addiction. Therefore, it is essential to provide additional information and treatment strategies to health care providers through an educational program that is designed to enhance the health care professionals' approach to pain management and ultimately result in improved patient outcomes.

The ESP programs, at their core, address selecting the right pain treatment for the right patient. Assessing the potential for risk and monitoring for risk throughout treatment is an ongoing theme in ESP educational programs and communications. Loyal users of the ESP programs have come to depend upon the resource to support their professional practice.

Therefore, MediCom Worldwide, Inc. proposes the ongoing support of the *Emerging Solutions in Pain* program. The purpose of this grant request is to support ESP in becoming even more visible, relevant,



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better utilized, and more effective in meeting its mission than ever before. Targeted education and outreach will include:

- Health care practitioner newsletters
- Practice tools for health care practitioners
- Continuing education for health care practitioners
- Disease awareness programs
- Patient education programs and tools
- Consent forms/treatment contracts
- Data collection programs
- Tracking of practitioner education completion
- Safe use programs

To ensure that the resources expended on ESP are actually achieving the desired goals, evaluation of the program has been addressed in greater detail for 2009 than in previous years. The metrics program for ESP will include a continuum of measurements that will allow for critical assessment of performance overall in achieving goals. MediCom has selected a set of well-defined, evidence-based, and objective performance measures tailored to ESP to determine whether the program's goals and objectives are being achieved.

- Ongoing Needs Assessments – Surveys of health care practitioners using various modes (in-person, web-based) will be used by ESP to assess knowledge, attitudes, policies, and practices of health care practitioners.
- Effectiveness of Educational Activities – Assessments of comprehension, knowledge, attitudes, and/or impact on desired treatment behaviors will be conducted across all parts of the ESP program.
- Performance Metrics – Reach, frequency, downloads, session length, user sessions, members, will all be monitored to ensure maximum performance.
- Outcomes Measurement – A range of programs will be developed to assess and measure impact of ESP on patient outcomes.
- Surveillance System Baseline and Monitoring – While it is true that adverse event data are potentially biased due to many variable factors, there are trends related to specific patient populations that may be observed across surveillance systems. ESP will monitor several surveillance systems and will recruit those most familiar with the relevant data to the advisory board of ESP.



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Specific tactics and initiatives to address the ongoing unmet educational needs of health care professionals managing chronic pain and risks of misuse, abuse and addiction with estimated budgets will follow in subsequent sections 6 through 14.

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#### **References:**

<sup>1</sup> Food and Drug Administration Center for Drug Evaluation and Research, Joint Meeting of the Anesthetic and Life Support Drugs and Drug Safety and Risk Management Advisory Committee May 5, 2008. Open Public Hearing Speaker Micke Brown.

<sup>2</sup> Kuehn BM. Scientists probe ways to curb opioid abuse without hindering pain treatment. *JAMA*. 2007;297(18):1965-1967.

<sup>3</sup> Trunzo D. Admissions to Substance Abuse Treatment for the Abuse of Opioid Analgesics: Findings from the Treatment Episode Data Set (TEDS). Presented to an FDA advisory committee meeting May 5, 2008.

<sup>4</sup> Fishman SM. Recognizing pain management as a human right: A first step. *Anesth Analg*. 2007;105(1):8-9.



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#### **ESP Overview**

As evidenced by the assessed needs of practicing pain management and addiction medicine health care professionals, an educational and practice gap clearly exists regarding appropriate management of patients with chronic pain. Moreover, while outstanding educational programs are available that focus on the appropriate treatment and management of this patient population, these programs and activities are available across a diverse number of venues and formats. This has resulted in an educational environment in which clinicians actively seeking tools, education and resources are required to investigate multiple sources of education prior to identifying the most appropriate source to fulfill their individual needs.

To address these gaps, *Emerging Solutions in Pain* was launched in February 2005 as a broad-based initiative employing an integrated communication approach to education and information dissemination, and has resulted in a dynamic repository of information, tools, resources, and education for health care professionals who provide care to patients suffering debilitating pain.

#### ***The Emerging Solutions in Pain Achievements in 2008***

##### ***Emerging Solutions in Pain Membership***

The *Emerging Solutions in Pain* membership has continually grown since launch. The current membership is 5,877<sup>\*</sup> with a forecast of 6,000 members by year-end. More than half of these users are MDs/DOs/PhDs, with the next biggest member group being nurses and physicians assistants. The top specialties of users is outlined in Exhibit 4.4 with one-third being pain management specialists. A review of the ESP member specialties versus the two highest circulation periodicals (each being focused on prescriptions for pain) subscribers' specialties will identify the targeted areas for membership expansion. Please note that not all print-based prescribers will be potential targets for the ESP website (and hence membership) as their preferred learning format is print rather than digital/web-based media. The figures in Table 4.1 will provide a guide for expanding our ESP member numbers and for targeted awareness mailings in 2009.

**Table 4.1: ESP Members' Specialties versus Two Highest Circulation Periodicals Subscribers' Specialties**

<b>Specialties</b>	<b>ESP Members</b>	<b>Pain Medicine Subscribers</b>	<b>Practical Pain Management Subscribers</b>
Pain Management	1,006	2,438	3,502
Anesthesiology	393	Not distinguished	3,568 <sup>†</sup>
Neurology	108	5,146	3,988
Orthopedic Surgery	76	5,538	4,587
Phys Medicine & Rehab	218	1,936	2,038
Primary Care	389	23,452	18,424
Oncology	65	783	287
Rheumatology	29	2,113	847
Psychiatry/Psychology	263	Not distinguished	948

Source: ESP Membership List, Pain Medicine Media Planner, PPMJ Prospectus Document

<sup>\*</sup>Date to 9<sup>th</sup> November 2008

<sup>†</sup>This is listed as Anesthesiology/Pain Medicine





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The users are distributed worldwide (see Exhibit 4.2), although when looking specifically at USA membership (Exhibit 4.5), the majority of ESP members are based in California followed closely by New York and Florida.<sup>‡</sup>

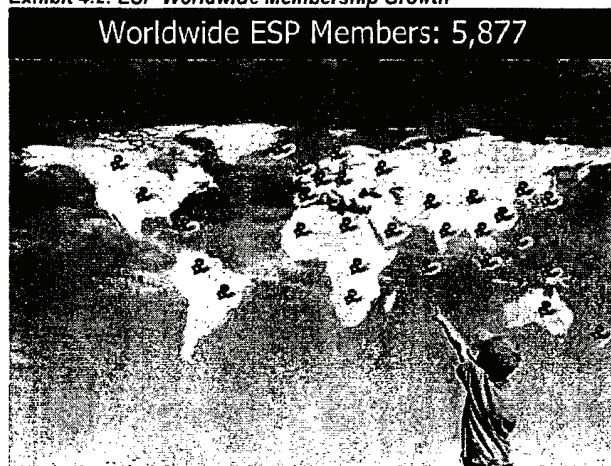
**Exhibit 4.1: ESP Membership Growth**

ESP Member Growth		
Year	Members	Growth
2005	343	N/A
2006	1,507	+339.4%
2007	3,601	+139.0%
2008*	5,877	+63.2%

\* 2008 Data to 9<sup>th</sup> Nov 2008



**Exhibit 4.2: ESP Worldwide Membership Growth**



<sup>‡</sup>The top 10 population rank amongst states are (1) CA-11.95%, (2) TX-7.81%, (3) NY-6.31%, (4) FL- 5.97%, (5) IL-4.20%, (6) PA-4.06%, (7) OH-3.75%, (8) MI-3.29%, (9) GA-3.12%, and (10) NC-3.08%





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Exhibit 4.3: The ESP Members Split by Degree

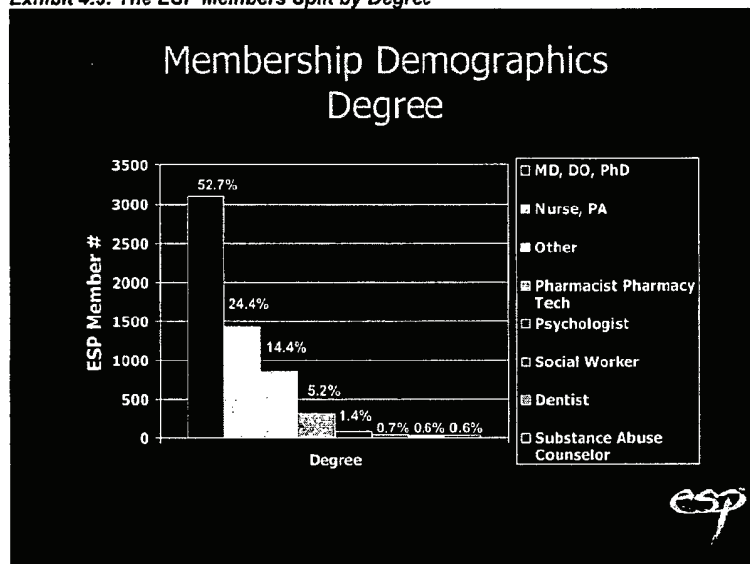
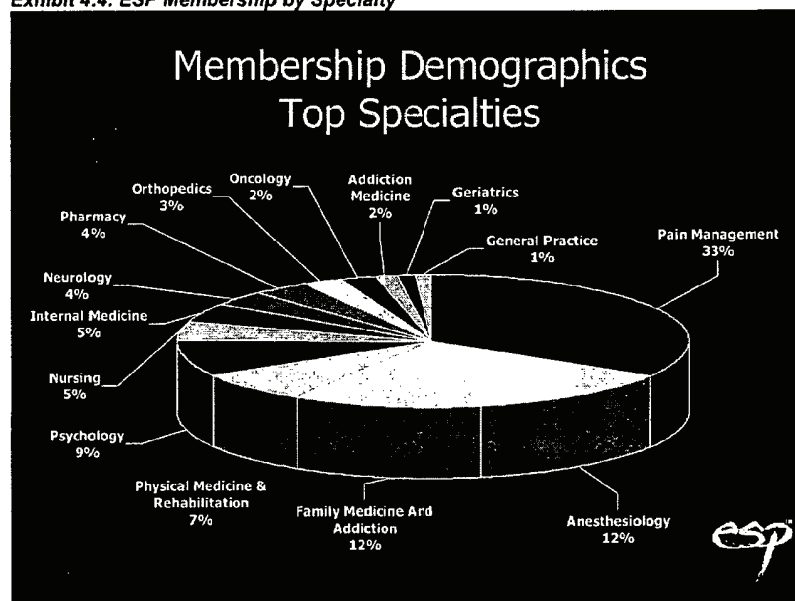


Exhibit 4.4: ESP Membership by Specialty



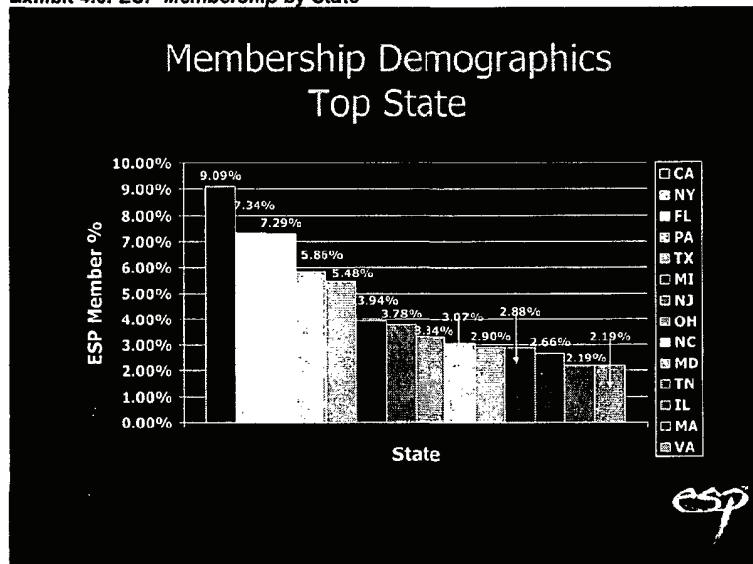


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Exhibit 4.5: ESP Membership by State



#### EmergingSolutionsinPain.com

The core educational component of this initiative is the ESP website, [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com), which offers the latest educational disease awareness information in the field of pain management. The website provides health care professionals with an extensive array of tools for assessing the potential for misuse, abuse and addiction in their patients with chronic pain, for monitoring their pain patients, and for accessing information regarding "best practices" in the long-term management of these patients. The website is sectioned into 6 main categories:

- Home
- About ESP
- Knowledge Center
- Tools
- Continuing Education
- Resources

Registered members of *EmergingSolutionsinPain.com* also have access to an array of clinical content to support the management of chronic pain. During 2008, the following achievements and content were added to the ESP website:

- About ESP
  - Worked with over 30 established and "rising star" KOLs (including, but not limited to: Abbott, Argoff, Bolen, Brookoff, Brown, Buckenmaier, Compton, Edwards, Fanciullo, Fine, Garcia, Gilson, Ginsberg, Good, Gourlay, Gudin, Haythornthwaite, Heit, Mao, McCarberg, Morris, Passik, Rajagopal, Schlyer, Schnierow, Shurman, Stanos, Strickland, Todd, Washington, Webster, Zeppetella, and Ziegler)



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- Won multiple quality, content and technology excellence awards (including Communicator Awards of Distinction, Videographer Awards of Excellence & Distinction, Gold & Honorable Mention Hermes Creative Awards, MarCom Awards, Telly Awards and Davey Awards)
- Released 5 press statements on the launch of new tools and awards
- Knowledge Center
  - 12 Expert Commentaries – 11 video-based and 1 print-based
  - 24 abstracts of medical journal articles relevant to the ESP initiative posted to the “In the Know” section from 17 different source journals
  - 24 video-based FAQs in the Knowledge Library
  - Multiple Multimedia postings, including high-definition videos
  - 12 Ask the Expert audio podcasts
  - 6 State Your Case columns
  - Converted 7 Pain & Addiction programs into high-definition full-screen videos
- Tools: ESP has launched 7 new and unique clinical tools including:
  - ESP Tool Kit II
  - ESP Patient Tool Kit
  - 9 Instruments of Assessment
  - Practitioners Guide to Patient Visits: Techniques and Tools
  - Patient Education Series
  - UDT PocketGuide<sup>§</sup>
  - UDT Interpretation Tool<sup>§</sup>
- Continuing Education
  - 4 Journal Club audio columns (including Ziegler, Gilson, Todd and Passik + Gudin<sup>§</sup>)
  - Management of 8 monographs as part of the Knowledge Series collections
  - 4 online monographs in pdf format with online evaluation and printable CE certificate (including Ziegler, Schnierow & Shurman, Webster, and Fanciullo & Washington<sup>§</sup>)
- Managed and sent 5 scholarship winners to national congresses
- Continually updated links and resources
- Produced 4 Beacon quarterly newsletters<sup>§</sup>

In addition, members are required to register prior to accessing the fundamental *Emerging Solutions in Pain* resources and tools. This enables tracking of information pertaining to member specialty and Tool use, and provides a method for updating site users with information regarding new programs and tools as they become available. As of November 9, 2008, membership at *EmergingSolutionsinPain.com* increased 163%, for a total of 5,877 clinician members.

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<sup>§</sup>Yet to be posted, Beacon Winter Newsletter is due to launch imminently



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Exhibit 4.6: The Emerging Solutions in Pain Home Page

The screenshot shows the homepage of the Emerging Solutions in Pain website. The layout includes a left sidebar with a Member Center login, a search bar, and a 'In the News' section. The main content area features a navigation bar, a 'Welcome to Emerging Solutions in Pain!' banner, a 'What's New?' section with links to various articles, and a 'Pain, Opioids and Sleep' expert commentary video player. The right sidebar contains a 'Cephalon' logo and a 'What topics would you like to see more of on this website?' section with radio button options.

**Member Center**  
Username  
Password  
☒ Remember me  
Lost Password?  
No account yet? [Register](#)  
[Membership Benefits](#)  
Search ESP for:  
62

**In the News**

- [SCOLR Pharma, Inc. Announces Positive Top-Line Results From...](#)
- [Ask Dr. Gott:](#)
- [Is aspirin right for you?](#)
- [BioDelivery Sciences to Meet with FDA to Finalize Proposed REMS for ONSOLIS](#)
- [Do You Have It?](#)

**HOME ABOUT ESP KNOWLEDGE CENTER TOOLS CE EDUCATION RESOURCES**

**Ask the Experts**  
Do you have challenging questions about pain management and addiction?  
[Click here for more details](#)

**Welcome to Emerging Solutions in Pain!**

**Practitioner's Guide to Patient Visits Official Launch**  
[Click here to visit now](#)

**What's New?**

- [Ask the Experts - Questions regarding the propriety of a family doctor continuing to give oxycodone or opiates to a patient with chronic back pain by Brookoff](#)
- [Knowledge Library - Are there new opioid therapy studies showing success vis-à-vis aberrant behaviors? - Steven D. Passik, PhD](#)
- [In the Know - Bidirectional Pain-Sleep Relationship](#)
- [Expert Commentary - Pain, Opioids, and Sleep - Lynn Webster, MD, FACPM, FASAM](#)
- [CE Monograph - A Multidisciplinary Approach to the Medical Management of Sleep, Chronic Pain, and Driving - by Bradley J. Schnierow, MD, MS and Joseph Shuman, MD](#)

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**esp EXPERT COMMENTARY**

**Pain, Opioids and Sleep**  
by Lynn Webster, MD

**What topics would you like to see more of on this website?**

- ☐ Different pain types - e.g., fibromyalgia
- ☐ Non pharmacologic therapies - e.g., acupuncture
- ☐ Personal development - e.g., medical writing
- ☐ Fun topics - e.g., jokes
- ☐ Other



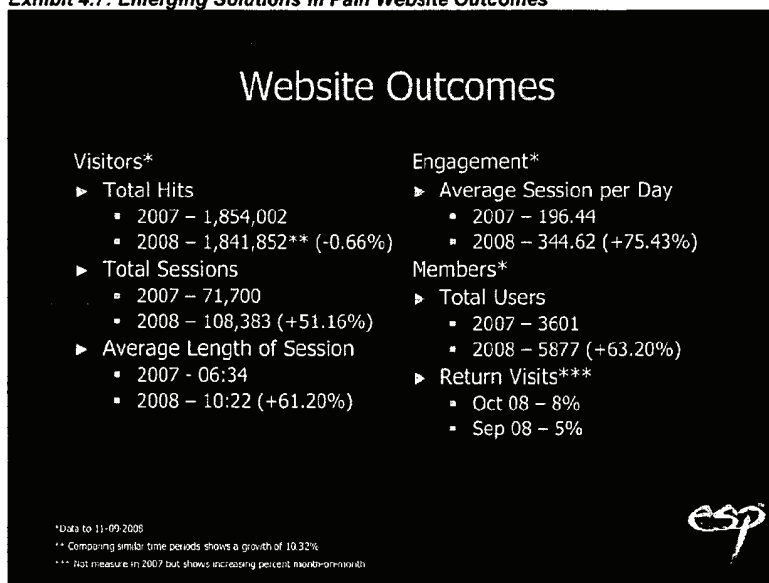
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Since the launch of the *Emerging Solutions in Pain* website in February 2005, almost 6.25 million hits to the site has resulted in more than 993 gigabytes<sup>1</sup> of information being downloaded directly from the ESP site to practicing clinicians; almost 750 megabytes of information is downloaded daily. Exhibit 4.7 demonstrates the trend of recent activity on the *Emerging Solutions in Pain* website in terms of visitor hits and sessions over time. A "session" is defined as a series of clicks on ESP by an individual visitor during a specific period of time; a session is initiated when the visitor arrives at ESP, and it ends when the browser is closed or after a period of inactivity. The average monthly ESP session for October 2008 is over 16 minutes. The significant number of monthly sessions is not surprising, given the many diverse tools available to practicing clinicians, both as printable documents and as electronic downloads.

**Exhibit 4.7: Emerging Solutions in Pain Website Outcomes**



**Please note that the Website Outcomes are comparing a complete year of 2007 to January-November 2008. When comparing a similar period of 2007 to 2008 all metrics show significant growth.**

#### **Meet the Expert Exhibit Booth**

The exhibit booth is an informational and interactive display for educating clinicians in the *Emerging Solutions in Pain* initiatives at national congresses and association meetings. In 2008, the ESP booth was tailored to activities to the size and specific purpose of the congress or association. Thus, at larger meetings, the full Meet the Expert Booth is utilized, while a smaller *Emerging Solutions in Pain* booth is displayed at smaller congress and association meetings.

<sup>1</sup> 1 gigabyte = 1,024 megabytes



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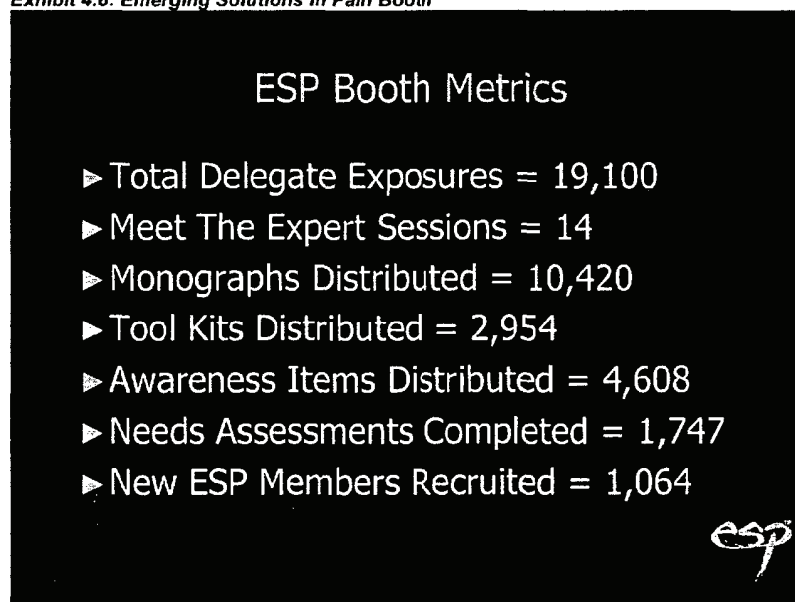
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In 2008, the ESP booth was displayed at the following congresses:

- American Academy of Pain Medicine
- American Pain Society
- American Association of Physician Assistants
- International Association for the Study of Pain
- American Society of Pain Management Nursing
- International Congress on Pain and Chemical Dependency
- American Academy of Physical Medicine and Rehabilitation

The purpose of the *Emerging Solutions in Pain Meet the Expert* booth is to disseminate information concerning the *ESP* initiative to clinicians practicing in the field of pain management, and to educate those clinicians on the assessment and monitoring of pain patients and on good practice management techniques. The 2008 booth metrics are as follows:

***Exhibit 4.8: Emerging Solutions in Pain Booth***





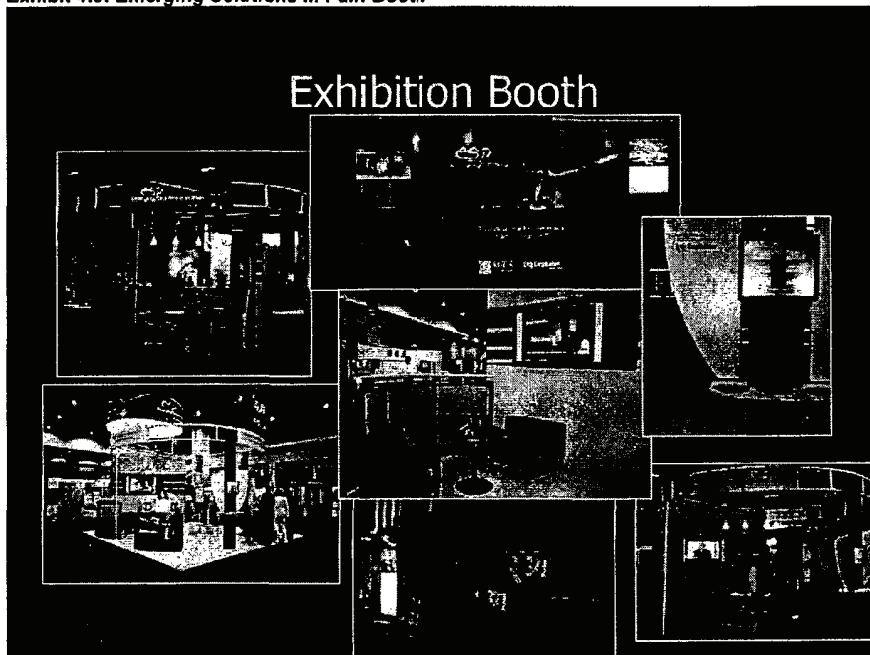
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***Exhibit 4.9: Emerging Solutions in Pain Booth***



#### ***Live Events***

A full-day conference satellite symposium entitled "Emerging Solutions in Pain: The Interface of Pain and Addiction" was presented at the 2008 American Academy of Pain Management Annual Conference. The core group of faculty included:

- Howard Heit, MD, FACP, FASAM
- Jennifer Bolen, JD
- Steven D. Passik, PhD
- Lynn R. Webster, MD, FACPM, FASAM
- Douglas Gourlay, MD, MSc, FRCPC

#### ***The Symposium Topics Included:***

- The Interface of Pain and Addiction: The Challenges of Safe and Effective Treatment that Maximizes Positive Outcomes  
*Howard Heit, MD, FACP, FASAM*
- Rational Pharmacotherapy: Opioids, Nonopioids, and Adjuvant Therapies  
*Lynn Webster, MD, FACPM, FASAM*





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- **Assessment Strategies: Identifying the Best Therapy for the Individual Patient: Practical Approaches to Successful Monitoring: Making a Differential Diagnosis**  
*Steven D. Passik, PhD*
- **Case Study: Chronic Pain and Substance Abuse Issues**  
*Douglas Gourlay, MD, FRCPC, FASAM*
- **Why You Need to Understand the Synergy of Pain and Addiction: An Interactive Session**  
*Jennifer Bolen, JD*

#### **The Symposium Evaluations:**

The 108 evaluation forms that have been returned are as follows:

- 62 CME
- 7 CPE
- 23 CNE
- 13 CE
- 3 Unknowns

The following exhibits (Exhibits 4.10 to 4.19) provide a top-line overview of the completed and returned meeting evaluations showing that 43% of the delegates prefer live meeting for their continuing education.

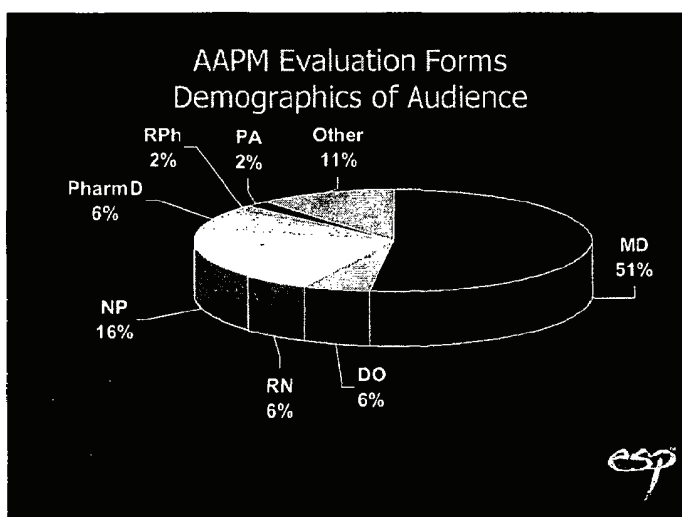


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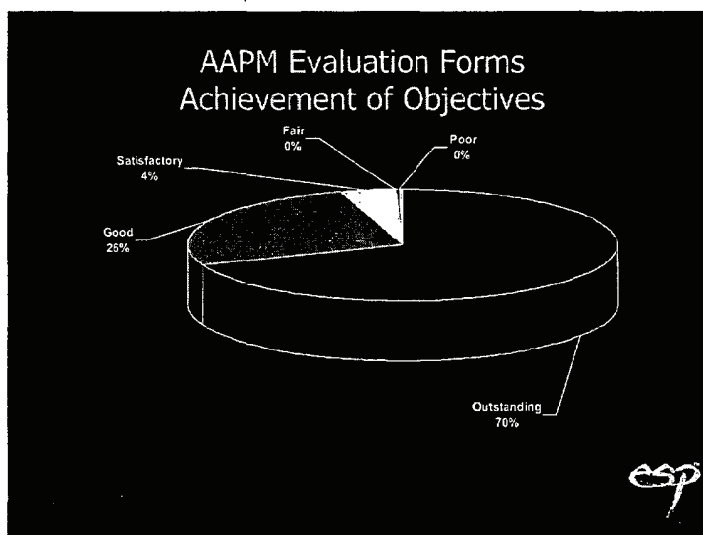
## *Emerging Solutions in Pain:*

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**Exhibit 4.10: Demographics of the AAPM Symposium Delegates**



**Exhibit 4.11: Achievement of the AAPM Symposium Objectives**



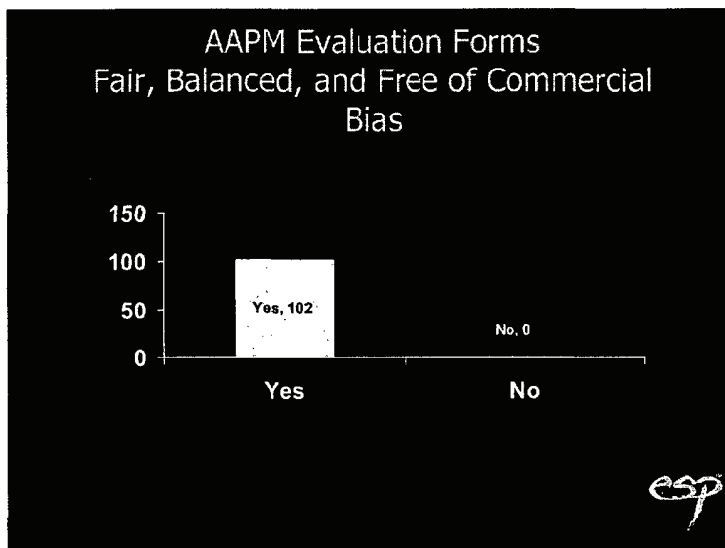


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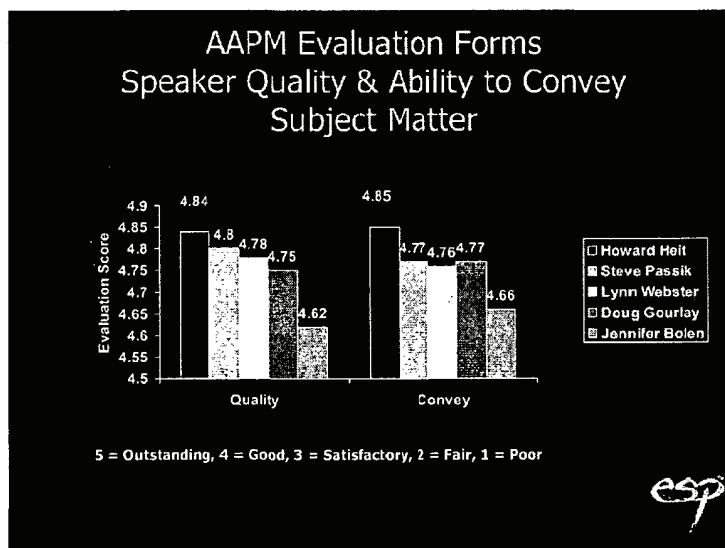
## ***Emerging Solutions in Pain:***

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***Exhibit 4.12: Fair, Balanced, and Free of Commercial Bias of the AAPM Symposium***



***Exhibit 4.13: AAPM Symposium Speaker Quality and Ability to Convey Subject Matter***





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Exhibit 4.14: AAPM Symposium Information

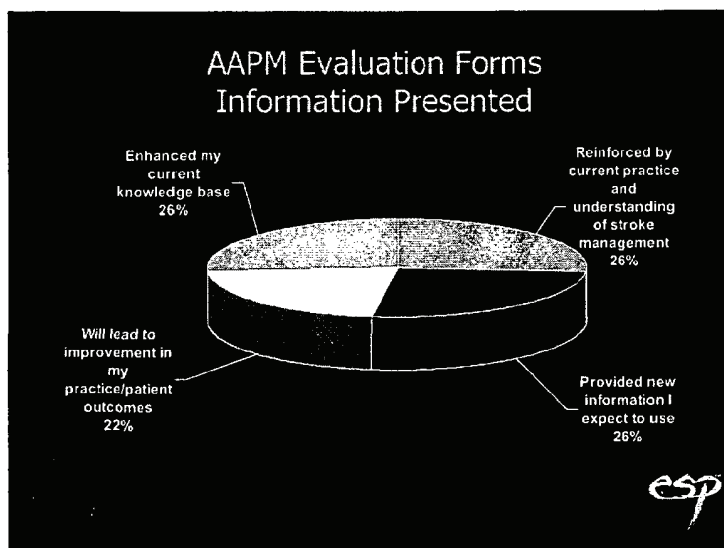
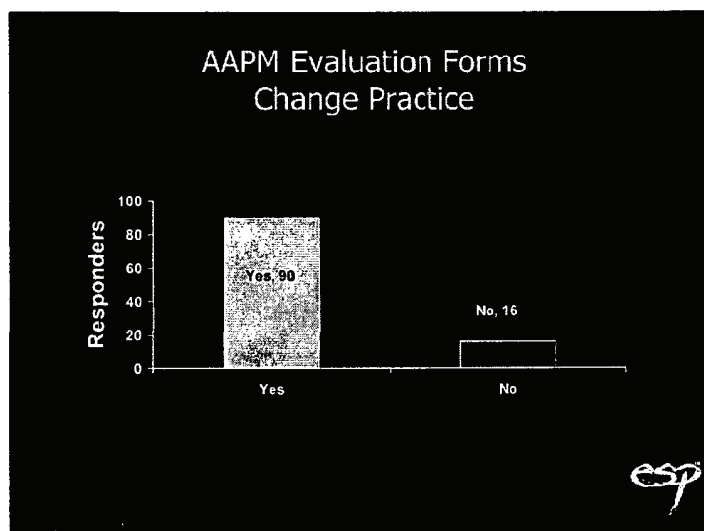


Exhibit 4.15: Did the AAPM Symposium Cause you to Clinical Practice



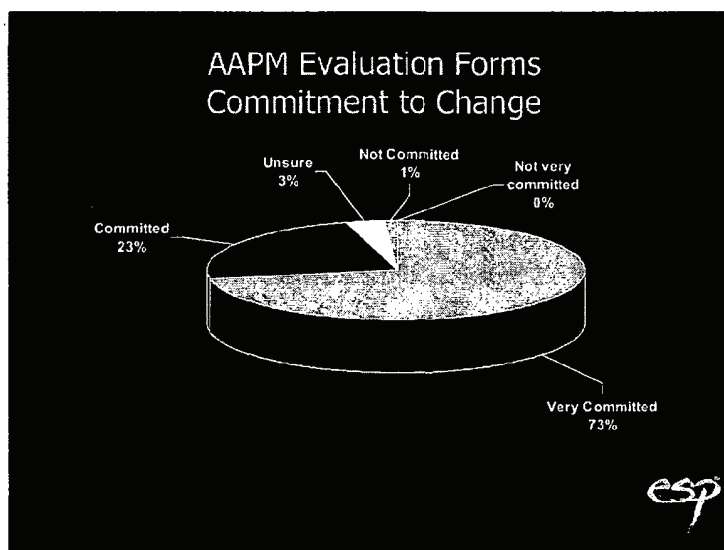


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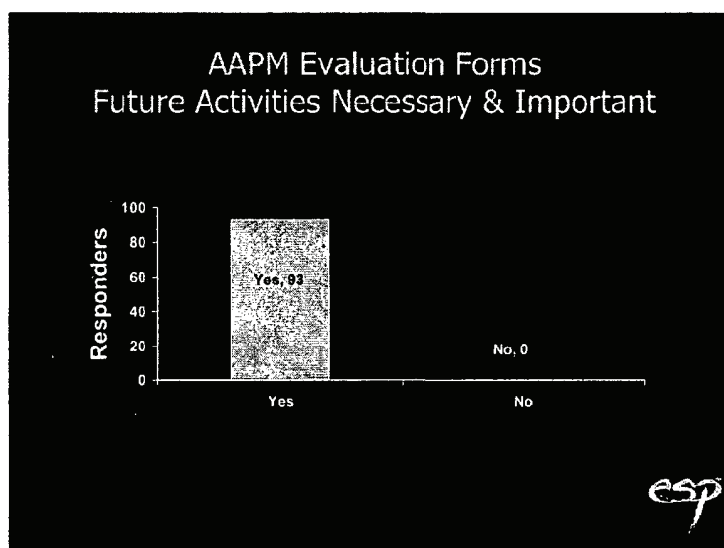
## Emerging Solutions in Pain:

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**Exhibit 4.16: AAPM Symposium Delegates Commitment to Change Practice**



**Exhibit 4.17: Are Activities Such as the AAPM Symposium Necessary & Important**



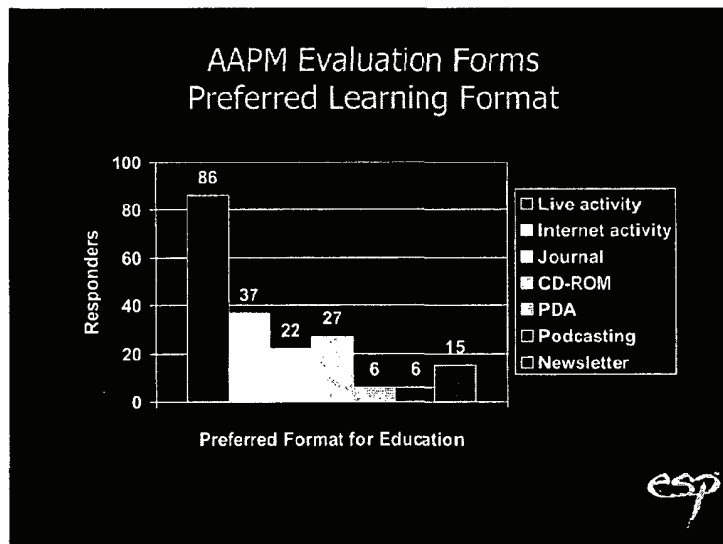


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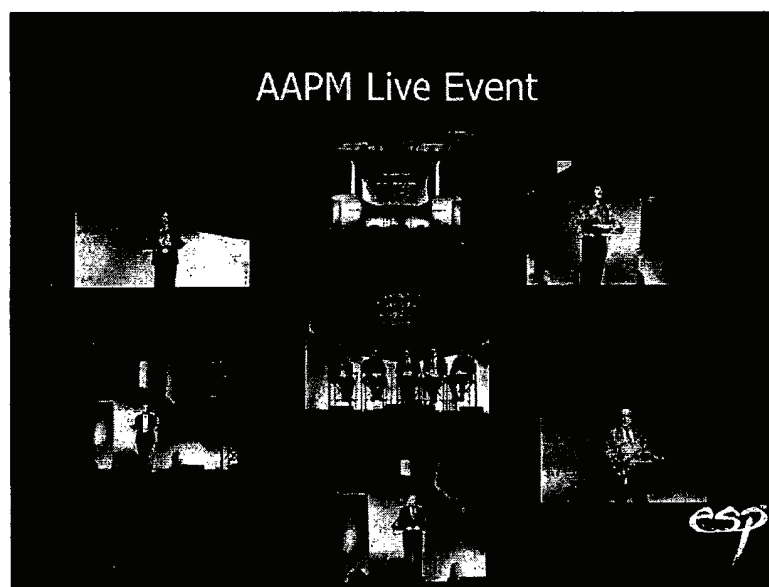
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Exhibit 4.18: AAPM Symposium Delegates Preferred Learning Formats



Delegates were able to select more than one preferred format.

Exhibit 4.19: Emerging Solutions in Pain Live Event





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#### **Emerging Solutions in Pain in 2009:**

In 2009, the *Emerging Solutions in Pain* Initiative will take the appropriate next steps to progressively change the educational programs, building on past learning, the current environmental changes, and future educational needs toward greater improvement in pain patient care outcomes.

We will continue to pioneer the creation and dissemination of educational tools, resources, and activities that support the goals and objectives outlined within this overview to ultimately become the "GO TO" resource for the best current evidence and practical tools for achieving optimal outcomes in the management of chronic pain while minimizing the risk of abuse, misuse, and diversion.

In 2009, MediCom Worldwide, Inc. will be seeking multi-educational support to further enhance the credibility of content provided and disseminated. The grants will be divided into two categories:

- Core Activity Operating Grants – to support the ongoing conduct of basic program with essential upgrades and enhancements
- Expansion Grants – to support ventures into new audience groups, expanded metrics, ramped-up distribution outlets

Cephalon, Inc. will be recognized as the founding grantor as appropriate within the 2009 ESP content.

#### **The Emerging Solutions in Pain Mission Statement**

*Emerging Solutions in Pain (ESP)* is an ongoing educational initiative developed to address some of today's most critical issues in pain management. These issues involve balancing fundamental rights of patients and clinicians with the challenge of risk containment for opioid misuse, abuse and addiction associated with medical prescribing and use of controlled substances. Through evidence-based scientific data, validated tools, and the expertise of a cadre of leading pain and addiction medicine experts, the *ESP* program provides clinicians with guidance in the implementation of good practice management techniques. Site features and programs emphasize favorable interaction with regulatory and law enforcement agencies, as well as effective assessment, monitoring and documentation strategies; all of which contribute to the overall goal of optimizing outcomes for patients in pain.

#### **The ESP Vision**

To unite professionals committed to relieving pain suffering; increase knowledge of best clinical evidence and promotion of skills for effective pain management; accredit and encourage clinicians who care for pain sufferers to actively participate in ongoing professional development; and foster interdisciplinary teamwork for the practice of pain management.

#### **The ESP Values**

ESP will achieve its objectives by continuing to be a valued resource to pain management and addiction medicine health care professionals. *ESP* will:

- Educate by providing peer-reviewed learning formats to keep our members informed of the critical issues in pain management today;
- Create an environment of coaching, education, skill acquisition and delivery that serves to validate improved patient care outcomes, and





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- Continually strive for excellence in all we do so that we may be seen by our members, our referral sources, our colleagues, and our community as the preferred provider of pain management educational services.

#### **ESP Global Educational Objectives**

The ESP 2009 objectives which are designed to fulfill the educational needs of health care professionals, who provide care to patients with chronic pain include the following:

- Grow the ESP Membership from 6,000 Members to 10,000
  - Retain current members
  - Recruit new members
    - Higher % of current audiences
    - New groups – pharmacy, high-prescribing opioid PCPs
  - Improved demographic data collection
  - Ongoing needs, utilization, and satisfaction data
- Enhance Credibility/Relevance of Content
  - More input from users and advisors
  - KOLs – add from recognized academic programs, state and federal agencies, surveillance community, VA, etc.
  - Up-to-minute, evidence-based content
  - Affiliation development – associations, academic institutions, external organizations involved in chronic pain, addiction treatment, surveillance, disease management, regulatory, programs, etc.
  - Demonstrate effectiveness – more metrics
  - Publication of performance metrics, practice data collected
  - Multi-sponsorship
- More Content via More Media
  - Incorporate existing highly valued content into alternate media
  - Key new content into best used online resources
  - Increased content distribution via booth, live, print, direct communication outlets

**Table 4.2. Summary of Proposed Tactics Matched to ESP Objectives**

<b>Tactic</b>	<b>Objective 1</b>	<b>Objective 2</b>	<b>Objectives 3</b>
Foundation Initiatives	X	XX	X
Website	X	X	X
Tools	XX	X	X
New Programs	XX	XX	X
Accredited Symposia	X	XX	XX
Accredited Print	X	XX	XX
Exhibit Booth	XX	X	XX
Outcomes Measure	X	XX	X
Targeted Recruit/Aware	XX	X	X



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## ***Emerging Solutions in Pain:***

### ***Section 4: Educational Initiative Overview***

#### **Components of the ESP Initiative**

ESP is designed to be a continuously evolving resource in which all content, media and format decisions are based upon an ongoing and proactive information collection strategy focusing on the needs of health care professionals who provide care to patients with chronic pain. The continuous nature of this information collection will serve as an ongoing needs assessment and, through careful analysis of the data and subsequent adaptation of strategy, will result in an initiative that is finely tuned to the needs, in terms of content and formats, of the target audience.

ESP will continue to understand both the content and format requirements of our members, ensuring we address the needs of the diverse interdisciplinary team. Formats will be developed to match individual learning styles.

**Table 4.2. Summary of Preferred Learning Style and ESP Format Available**

<b>Learning Preference</b>	<b>Format Available</b>
Read	Transcripts, Information Brochures, Direct Mailings, Monographs, Emails
See	Videos, Online Guides
Hear & See	Video, Audio, Podcast, Holograms
Hear, See, Say & Write	Interactive Tools, Live Events, Booth Activities
Hear, See, Say, Write & Practice Doing	Simulation

The subsequent sections in this proposal will outline the 2009 tactical plan, and provide detailed line item budgets for each tactic and initiative component. In addition to the above, brief outlines of optional tactics are included in relevant sections. Pending availability of additional funding, these optional tactics may be employed to further extend the reach and build awareness utilization of ESP as the "GO TO" resources for practical and educational information supporting improved patient outcomes in pain management and addiction medicine.

#### **In Summary, We Plan to:**

- Continue what is working well
- Reach more of those who impact chronic pain patient outcomes
- Continually understand what information is needed and assess our effectiveness against those needs
- Provide the best and latest evidence and practical tools
- Apply innovative technology to deliver education in formats valued by our members
- Provide the right information at the right time and in the right format
- Establish a dominant presence as the "GO TO" resource, building upon our reputation for quality, relevance, credibility, and utility



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### ***Emerging Solutions in Pain:***

#### ***Section 5: 2009 ESP Grant Budget Summary***

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Category	Tactic	Est. Costs	Notes
ESP Foundation Initiatives	2009 ESP Peer Review Panel and Expanded Clinical Advisors	\$26,890.00	Expansion of ESP clinical advisors to include diverse specialties in pain management, addiction medicine and related clinical fields; includes community-based pain physicians and addiction medicine physicians, nurses, physician assistants, pharmacists and legal/law enforcement specialists; expanded advisory panel will contribute peer-to-peer recommendations for new content and review of content for interdisciplinary updates
	2009 Scientific and Clinical Expert Advisory Board Meeting	\$115,793.20	Meeting of ESP clinical experts and advisors to recommend and review ESP initiatives and strategies; to analyze current ESP content archives for relevancy to current clinical audiences; and to provide guidance for future directions
ESP Website: Programming, Infrastructure and Maintenance of Content	Website Update to Joomla! 1.5: Infrastructure Development and Site Programming	\$196,854.20	Reprogramming of site infrastructure to utilize Joomla! 1.5 technology, to enable more robust tracking and metrics collection, to allow for deployment of a greater diversity of educational content in multiple media types; includes all management and analysis of site utilization data, hosting, co-location and maintenance/troubleshooting
	Clinical Expert Commentaries	\$54,073.45	Series of video-based expert commentaries on topics pertinent to pain management, addiction medicine, safe opioid prescribing, patient assessment and monitoring, and practice management; 1 column/month, 6 of 12 columns are included in this grant (see note at the bottom of Page 43)
	In the Know Summaries	\$21,064.00	Relevant articles from leading pain management/addiction medicine journals are summarized and posted; 1 summary to be posted/month, 12 of 24 summaries are included in this grant (see note at the bottom of Page 43)
	Knowledge Library	\$26,337.00	Series of 12 video answers to commonly asked questions concerning pain management and addiction medicine; each video clip to feature one clinical expert faculty; 1 - 4 minutes per video clip; 2 FAQs per month, 12 of 24 FAQs are included in this grant* (see note at the bottom of Page 43)



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**Emerging Solutions in Pain:**  
**Section 5: 2009 ESP Grant Budget Summary**

	Ask the Experts	\$16,615.00	Column in which ESP members may submit questions to ESP faculty; faculty questions are posted as MP3 files for audio podcasts; 1 column per month, 6 of 12 columns are included in this grant* (see note at the bottom of Page 43)
	In the News	\$5,864.60	Daily news feed of pain management, addiction medicine-focused news headlines
	Web Resources and Links	\$10,787.50	Identification of and link programming to pain management and addiction medicine-related base resources, links, suggested articles
	The ESP Case Library	\$65,205.00	Clinical expert authored case vignette column, posted as both audio recorded files for podcasting and transcript; 12 case vignettes total
	ESP Interdisciplinary Content Integration	\$50,180.00	Selected content on ESP will be differentially interpreted by relevant clinical specialties; interpretations posted as audio or text files; 24 interpretations total
ESP Tools: Updates and Distribution	Update of 2008 ESP Content and Tools	\$52,311.30	Update of content and/or programming of tools and resources posted on ESP in 2008 to reflect data and content that has changed since original posting; 4 updates total
	Online Distribution of the ESP Patient Tool Kit	\$18,468.30	Online request form for clinicians who have the need for the ESP Video Patient Tool Kit; 1,500 Tool Kits to be distributed total
ESP Programs: New Content, Tools and Resources	The ESP Patient Interview Decision Tree Algorithm: How to Talk to Real Patients About Real Problems	\$88,284.20	Case-based series of patient vignettes that allows the individual user to work through a series of interview/assessment techniques, with assessment outcomes determined by choices made by the user, with multiple possible outcomes to each assessment interview; 3 cases total
	The ESP Referral Tool: When, How and Why to Refer, and What to Expect from a Referral	\$69,024.55	Tool to allow PCPs to efficiently and effectively categorize potential pain patients into one of three groups for referral strategies; tool to include a checklist of questions/behavior types utilized early in the physician – patient relationship; consultation request form/tool for use by the PCP in requesting a consult; and consultation reply form/tool for use by the pain specialist/addiction medicine specialist to provide information back to the referring PCP



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## ***Emerging Solutions in Pain:***

### ***Section 5: 2009 ESP Grant Budget Summary***

	ESP Resource Center: A Subscription-Based Communication Series	\$162,778.35	Subscription-based print initiative for pain specialists, clinics; subscribing ESP members receive poster with important clinician-focused facts and information supporting safe and effective prescribing of opioids, an adhesive poster pocket for distribution of quarterly information resources and first quarter's information resource; four new information resources will be produced in 2009, and may include assessment, monitoring or documentation tools; monographs or monograph collections; patient education fact sheets; and/or journal article summary collections
Accredited ESP Symposia	2009 AAPainMgmt Satellite Symposia Series	\$206,360.00	Two 2-hour satellite symposia held in conjunction with the 2009 American Academy of Pain Management Meeting; each symposium to be held as part of a plenary session, and to focus on the role of risk assessment in returning pain patients to functionality
	Enduring Material Adaptation: Slide-Audio Activities	\$91,763.20	Enduring material adaptation of the 2009 satellite symposia series; programmed as 2 automated slide-audio activities on ESP
Accredited ESP Print Series	Accredited Monograph Series	\$239,723.80	Four issue series focusing on relevant topics in pain management and addiction medicine; each issue accredited for one hour; 8-page format; monographs to be published in one of several journals appropriate for the ESP target audiences
	2008 Monograph Collection	\$38,412.95	Accredited collection of the four issues of the 2008 Monograph Series
ESP Exhibit Booth Program	ESP Booth Maintenance, Storage and General Support	\$69,574.70	Includes storage of booth, additional Faces of Pain assessment sets, new graphics as appropriate, updates to equipment and other support materials as required
	20x20 Island Exhibit Booth	\$262,407.40	Two meetings total; suggested congresses are APS & AAPM&R but final meeting schedule TBD
	10x20 Mini Exhibit Booth	\$158,222.60	Two meetings total; suggested congresses are AAPA & ASPMN but final meeting schedule TBD
ESP Outcomes Measurement Initiatives	Ongoing Web-Based Outcomes Data Collection	\$35,117.00	Ongoing initiative to collect outcomes data on the impact of web-based ESP activities on clinician practices; a new outcomes question will be posted monthly, to identify effectiveness of ESP activities and to determine ongoing educational needs of ESP users



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**Emerging Solutions in Pain:**  
**Section 5: 2009 ESP Grant Budget Summary**

	2009 ESP Initiative Outcomes Study	\$138,568.40	Outcomes study to examine the impact of ESP tools, education and resources; primary study outcome will focus on impact of ESP tools, resources on management of chronic pain patients; secondary study outcomes will support identification of gaps in clinician knowledge about methods for safe and effective prescribing of opioids that minimize risk of opioid misuse, abuse and addiction; the outcomes study will result in the generation of an executive summary, with full details of all outcomes data collected
ESP Targeted Specialist Recruitment and Awareness Campaign	Targeted Specialist Recruitment Campaigns	\$149,514.40	Includes blast email and fax campaigns, banner advertisements, and direct mail postcard campaigns to targeted specialist audiences of nurses, pharmacists, physician assistants and practitioners concerned with safe and effective opioid prescribing
	The Beacon: A Weekly ESP e-Newsletter Series for Members	\$101,247.30	Weekly electronic newsletter sent to subscribing members of ESP; each issue to contain highlights and links to information, tools, and resources posted on the ESP website in the prior week
	ESP Scholarship Fund	\$46,166.80	Scholarship for 4 residents, fellows and nurses; one scholarship awarded per major pain meeting; scholarship would include conference registration fees, airfare, hotel and small stipend; recipient will write abstracts of conference plenary sessions that can be posted on the ESP website
<b>Total</b>		<b>\$2,517,609.20</b>	

\*Represents funding for one-half of 2009 programming for these resources; funding to support the other half of these resources is identified as an option only for this grant, and, unless this option is exercised, funding will be sought from other grantors





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## Program Summary: Emerging Solutions in Pain Section 6: Foundation Initiatives

### Program Title

The ESP Scientific and Clinical Expert Advisory Board, Peer Review Panels

### Background

The ESP Advisory Board has traditionally been comprised of the following thought leaders:

Advisor	Degree	Pain	Addict	Legal/Reg	Nursing	Pharm
Jennifer Bolen	JD			XX		
Daniel Brookoff	MD, PhD	XX	X			
David Brushwood	RPh, JD			XX		X
Peggy Compton	RN, PhD	X	X		X	
Patricia Good				XX		
Douglas Gourlay	MD	XX	X			
Jeffrey Gudin	MD	XX	X			
Howard Heit	MD	X	XX	X		
David Joranson				XX		
Steve Passik	PhD	X	XX			
Joe Shurman	MD	XX	X			
Steve Stanos	DO	XX	X			
Jennifer Strickland	PharmD					XX
April Vallerand	RN, PhD				XX	
Lynn Webster	MD	X	XX			
Penelope Ziegler	MD	X	XX			

This faculty panel has been instrumental in assisting ESP in developing educational content of the greatest benefit to health care professionals who treat patients with chronic pain. However, treatment of chronic pain remains a challenge to a diverse array of health care professionals. More primary care physicians are prescribing opioids, and are encountering the associated challenges of side effects, risk of addiction and legal regulations.





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## ***Program Summary: Emerging Solutions in Pain***

### ***Section 6: Foundation Initiatives***

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#### **Proposed Program/Educational Solution**

##### **ESP Scientific and Clinical Expert Advisory Board and Meeting**

MediCom is proposing to recruit a new faculty panel to create a "refreshed" ESP Scientific and Clinical Expert Advisory Board which:

- Represents all target audiences
- Has fresh perspectives on the current education requirements and challenges
- Catalyzes new interactions between current and new faculty members
- Provides increased resources to aid achievement of 2009 ESP objectives

##### **ESP Peer-Review Panel**

Since the ESP website is a resource for the entire community of clinical practitioners, it is vital that there be sensitivity to the realities of practice among the non-specialists. MediCom Worldwide, Inc. believes in the application of the accepted standards for excellence in peer-reviewed scientific and medical publishing as a means to communicating to participants that the content comes from a program of credible authorities and can be relied on for current and best practice information that affects their clinical practice. These standards address bias, conflict of interest, data integrity, statistical strength, study design, validity, scientific rigor, and other factors that contribute to credibility, quality, and usefulness.

It will be the role of the ESP Peer-Review Panel to evaluate content for both relevance to the broad practice community and the conformity of content to stated standards that address bias, conflict of interest, data integrity, statistical strength, study design, validity, and scientific rigor.

MediCom Worldwide, Inc. will develop a network of peer reviewers from a range of practice settings and disciplines. Educational content will be evaluated by appropriate reviewers who will be selected for their particular specialty, knowledge, or experience with the content area as well as geographical representation, understanding of evidence-based practice, and the absence of outside interest. If the evaluations are aligned, then content will be developed into educational activities. If, however, there are divergent evaluations, content will be revised and additional reviews will be obtained. This will ensure that content meets the diverse membership needs.

#### **Objectives**

1. To expand the ESP Scientific and Clinical Expert Advisory Board to:
  - Include a more interdisciplinary team including nurses/nurse practitioners, pharmacists in retail and clinical, physician assistants, legal and law enforcement, and primary care practitioners with a special interest in pain and addiction medicine
  - Include more renowned and diverse KOLs with more nationally revered credibility, higher levels of expertise based upon clinical and research experience, high-volume and recognized centers of excellence clinical settings and university-based pain clinics, government agencies and associations, as well as "rising star" KOLs at a fellow level
  - Include new areas of expertise thought leaders including oncology, surveillance, epidemiology, pharmacology, and toxicology
2. To convene the identified ESP Scientific and Clinical Expert Advisory Board meeting to:
  - Summarize the current clinical challenges facing health care professionals in managing pain, the current environmental challenges including the increasing rates of abuse of prescription opioids with the associated increasing legal and regulatory restraints and,



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## ***Program Summary: Emerging Solutions in Pain***

### ***Section 6: Foundation Initiatives***

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most importantly, the fundamental rights of pain patients to receive adequate treatment for their debilitation and associated comorbidities, including addiction disease

- Summarize potential activities and programs to address these challenges
- Based on the above:
  - Identify potential areas for the development of future *Emerging Solutions in Pain* programs and activities
  - Assist in the development, recruitment and potential publication for the ESP outcomes study to examine the impact of ESP tools, education and resources
  - Identify content and tactics that will reach the widest possible clinical audience
  - Develop "content teams" who will work together throughout the year to develop multidisciplinary content
  - Educate new faculty in ESP
  - Gain new perspectives from new faculty on current ESP strategies/tactics
  - Reach faculty consensus on updating current tools, outlining any requirements for new tools, resources, programs that might be offered through ESP
- 3. To ensure that all content meets MediCom standards of providing information:
  - Free of bias and conflict of interest
  - Maintains the highest data integrity, statistical strength, study design, validity, scientific rigor, quality, and
  - Meets the diverse ESP membership needs and disciplines

### **Program Overview**

MediCom Worldwide, Inc. will employ its criteria-based approach to building a team of scientific and clinical experts and generalists in the development and delivery of content for the ESP website. While the utilization of key thought leaders in a therapeutic category for content development and review is common, and generally contributes positively to educational activities, MediCom seeks to guarantee the development and distribution of the most rigorous and relevant content by applying principles of peer-reviewed scientific communications, and by recruiting multiple tiers of specialists. These thought leaders will be identified from multiple specialties and backgrounds to assist in the development and delivery of educational content, and will include not only recognized experts in the field of chronic pain, but also lesser-known "rising star" clinical experts and practitioners, as well. This blend of advisors and peer reviewers will ensure content that is not only rigorous, scientifically accurate and evidence-based, but also relevant and practice/patient care oriented, as well.

MediCom Worldwide, Inc. is recommending that the *Emerging Solutions in Pain* Scientific and Clinical Expert Advisory Board convene for a one-day meeting early Quarter 2, 2009. At this meeting, the faculty will address the current needs of clinicians involved in the field of pain management, identify potential areas for the development of future *Emerging Solutions in Pain* programs and activities, and reach consensus on updated tools and resources for inclusion on the *Emerging Solutions in Pain* website, booth program, and print materials.

MediCom Worldwide, Inc. is recommending that the 2009 *Emerging Solutions in Pain* Scientific and Clinical Expert Advisory Board be comprised of two groups of clinical experts. One group, which will form approximately half of the final Board, will include currently active *Emerging Solutions in Pain* faculty members who have participated in prior ESP advisory board activities. The remaining half of the Advisory



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## ***Program Summary: Emerging Solutions in Pain***

### ***Section 6: Foundation Initiatives***

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Board will be comprised of expanded clinical experts. While final selection of Advisory Board members will be based upon availability, the faculty will be selected from those identified within the ESP current needs assessment, as well as continual review for those thought leaders matching the ESP criteria.

For comprehensive programs such as *Emerging Solutions in Pain*, a spectrum of content must be developed that allows for individual practitioners, at all levels of expertise and experience, to find the information they need to meet their current clinical pain management challenges. MediCom has, therefore, developed a Knowledge Continuum that ranges from genomics through standardized practice guidelines to ensure that ESP content meet a diverse range of educational needs.

#### **Intended Audience**

Twelve is an optimal number of scientific and clinical experts for the advisory meeting, with medical and scientific representatives from academia and the community, comprised of diverse thought leader representatives. It will be the role of this group to define the most compelling and current evidence available, providing the basis for continual needs assessments as well as ongoing educational content.

#### **Format**

The format for this activity will be a one-day meeting, to be tentatively held in April 2009. The exact date and location of this meeting will be based on the schedules of the attending faculty.

#### **Distribution**

Attendance at the 2009 *Emerging Solutions in Pain* Scientific and Clinical Expert Advisory Board Meeting will be determined by past participation in the *Emerging Solutions in Pain* initiatives, and new faculty, by contributions to *Emerging Solutions in Pain* and in the fields of pain or addiction medicine.

#### **Total Budget**

The total budget to fund this activity is \$142,683.



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## ***Program Summary: Emerging Solutions in Pain Section 6: Foundation Initiatives Budget***

<b><i>Program Parameters: The Emerging Solutions in Pain Advisory Panel</i></b>	
Participating faculty	11
Clinical expert moderator	1
Number of one-day advisory board meetings	1
Number of new Advisory Panel Members identified	50
Number of new Advisory Panel Members recruited	25

<b><i>Cost Summary</i></b>	
<i>2009 ESP Advisory Panel</i>	
Approximate Total, Direct Expenses	\$1,000.00
Total, Indirect Expenses	\$25,890.00
Subtotal, 2009 Advisory Panel	\$26,890.00
<i>2009 ESP Advisory Board Meeting</i>	
Approximate Total, Direct Expenses	\$82,690.00
Total, Indirect Expenses	\$33,103.20
Subtotal, 2009 ESP Advisory Board Meeting	\$115,793.20
<b><i>2009 ESP Advisory Panel and Meeting</i></b>	<b><i>\$142,683.20</i></b>



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## Program Summary: Emerging Solutions in Pain

### Section 6: Foundation Initiatives Budget

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<b>Detailed Budget Itemization: 2009 ESP Advisory Panel</b>	
<b>Direct Expenses, Approximate</b>	<b>Total</b>
Miscellaneous (pre-meeting shipping, faxes, FedEx, etc.)	\$1,000.00
<b>Approximate Total, Direct Expenses</b>	<b>\$1,000.00</b>
<b>Indirect Expenses</b>	<b>Total</b>
<b>Project management</b>	
Recruitment of 25 new ESP Advisory Panel Members	\$7,500.00
Ongoing coordination with faculty	\$7,800.00
Coordination of internal teams	\$960.00
Preparation and coordination of status meetings/updates	\$450.00
<b>Medical services</b>	
Medical direction/account supervision	\$5,950.00
Identification of 50 new ESP Advisory Panel Members	\$3,200.00
<b>Administrative and accounting fees</b>	<b>\$30.00</b>
<b>Total, Indirect Expenses</b>	<b>\$25,890.00</b>



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## Program Summary: Emerging Solutions in Pain

### Section 6: Foundation Initiatives Budget

<b>Detailed Budget Itemization: 2009 ESP Advisory Board Meeting</b>	
<i>Direct Expenses, Approximate</i>	Total
<b>Print materials</b>	\$2,500.00
Meeting kits to include agenda, handout materials, reference materials and meeting slides	
<b>Speaker honoraria (11 faculty members + 1 moderator)</b>	
Moderator (1)	\$5,000.00
Faculty (11 faculty, \$2,500 per faculty member)	\$27,500.00
<b>Speaker travel</b>	
Air	\$6,600.00
Accommodations	\$6,000.00
Ground transportation	\$2,400.00
OOP	\$1,200.00
<b>MediCom expenses: four MCWW staff</b>	
Accommodations	\$2,000.00
Ground transportation	\$360.00
OOP	\$600.00
<b>Venue rental fee</b>	\$2,500.00
<b>Food &amp; beverage</b>	
Pre-meeting dinner (10 people)	\$1,400.00
Buffet breakfast (16 people)	\$960.00
Buffet lunch (16 people)	\$1,360.00
Breaks (two, 16 people each)	\$1,280.00
<b>Graphic design</b>	
Creation of meeting slides	\$3,480.00
Typesetting, layout of meeting support materials	\$1,500.00
Participant package assembly	\$750.00
<b>Meeting management</b>	
Venue coordination	\$2,250.00
Travel coordination for faculty and staff	\$3,000.00
<b>Audio/visual services</b>	\$6,500.00
<b>Transcription</b>	\$2,750.00
<b>Reference purchase</b>	\$300.00
<b>Miscellaneous (on-site printing, non-fulfillment shipping, faxes, FedEx, etc.)</b>	\$500.00
<b>Approximate Total, Direct Expenses</b>	<b>\$82,690.00</b>



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## Program Summary: Emerging Solutions in Pain

### Section 6: Foundation Initiatives Budget

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<b>Detailed Budget Itemization: 2009 ESP Advisory Board Meeting</b>	
<i>Indirect Expenses</i>	Total
<b>Project management</b>	
Coordination with faculty	\$2,700.00
Coordination of internal teams	\$5,760.00
Preparation and coordination of status meetings/updates	\$600.00
<b>Medical services</b>	
Medical direction/account supervision	\$4,200.00
Identification of faculty and alternate faculty	\$400.00
Content development for meeting slides	\$8,500.00
Proofreading	\$1,562.50
Identification of supporting references and material gathering	\$1,000.00
Fact-checking	\$500.00
<b>Onsite management (4 staff members)</b>	\$5,400.00
<b>Administrative and accounting fees</b>	\$2,480.70
<b>Total, Indirect Expenses</b>	<b>\$33,103.20</b>





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## **Program Summary:**

### **Section 7: The Emerging Solutions in Pain Website: Programming, Infrastructure and Maintenance**

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#### **Program Title**

The *Emerging Solutions in Pain* (ESP) website

#### **Background**

Please refer to the extensive ESP Needs Assessment on pages 6 to 21. Treatment of chronic pain is a challenge, with more than 30 million Americans suffering debilitating chronic pain. An increasing number of primary care physicians (PCPs) prescribe opioids and encounter the associated challenges of side effects, addiction and legal regulations. The ESP online community was developed using current evidence, clinical guidelines, best practice tools and expert opinions to assist clinicians in making therapeutic decisions regarding health care for managing chronic pain. Thus far, the ESP website has achieved the following:

- *Emerging Solutions in Pain* Key Achievements
  - Launched in 2005 and currently has 5,871\* members
  - Website was last upgraded in March 2007 to improve delivery of content
  - Won multiple awards recognizing creative, media and content excellence
  - Has a monthly return visits of 8% with a low unsubscribe rate
- Top Pages Requested Overall†:
  - Tool Kit I & II (ORT)
  - Pain & Addiction 101 Module: Goals of the Game
  - Ziegler Monograph – Treating Chronic Pain in the Shadow of Addiction
  - McCarberg Journal Club – Systemic Review of Chronic Opioids for Back Pain
  - Brookoff – Demystifying the Death of Elvis
  - 9 Instruments of Assessment
- Top Pain Topics Selected within ESP (other than tools)‡:
  - Managing Pain and Addiction (3,007)
  - Treating Chronic Pain in the Shadow of Addiction (2,116)
  - Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction (1,130)
  - Demystifying the Death of Elvis (1,066)
  - Determining the Risk of Opioid Abuse (784)

#### **Proposed Program/Educational Solution**

MediCom Worldwide, Inc. is proposing the following tactics for 2009 to further build on ESP achievements to-date and for achieving the 2009 objectives:

- Migrate the website to Joomla! 1.5
- Provide valued information resources
- Provide valued communication resources

\*Members Count up to 9 November 2008

†Top Pages Requested between 1 Jan 2007 and 9 Nov 2008

‡Top Pages Requested between 1 Jan 2007 and 9 Nov 2008



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## **Program Summary:**

### **Section 7: The Emerging Solutions in Pain Website: Programming, Infrastructure and Maintenance**

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#### **Program Overview**

The heart of the educational component of *Emerging Solutions in Pain* is the online community hub website [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com), which is a central repository for all programs, activities and resources. By acting as a key point of distribution for the latest educational disease awareness information in the field of pain management and addiction medicine, the ESP website has become a fundamental resource to health care professionals in the field of pain management, as evidenced by 2008 usage statistics presented in the Needs Assessment Section (pages 6-21). On the ESP website, clinicians, nurses, pharmacists and residents/fellows have complimentary access to a comprehensive selection of educational information, resources and tools for assessing the potential for abuse, addiction and diversion in their patients with chronic pain, for assessment and monitoring their pain patients, for complying with federal and state regulations, and for accessing the latest information regarding "best practices" in the long-term management of patients suffering excruciating pain.

Due to the increasing complexity of the *Emerging Solutions in Pain* website, which reflects the multifaceted and continually changing needs of health care professionals who provide care to patients with chronic pain, the site's three areas of core functionality will be addressed individually. These three areas are as follows:

- (1) Site Migration, Site Management, and Member Management
- (2) Information Resources
- (3) Communication Resources

#### **Site Migration**

The ESP website will be migrated to Joomla!<sup>§</sup> version 1.5 for several reasons. Joomla! Version 1.0 will not be supported due to "bugs"<sup>†</sup> and security issues<sup>††</sup> after July 22, 2009. As a result, development and support for new components and features is being phased out. The key security concerns for ESP will be:

- Physically limit access to computers to only those that will not compromise security
- Hardware mechanisms that impose rules on computer programs, thus avoiding depending on computer programs for computer security
- Operating system mechanisms that impose rules on programs to avoid trusting computer programs
- Programming strategies to make computer programs dependable and resist subversion

There is no upgrade path from Joomla! 1.0.12 to Joomla! 1.5,<sup>††</sup> thus the conversion of ESP to Joomla! 1.5 is not an upgrade; it is instead a site migration. In addition, all new programs and activities will be developed for version 1.5.

<sup>§</sup>Joomla! = is a dynamic portal engine and content management system for publishing content on the World Wide Web and intranets.

<sup>†</sup>Bugs = errors in computer programs are called bugs. Sometimes bugs are benign and do not affect the usefulness of the program, in other cases they might cause the program to completely fail (crash), in yet other cases there may be subtle problems. Sometimes otherwise benign bugs may be used for malicious intent, creating a security vulnerability.

<sup>††</sup>Computer security includes protection of information from theft or corruption, and the preservation of availability.

<sup>††</sup> There has been a significant rise in developer activity on Joomla! 1.5 and the platform has been called the version of tomorrow (or a robust web platform that will have longevity on the web).



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## **Program Summary:**

### **Section 7: The Emerging Solutions in Pain Website: Programming, Infrastructure and Maintenance**

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Migrating to Joomla! 1.5 will enable incorporation of components and features such as:

- CE component custom tracking, reporting, and issuing of certificates
- Integrated video management (currently the full-screen HD content is managed externally on a separate Joomla! 1.5 website)
- New message boards (forums) with robust security measures to ensure privacy of members and control of general public access
- New pull-down menus (resolving current Internet Explorer 6 issues)
- Back-end management for rotating banners
- Conversion of old content to new video player (SD full-screen)
- New quiz and polling functionality
- An interactive calendar
- Improved content organization (auto-populated top 10 items on Home Page)
- Easily integrated and flexible RSS<sup>ss</sup> feed
- Robust community tools for user registration and maintenance
- Content feedback features
- Efficient back-end maintenance and support
- Automated database back-ups
- Much more robust and flexible content management – streamlined navigation system to reflect the increasing complexity, variety and depth of information available to registered members
- A new template designed for Joomla! 1.5 with the same look and feel (or possibly an updated look and feel) will fix some current template issues (ie, bulleted list problems)
- Better collection of utilization metrics
- Integration of interactive challenges and case studies
- New video and audio search feature (iTunes-like interface)
- The utilization of the Joomla! 1.5 migration will enable users to select their content and learning format preferences to enable quick and easy identification of the information that is important to their own unique patients and practices

**The budget for the site migration can be found on page 66.**

#### **Site Management/Member Management**

A fundamental of the *Emerging Solutions in Pain* website is the requirement that registration is necessary to access much of the clinical information available on the site. This requirement supports the concept that *Emerging Solutions in Pain* develops tools and resources solely for health care professionals, and

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<sup>ss</sup> RSS = RSS is a family of Web feed (data) formats used to publish frequently updated works such as blog (web log) entries, news headlines, audio, and video in a standardized format



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does not provide any direct-to-patient information. All patient educational programs are developed for the clinician to select for their individualized patient population requirements. Registration also enables tracking of information pertaining to member specialty and program utilization, and provides a method for updating site users with information regarding new programs, information and tools as they become available. Data management of member information and utilization tracking of individual tools, activities and resources will remain a critical function of the *Emerging Solutions in Pain* website, as ongoing analysis of this information will support not only accurate assessment of the needs of health care professionals, but identification of the most valued tools and resources of this audience, as well. In 2009, we intend to actively recruit new members to join the online community and increase ESP users to 10,000. The migration to Joomla! 1.5 will also enable members to select their preferred information interests as well as educational style, thereby enabling us to provide content and formats specific to the user's needs. All of the above will assist in achieving one of the key objectives for Emerging Solutions in Pain in 2009: to become the "GO TO" source for all educational requirements, giving the right people, the right information in the right format at the right time.

In 2009, the *Emerging Solutions in Pain* website will work toward obtaining level 1 to 3 outcome metrics for every new piece of content posted. Metrics will be collected as a standard on the following:

- Usefulness
- Quality of content
- Will the information presented cause you to make changes in your practice?
- How committed are you to making the changes in your practice?

The site migration to Joomla! 1.5 will assist in the gathering and analysis of more robust outcome data. Gathering more intelligence, more metrics and more outcome measures will drive content identification and decisions. It is only by continually analyzing what information is needed, assessing our effectiveness in providing that information and by assessing the effectiveness of that information can we become the "GO TO" resource. Some of the continual data collections include:

- Needs survey fielded to targeted users
- Learning preferences and habits survey
- User credibility and satisfaction surveys
- Utilization metrics
- Integrated polling, mini data collection
- Clinician – patient – data collection loop on specific information/outcomes

This information will assist in continually:

- Identifying content that is valued
- Reaching more of those who impact patient care outcomes
- Understanding what information is needed
- Assessing our effectiveness for actively changing practices
- Providing best evidence, practical tools and clinical support
- Ultimately establishing dominance in the pain community with a reputation for quality, relevance, credibility and clinical utility



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#### **Information Resources**

One of the fundamental goals of the *Emerging Solutions in Pain* website is the development and dissemination of information, tools and resources to health care professionals who provide care to patients with chronic pain. These tools and resources will provide information and resources across the entire treatment algorithm for long-term chronic pain patient care as follows:

- (1) Initial Patient Assessment including:
  - a. Medical history, physical examination, diagnostic, therapeutic and laboratory tests
  - b. Evaluations & consultations
  - c. Therapeutic goals
  - d. Assessment tools identifying:
    - i. Suitability for long-term opioid therapy
    - ii. Comorbidities
    - iii. Patient's potential risk for misuse, abuse or addiction of prescribed opioids
  - e. Treatment plan
  - f. Regulatory requirements for documentation – informed consent, treatment agreements and HIPAA
  - g. Treatments – pharmacological and non-pharmacological
- (2) Ongoing monitoring and effective management of the chronic pain patient who is prescribed opioids and other controlled substances including:
  - a. Adverse drug reaction monitoring
  - b. Periodic monitoring
    - i. Identifying BTP,<sup>\*\*\*</sup> end-of-dose failures
    - ii. Opioid customization – including changes to dose, formulations, including adding long- or short-acting and opioid rotation
    - iii. Monitor progress of treatment goals, identify strengths and limitations of treatment
    - iv. Managing tolerance, pseudoaddiction, hyperalgesia
  - c. Treatment transition or referral to specialist
  - d. Managing patient with a history of substance abuse
  - e. Managing addiction in chronic pain patients
  - f. Exit strategy plans
  - g. Documentation of outcomes
- (3) “Best practice” information, associated with knowledge and information clinicians may utilize to safely and effectively prescribe opioids
  - a. Patient advocacy and education support (as selected by the clinician)
  - b. Regulatory and legal requirements for prescribing controlled substances

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<sup>\*\*\*</sup>BTP = breakthrough pain



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The goal of the Information Resources on the ESP website is to disseminate timely, relevant and accurate tools and resources in each of the above areas. The following Information Resources are currently available on the ESP website; based on analysis of current utilization, these resources should continue to be available to registered members (with updated content as required) through 2009:

- (1) Overall – this section will be updated so that each new content page will include a section at the bottom to obtain suggestion information as well as outcome measures:
  - a. *Page Suggestions*
    - i. *Content Suggestion*
    - ii. *Design Suggestion*
    - iii. *Error on Page Suggestion*
    - iv. *Further Information Suggestion*
    - v. *Other Suggestion*
  - b. *Outcomes*
    - i. *Usefulness*
    - ii. *Quality of content*
    - iii. *Will the information presented cause you to make changes in your practice?*
    - iv. *How committed are you to make the changes?*
  - c. *Registration – this section will be upgraded to provide more robust user information*
- (2) Home
  - a. *Providing regular reports on all metrics data*





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Exhibit 7.1: The ESP Home Page

**esp**  
Emerging Solutions in Pain

HOME ABOUT ESP KNOWLEDGE CENTER TOOLS CE EDUCATION RESOURCES

**Member Center**  
Username: \_\_\_\_\_  
Password: \_\_\_\_\_  
☐ Remember me  
Log In  
Lost Password?  
No account yet? Register  
Membership Benefits

Search ESP for: \_\_\_\_\_

**In the News**

- Melanoma Headaches May Diminish Breast Cancer Risk
- Award to HLE Nursing Students Recognizes Excellence in Caring
- High doses of statins cause high rates of side effects like muscle pain and weakness
- How to Pet-Proof Your Home
- Bummed by the big S-O

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**Scholarship Program**  
A wonderful opportunity for residents, fellows, and registered nurses to attend a leading pain management conference!  
Click here to enter NOW!

**Welcome to Emerging Solutions in Pain!**

Practitioner's Guide to Patient Visits Official Launch  
Click here to visit NOW!

**What's New?**

- Ask the Experts - Questions regarding the propriety of a family doctor continuing to give oxycodone to a patient with chronic back pain by Breakoff
- Know-Node Viter - Are there new opioid therapy studies showing success on-line shunters babbles? - Steven D. Prosk, PhD
- In the Know - Educational Pan-Stop Response
- Expert Commentary - Pain, Opioids, and Sleep - Lynn Webster, MD, FACP, FASAM
- CE Monthlong - A Multidisciplinary Approach to the Medical Management of Sleep, Chronic Pain, and Opioids - by Bradley J. Schnitzler, MD, HS and Joseph Shuman, MD
- Steps Your Case - Patient with Chronic Pain Issues and a Substance Use Disorder - by Patricia P. Ziegler, MD, FASAM

**The Latest Tools Available on ESP**

- ESP 9 Instruments of Assessment - a collection of nine valuable tools to assist pain management clinicians in identifying active or potential drug or alcohol misuse. The results of these tools can help determine the most appropriate individualized therapy plan.
- ESP Patient Education Series - is an educational resource for clinicians to use to empower their patients to play a more active role in their pain management. Specific topics can be selected relevant to an individual patient's needs.
- ESP Practitioner's Guide to Patient Visits - is an assortment of techniques and tools that may be used to help practitioners better assess the patient in pain and also help to demonstrate patient visit documentation for improved regulatory compliance and patient management.

Supported by an independent educational grant from  
**Cephalon**  
Discover more!

**New Release!**  
ESP Patient Education Series  
Announcing the launch of the ESP Patient Education Series

What topics would you like to see more of on this website?  
☐ Different pain scales - e.g., terminology  
☐ Non-pharmacologic measures - e.g., acupuncture  
☐ Patient education - e.g., movies  
☐ Long-term  
☐ Other

Vote Results

**Today's source for tomorrow's pain management!**





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#### (3) About ESP

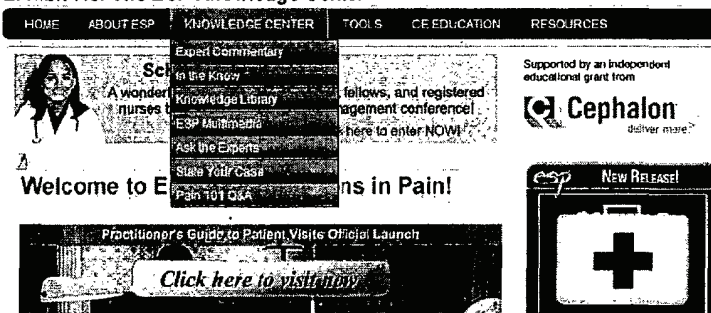
**Exhibit 7.2: The About ESP**



- a. *Clinical Advisors – including a new selection of advisors to call on for expert opinion on varying topics*
- b. *Awards – continuing to apply for both clinical content and technology excellence awards*
- c. *Calendar – calendar of events including all pain management and addiction medicine events and not just those with ESP activities.*
- d. *Press Room – continuing to increase awareness and outreach on ESP*
- e. *Contact Us – including a FAQ section on the most queried topics eg, resetting password*
- f. *Site Map*

#### (4) Knowledge Center

**Exhibit 7.3: The ESP Knowledge Center**



- a. *Expert Commentary – each month, a different Emerging Solutions in Pain faculty member authors a new column in the ESP Clinical Expert Commentary series. Each commentary addresses a topic associated with safe and effective prescribing of opioids and/or minimization of the risk of opioid misuse, abuse and addiction. To extend the reach of each installment in this series, each commentary is archived upon release of the next column and is available for review by*



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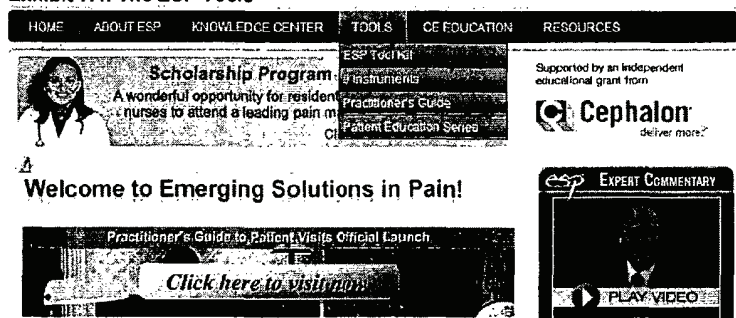
registered members. Since 2008, all commentaries are now available in multiple formats, including high-definition video, audio and transcript to reflect the diverse and different learning preferences of the ESP membership.

**The budget for the 2009 Expert Commentaries can be found on page 69.**

- b. **In the Know** – the ESP In the Know series is a column that provides focused, easy-to-read summaries of relevant scientific articles published in peer-reviewed journals in the field of pain management. A new article is summarized bi-weekly, with previous summaries archived for review by registered members.  
**The budget for the 2009 In the Know series can be found on page 70.**
- c. **Knowledge Library** – the ESP Knowledge Library includes an extensive series of case studies, video clips and video-based FAQs that provide information for health care professionals who provide care to chronic pain patients. Topics are posted biweekly and include pharmacotherapy; assessment; abuse, misuse and addiction; best practices; and legal information. This section will be refurbished for ease of selecting topics with an iTunes-like scroll across the selection available.  
**The budget for the 2009 Knowledge Library series can be found on page 71.**
- d. **ESP Multimedia** – ESP Multimedia is a library that includes a comprehensive array of video and other digital media content from live symposia. The content from the Pain & Addiction Q&A 101 section will be selectively repurposed for inclusion into the ESP Multimedia section.
- e. **Ask the Experts** – through this web-based functionality, ESP members submit questions online pertaining to issues of pain management and/or addiction. MediCom screens all questions submitted, and forwards selected questions to the appropriate ESP faculty member. The selected faculty member then creates an audio recording of his/her answer to the question, and MediCom posts the recorded answer, as both an MP3 file for audio playback and in a text-based format; the member who asked the question is notified via email as to the availability of the answer. MediCom coordinates the monthly selection of questions from all those submitted and the posting of the ESP faculty member's response. All Ask the Expert questions are archived upon posting of the newest question and are available for review by registered members. This section will also have the iTunes-like scroll of available questions.  
**The budget for the 2009 Ask the Expert series can be found on page 72.**

#### **(5) ESP Tools**

**Exhibit 7.4: The ESP Tools**





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*Based on feedback from ESP members, previous faculty advisory meetings, and on interaction with health care professionals at live ESP events, Emerging Solutions in Pain released a number of multimedia clinician tools in 2008. These included the:*

- a. *ESP Tool Kit Volume II – A comprehensive resource to assist pain management clinicians with assessing, monitoring, and protecting their practices. It offers new modules, updated content, and more information designed to address today's critical issues.*
- b. *ESP 9 Instruments of Assessment – A collection of 9 valuable assessment tools to assist pain management clinicians in stratifying patients according to risk and identifying active or potential drug or alcohol misuse.*
- c. *ESP Patient Tool Kit – A companion to the ESP Tool Kit Volume II and a valuable tool to assist pain management clinicians in educating their patients on the rationale and use of assessment, monitoring, and documentation for their chronic pain.*
- d. *ESP Patient Educational Series – 13 fact sheets to assist patients in becoming more active in their pain management. Many sections have "tear-out" sections for the patient to complete before their next office visit.*
- e. *ESP Practitioner's Guide to Patient Visits: Techniques and Tools – A virtual reality physician's office providing an assortment of techniques and tools that may be used to help practitioners better assess the patient in pain and also help to demonstrate patient visit documentation for improved regulatory compliance and improved patient management. This tool provides a fun learning environment where office furnishings come alive and file drawers provide valuable patient visit resources.*
- f. *ESP UDT Tool – An interactive tool applying relevant clinical case studies with key learning points on the utilization and interpretation of UDT (not launched yet).*
- g. *ESP UDT PocketGuide – a quick and easy reference guide to explain the utilization and interpretation of urine toxicology (not launched yet).*
- h. *Other tools available on the website include the ESP Assessment Tool – includes the Faces of Pain scale, the ORT and the acute pain analgesic ladder.*

*The CD-ROM based tools described above were distributed directly to health care professionals through the Emerging Solutions in Pain Booth Series. The remaining tools are included on the ESP website for health care professionals to directly access. There have been numerous requests to have the CD-ROMs available to more health care professionals, so MediCom is proposing to produce further copies of this tool for distribution via direct request through the website. We have included a budget for distribution costs of the CD-ROM tools. We have also included a nominal amount in the budget to update online content of this program to ensure continued accuracy of information provided.*

***The ESP Tools are discussed further with detailed budgets in Section 8 (pages 75-79).***



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#### (6) CE Education:

**Exhibit 7.5: The ESP CE Education**



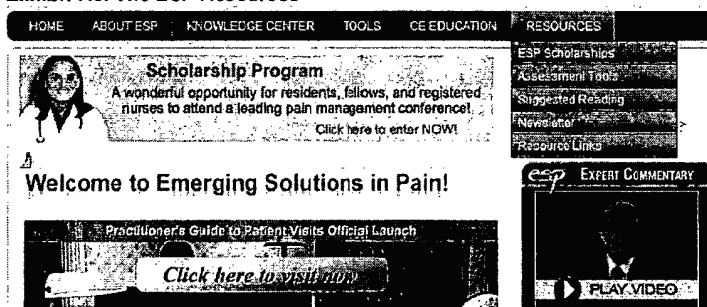
The *Emerging Solutions in Pain* website is an important resource for clinicians who are interested in accredited programs and activities supporting safe and effective prescribing of opioids while minimizing the risk of opioid misuse, abuse and addiction. Each accredited activity on the ESP website is available in multiple formats and/or viewing options, and each supports immediate printing of earned CE certificates. The accredited activities available at the ESP website include:

- a. *P&A 101 – streaming video modules adapted from the American Academy of Pain Management, Nashville, 2008 full-day symposium focusing on issues at the interface of pain and addiction; audio-only and text formats are also available for this program (not launched yet)*
- b. *The Emerging Solutions in Pain 2009 monograph series, including all PDFs of all print monographs published in a selection of pain journals*
- c. *The Emerging Solutions in Pain 2008 monograph collection, including all PDFs of all print monographs previously published in the Practical Pain Management journal*

**The ESP accredited Monograph Collection is discussed further with detailed budgets in Section 11 (pages 98-104).**

#### (7) Resources

**Exhibit 7.6: The ESP Resources**





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- a. *In the News Feature* – the ESP *In the News* series is a daily news feed of headlines and articles published online and in print in the field of pain management. The *In the News* feature is a real-time feed, and, as such, is updated throughout each 24-hour period.  
**The budget for the 2009 *In the News* series can be found on page 72.**
- b. *Resources* – the *Resources* section of the *Emerging Solutions in Pain* website is a diverse collection of PDFs, articles and live links relevant to important information in the field of pain management. These include:
  - i. The *Suggested Reading* section which includes a series of PDFs for numerous articles supporting safe and effective prescribing of pain management
  - ii. Links to online resources for information on government resources, legal resources and professional associations**The budget for the 2009 *Resources* and *Links* can be found on page 73.**
- c. *ESP Scholarship Calendar* – ESP members may view a schedule of upcoming ESP scholarship events as well as past scholarship winners' publications from their attended congress.  
*The ESP Beacon Weekly Newsletter* – this newsletter was previously published on a quarterly basis and in 2009, will provides highlights of the postings or program launches occurring in previous week. The archived issues will be contained in the resource section.  
**The *Beacon* is discussed further with detailed budgets in Section 14.**

### **Communication Resources**

The challenges of treating chronic pain patients safely and effectively with opioid analgesics are numerous and diverse. Resolution of these challenges often requires the active management by a multidisciplinary team of pain specialists, nurses, pharmacists and other allied health care professionals. Communication, understanding and information sharing among the diverse members of the pain management team are thus important components of chronic pain management. In 2008, *Emerging Solutions in Pain* developed, disseminated and implemented of a series of tools and resources that would support the development of enhanced interdisciplinary management of chronic pain.

The Communication Resources currently available on the ESP website are designed to promote peer-to-peer communication, not only between registered members and the ESP faculty, but also directly between members of the ESP community itself. These resources have an additional goal of increasing the amount and diversity of information available at *EmergingSolutionsinPain.com*; by creating interactive tools that encourage member posting of information and dialog among members, the content available for review and dissemination on the ESP website is significantly increased. In addition, because members are actively involved in contributing to these tools and resources, the resulting content, once validated, is an accurate and immediate assessment of the ongoing needs of the target audience of health care professionals who provide care to patients with chronic pain.





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These resources and tools which will be available in the ESP Communication Resources include:

- (1) *The ESP Case Vignette Library – In this program, clinical experts on the ESP Faculty Advisory Team will author case vignettes, which will be posted bi-monthly as audio recorded files for podcasting and transcript format. A new case is posted every 4 months, with previous cases archived for review by registered members.  
**The budget for the 2009 ESP Case Vignette Library can be found on page 73.***
- (2) *The ESP Interdisciplinary Content Integration – Selected content on ESP will be differentially interpreted by relevant and highly experienced clinical specialties to ensure ESP content is relevant to a multidisciplinary pain management team; interpretations will be posted on the ESP website as audio or text files; 24 interpretations will be posted in total.  
**The budget for the ESP Interdisciplinary Content Integration can be found on page 74.***

#### **Intended Audience**

The primary audience of the *Emerging Solutions in Pain* website includes physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain.

#### **Program Objectives**

In 2009, one goal of the *Emerging Solutions in Pain* website will be to continue to provide clinicians with tools and resources for assessing and monitoring the risk potential of their patients for opioid misuse, abuse and addiction. Goals of the *Emerging Solutions in Pain* website include the following:

- (1) Attract new members while maintaining current members increasing subscribers to 10,000
- (2) Increase usage, as tracked by membership, user sessions and hits, by 25% in 2009, through continuation of current programs and initiatives that have been identified as having value by ESP members
- (3) Reinforce the structural integrity of the existing site to ensure uninterrupted service to members despite significantly increased usage
- (4) Update rotating "featured programs" section call-outs to draw member attention to each new program and feature of the website
- (5) Update member-only email communications concerning the newest functionality available at *EmergingSolutionsinPain.com*
- (6) Continue to expand the reach of this website and the important information it contains to the following groups:
  - a. Non-physician members of the pain management community, eg, nurses, physician assistants, pharmacists
  - b. Pain specialists, addictionologists and other physicians who have not yet registered at the website
  - c. Residents and fellows who have an interest in treating pain as part of their studies
- (7) Further build and develop the virtual "ESP Community" of health care professionals through:
  - a. Reinforcement of current communication-focused resources to existing members
  - b. Development of additional forums related to existing forums and discussion resources
  - c. Additional announcement of this resource to new/non-members



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### **Format**

A multimedia website, with separate sections for accessing knowledge, tools and continual learning for assessing and monitoring patients whose chronic pain is being treated with opioids; for "best practice" information; for continuing education activities and journal articles relevant to the *Emerging Solutions in Pain* initiative; for other *Emerging Solutions in Pain* information and programs.

### **Distribution**

The *Emerging Solutions in Pain* website will be available to all health care professionals via the Internet at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com). Free registration will be required to access the majority of information on the website, including all of the *Emerging Solutions in Pain* tools and journal articles

### **Request for Sponsor Support**

MediCom Worldwide, Inc. will announce and promote the *Emerging Solution in Pain* website through identified sources for the *Emerging Solutions in Pain* initiative.

As a supplement to these primary methods, MediCom Worldwide, Inc. may request the assistance of Cephalon, Inc. sales representatives in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of MediCom Worldwide, Inc., and any such distribution will solely be as a supplement to MediCom's primary methods of announcement and promotion.

### **Total Budget**

The total budget to fund the activities outlined above is \$446,981.





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**Program Summary:**  
**Section 7: The Emerging Solutions in Pain Website: Programming,  
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<b>Cost Summary</b>	
<b>Approximate Total, Direct Expenses</b>	<b>\$144,710.00</b>
<b>Total, Indirect Expenses</b>	<b>\$52,144.20</b>
<b>Emerging Solutions in Pain: 2009 Website Infrastructure Development and Site Programming</b>	<b>\$196,854.20</b>

<b>Direct Expenses, Approximate: ESP Website Upgrade</b>	
	<b>Total</b>
<b>IT / programming services</b>	
Storyboard development for website, including identification and development of navigation, sitemap and internal linkages	\$750.00
Programming of site infrastructure, including integration of identified Learning Management System	\$11,600.00
Programming of PHP database for collection, management of utilization information	\$4,640.00
Programming of user interface and support pages	\$2,250.00
Programming of administrative interface, data management interfaces and report generation systems	\$4,640.00
Programming of security protocols and redundant back-up systems	\$8,410.00
Programming of participant CE tracking system	\$5,075.00
Migration of content from old ESP site to new site	\$23,200.00
<b>Graphic design / production services</b>	
Adaptation of old ESP site look/feel for new site	\$4,000.00
Design and programming of Flash animations for banners, call-outs, teasers	\$5,220.00
Monthly adaptation of banners, call-outs, teasers	\$10,000.00
<b>Website maintenance, 12 months</b>	
Streaming server license and fees	\$3,500.00
Dedicated server space	\$3,000.00
Hosting and co-location fees	\$18,000.00
Routine website maintenance	\$6,500.00
Technical support	\$11,700.00
<b>Data management</b>	
Data retrieval	\$4,875.00
Data analysis	\$15,600.00
<b>Stock photography / illustrations</b>	\$1,000.00
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$750.00
<b>Approximate Total, Direct Expenses</b>	<b>\$144,710.00</b>



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<b>Indirect Expenses: ESP Website Upgrade</b>	
	<b>Total</b>
<b>Project management</b>	
Coordination with internal programming team	\$6,000.00
Coordination of internal teams	\$16,800.00
Preparation and coordination of status meetings/updates	\$3,750.00
Ongoing review and beta testing of site, site components	\$6,000.00
<b>Medical direction/account supervision</b>	\$5,600.00
<b>Copy writing /editing</b>	
Content development for static web pages	\$3,600.00
Proofreading	\$7,500.00
<b>Administrative and accounting fees</b>	\$2,894.20
<b>Total, Indirect Expenses</b>	<b>\$52,144.20</b>



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**Program Summary:**  
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<b>Cost Summary</b>	
<i>Clinical Expert Commentaries (6 of 12 total)</i>	
<b>Approximate Total, Direct Expenses</b>	\$42,365.00
<b>Total, Indirect Expenses</b>	\$11,708.45
<b>Subtotal, Clinical Expert Commentaries (6 of 12 total)</b>	\$54,073.45
<i>In the Know Summaries (12 of 24 total)</i>	
<b>Approximate Total, Direct Expenses</b>	\$3,800.00
<b>Total, Indirect Expenses</b>	\$17,264.00
<b>Subtotal, In the Know Summaries (12 of 24 total)</b>	\$21,064.00
<i>Knowledge Library (12 of 24 total)</i>	
<b>Approximate Total, Direct Expenses</b>	\$19,150.00
<b>Total, Indirect Expenses</b>	\$7,187.00
<b>Subtotal, Knowledge Library (12 of 24 total)</b>	\$26,337.00
<i>Ask the Expert Column (6 of 12 total)</i>	
<b>Approximate Total, Direct Expenses</b>	\$9,175.00
<b>Total, Indirect Expenses</b>	\$7,440.00
<b>Subtotal, Ask the Expert Column (6 of 12 total)</b>	\$16,615.00
<i>In the News Feature</i>	
<b>Approximate Total, Direct Expenses</b>	\$4,820.00
<b>Total, Indirect Expenses</b>	\$1,044.60
<b>Subtotal, In the News Feature</b>	\$5,864.60
<i>Web Resources and Links</i>	
<b>Approximate Total, Direct Expenses</b>	\$1,250.00
<b>Total, Indirect Expenses</b>	\$9,537.50
<b>Subtotal, Web Resources and Links</b>	\$10,787.50
<i>The ESP Case Library</i>	
<b>Approximate Total, Direct Expenses</b>	\$28,500.00
<b>Total, Indirect Expenses</b>	\$36,705.00
<b>Subtotal, The ESP Case Library</b>	\$65,205.00
<i>ESP Interdisciplinary Content Integration</i>	
<b>Approximate Total, Direct Expenses</b>	\$27,450.00
<b>Total, Indirect Expenses</b>	\$22,730.00
<b>Subtotal, ESP Interdisciplinary Content Integration</b>	\$50,180.00
<b>Emerging Solutions in Pain: 2009 Website Content</b>	<b>\$250,126.55</b>



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**Program Summary:**  
**Section 7: The Emerging Solutions in Pain Website: Programming,  
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<b>Detailed Budget Itemization: Clinical Expert Commentaries (6 of 12 2009 Video Commentaries)</b>	
<i>Direct Expenses, Approximate</i>	Total
<b>Clinical expert honoraria</b>	\$4,500.00
Honoraria for 6 clinical experts to produce 6 video clinical commentaries	
<b>Studio rental, crew fees plus associated costs</b>	\$18,525.00
<b>Transcription</b>	\$440.00
<b>Digital media production</b>	
Pre-filming coordination	\$1,125.00
Filming	\$2,250.00
Editing of video footage and graphic animations	\$8,700.00
Production of streaming file	\$750.00
<b>Posting of content</b>	\$750.00
<b>Travel, film crew</b>	\$4,275.00
<b>Miscellaneous (phone, fax, non-fulfillment Fed Ex)</b>	\$1,050.00
<b>Approximate Total, Direct Expenses</b>	\$42,365.00
<i>Indirect Expenses</i>	Total
<b>Project management</b>	
Coordination with speakers for content delivery, audio or video recording	\$1,350.00
Coordination with internal teams	\$2,800.00
Preparation and coordination of status meetings/updates	\$450.00
<b>Content development: video-based commentaries</b>	
Medical direction/account management	\$1,225.00
Identification of content/topic/speaker	\$1,200.00
Editing direction for video footage	\$1,350.00
Creation of content templates	\$375.00
Proof-reading	\$1,500.00
Fact-checking	\$187.50
<b>Administrative and accounting fees</b>	\$1,270.95
<b>Total, Indirect Expenses</b>	\$11,708.45



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**Program Summary:**  
**Section 7: The Emerging Solutions in Pain Website: Programming,  
Infrastructure and Maintenance Budget**

<b>Detailed Budget Itemization: In the Know Summaries (12 of 24 2009 Summaries)</b>	
<i>Direct Expenses, Approximate</i>	Total
<b>Digital Media,</b>	
HTML production	\$2,250.00
Posting of HTML summaries	\$750.00
<b>Reference purchase</b>	\$450.00
<b>Miscellaneous (phone, fax, non-fulfillment Fed Ex)</b>	\$350.00
<b>Approximate Total, Direct Expenses</b>	<b>\$3,800.00</b>
<i>Indirect Expenses</i>	Total
<b>Project management</b>	
Coordination with internal teams	\$1,200.00
Preparation and coordination of status meetings/updates	\$900.00
<b>Content development</b>	
Medical direction/account supervision	\$1,925.00
Research and identification of appropriate journal articles for summary	\$4,500.00
Writing of article summaries	\$6,000.00
Identification of supporting references and material gathering	\$375.00
Proof-reading	\$1,500.00
Fact-checking	\$750.00
<b>Administrative and accounting fees</b>	<b>\$114.00</b>
<b>Total, Indirect Expenses</b>	<b>\$17,264.00</b>



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**Program Summary:**  
**Section 7: The Emerging Solutions in Pain Website: Programming,  
 Infrastructure and Maintenance Budget**

<b>Detailed Budget Itemization: Knowledge Library (12 of 24 2009 Video Clips)</b>	
<b>Direct Expenses, Approximate</b>	<b>Total</b>
<b>Speaker honoraria: video filming</b>	\$1,200.00
<b>Studio rental, crew fees plus associated costs</b>	\$10,120.00
<b>Transcription</b>	\$220.00
<b>Graphic production</b>	
Development of title graphics, transitions as needed	\$725.00
Background development	\$290.00
<b>FAQ Library video production</b>	
Pre-filming coordination	\$750.00
Filming	\$870.00
Editing of video footage and graphic animations	\$3,480.00
Production of streaming file	\$375.00
<b>Miscellaneous (phone, fax, non-fulfillment Fed Ex)</b>	\$500.00
<b>Travel</b>	\$620.00
<b>Approximate Total, Direct Expenses</b>	<b>\$19,150.00</b>
<b>Indirect Expenses</b>	<b>Total</b>
<b>Project management</b>	
Coordination with speakers for content delivery, video recording	\$750.00
Coordination with internal teams	\$1,300.00
Preparation and coordination of status meetings/updates	\$225.00
<b>Content development</b>	
Medical direction/account supervision	\$525.00
Identification of content/topic/speaker	\$600.00
Editing direction of video footage	\$900.00
Coordination of content with internal teams	\$750.00
Creation of content templates	\$625.00
Proof-reading	\$937.50
<b>Administrative and accounting fees</b>	\$574.50
<b>Total, Indirect Expenses</b>	<b>\$7,187.00</b>



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**Program Summary:**  
**Section 7: The Emerging Solutions in Pain Website: Programming,  
Infrastructure and Maintenance Budget**

<b>Detailed Budget Itemization: Ask the Experts Column (6 of 12 2009 Columns)</b>	
<i>Direct Expenses, Approximate</i>	Total
<b>Honoraria</b>	\$5,000.00
All faculty honoraria for 6 months of Ask the Experts columns; faculty will create audio recording in answer to questions from ESP members and/or ESP live events; final audio answers posted as MP3 files	
<b>Digital media production</b>	
Digital audio recording session, including 800 number for recording	\$1,500.00
Editing of audio files	\$1,740.00
Production of streaming file	\$435.00
<b>Miscellaneous (phone, fax, non-fulfillment Fed Ex)</b>	\$500.00
<b>Approximate Total, Direct Expenses</b>	<b>\$9,175.00</b>
<i>Indirect Expenses</i>	Total
<b>Project management</b>	
Question source verification	\$750.00
Monthly submission of selected question(s) to faculty	\$450.00
Coordination for audio recording of answer(s) from faculty	\$600.00
Coordination with internal teams	\$960.00
<b>Content development</b>	
Medical direction/account supervision	\$1,050.00
Selection of appropriate question(s) and answering faculty	\$1,200.00
Review/approval of faculty answer	\$900.00
Proof-reading	\$750.00
<b>Administrative and accounting fees</b>	\$780.00
<b>Total, Indirect Expenses</b>	<b>\$7,440.00</b>

<b>Detailed Budget Itemization: In the News Feature</b>	
<i>Direct Expenses, Approximate</i>	Total
<b>12 month real-time news feed from Topix.net</b>	\$3,600.00
<b>Feed-specific programming</b>	\$870.00
<b>Miscellaneous (phone, fax, non-fulfillment Fed Ex)</b>	\$350.00
<b>Approximate Total, Direct Expenses</b>	<b>\$4,820.00</b>
<i>Indirect Expenses</i>	Total
<b>Project management</b>	
Coordination and troubleshooting with third party vendor, Topix.net	\$450.00
Coordination with internal teams	\$450.00
<b>Administrative and accounting fees</b>	\$144.60
<b>Total, Indirect Expenses</b>	<b>\$1,044.60</b>





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**Program Summary:**  
**Section 7: The Emerging Solutions in Pain Website: Programming,  
Infrastructure and Maintenance Budget**

<b>Detailed Budget Itemization: Web Links and Resources</b>	
<i>Direct Expenses, Approximate</i>	Total
Licensing fees for PDFs	\$500.00
Posting of content	\$750.00
<b>Approximate Total, Direct Expenses</b>	<b>\$1,250.00</b>
<i>Indirect Expenses</i>	Total
<b>Project management</b>	
Research and identification of appropriate new resources for posting on ESP site	\$3,500.00
Maintenance of current links	\$1,800.00
Recruitment of new links	\$2,700.00
Medical direction/account supervision	\$1,400.00
Administrative and accounting fees	\$37.50
<b>Total, Indirect Expenses</b>	<b>\$9,537.50</b>
<b>Detailed Budget Itemization: The ESP Case Library (12 Case Vignettes Total)</b>	
<i>Direct Expenses, Approximate</i>	Total
Honoraria, 12 total	\$12,000.00
Audio recording & transcription	\$1,320.00
<b>Digital media production</b>	
Pre-recording coordination	\$2,250.00
Recording phone line	\$3,600.00
Audio recording	\$750.00
Editing of audio files	\$6,960.00
Production of streaming file	\$870.00
Miscellaneous (non-fulfillment shipping, faxes, etc.)	\$750.00
<b>Approximate Total, Direct Expenses</b>	<b>\$28,500.00</b>
<i>Indirect Expenses</i>	Total
<b>Project management</b>	
Coordination with faculty	\$5,400.00
Coordination of internal teams	\$3,500.00
Preparation and coordination of status meetings/updates	\$1,800.00
<b>Content development</b>	
Medical direction/account supervision	\$5,250.00
Identification, recruitment of faculty for case vignette development	\$2,700.00
Review of case vignettes and suggestions for faculty pre-recording	\$9,000.00
Editing direction for case vignettes	\$3,500.00
Proofreading	\$4,500.00
Administrative and accounting fees	\$855.00
<b>Total, Indirect Expenses</b>	<b>\$36,705.00</b>



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### Program Summary:

## Section 7: The Emerging Solutions in Pain Website: Programming, Infrastructure and Maintenance Budget

<b>Detailed Budget Itemization: ESP Interdisciplinary Content Integration (24 Integrations Total)</b>	
<b>Direct Expenses, Approximate</b>	<b>Total</b>
<b>Honoraria</b>	\$12,000.00
All faculty honoraria for 24 "interpretations" of ESP content for other specialties, i.e., nurse commentary on the application for nurses of physician-authored column or physician commentary on the application for physicians of pharmacist-authored column; faculty will create audio recording on specialty commentaries and final audio posted as MP3 files	
<b>Digital media production</b>	
Digital audio recording session, including 800 number for recording	\$6,000.00
Editing of audio files	\$6,960.00
Production of streaming file	\$1,740.00
<b>Miscellaneous (phone, fax, non-fulfillment Fed Ex)</b>	\$750.00
<b>Approximate Total, Direct Expenses</b>	<b>\$27,450.00</b>
<b>Indirect Expenses</b>	<b>Total</b>
<b>Project management</b>	
Submission of selected commentaries/activities to commenting faculty	\$1,800.00
Coordination for audio recording of answer(s) from faculty	\$1,800.00
Coordination with internal teams	\$3,600.00
<b>Content development</b>	
Medical direction/account supervision	\$4,550.00
Identification of commentaries/activities for specialty comments and commenting faculty	\$2,400.00
Review/approval of faculty answer	\$4,800.00
Proof-reading	\$3,000.00
<b>Administrative and accounting fees</b>	\$780.00
<b>Total, Indirect Expenses</b>	<b>\$22,730.00</b>



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## **Program Summary: Emerging Solutions in Pain**

### **Section 8: Tools Content Updating and Wider Distribution**

#### **Program Title**

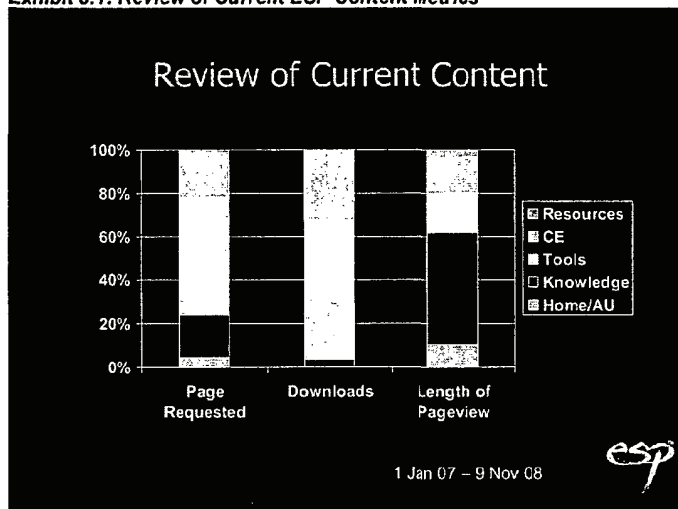
The *Emerging Solutions in Pain* increased distribution and updating of currently available tools including:

- Tool Kit Volume II
- Patient Tool Kit and Educational Fact Sheets
- 9 Instruments of Assessment
- Practitioners Guide to Patient Visits: Tools and Techniques
- Assessment Tools
- UDT Interpretation Chart
- UDT Pocket Guide

#### **Background**

The *Emerging Solutions in Pain* (ESP) Tools contains a multimedia collection of educational resources focusing on patient assessment for the risk of misuse, abuse and addiction with pain, patient monitoring throughout the treatment plan, and best practices for clinicians to optimize pain patient care. These tools remain one of the most popular requested pages on the ESP website but also via the ESP Booth program and via direct contact.

**Exhibit 8.1: Review of Current ESP Content Metrics**



#### **Proposed Program/Educational Solution**

The ESP Tools are both valued and well-utilized resources; it is imperative to ensure that the content remains both accurate and relevant, as well as ensuring that pain management clinicians have access to these clinical tools. MediCom is proposing in 2009 to update the content of these tools as required and also make the CD-ROM tools available for wider distribution to ESP members.

#### **Program Overview**

MediCom Worldwide, Inc. is proposing to continually identify and develop currently available tools within the ESP initiatives, and to ensure accuracy of information to reflect the current state of pain management and addiction medicine. These tools have been identified as a valued resource by ESP members and the larger pain community (as evidence by request for copies). Updating of content for these tools will be developed in conjunction with Peer Review Panels as described in Section 6. While the final number and



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## ***Program Summary: Emerging Solutions in Pain***

### ***Section 8: Tools Content Updating and Wider Distribution***

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scope of the new updates will be determined based solely on the guidance provided by the peer review panel throughout the year, but will not be limited to, revision of the tools summarizing the new guidelines for low back pain, federal regulations pertaining to controlled substances, as well as inclusion of new tools in risk assessment. There is a critical need to make available both the Tool Kit II and the Patient Tool Kit for wider distribution as evidenced by the number of request obtained via the website.

#### **Program Objectives**

The objectives of the *Emerging Solutions in Pain* Tools are to provide updated tools, resources and information to a wider selection of clinicians who care for patients with chronic pain. Distribution will be set-up via a Google checkout to those who manage the supply chain of requests.

#### **Intended Audience**

The primary audience of the ESP Tools will be physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain and also those who educate on best practices of chronic patient care.

#### **Format**

Multimedia CD-ROMs and online at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com)

#### **Distribution**

The *Emerging Solutions in Pain* Tools will be available as appropriate through the following avenues:

- (1) Through electronic download at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com)
- (2) Through distribution at the *Emerging Solutions in Pain* Meet the Expert Booth
- (3) Through ordering of the CD-ROM online at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com)
- (4) At live programs and activities developed by *Emerging Solutions in Pain*

#### **Request for Sponsor Support**

MediCom Worldwide, Inc. will coordinate updating content, further development and wider distribution of the *Emerging Solution in Pain* Tools through the tactics outlined above.

As a supplement to these primary methods, MediCom Worldwide, Inc. may request the assistance of Cephalon, Inc. sales force in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of MediCom Worldwide, Inc., and any such distribution will solely be as a supplement to MediCom's primary methods of announcement and promotion.

#### **Total Budget**

The total budget to fund this activity is \$70,780.



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**Program Summary: Emerging Solutions in Pain**  
**Section 8: Tools Content Updating and Wider Distribution Budget**

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<b>Cost Summary</b>	
<i>Update of 2008 ESP Content/Tools</i>	
<b>Approximate Total, Direct Expenses</b>	\$22,710.00
<b>Total, Indirect Expenses</b>	\$29,601.30
<b>Subtotal, Update of 2008 ESP Content/Tools</b>	\$52,311.30
<i>Online Distribution of the ESP Patient Tool Kit CD</i>	
<b>Approximate Total, Direct Expenses</b>	\$11,110.00
<b>Total, Indirect Expenses</b>	\$7,358.30
<b>Subtotal, Online Distribution of the ESP Patient Tool Kit CD</b>	\$18,468.30
<b>The Emerging Solutions in Pain Tools: Updates and Distribution</b>	<b>\$70,779.60</b>



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**Program Summary: Emerging Solutions in Pain**  
**Section 8: Tools Content Updating and Wider Distribution Budget**

<b>Detailed Budget Itemization: Update of 2008 ESP Content/Tools (4 Updates Total)</b>	
<i>Direct Expenses, Approximate</i>	Total
<b>Audio track recording</b>	\$1,800.00
Professional voice talent narration of updated slide/audio modules	
<b>Clinical expert honoraria (2)</b>	
Review of MediCom-authored updates (2)	\$1,000.00
Creation of updates (2)	\$3,000.00
<b>Transcription</b>	\$440.00
<b>Graphic design</b>	
Update of graphic user interface (3)	\$2,610.00
Creation of update slides for slide/audio format (10 slides per update)	\$2,320.00
Typesetting, layout of PDFs (4)	\$1,500.00
<b>IT, programming services</b>	
Audio recording	\$2,400.00
Editing of audio track	\$2,250.00
Programming	\$4,800.00
<b>Reference purchase</b>	\$240.00
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$350.00
<b>Approximate Total, Direct Expenses</b>	<b>\$22,710.00</b>
<i>Indirect Expenses</i>	Total
<b>Project management</b>	
Review of audio files for editing direction	\$1,200.00
Coordination of internal teams	\$4,320.00
Coordination with faculty for authoring or review, approval	\$2,100.00
Preparation and coordination of status meetings/updates	\$1,200.00
<b>Medical/scientific services</b>	
Medical direction/account supervision	\$3,850.00
Creation of updated content (4)	\$6,000.00
Creation of slides for slide/audio updates (40 slides total)	\$3,500.00
Review and incorporation of clinical expert comments	\$3,000.00
Identification of supporting references, materials	\$500.00
Proofreading	\$2,250.00
Fact-checking	\$1,000.00
<b>Administrative and accounting fees</b>	\$681.30
<b>Total, Indirect Expenses</b>	<b>\$29,601.30</b>



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**Program Summary: Emerging Solutions in Pain**  
**Section 8: Tools Content Updating and Wider Distribution Budget**

<b>Detailed Budget Itemization: Online Distribution of ESP Patient Tool Kit</b>	
<b>Direct Expenses, Approximate</b>	<b>Total</b>
Digital media: programming of online request form	\$1,160.00
Data management	
Database development	\$435.00
Data collection and review	\$1,740.00
Shipping and fulfillment: 1,500 Tool Kits	
Packaging and mail services	\$525.00
Shipping (USPS)	\$1,500.00
Fulfillment	\$5,250.00
Miscellaneous (phone, fax, non-fulfillment Fed Ex)	\$500.00
<b>Approximate Total, Direct Expenses</b>	<b>\$11,110.00</b>
<b>Indirect Expenses</b>	<b>Total</b>
Project management	
Re-confirmation of clinician status for all requesting individuals	\$3,200.00
Communication with requesting clinicians	\$500.00
Coordination with internal teams	\$1,200.00
Preparation and coordination of status meetings/updates	\$300.00
Content development	
Medical direction/account supervision	\$1,050.00
Copy editing of request page	\$400.00
Proof-reading	\$375.00
Administrative and accounting fees	\$333.30
<b>Total, Indirect Expenses</b>	<b>\$7,358.30</b>





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## ***Program Summary: Emerging Solutions in Pain***

### ***Section 9: New Content, Tools and Resources***

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#### **Program Title**

The *Emerging Solutions in Pain* New Content, Tools and Resources.

#### **Background**

*Emerging Solutions in Pain* is an ongoing educational initiative developed to address some of today's most critical issues in pain management. The dynamic nature of the website mandates that content is regularly updated and new content, tools and resources are developed according to the changing needs of clinical pain management and addiction medicine health care professionals.

#### **Proposed Program/Educational Solution**

In 2009, the *Emerging Solutions in Pain* Initiative will take the appropriate next steps to progressively change the educational programs, building on the past learning, the current environmental changes and future educational needs toward greater improvement in pain patient care outcomes.

We will continue to pioneer the creation and dissemination of educational tools, resources and activities that support the goals and objectives outlined within this overview to ultimately become the "GO TO" resource for the best current evidence and practical tools for achieving optimal outcomes in the management of chronic pain while minimizing the risk of abuse, misuse, and diversion.

MediCom is proposing the following new tactics:

1. ESP Patient Interview and Decision Tree Algorithm – a case-based series of patient vignettes that enables the user to work through a series of interview/assessment techniques with associated assessment outcomes
2. ESP Referral Tool – a tool to allow PCPs to efficiently and effectively categorize potential pain patients into one of three groups for referral strategies; (1) tool to include a checklist of questions/behavior types utilized early in the physician–patient relationship; (2) consultation request form/tool for use by the PCP in requesting a consult; and (3) consultation reply form/tool for use by the pain specialist/addiction medicine specialist to provide information back to the referring PCP
3. ESP Learning Resource Center – a subscription-based print initiative for pain specialists and clinics. Subscribing members of ESP receive a poster with a yearly planner, important clinician-focused facts and information supporting safe and effective prescribing of opioids, an adhesive poster pocket for distribution of quarterly information resources and first quarter's information resource. Four new information resources will be produced in 2009 and may include assessment, monitoring or documentation tools, monographs or monograph collections, patient education fact sheets, and/or journal article summaries to be utilized individually or as a practice group learning session

#### **Program Objectives**

The purpose of the *Emerging Solutions in Pain* new programs is to address identified gaps in the educational content of pain management and addiction medicine physicians. The key objectives of the new programs are to:

1. Grow the membership to 10,000
2. Provide information resources which are valued by the diverse members (as evidence by the usefulness and quality metrics to be posted on every content page)



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## ***Program Summary: Emerging Solutions in Pain Section 9: New Content, Tools and Resources***

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3. Provide communication resources to share best practices to clinicians (as evidence by the membership feedback and case vignette sessions)

### **Program Overview**

#### ***The ESP Resource Learning Center***

##### **Objectives:**

The ESP Resource Learning Center will establish an information and resource repository in pain clinics and centers for the distribution of ESP-branded educational content. The content within this resource can form the basis of regular staff education sessions to improve the pain practice.

**Format:** The ESP Resource Learning Center will be a durable poster which can be placed on a pain practice central office wall which is not within the patient waiting area (areas can be the staff room or practice manager's office). It will contain the ESP branding, look & feel and will have a plastic literature holder. The poster may even be a useful tool like a 2009 yearly planner to track staff rosters and training sessions. The plan for this program is as follows:

1. Centers will subscribe to the ESP Resource Center via the ESP website or booth initiatives
2. New subscribers will receive a poster including the first quarter's information resource
3. The content of each plastic holder may form the basis of a group education session, ie, the group may read a monograph individually and discuss the learning points as a group
4. The quarterly information resources will include (but will not be limited to) the following:
  - a. Assessment, monitoring or documentation tools
  - b. Monographs or monograph collections
  - c. Patient education fact sheets
  - d. Journal article summary collections
5. Each quarter, subscribers will receive a new resource for placement in the poster's remaining pockets and distribution to other HCPs within the pain management clinic/center for "group" learning sessions
6. Subscribers would be able to submit future topics/content to provide a continual resource

**Cost:** \$162,778 (The detailed budget for the ESP Resource Learning Center can be found on page 87)

#### ***The ESP Patient Interview Decision Tree Algorithm: How to Talk to Real Patients about Real Problems***

##### **Objectives:**

The ESP Patient Interview Decision Tree Algorithm will enable the individual user to work through a series of case-based patient vignettes to simulate clinical learning about interview/assessment techniques. Each assessment outcome is determined by the choices made by the user, with multiple possible outcomes to each assessment interview.

##### **Format:**

- This tool will be a case-based series of patient vignettes that engages the user by allowing the individual user to work through a series of interview/assessment techniques
  - The user will select from a series of patient presentations
  - Each patient case study will be presented in video format



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## ***Program Summary: Emerging Solutions in Pain***

### ***Section 9: New Content, Tools and Resources***

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- The user will be required to determine the type and style of questions asked to acquire the patient history
- The assessment outcome will be determined by choices made by the individual user, with multiple possible outcomes to the assessment interview
- The user may repeat each case indefinitely, selecting alternative interview techniques to identify how each alternative impacts collection of information
- By allowing the user to determine the case outcome, the learner will be:
  - More likely to participate because they will be selecting patients/cases that are of interest to them
  - More engaged
  - Better able to apply learning in "real-life"
- Case-based teaching is model familiar to many clinicians
  - It has been used as training in medical school for 45+ years
- Programs will be of interest to all levels of users, from novice to experienced, as each user will select the options they are most familiar with
- Three case will presented throughout the year

**Cost:** \$88,284 (The detailed budget for the ESP Patient Interview Decision Tree can be found on page 85)

#### ***The ESP Referral Tool***

##### **Objectives:**

The ESP Referral Tool is aimed to allow primary care physicians to efficiently and effectively categorize potential pain patients into one of three groups for referral strategies. This will enable early referral to a specialist to ensure pain patients receive optimal care for their chronic pain. It will also assist the specialist to convey patient information back to the referring PCP. The tool is aimed to streamline the communication process and responsibilities between the interdisciplinary team.

##### **Format:**

- The ESP patient referral tool will allow PCPs to efficiently and effectively categorize potential pain patients into one of three groups
  - Patients I - manage alone
  - Patients II - manage in consultation with a specialist
  - Patients III - should not manage
- The tool will outline guidelines on patient types with differing needs for referral
- The tool may include but is not limited to:
  - A checklist of questions/behavior types utilized early in the physician-patient relationship
  - Consultation request form/tool for use by the PCP in requesting a consult
  - Consultation reply form/tool for use by the pain specialist/addiction medicine specialist to provide information back to the referring PCP
  - Case studies

**Cost:** \$69,025 (The detailed budget for the ESP Referral Tool can be found on Page 86)



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## ***Program Summary: Emerging Solutions in Pain***

### ***Section 9: New Content, Tools and Resources***

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#### **Intended Audience**

The primary audience of the *Emerging Solutions in Pain* new tools will be physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain.

#### **Format**

Refer to the format under each individual new tool.

#### **Distribution**

The Emerging Solutions in Pain new tools will be via the ESP website.

#### **Request for Sponsor Support**

MediCom Worldwide, Inc. is promoting the Emerging Solutions in Pain New Tools through a variety of methods, including direct mail, and banner advertisements.

#### **Total Budget**

The total budget to fund these activities is \$320,087.



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***Program Summary: Emerging Solutions in Pain***  
***Section 9: New Content, Tools and Resources Budget***

<b>Cost Summary</b>	
<i>ESP Interview Decision Tree Algorithm</i>	
<b>Approximate Total, Direct Expenses</b>	\$49,140.00
<b>Total, Indirect Expenses</b>	\$39,144.20
<b>Subtotal, ESP Interview Decision Tree Algorithm</b>	\$88,284.20
<i>ESP Referral Tool</i>	
<b>Approximate Total, Direct Expenses</b>	\$30,985.00
<b>Total, Indirect Expenses</b>	\$38,039.55
<b>Subtotal, ESP Referral Tool</b>	\$69,024.55
<i>The ESP Quarterly Resource Center Subscription</i>	
<b>Approximate Total, Direct Expenses</b>	\$129,445.00
<b>Total, Indirect Expenses</b>	\$33,333.35
<b>Subtotal, The ESP Quarterly Resource Center Newsletter</b>	\$162,778.35
<b>The Emerging Solutions in Pain Website: New Activities and Resources</b>	<b>\$320,087.10</b>



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**Program Summary: Emerging Solutions in Pain**  
**Section 9: New Content, Tools and Resources Budget**

<b>Detailed Budget Itemization: ESP Interview Decision Tree Algorithm (3 Cases Total)</b>	
<i>Direct Expenses, Approximate</i>	Total
<b>Video Case Development (3 cases, approximately 15 mins per case)</b>	
Clinician honoraria for consultation, review	\$3,500.00
Professional video talent (3 patient actors)	\$2,250.00
<b>Faculty travel to film cases at MediCom location</b>	
Air	\$550.00
Hotel	\$250.00
Ground transportation	\$200.00
OOP	\$200.00
<b>Digital Media: video cases</b>	
Filming of three case studies	\$9,000.00
Creation of animations, highlights, additional graphics	\$4,640.00
Editing	\$13,050.00
<b>Digital Media: programming</b>	
Programming of 3 3-tier decision trees	\$8,700.00
Incorporation of programmed trees into ESP infrastructure	\$5,800.00
<b>Miscellaneous (phone, fax, non-fulfillment Fed Ex)</b>	\$1,000.00
<b>Approximate Total, Direct Expenses</b>	<b>\$49,140.00</b>
<i>Indirect Expenses</i>	Total
<b>Project management</b>	
Coordination with faculty	\$2,400.00
Coordination of internal teams	\$7,920.00
Preparation and coordination of status meetings/updates	\$1,200.00
<b>Content development</b>	
Medical direction/account supervision	\$6,650.00
Identification, recruitment of faculty for case development	\$900.00
Creation of cases based on faculty consultation	\$7,000.00
Review of faculty comments and incorporation of changes	\$2,000.00
Storyboard development	\$2,700.00
Script preparation	\$2,400.00
Editing review post-filming	\$1,500.00
Proofreading	\$3,000.00
<b>Administrative and accounting fees</b>	<b>\$1,474.20</b>
<b>Total, Indirect Expenses</b>	<b>\$39,144.20</b>



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**Program Summary: Emerging Solutions in Pain**  
**Section 9: New Content, Tools and Resources Budget**

<b>Detailed Budget Itemization: ESP Referral Tool</b>	
<b>Direct Expenses, Approximate</b>	<b>Total</b>
<b>Clinical expert honoraria, 6 faculty</b>	<b>\$12,000.00</b>
Two pain specialists, two addictionologists, 2 PCPs	
<b>Conference calls (3)</b>	<b>\$600.00</b>
<b>Transcription</b>	<b>\$660.00</b>
<b>Graphic design</b>	
Creation of graphic user interface	\$1,740.00
Slide design, creation for slide/audio portion of tool	\$1,450.00
Typesetting, layout of tool (3 PDFs total)	\$2,250.00
<b>Digital media</b>	
Professional voice talent narration of slide/audio module	\$600.00
Pre-recording coordination	\$900.00
Audio recording	\$900.00
Editing of audio track	\$725.00
Programming	\$5,800.00
Incorporation of programmed tool into ESP infrastructure	\$2,610.00
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	<b>\$750.00</b>
<b>Approximate Total, Direct Expenses</b>	<b>\$30,985.00</b>
<b>Indirect Expenses</b>	<b>Total</b>
<b>Project management</b>	
Coordination with faculty	\$3,600.00
Coordination with internal teams	\$4,560.00
Preparation and coordination of status meetings/updates	\$900.00
<b>Medical/scientific services</b>	
Medical direction/account supervision	\$5,950.00
Research/preparation	\$2,000.00
Preparation of briefing document for faculty discussion during first conference call	\$1,750.00
Participation in faculty conference calls (3)	\$2,250.00
Outline creation	\$1,500.00
Script development	\$4,000.00
Tool development (3)	\$4,500.00
Incorporation of revisions	\$1,600.00
Proofreading	\$3,600.00
Fact-checking	\$900.00
<b>Administrative and accounting fees</b>	<b>\$929.55</b>
<b>Total, Indirect Expenses</b>	<b>\$38,039.55</b>





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## Program Summary: Emerging Solutions in Pain

### Section 9: New Content, Tools and Resources Budget

<b>Detailed Budget Itemization: ESP Resource Center</b>	
<b>Direct Expenses, Approximate</b>	<b>Total</b>
<b>Clinical expert honoraria, 5 faculty</b>	<b>\$7,500.00</b>
Five faculty to provide consultation and review for the poster and four resources	
<b>Print production</b>	
<b>Poster; quantity, 500</b>	
Poster production: four-color, gloss finish, gator-board poster, 36"x48"x3/16" with plastic pocket	\$47,000.00
Graphic design of poster	\$2,320.00
Typesetting, layout of poster	\$1,000.00
<b>Subscription resource #1: Patient Fact Sheet #1; quantity, 10,000 (20/poster)</b>	
Printing, 10,000 pieces, 6 pages each (1 backgrounder cover sheet + 5 pages of Patient Fact Sheet #1), four-color, stapled	\$7,500.00
Adaptation of Fact Sheet #1 for printing (typesetting, layout)	\$870.00
Typesetting, layout of backgrounder cover sheet	\$435.00
<b>Subscription resource #2: UDT Pocket Guide; quantity, 10,000 (20/poster)</b>	
Printing, 10,000 pieces, 3 pages each (1 backgrounder cover sheet + 2 pages of UDT Pocket Guide), two-color, stapled	\$4,000.00
Adaptation of UDT Pocket Guide for printing (typesetting, layout)	\$580.00
Typesetting, layout of backgrounder cover sheet	\$435.00
<b>Subscription resource #3: ORT; quantity, 10,000 (20/poster)</b>	
Printing, 10,000 pieces, 4 pages each (2 backgrounder cover sheets + 1 page ORT/Clinician Interview Form + 1 page ORT/Patient Self-report Form), two-color, stapled	\$5,000.00
Adaptation of ORT forms for printing (typesetting, layout)	\$580.00
Typesetting, layout of backgrounder sheet	\$435.00
<b>Subscription resource #4: Interdisciplinary Forms Collection; quantity, 10,000 (20/poster)</b>	
Printing, 10,000 pieces, 7 pages each (2 backgrounder cover sheets + 3 forms from Referral Tool + 2 forms from Physician/Pharmacist Communication Tool), two-color, stapled	\$8,000.00
Adaptation of Interdisciplinary Forms for printing (typesetting, layout)	\$1,160.00
Typesetting, layout of backgrounder sheets	\$580.00
<b>Shipping and Fulfillment</b>	
<b>Poster; quantity, 500</b>	
Packaging and mail services	\$4,125.00
Shipping (Fed Ex Ground)	\$3,750.00
Fulfillment	\$5,000.00
<b>Subscription resource #1: Patient Fact Sheet #1; quantity, 10,000 (20/poster)</b>	
Packaging and mail services	\$1,500.00
Shipping (Fed Ex Ground)	\$3,000.00
Fulfillment	\$1,750.00
<b>Subscription resource #2: UDT Pocket Guide; quantity, 10,000 (20/poster)</b>	
Packaging and mail services	\$1,500.00
Shipping	\$2,500.00
Fulfillment	\$1,750.00



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**Program Summary: Emerging Solutions in Pain**  
**Section 9: New Content, Tools and Resources Budget**

<b>Detailed Budget Itemization: ESP Resource Center (continued)</b>	
<i>Direct Expenses, Approximate</i>	<b>Total</b>
<b>Subscription resource #3: ORT; quantity, 10,000 (20/poster)</b>	
Packaging and mail services	\$1,500.00
Shipping (Fed Ex Ground)	\$3,000.00
Fulfillment	\$1,750.00
<b>Subscription resource #4: Interdisciplinary Forms Collection; quantity, 10,000 (20/poster)</b>	
Packaging and mail services	\$1,500.00
Shipping (Fed Ex Ground)	\$3,000.00
Fulfillment	\$1,750.00
<b>HTML posting of subscription availability on ESP website</b>	\$1,000.00
<b>Subscription database management</b>	\$2,175.00
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$1,500.00
<b>Approximate Total, Direct Expenses</b>	<b>\$129,445.00</b>
<i>Indirect Expenses</i>	<b>Total</b>
<b>Project management</b>	
Coordination with faculty	\$1,500.00
Coordination with internal teams	\$4,800.00
Preparation and coordination of status meetings/updates	\$1,800.00
<b>Medical/scientific services</b>	
Medical direction/account supervision	\$3,850.00
Content development, poster	\$4,900.00
Content development, backgrounders for each issue, 4 issues total	\$6,000.00
Incorporation of revisions	\$3,000.00
Proofreading	\$3,600.00
Fact-checking	\$900.00
<b>Administrative and accounting fees</b>	\$3,883.35
<b>Total, Indirect Expenses</b>	<b>\$33,333.35</b>



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## **Program Summary: Emerging Solutions in Pain**

### **Section 10: Accredited ESP Symposia & Enduring**

#### **Program Title**

*The Emerging Solutions in Pain Accredited ESP Symposia*

#### **Background**

Chronic pain presents a complex challenge for the patient, family, friends, and caregivers, as well as for the clinicians involved in managing the patient's care.

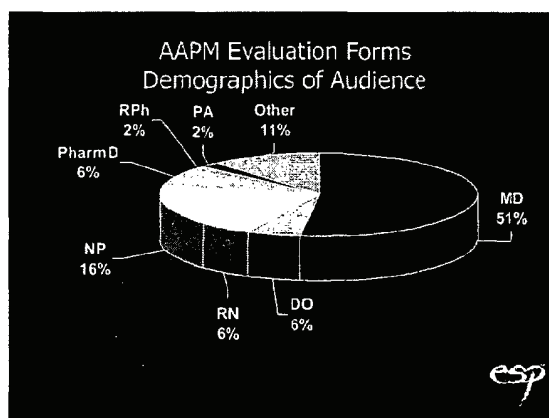
The main challenge to the treatment of chronic pain is the alarming risk of addiction, misuse, and diversion. These associated risks affect the clinical decision making, and often leads to "opiophobia", thereby, impeding treatment.

The ESP Needs Assessment (please refer to Pages 6 to 21) clearly highlights the need for additional education to help provide information on managing chronic pain with the associated risk issues. The goal of such programs must be to support clinicians with practical day-to-day information to improve pain patient care while reducing the potential for abuse, addiction, diversion, as well as the medical regulatory/malpractice liability issues.

The evaluation forms from the 2008 AAPM symposium identified (refer to Exhibits 10.1 to 10.5) that:

- 100% thought the symposium was satisfactory or above with a majority (70%) considering it to be outstanding
- 74% felt that the content presented provided new information to improve their clinical practice
- 85% felt motivated to change their clinical practice after hearing the presentations with 99% being committed to that change
- 100% felt that activities such as this symposium were necessary and important to their education
- 43% of the delegates preferred live meeting for their continuing education.

*Exhibits 10.1: Demographics of the AAPM Symposium Delegates*



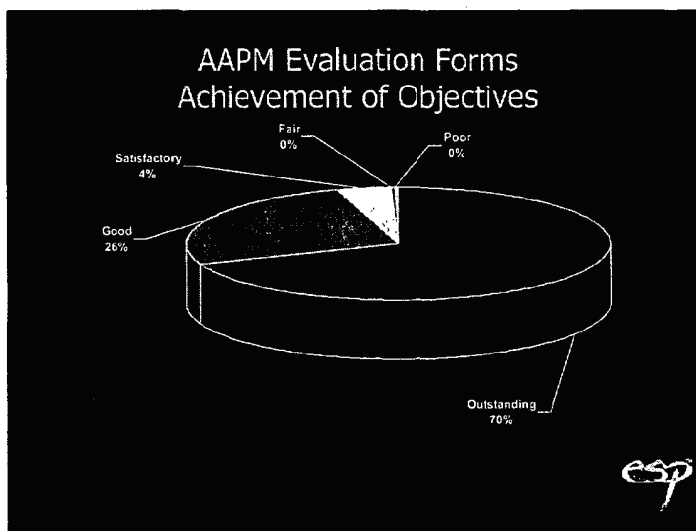


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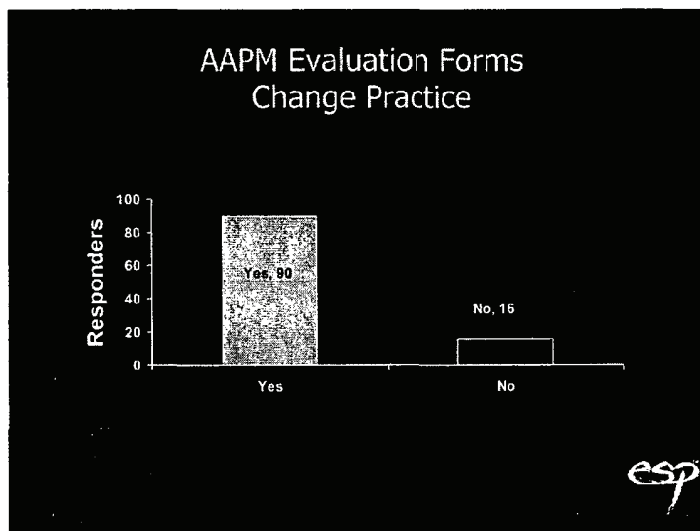
## **Program Summary: Emerging Solutions in Pain**

### **Section 10: Accredited ESP Symposia & Enduring**

*Exhibits 10.2: Achievement of the AAPM Symposium Objectives*



*Exhibits 10.3: Did the AAPM Symposium Cause you to Change Clinical Practice*

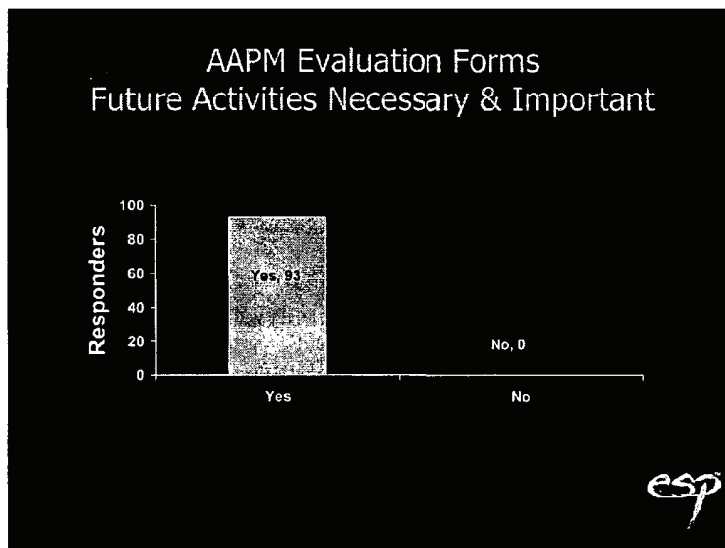




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## **Program Summary: Emerging Solutions in Pain Section 10: Accredited ESP Symposia & Enduring**

*Exhibits 10.5: Are Activities Such as the AAPM Symposium Necessary & Important*



### **Proposed Program/Educational Solution**

MediCom Worldwide, Inc. is proposing to hold two 2-hour satellite symposia held in conjunction with the 2009 American Academy of Pain Management Meeting; each symposium to be held as part of a plenary session, and will focus on the role of risk assessment in returning pain patients to optimal functionality

Symposia Title:           The Right Patient, The Right Therapy, The Right Outcomes:  
                                  Maximizing Patient Care Outcomes whilst Minimizing Risks

### **Program Overview**

As outlined above, one of the main challenges in pain management today is the appropriate assessment of the chronic pain patient. This assessment must focus on identifying the right therapy for the right patient as well as continual assessment of the risk potential for opioid misuse, abuse and addiction.

The tactics of proactive and thorough assessment, followed by ongoing monitoring, are both good medical practices and supportive of improved pain patient care outcomes. In today's challenging clinical milieu, clinicians are required to have knowledge of clinical but also legal and regulatory requirements with regard to their prescribing of controlled substances.

Together, these factors make it imperative that clinicians must have a thorough understanding of:

- The complex challenges of treating pain and addiction
- Selecting the right therapy for the right patient



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## ***Program Summary: Emerging Solutions in Pain Section 10: Accredited ESP Symposia & Enduring***

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- Clinically differentiating between the associated risk of addiction, physical dependency, tolerance and pseudoaddiction
- Legal and regulatory requirements of prescribing of controlled substances
- Individualized treatment plans that maximize the patient care outcomes and minimize the potential risks

### **Proposed Agenda**

#### **Day 1:**

2:00 – 2:10 PM	Welcome and Introductions including ARS
2:10 – 2:30 PM	Outline of the Challenges of Managing Chronic Pain in the Shadow of Addiction
2:30 – 2:50 PM	Outline of the Current Clinical Practice Guidelines for Managing Chronic Pain with Comorbid Addiction Disease
2:50 – 3:00 PM	Q&A
3:00 – 3:15 PM	Break
3:15 – 3:35 PM	Practical Approaches to Risk Assessment for Misuse, Abuse and Addiction
3:35 – 3:45 PM	Case Studies
3:45 – 4:00 PM	Q&A and Closing

#### **Day 2:**

2:00 – 2:10 PM	Welcome and Introductions including ARS
2:10 – 2:30 PM	Differential Diagnosis of Addiction, Tolerance, Physical Dependence and Pseudoaddiction
2:30 – 2:50 PM	Regulatory and Legal Requirements of Managing Patients with Controlled Substances
2:50 – 3:00 PM	Q&A
3:00 – 3:15 PM	Break
3:15 – 3:35 PM	Practical Outlines of Resources Available to Document Patient Visits
3:35 – 3:45 PM	Case Studies
3:45 – 4:00 PM	Q&A and Closing



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## ***Program Summary: Emerging Solutions in Pain Section 10: Accredited ESP Symposia & Enduring***

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### **Program Objectives**

Upon completion of this activity, participants should be better able to:

- Recognize the key challenges surrounding the treatment of chronic pain with opioids and specifically, the risk of opioid misuse, abuse and diversion among chronic pain patients
- Discuss the consequences of both undertreatment of pain and prescription opioid diversion
- Identify the clinical management options to prescribing the right therapy for the right patient and proactively identify patients with increased potential for opioid misuse, abuse and diversion
- Identify the federal regulations and legal statutes regarding opioid medications
- Integrate risk management tools and strategies into everyday clinical practice

The second part of this program will be producing enduring material adaptation of the 2009 satellite symposia series programmed as two automated slide-audio activities on ESP.

### **Intended Audience**

The primary audience of the ESP symposia will be physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain and also those who educate on best practices of chronic patient care.

### **Format**

Live Symposia with automated slide audio will be posted on the ESP website.

### **Distribution**

The *Emerging Solutions in Pain* symposia will be held at the American Academy of Pain Management, 20th Annual Clinical Meeting, October 8-11, 2009, Sheraton Phoenix Downtown Hotel, Phoenix, Arizona. The enduring materials will be placed on [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com).

### **Request for Sponsor Support**

MediCom Worldwide, Inc. will coordinate the content, advertisement and wider distribution of the *Emerging Solution in Pain* symposia and enduring materials.

### **Total Budget**

The total budget to fund this activity is \$298,123.





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***Program Summary: Emerging Solutions in Pain***  
***Section 10: Accredited ESP Symposia & Enduring Budget***

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<b><i>Program Parameters</i></b>	
Number of accredited symposia	2
Number of credit hours	4
Faculty presenters per symposia	3
Approximate number, health care professional attendees per meeting	250

<b><i>Cost Summary</i></b>	
Approximate Total, Direct Expenses	\$139,500.00
Total, Indirect Expenses	\$66,860.00
<b>Cost of the 2009 AAPM Plenary Session Symposia Series</b>	<b>\$206,360.00</b>



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**Program Summary: Emerging Solutions in Pain**  
**Section 10: Accredited ESP Symposia & Enduring Budget**

<b>Direct Expenses, Approximate: 2009 AAPM Plenary Session Symposia Series</b>	
<b>Direct Expenses, Approximate</b>	<b>Total</b>
<b>Association Fee</b>	<b>\$40,000.00</b>
<b>Speaker honoraria</b>	
Chairman (1)	\$3,500.00
Faculty (5)	\$12,500.00
<b>Graphic design and print materials</b>	
Graphic design of look/feel	\$5,800.00
Slide creation	\$7,500.00
Handout binders, includes binder shell plus all internal sheets; binders to include accreditation information, speaker biographical and disclosure information, agenda, reference materials and presentation slides	\$22,800.00
Typesetting, layout of handout binders	\$4,500.00
Set design pieces: banners	\$2,000.00
Set design pieces: signage	\$1,800.00
Program book advertisements	\$3,000.00
Typesetting, layout of program advertisements	\$1,000.00
Typesetting, layout of signage	\$1,500.00
Typesetting, layout of banners	\$1,000.00
<b>Faculty travel (6 faculty; air, OOP, hotel)</b>	
Speaker air	\$3,300.00
Speaker hotel	\$4,200.00
Speaker OOP	\$600.00
Speaker ground transportation	\$1,200.00
<b>MCWW travel (5 staff; air, OOP, hotel)</b>	
MediCom air	\$2,750.00
MediCom hotel	\$5,250.00
MediCom OOP	\$500.00
MediCom ground transportation	\$500.00
<b>Audio/visual services; upgrade from basic AV included in association fee</b>	<b>\$10,000.00</b>
<b>Reference purchase</b>	<b>\$300.00</b>
<b>Stock photo purchase</b>	<b>\$1,500.00</b>
<b>Shipping/Fed Ex</b>	<b>\$1,500.00</b>
<b>Miscellaneous</b>	<b>\$1,000.00</b>
<b>Approximate Total, Direct Expenses</b>	<b>\$139,500.00</b>



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**Program Summary: Emerging Solutions in Pain**  
**Section 10: Accredited ESP Symposia & Enduring Budget**

<b>Indirect Expenses: 2009 AAPM Plenary Session Symposia Series</b>	
<b>Indirect Expenses</b>	<b>Total</b>
<b>Project management</b>	
Negotiation with association	\$300.00
Coordination with vendors	\$1,800.00
Coordination with faculty	\$2,400.00
Coordination with internal teams	\$7,440.00
Preparation and coordination of status meetings/updates	\$500.00
<b>Medical services</b>	
Medical direction/account supervision	\$2,450.00
Development of agenda, objectives, program outline	\$800.00
Identification of faculty	\$400.00
Development of needs assessment	\$4,000.00
Development of supporting materials	\$1,200.00
Development of copy for posters, advertisements, set design	\$600.00
Proofreading	\$2,250.00
Fact-checking	\$1,000.00
<b>Accreditation of program for CME, CPE, CNE</b>	<b>\$16,000.00</b>
<b>Continuing Education participant certificates (est. 500)</b>	<b>\$7,500.00</b>
<b>Onsite CME coordination</b>	<b>\$1,350.00</b>
<b>Meeting management</b>	
Venue coordination	\$2,000.00
Travel coordination for faculty and staff	\$2,000.00
Coordination of associated meeting logistics	\$1,500.00
<b>Onsite management (5 staff members)</b>	<b>\$6,750.00</b>
<b>Participant database development/management</b>	<b>\$435.00</b>
<b>Administrative and accounting fees</b>	<b>\$4,185.00</b>
<b>Total, Indirect Expenses</b>	<b>\$66,860.00</b>



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## Program Summary: Emerging Solutions in Pain

### Section 10: Accredited ESP Symposia & Enduring Budget

<b>Cost Summary</b>	
<b>Approximate Total, Direct Expenses</b>	<b>\$45,440.00</b>
<b>Total, Indirect Expenses</b>	<b>\$46,323.20</b>
<b>ESP/AAPM Accredited Self-Study Slide-Audio Program Series</b>	<b>\$91,763.20</b>

<b>Detailed Budget Itemization: Accredited Slide Audio Program</b>	
<b>Direct Expenses, Approximate</b>	<b>Total</b>
<b>Clinical expert honoraria, review</b>	<b>\$1,500.00</b>
<b>Transcription</b>	<b>\$1,100.00</b>
<b>Graphic design</b>	
Creation of graphic user interface	\$2,610.00
Adaptation of meeting slides to slide/audio format	\$2,610.00
Creation of animations, highlights, additional graphics	\$3,480.00
Typesetting, layout	\$1,150.00
<b>IT, programming services</b>	
Editing of audio track	\$8,700.00
Slide-audio programming	\$23,200.00
Preparation of slide-audio for online posting	\$580.00
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	<b>\$500.00</b>
<b>Approximate Total, Direct Expenses</b>	<b>\$45,440.00</b>
<b>Indirect Expenses</b>	<b>Total</b>
<b>Project management</b>	
Review of audio files for editing direction	\$1,200.00
Coordination with internal teams	\$9,840.00
Preparation and coordination of status meetings/updates	\$1,800.00
<b>Medical/scientific services</b>	
Medical direction/account supervision	\$2,100.00
Development of supporting verbiage (needs assessment, objectives, etc.) and self-assessment	\$1,800.00
Proofreading	\$4,000.00
Fact-checking	\$1,000.00
<b>Accreditation of program for CME, CPE, CNE; includes 300 Continuing Education participant certificates total</b>	<b>\$18,000.00</b>
<b>Data management</b>	
Management of participant database	\$1,740.00
Data analysis and reporting	\$3,480.00
<b>Administrative and accounting fees</b>	<b>\$1,363.20</b>
<b>Total, Indirect Expenses</b>	<b>\$46,323.20</b>



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## **Program Summary: Emerging Solutions in Pain**

### **Section 11: Accredited Monograph Series and Collection**

#### **Program Title**

The *Emerging Solutions in Pain* Accredited Monograph Series and Monograph Collection

#### **Background**

The ESP monographs are one of the most requested items within the website. The most requested topics in the monograph series selected include:

- Ziegler – Treating Chronic Pain in the Shadow of Addiction (2124)
- Webster – Determining the Risk of Opioid Abuse (784)
- Vallerand – A Closer Look at Racial/Ethnic Disparities in Pain Management (562)
- Vallerand – Patient and Clinician: Mutual Shareholders in the Treatment of Chronic Pain (432)
- Brushwood – Electronic Prescription Monitoring Programs: A Data-Reporting Tool Designed to Prevent Drug Diversion (357)
- Ziegler – When Should Opioids be Discontinued? Assessing Aberrant Medication-Use Behaviors in Patients with Chronic Pain (357)
- Schyler – Neuroimaging: Interpreting Addiction (316)
- McCarberg – What Role Does Age Play in the Management of Chronic Pain in Adult Patients? (300)
- Miguel – Pain Patients at Risk of Abuse and Those with Comorbid Psychopathology (294)

Overall, the preferred topics center on management of the chronic pain patient with comorbidities, including addiction disease, elderly and psychopathologies.

#### **Proposed Program/Educational Solution**

MediCom Worldwide, Inc. is proposing two parts to the 2009 monograph program. The first part is to extend the success of the *Emerging Solutions in Pain* Accredited Monograph Series to include a selection of the preferred topics and to extend the authors/review panel to a more interdisciplinary team. Some of the topics & faculty (in no particular order) to be considered will include:

Topic	Physician	Nurse/NP	Pharmacist
New practice guidelines: Implementation in a real-life practice/What do the currently available guidelines suggest for the management of chronic pain with comorbid addiction disease	Nancy Wiedemer	Peggy Compton	TBC
Tolerance and the chronic pain patient	TBC	Anna Du Pen	GM Pollack
Assessment and treatment strategy development	Steve Passik	Micke Brown	TBC
The evolving paradigm of chronic cancer pain	TBC	Judy Paice	TBC

The second part is to collect and reaccredit the series of 4 monographs developed during 2008, and release the collection as a single file document

\* ESP User Data from 1 Jan 2007 to 9 Nov 2008



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## ***Program Summary: Emerging Solutions in Pain*** ***Section 11: Accredited Monograph Series and Collection***

### **Program Overview**

MediCom Worldwide, Inc. is proposing to extend the success of the *Emerging Solutions in Pain* Accredited Monograph Series by developing and producing an accredited series of four, 8-page monographs, directed toward physicians, pharmacists, nurses and other health care professionals involved in the care of patients with chronic pain. This series of accredited monographs will initially be published in a selection of pain journals including but not limited to *Practical Pain Management* journal and *Pain Medicine*, all monographs will also be available for credit online at the *Emerging Solutions in Pain* website.

MediCom will also improve the CE Education section of the website to enable users to manage their CE online using a "My CE" resource. This will enable users to store their completed CE programs as their preferences of topics.

The CE evaluation will also be enhanced to be more user-friendly and include more robust data collection. The questions will be formatted into the following categories:

CE Questionnaire

Feedback Questionnaire

Followed by (if user has passed)

Print CE Certificate

Download CE Certificate

Email CE Certificate

### **CE Provider**

Based on the need to educate clinicians in the assessment and treatment of chronic pain patients who may be at risk for abuse, addiction and diversion, the *Emerging Solutions in Pain* Accredited Monograph Series will be accredited for:

- CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each activity will be approved for a maximum of one hour of *AMA PRA Category 1 Credit*
- CPE credit for pharmacists by the Accreditation Council for Pharmacy Education. Each activity will be approved for a maximum of 1.0 contact hour for Continuing Pharmacy Education
- CNE credit for nurses. Each activity will be approved for a maximum of 1.0 contact hour



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## **Program Summary: Emerging Solutions in Pain**

### **Section 11: Accredited Monograph Series and Collection**

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#### **Program Objectives**

The purpose of the *Emerging Solutions in Pain* Accredited Monograph Series is to

- (1) Educate clinicians on key topics relating to the *Emerging Solutions in Pain* initiatives. The first monograph topic of 2009 will be selected using the guidance of the Practitioner Peer Review Panel. The next 3 topics will be selected with the guidance of the *Emerging Solutions in Pain* Advisory Board
- (2) Utilizing an interdisciplinary author/reviewing team will broaden the value of this educational initiative to a wider range of ESP members
- (3) The target for each monograph will be to achieve a minimum of 1,000 web sessions

The purpose of the *Emerging Solutions in Pain* 2008 Accredited Monograph Collection is to provide a collection of educational topics relating to the *Emerging Solutions in Pain* initiatives. The topics that will be included in the collection are:

- Ziegler: When Should Opioids Be Discontinued? Assessing Aberrant Medication-Use Behaviors in Patients with Chronic Pain
- Schnierow & Shurman: A Multidisciplinary Approach to the Medical Management of Sleep, Chronic Pain, and Driving
- Webster: Determining Appropriate Candidates for Opioid Therapy
- Fanciullo & Washington: Evidence-Based Guidelines for Opioid Therapy

#### **Intended Audience**

The primary audience of the *Emerging Solutions in Pain* Accredited Monograph Series and Collection includes physicians, pharmacists, nurses and other health care professionals who provide care to patients with pain.

#### **Format**

Four-issue series focusing on relevant topics in pain management and addiction medicine; each issue accredited for one hour; 8-page format; monographs to be published in one of several journals appropriate for the ESP target audiences.

#### **Post-Activity Feedback**

Course evaluation forms will be required of all participants who wish to receive continuing education credit. MediCom Worldwide, Inc. will summarize the information collected from these forms in a formal report to evaluate program effectiveness.

Participants will evaluate the following as excellent, good, fair or poor:

- (1) Overall content
- (2) Faculty teaching effectiveness
- (3) Format

Participants will also respond to the following questions:

- (1) How well did the program achieve its educational objectives?
- (2) Do you feel the program material was useful and practice-oriented?
- (3) Do you feel that the information provided in this educational activity will aid in improving patient care in your practice?
- (4) Do you feel that fair balance was maintained for all therapeutic options?
- (5) Would you participate in future educational activities?





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***Program Summary: Emerging Solutions in Pain***  
***Section 11: Accredited Monograph Series and Collection***

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**Distribution**

MediCom Worldwide, Inc. will announce and promote the *Emerging Solutions in Pain* Accredited Monograph Series and Collection primarily through advertisement at the *Emerging Solutions in Pain* website and Booth Series. MediCom will also distribute the ESP Monograph Series and Collection as appropriate via the ESP Resource Learning Center: a subscription-based communication series for pain clinics and centers as well as all ESP live activities.

**Total Budget**

The total budget to fund this activity is \$278,137.



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**Program Summary: Emerging Solutions in Pain**  
**Section 11: Monograph Series and Collection Budget**

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<b>Cost Summary</b>	
<i>2009 Accredited Monograph Series</i>	
<b>Approximate Total, Direct Expenses</b>	<b>\$117,460.00</b>
<b>Total, Indirect Expenses</b>	<b>\$122,263.80</b>
<b>Subtotal, 2009 Accredited Monograph Series</b>	<b>\$239,723.80</b>
<i>2008 ESP Monograph Collection</i>	
<b>Approximate Total, Direct Expenses</b>	<b>\$20,265.00</b>
<b>Total, Indirect Expenses</b>	<b>\$18,147.95</b>
<b>Subtotal, 2008 ESP Monograph Collection</b>	<b>\$38,412.95</b>
<b>2009 ESP Print Tactics: Accredited Monograph Series and Collection</b>	<b>\$278,136.75</b>



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## Program Summary: Emerging Solutions in Pain

### Section 11: Monograph Series and Collection Budget

<b>Detailed Budget Itemization: Monograph Series, Four Monographs Total</b>	
<b>Direct Expenses, Approximate</b>	<b>Total</b>
<b>Clinical expert honoraria</b>	\$16,000.00
<b>Insert page charges*</b>	\$83,820.00
Eight-page article printed on matte cover stock as journal insert	
<b>Production services</b>	
Layout and typesetting of articles	\$6,960.00
Creation of supporting web pages for online posting	\$1,740.00
<b>Programming of finished monographs for Web-posting, archiving</b>	\$1,740.00
<b>Data management</b>	\$4,000.00
<b>References</b>	\$1,200.00
<b>Miscellaneous (phone, fax, non-fulfillment Fed Ex)</b>	\$2,000.00
<b>Approximate Total, Direct Expenses</b>	\$117,460.00
<b>Indirect Expenses</b>	<b>Total</b>
<b>Project management</b>	
Coordination with faculty	\$2,400.00
Coordination with journal staff	\$1,800.00
Coordination with internal teams	\$5,040.00
Preparation and coordination of status meetings/updates	\$1,800.00
<b>Medical services</b>	
Medical direction/account supervision	\$9,100.00
Topic/author identification/research	\$2,400.00
Outline creation	\$4,000.00
Creation of monographs based on consultation, review with faculty	\$32,000.00
Development of supporting verbiage (needs assessment, objectives, etc.) and self-assessment	\$4,800.00
Incorporation of revisions	\$6,400.00
Proofreading	\$6,000.00
Fact-checking	\$3,000.00
<b>Accreditation of program for CME, CPE, CNE; includes 800 Continuing Education participant certificates total</b>	\$40,000.00
<b>Administrative and accounting fees</b>	\$3,523.80
<b>Total, Indirect Expenses</b>	\$122,263.80

\*Each of the four monographs will be published in one of several select journals, which may include, but are not limited to, *Practical Pain Management Journal* and *Pain Medicine Journal*



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## Program Summary: Emerging Solutions in Pain

### Section 11: Monograph Series and Collection Budget

<b>Detailed Budget Itemization: 2008 Monograph Collection</b>	
<b>Direct Expenses, Approximate</b>	<b>Total</b>
<b>Printing, quantity 2,000</b>	<b>\$16,000.00</b>
Includes printing of 4 8-page saddle-stitched booklets, reproducing all 2008 PPMJ monographs plus four-color card stock envelope	
<b>Graphic design</b>	
Typesetting, layout	\$3,480.00
Coordination with print vendor	\$435.00
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	<b>\$350.00</b>
<b>Approximate Total, Direct Expenses</b>	<b>\$20,265.00</b>
<b>Indirect Expenses</b>	<b>Total</b>
<b>Project management</b>	
Coordination with internal teams	\$1,440.00
Preparation and coordination of status meetings/updates	\$300.00
<b>Medical/scientific services</b>	
Medical direction/account supervision	\$1,400.00
Editing review	\$1,600.00
Creation of supporting documents for individual accredited self-study programs	\$800.00
Proofreading	\$1,000.00
<b>Accreditation of program for CME, CPE, CNE</b>	<b>\$5,000.00</b>
<b>Continuing Education participant certificates (estimate 750 certificates per program)</b>	<b>\$6,000.00</b>
<b>Administrative and accounting fees</b>	<b>\$607.95</b>
<b>Total, Indirect Expenses</b>	<b>\$18,147.95</b>



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## ***Program Summary: Emerging Solutions in Pain*** ***Section 12: Exhibition Booth & Meet the Expert Series***

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### **Program Title**

The *Emerging Solutions in Pain* Exhibition and Meet the Expert Exhibit Booth Series

### **Background**

In 2008, the *Emerging Solutions in Pain* Exhibition Series\* will have achieved the following:

- Reached approximately 19,100 pain professionals
- Enabled delegates to discuss key pain management issues with 12 expert faculty
- Distributed 10,420 monographs, 3,254 tool kits, and 4,608 awareness items
- Completed 1,747 needs assessments and recruited 1,064 new ESP members

### **Proposed Program/Educational Solution**

MediCom Worldwide, Inc. is proposing to utilize the Meet the Expert Booth as an informational and interactive display for educating clinicians regarding the *Emerging Solutions in Pain* initiatives at national congresses and association meetings. To ensure maximum effectiveness and value of the exhibit booth program, MediCom will tailor the size and activities of the Meet the Expert Booth to reflect the attendance and specific purpose of the congress or association. Thus, at larger meetings, an island-style, 20' x 20' Meet the Expert Booth will be utilized, while an inline style, 10' x 20' mini booth will be displayed at smaller congress and association meetings. The ESP Meet the Expert Booth will be constructed such that the same structural components, equipment, and supportive elements may be used in both island and inline styles.

MediCom will also develop more surveys to collect delegate information on every exhibition day, that is, a new survey will be developed for each day of the congress. This will encourage return visits to the exhibition booth to ensure delegates become fully aware of the educational benefits of ESP.

MediCom will update both the graphic imagery and multimedia displays to reflect current information in the fields of pain management and addiction medicine, as well as the tools, resources and activities available through ESP at the time of each meeting. Functionality for the full-size Meet the Expert Booth will include a seating area for meeting attendees to interact with *Emerging Solutions in Pain* booth staff; computer terminals featuring interactive displays highlighting the *Emerging Solutions in Pain* initiatives, membership registration for the *Emerging Solutions in Pain* website; the *Emerging Solutions in Pain* Tool Kits; and Monograph Series and Collection. The smaller *Emerging Solutions in Pain* Booth will focus on interactive displays of the Tool Kits and video highlights of previous Expert Clinical Commentary presentations; membership registration; and distribution of the *Emerging Solutions in Pain* Tool Kits and Monograph Series and Collection.

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\*The figure includes the 2,200 currently registered delegates as of 6 Nov 2008, attending the AAPM&R, 20-23 Nov, San Diego, CA with an estimation of the total delegates visiting the ESP booth



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## ***Program Summary: Emerging Solutions in Pain*** ***Section 12: Exhibition Booth & Meet the Expert Series***

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### **Program Objectives**

The purpose of the *Emerging Solutions in Pain* Meet the Expert Booth is to disseminate information concerning the *Emerging Solutions in Pain* initiative to clinicians practicing in the field of pain management, and to educate those clinicians on the assessment and monitoring of pain patients, and on good practice management techniques. Clinicians visiting the booth will have opportunities to:

- (1) Interact with *Emerging Solutions in Pain* clinical experts in small discussion groups, focusing on tools and strategies that will contribute to a proper balance of pain control and risk minimization (full-size Meet the Expert Booth only)
- (2) View multimedia, interactive programs highlighting the issues associated with minimization of misuse, abuse and addiction, the *Emerging Solutions in Pain* Tool Kits and associated case studies
- (3) Utilize interactive survey terminals to allow participants to earn educational tools as well as obtain continual information of the educational needs of clinicians
- (4) Receive copies of the *Emerging Solutions in Pain* Tool Kits and other support materials, such as the ESP Accredited monograph series and collection
- (5) Gain exposure to the resources available at the *Emerging Solutions in Pain* website, and register as a "member," thereby expediting their ability to access online resources

There are multiple objectives that are achieved with the ESP Meet the Expert Booths:

1. Disseminate information and awareness generation for the ESP initiatives
2. Disseminate information concerning accredited activities
3. Showcase hot new topics and newsworthy information from the pain management field
4. Disseminate existing content from the website
5. Gather needs assessment survey data

### **Intended Audience**

The primary audience of the *Emerging Solutions in Pain* Meet the Expert Booth will be physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain and who attend selected national association meetings and congresses. MediCom is proposing to utilize the full-size exhibit booth at two national association meetings, and the mini exhibit booth at two national association meetings in 2007; each association conference demographic profile and other scientific agenda, and public relations information will be analyzed on a continuing basis throughout the year to determine the best audience reach and utilization of exhibit booth funds. Possible meetings for both the full-size meeting and mini exhibit booths are listed on the next page.

### **Format**

The format of the *Emerging Solutions in Pain* Exhibition Booth Series is an interactive meeting booth to be presented at national association meetings and congresses. The full-size Meet the Expert Booth will feature live peer-to-peer interactions with *Emerging Solutions in Pain* clinical experts, as well as interactive, multimedia programs that highlight the *Emerging Solutions in Pain* initiatives. The smaller *Emerging Solutions in Pain* booth will focus on educating clinicians in the availability of the *Emerging Solutions in Pain* initiatives.



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## ***Program Summary: Emerging Solutions in Pain Section 12: Exhibition Booth & Meet the Expert Series***

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### **Potential Meetings, Full-Size (20' x 20' island) Exhibit Booth**

- American Academy of Pain Medicine, 28-31 Jan, Honolulu, Hawaii (this has been approved under a separate grant #2489 and is not included in the overall Exhibition Booth budget)
- American Pain Society, 7-9 May, San Diego, CA
- American Academy of Physical Medicine and Rehabilitation, 22-25 Oct, Austin, TX

### **Potential Meetings, Mini (10' x 20" in-line) Exhibit Booth**

- American Association for the Treatment of Opioid Dependence, 25-29 Apr, New York, NY (this has been approved under a separate grant and is not included in the overall Exhibition Booth budget)
- American Academy of Physician Assistants, 23-28 May, San Diego, CA
- American Society for Pain Management Nurses, 12-15 Sep, Jacksonville, FL

### **The Components of the 2009 ESP Booth Exhibition Include:**

- Interactive needs analysis kiosks
  - Faces of Pain currently associated with the tolerance survey
  - Additional surveys will be developed for subsequent days of meeting
- Video wall outlining ESP for clinicians who are hesitant to speak with an ESP representative
  - Continual updates to include the latest ESP website content as well as pain news tickers<sup>†</sup>
- Plasma screen with video highlights of ESP resources and activities
- Distribution of ESP information and resources
  - Tool Kit Volume II
  - Patient Tool Kit
  - ESP monograph series and collections

### **Distribution**

The *Emerging Solutions in Pain* Meet the Expert Booth will be available at selected national association meetings and congresses; meetings identified to date include the AAPMed,<sup>‡</sup> APS, ASPMN, AAPM&R, AATOD<sup>3</sup>, and AAPA. The announcement of the booth will be made via direct mail to registered meeting attendees and members, and via banner advertisements. Information at the booth will be provided by *Emerging Solutions in Pain* clinical experts and by MediCom Worldwide, Inc. staff members.

### **Request for Sponsor Support**

MediCom Worldwide, Inc. is promoting the *Emerging Solutions in Pain* Meet the Expert Booth through a variety of methods, including direct mail, and journal and banner advertisements.

### **Total Budget**

The total budget to fund these activities is \$490,205.

<sup>†</sup>A news ticker is (can be referred to as a "crawler") is a small screen space on the ESP video wall dedicated to presenting pain news headlines.

<sup>‡</sup>This is not included in the budget of this grant





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## ***Program Summary: Emerging Solutions in Pain***

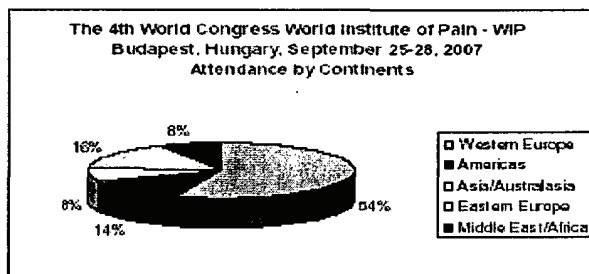
### ***Section 12: Exhibition Booth & Meet the Expert Series***

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#### **Optional Tactics**

In addition to the tactics, programs, and activities described above, the following optional tactics may be developed and implemented, as well, if sufficient need and funding exists:

- ***International and extended audiences ESP Exhibit Booth Program***  
The need for educational information, tools and resources for health care professionals who provide care to patients with chronic pain patients is not limited to the United States. In addition to the above-mentioned meetings, the ESP Exhibit Booth may be cost-effectively utilized to extend the reach of the ESP initiatives to an international audience of health care professionals via the World Institute of Pain meeting in New York and other extended audiences selected national meetings. The cost differential of utilization of the ESP Exhibit Booth at these meetings will obviously vary with the location, and will be quoted upon request. Potential further meetings include:
  - The World Institute of Pain (WIP), 13-16 Mar, New York, NY (option of sponsoring ONLY the Cyber Center)
    - The ESP Cyber Center are workstations where attendees may check emails with the following opportunities:
      - The ESP logo will be prominently displayed above the workstation
      - The ESP website could be set as the homepage or the ESP logo as the screen saver
      - Opportunity to distribute the ESP mouse pads from the Cyber Center
      - Opportunity to provide your ESP watermarked paper for the Cyber Center printers
      - ESP logo and website link placed on the Congress website
      - Acknowledgement on Supporters' Board on-site
      - Acknowledgement in the Supporters' List in the Final Program
    - The WIP delegates are as follows:



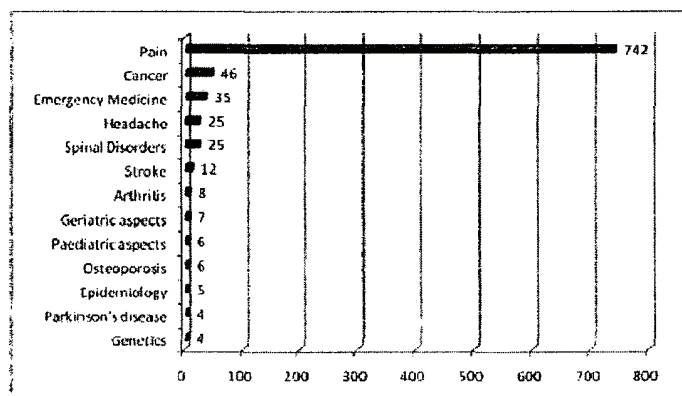
**Over 2,000 participants from over 70 countries**



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## ***Program Summary: Emerging Solutions in Pain*** ***Section 12: Exhibition Booth & Meet the Expert Series***

***Participants by Fields of Professional Interest, 80% Pain - \* 925 Total Records***



- The list of potential national congresses include:
  - American Pharmacists Association, 3-6 Apr, San Antonio, TX
  - American College of Physicians, 23-25 Apr, Philadelphia, PA
  - American Society for Addiction Medicine, 30 Apr-3 May, New Orleans, LA
  - American Academy of Nurse Practitioners, 17-21 Jun, Nashville, TN
  - Pain Week, 9-13 Sep, Las Vegas, NV
  - National Community Pharmacists Association, 17-21 Oct, New Orleans, LA



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## Program Summary: Emerging Solutions in Pain

### Section 12: Exhibition Booth & Meet the Expert Series

<b>Program Parameters</b>	
<b>Number of 2009 Exhibitions of the Island-style 20x20 ESP Booth</b>	2
<b>Number of 2009 Exhibitions of the Inline-style 10x20 ESP Booth</b>	2

<b>Cost Summary</b>		
	Per Meeting	Total
<i>One-Time Expenses</i>		
<b>Approximate Total, Direct Expenses</b>	\$0.00	\$59,490.00
<b>Indirect Expenses</b>	\$0.00	\$10,084.70
<b>Subtotal, One-Time Expenses</b>	\$0.00	\$69,574.70
<i>Island-style, 20x20 Exhibit Booth Series, 2 Meetings Total</i>		
<b>Approximate Total, Direct Expenses</b>	\$91,790.00	\$183,580.00
<b>Total, Indirect Expenses</b>	\$39,413.70	\$78,827.40
<b>Subtotal, Island-style 20x20 Exhibit Booth Series, 2 Meetings Total</b>	\$131,203.70	\$262,407.40
<i>Inline-style 10x20 Exhibit Booth Series, 2 Meetings Total</i>		
<b>Approximate Total, Direct Expenses</b>	\$49,710.00	\$99,420.00
<b>Total, Indirect Expenses</b>	\$29,401.30	\$58,802.60
<b>Subtotal, Inline-style 10x20 Exhibit Booth Series, 2 Meetings Total</b>	\$79,111.30	\$158,222.60
<b>Total Cost of the 2009 ESP Meet the Expert Exhibition Booth Series</b>		<b>\$490,204.70</b>



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## Program Summary: Emerging Solutions in Pain

### Section 12: Exhibition Booth & Meet the Expert Series

<b>Detailed Budget Itemization: One-Time Expenses, Exhibition Booth Series</b>	
<b>Direct Expenses, Approximate</b>	<b>Total</b>
Update and maintenance of the 20x20 exhibit booth	\$5,000.00
Update and maintenance of the 10x20 exhibit booth	\$10,000.00
Graphic design for new booth graphics	\$1,740.00
Booth survey educational tools, 2,000 quantity	\$36,000.00
Exhibit booth storage fee	\$6,000.00
Miscellaneous (non-fulfillment shipping, faxes, etc.)	\$750.00
<b>Subtotal, One-Time Approximate Direct Expenses</b>	<b>\$59,490.00</b>
<b>Indirect Expenses</b>	<b>Total</b>
<b>Project management</b>	
Coordination of internal teams	\$3,600.00
Coordination with third-party vendors	\$2,700.00
Preparation and coordination of status meetings/updates	\$450.00
<b>Medical/scientific services</b>	
Medical direction/account supervision	\$700.00
Creation of text for booth graphics	\$600.00
Proofreading	\$250.00
<b>Administrative, accounting fees</b>	<b>\$1,784.70</b>
<b>Subtotal, One-Time Indirect Expenses</b>	<b>\$10,084.70</b>



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**Program Summary: Emerging Solutions in Pain**  
**Section 12: Exhibition Booth & Meet the Expert Series**

<b>Detailed Budget Itemization: Island-style, 20x20 Exhibit Booth Series</b>		
<b>Direct Expenses, Approximate</b>	<b>Per Meeting</b>	<b>Total</b>
<b>Exhibit space plus liability insurance</b>	\$14,800.00	\$29,600.00
<b>Exhibit booth logistics</b>	\$23,500.00	\$47,000.00
Includes meeting floor plan design, shop prep, warehouse load in/out, exhibit hall drayage, electrical charges, exhibit hall engineering fees, installation and dismantling including labor supervision and expenses		
<b>Equipment rental</b>	\$9,800.00	\$19,600.00
Includes rental of all necessary computer units, plasma screens, audio, telecommunication links, staging, booth arrangements, etc.		
<b>Shipping of booth to meeting site</b>	\$8,500.00	\$17,000.00
<b>Shipping of supplies</b>	\$2,300.00	\$4,600.00
Includes shipping of literature, educational surveys and educational items to meeting site and delivery to booth charges		
<b>Digital media</b>		
Adaptation of display graphics for plasma loop and all associated tickers	\$4,800.00	\$9,600.00
Touchscreen kiosk programming and set-up	\$450.00	\$900.00
<b>Graphic design / production services</b>		
Typesetting and layout of booth posters, schedules, surveys	\$1,000.00	\$2,000.00
Typesetting and layout of advertisements (direct mail plus meeting catalog)	\$1,500.00	\$3,000.00
Coordination with third-party print vendors	\$500.00	\$1,000.00
<b>Conference management services</b>		
Management of pre-meeting booth set-up	\$3,000.00	\$6,000.00
Management of post-meeting booth set-up	\$2,400.00	\$4,800.00
<b>Booth advertisement</b>		
Advertisement in meeting catalog/publication (full page, 4/c)	\$3,000.00	\$6,000.00
<b>KOL expenses: three KOL faculty per meeting; each KOL attends two Meet-the-Expert sessions; 2 of 3 KOLs will already be attending (no travel required)</b>		
Honoraria	\$6,000.00	\$12,000.00
Faculty air	\$550.00	\$1,100.00
Faculty hotel	\$700.00	\$1,400.00
Faculty ground transportation	\$200.00	\$400.00
Faculty OOP	\$300.00	\$600.00
<b>MediCom expenses: three MCWW staff</b>		
MCWW air	\$1,650.00	\$3,300.00
MCWW hotel	\$4,200.00	\$8,400.00
MCWW ground transportation	\$765.00	\$1,530.00
MCWW OOP	\$1,125.00	\$2,250.00
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$750.00	\$1,500.00
<b>Approximate Total, Direct Expenses</b>	<b>\$91,790.00</b>	<b>\$183,580.00</b>



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**Program Summary: Emerging Solutions in Pain**  
**Section 12: Exhibition Booth & Meet the Expert Series**

<b>Detailed Budget Itemization: Island-style, 20x20 Exhibit Booth Series (con't)</b>		
<b>Indirect Expenses</b>	<b>Per Meeting</b>	<b>Total</b>
<b>Project management</b>		
Coordination with conference vendors	\$4,000.00	\$8,000.00
Coordination with KOLs for The Doctor is In schedule	\$450.00	\$900.00
Coordination of pre-meeting processes	\$2,400.00	\$4,800.00
Coordination of booth advertising and other support materials	\$1,800.00	\$3,600.00
Coordination with internal teams	\$3,360.00	\$6,720.00
Preparation and coordination of status meetings/updates	\$600.00	\$1,200.00
<b>Medical / scientific services</b>		
Medical direction/account supervision	\$2,100.00	\$4,200.00
Development of copy for meeting advertisements	\$450.00	\$900.00
Development of copy for plasma screen loop, other booth support materials	\$1,200.00	\$2,400.00
Proofreading	\$1,500.00	\$3,000.00
Staffing of booth during meeting (1 director, 1 senior, 1 junior)	\$18,000.00	\$36,000.00
Coordination with KOLs during meeting	\$800.00	\$1,600.00
<b>Administrative and accounting fees</b>	\$2,753.70	\$5,507.40
<b>Total, Indirect Expenses</b>	<b>\$39,413.70</b>	<b>\$78,827.40</b>



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**Program Summary: Emerging Solutions in Pain**  
**Section 12: Exhibition Booth & Meet the Expert Series**

<b>Detailed Budget Itemization: Inline-style 10x20 Exhibit Booth Series</b>		
<b>Direct Expenses, Approximate</b>	<b>Per Meeting</b>	<b>Total</b>
<b>Exhibit space plus liability insurance</b>	\$6,250.00	\$12,500.00
<b>Exhibit booth logistics</b>	\$8,000.00	\$16,000.00
Includes meeting floor plan design, shop prep, warehouse load in/out, exhibit hall drayage, electrical charges, exhibit hall engineering fees, installation and dismantling including labor supervision and expenses		
<b>Equipment rental</b>	\$3,600.00	\$7,200.00
Includes rental of all necessary computer units, plasma screens, audio, telecommunication links, staging, booth arrangements, etc.		
<b>Shipping of booth to meeting site</b>	\$7,500.00	\$15,000.00
<b>Shipping of supplies</b>	\$2,300.00	\$4,600.00
Includes shipping of literature, educational surveys and educational items to meeting site and delivery to booth charges		
<b>Digital media</b>		
Adaptation of display graphics for plasma loop and all associated tickers	\$4,800.00	\$9,600.00
Touchscreen kiosk programming and set-up	\$450.00	\$900.00
<b>Graphic design / production services</b>		
Typesetting and layout of booth posters, surveys	\$750.00	\$1,500.00
Typesetting and layout of advertisements (direct mail plus meeting catalog)	\$1,500.00	\$3,000.00
Coordination with third-party print vendors	\$500.00	\$1,000.00
<b>Conference management services</b>		
Management of pre-meeting booth set-up	\$3,000.00	\$6,000.00
Management of post-meeting booth set-up	\$2,400.00	\$4,800.00
<b>Booth advertisement</b>		
Advertisement in meeting catalog/publication (full page, 4/c)	\$3,000.00	\$6,000.00
<b>MediCom expenses: two MCWW staff</b>		
MCWW air	\$1,100.00	\$2,200.00
MCWW hotel	\$2,800.00	\$5,600.00
MCWW ground transportation	\$510.00	\$1,020.00
MCWW OOP	\$750.00	\$1,500.00
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$500.00	\$1,000.00
<b>Approximate Total, Direct Expenses</b>	<b>\$49,710.00</b>	<b>\$99,420.00</b>





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**Program Summary: Emerging Solutions in Pain**  
**Section 12: Exhibition Booth & Meet the Expert Series**

<b>Detailed Budget Itemization: Inline-style 10x20 Exhibit Booth Series (con't)</b>		
<b>Indirect Expenses</b>	<b>Per Meeting</b>	<b>Total</b>
<b>Project management</b>		
Coordination with conference vendors	\$4,000.00	\$8,000.00
Coordination of pre-meeting processes	\$1,200.00	\$2,400.00
Coordination of booth advertising and other support materials	\$1,500.00	\$3,000.00
Coordination with internal teams	\$3,360.00	\$6,720.00
Preparation and coordination of status meetings/updates	\$600.00	\$1,200.00
<b>Medical / scientific services</b>		
Medical direction/account supervision	\$2,100.00	\$4,200.00
Development of copy for meeting advertisements	\$450.00	\$900.00
Development of copy for plasma screen loop, other booth support materials	\$1,200.00	\$2,400.00
Proofreading	\$1,500.00	\$3,000.00
Staffing of booth during meeting (1 director, 1 junior)	\$12,000.00	\$24,000.00
<b>Administrative and accounting fees</b>	\$1,491.30	\$2,982.60
<b>Total, Indirect Expenses</b>	<b>\$29,401.30</b>	<b>\$58,802.60</b>



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## ***Program Summary: Emerging Solutions in Pain***

### ***Section 13: Outcomes Initiatives***

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#### **Program Title**

*The Emerging Solutions in Pain Outcomes Study*

#### **Background**

It is critical in the current education environment to make greater use of outcome assessment in medical education. As a result, MediCom will expand our current use of outcome measures in all ESP programs. Once outcomes become measurable, they become manageable.

#### **Proposed Program/Educational Solution**

Since the launch of ESP in 2005, we have developed extensive tools, resources that support pain management and risk minimization. The ESP members are a defined group of loyal users. MediCom Worldwide, Inc. is proposing to implement the ESP Outcome Study as an ongoing initiative to collect outcomes data on the impact of web-based ESP activities on clinician practices; a new outcomes question will be posted monthly to identify effectiveness of ESP activities and to determine ongoing educational needs of ESP users. The outcomes study will result in the generation of an executive summary, with full details of all outcomes data collected.

#### **Program Objectives**

The ESP Outcomes Study aims to:

##### **Primary study outcome:**

- Examine the impact of ESP tools, education and resources on management of chronic pain patients

##### **Secondary study outcome: results will support:**

- Support identification of gaps in clinician knowledge about methods for safe and effective prescribing of opioids that minimize risk of opioid misuse, abuse and addiction
- Facilitate continuous improvement in ESP programs and develop new tools and resources needed by clinicians who treat patients with chronic pain
- Identify areas of improvement/expansion needed by clinicians in the *Emerging Solutions in Pain* initiatives

#### **Program Overview**

With some of the platform upgrades and data collection capabilities enhanced, ESP will be well-positioned to begin to capture and report relevant data on the impact of the ESP program overall and that of specific tools and features on both educational and patient outcomes. To accomplish this, there are two initiatives planned.

Ongoing Collection of Data Related to Specific Tools: As ESP utilization metrics demonstrate, the most frequently accessed and downloaded features of the site are those that provide practitioners with tools and resources that can be used in day-to-day practice. While those metrics are informative of need and interest, more relevant data are to be gained by asking how well specific tools are working in terms of achieving desired outcomes and avoiding unwanted outcomes. ESP will poll all downloading of specific instruments on the real-world challenges faced by clinicians and then resurvey to determine the effectiveness of the tools. Respondents to these mini-surveys will be followed-up periodically.



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## ***Program Summary: Emerging Solutions in Pain***

### ***Section 13: Outcomes Initiatives***

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**Overall Educational Outcomes Survey:** ESP will recruit 400 clinicians to participate in a survey that is designed to measure the impact of ESP over time in the practice of individual practitioners. Recruitment will occur via enlistment at the ESP "Meet the Expert" booths at American Academy of Physical Medicine and Rehabilitation (AAPM&R), American Academy of Pain Medicine (AAPM), and online at the ESP website. Participants will be asked to complete a baseline assessment of four case vignettes with questions. The survey instrument will be developed with expert clinical advisors and in consultation with MediCom's professional research organization. The results of the baseline tool will be used to develop an educational and informational action plan. For a period of three months following the baseline administration, ESP content appropriate to the action plan will be brought to the attention of the survey participants. After that time, a follow-up assessment will be administered to determine the impact of ESP on practitioners' knowledge. The case vignette format will again be used. Analysis of data from all parts of the survey will be conducted and a summary report prepared. As appropriate, publication of results will be considered. It is anticipated that the data will provide additional insight into gaps in clinician knowledge about methods for safe and effective prescribing of opioids that minimize risk of opioid misuse, abuse and addiction that will be used in developing future content.

#### **Intended Audience**

The primary audience of the ESP Outcomes Study will be ESP members including physicians, pharmacists, nurses and other allied health care professionals who provide care to patients with chronic pain and also those who educate on best practices of chronic patient care.

#### **Format**

Ongoing web-based outcomes data collection will collect outcomes data on the impact of web-based ESP activities on clinician practices; a new outcomes question will be posted monthly to identify effectiveness of ESP activities and to determine ongoing educational needs of ESP users.

The 2009 ESP Outcomes Study will examine the impact of ESP tools, education and resources. The outcomes study will result in the generation of an executive summary, with full details of all outcomes data collected.

#### **Distribution**

The ESP Outcomes Study is based on two parts:

- The ongoing data collection will be provided via the *Emerging Solutions in Pain* website
- A case vignette-based educational outcomes survey of clinicians and new ESP members recruited through the ESP "Meet the Expert" booths at AAPM&R, AAPM, and online at the ESP website

#### **Request for Sponsor Support**

MediCom Worldwide, Inc. will coordinate the content, recruitment, data management, analysis, and reporting (and potential publication) of the *Emerging Solution in Pain* Outcomes Study.

#### **Total Budget**

The total budget to fund this activity is \$173,685.



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**Program Summary: Emerging Solutions in Pain**  
**Section 13: Outcomes Initiatives Budget**

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<b>Cost Summary</b>	
<i>Ongoing Web-based Outcomes Data Collection</i>	
<b>Approximate Total, Direct Expenses</b>	<b>\$17,900.00</b>
<b>Total, Indirect Expenses</b>	<b>\$17,217.00</b>
<b>Subtotal, Ongoing Web-based Outcomes Data Collection</b>	<b>\$35,117.00</b>
<i>Outcomes Study and Analysis</i>	
<b>Approximate Total, Direct Expenses</b>	<b>\$61,280.00</b>
<b>Total, Indirect Expenses</b>	<b>\$77,288.40</b>
<b>Subtotal, Outcomes Study and Analysis</b>	<b>\$138,568.40</b>
<b>Total Cost, 2009 Emerging Solutions in Pain Initiative Outcomes Study</b>	<b>\$173,685.40</b>



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## Program Summary: Emerging Solutions in Pain

### Section 13: Outcomes Initiatives Budget

<b>Detailed Budget Itemization: Ongoing Web-based Outcomes Data Collection</b>	
<b>Direct Expenses, Approximate</b>	<b>Total</b>
Digital media: posting of monthly outcomes-focused questions	\$6,960.00
Data management	
Data collection	\$3,480.00
Data analysis	\$6,960.00
Miscellaneous (non-fulfillment shipping, faxes, FedEx, etc.)	\$500.00
<b>Approximate Total, Direct Expenses</b>	<b>\$17,900.00</b>
<b>Indirect Expenses</b>	<b>Total</b>
Project management	
Coordination of internal teams	\$1,680.00
Preparation and coordination of status meetings/updates	\$450.00
Medical services	
Medical direction/account supervision	\$4,200.00
Identification of questions	\$2,400.00
Review, analysis of data	\$7,200.00
Proofreading	\$750.00
Administrative and accounting fees	\$537.00
<b>Total, Indirect Expenses</b>	<b>\$17,217.00</b>



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## Program Summary: Emerging Solutions in Pain

### Section 13: Outcomes Initiatives Budget

<b>Detailed Budget Itemization: Outcomes Study and Analysis</b>	
<i>Direct Expenses, Approximate</i>	<b>Total</b>
<b>Clinical expert honoraria (2)</b>	<b>\$5,000.00</b>
To provide input and guidance on case vignette development	
<b>Production</b>	
Graphic design of recruitment materials (print plus online)	\$2,610.00
Typesetting, layout of recruitment materials (print plus online)	\$1,160.00
Typesetting, layout of final report	\$870.00
<b>Outcomes study honoraria, quantity 50 physicians</b>	<b>\$20,000.00</b>
<b>Digital media</b>	
Programming of recruitment form on ESP website	\$2,320.00
Programming of 3 web-based outcomes measurement surveys; each survey to include registration of user from the target group of 400 clinicians plus 4 case vignettes plus 10 multiple choice questions	\$17,980.00
<b>Target audience-specific blast email campaigns (3 total)</b>	
Design and layout	\$870.00
HTML programming	\$1,305.00
List management	\$435.00
Transmission fee	\$90.00
<b>Database management</b>	
Database development	\$1,740.00
Data collection, report generation	\$5,800.00
<b>Stock photo purchase</b>	<b>\$750.00</b>
<b>Miscellaneous</b>	<b>\$350.00</b>
<b>Approximate Total, Direct Expenses</b>	<b>\$61,280.00</b>



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## Program Summary: Emerging Solutions in Pain

### Section 13: Outcomes Initiatives Budget

<b>Detailed Budget Itemization: Outcomes Study and Analysis</b>	
<b>Indirect Expenses</b>	<b>Total</b>
<b>Project management</b>	
Coordination with faculty	\$900.00
Coordination with internal teams	\$3,900.00
Preparation and coordination of status meetings/updates	\$900.00
<b>Medical/scientific services</b>	
Medical direction/account supervision	\$7,350.00
Development of copy for recruitment initiative	\$450.00
Collaboration with faculty	\$3,000.00
Development of baseline outcomes measurement survey of 4 case vignettes plus 10 questions, in collaboration with clinical expert faculty; incorporation of revisions post-faculty review	\$6,000.00
Analysis of data from baseline outcomes measurement survey and development of action plan based on data analysis	\$10,800.00
Development of outcomes measurement survey for conclusion of active study phase; survey to include 4 case vignettes plus 10 questions, similar to baseline survey, in collaboration with clinical expert faculty; incorporation of revisions post-faculty review	\$4,000.00
Development of outcomes measurement survey for follow-up 3 months post-active study phase; survey to include 4 case vignettes plus 10 questions, in collaboration with clinical expert faculty; incorporation of revisions post-faculty review	\$4,000.00
Analysis of data from all outcomes measurement surveys	\$14,400.00
Executive summary generation	\$6,000.00
Proofreading	\$3,000.00
Fact checking	\$750.00
<b>Outcomes study participant recruitment, quantity 400 physicians</b>	<b>\$10,000.00</b>
Recruitment to occur via sign-up at AAPM&R, AAPainMed Meet-the-Expert booths and via posting on the ESP website	
<b>Administrative and accounting fees</b>	<b>\$1,838.40</b>
<b>Total, Indirect Expenses</b>	<b>\$77,288.40</b>





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## **Program Summary: Emerging Solutions in Pain Section 14: Targeted Specialist Recruitment and Awareness Campaign**

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### **Program Title**

The *Emerging Solutions in Pain* Targeted Specialist Recruitment and Awareness Campaign.

### **Background**

*Emerging Solutions in Pain* currently has an outreach to 5,871\* members. Within this membership, ESP has a number of users who view page content for < 10 seconds. The objective in 2009 is to reach 10,000 regular users of the ESP initiatives and to engage these members into becoming habitual users of ESP.

The stages of adoption includes:

1. Awareness of ESP and the benefits we offer
2. Develop interest in ESP after hearing about the benefits
3. Willingness to trial ESP
4. Accepting the learning of ESP to adopt into clinical practice
5. Practice of regular utilization of ESP and making a difference to patient care outcomes

### **Proposed Program/Educational Solution**

MediCom Worldwide, Inc. is proposing the following initiatives to actively recruit regular users of ESP programs:

- o Targeted awareness campaigns
- o Beacon weekly newsletter
- o ESP scholarship fund

### **Program Objectives**

The overall objective of the 2009 Awareness Campaign is to increase the number of health care professionals who are active, regular members the *Emerging Solutions in Pain* community. The specific objectives of the Awareness Campaign include, but are not limited to:

- (1) Increase the number of registered users and those health care professional who impact pain patient care outcomes from 6,000 to 10,000 at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com) in all target audience groups, including expanding existing member groups and inviting new groups actively involved in pain medicine:
  - a. Pain specialists, addictionologists and other physicians who treat patients with chronic pain
  - b. Non-physician members of the pain management community, eg, nurses, physician assistants, pharmacists
  - c. Residents and fellows who have an interest in treating pain as part of their studies
- (2) Increase the number of user sessions at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com)
- (3) Increase the total amount of information downloaded at [www.EmergingSolutionsinPain.com](http://www.EmergingSolutionsinPain.com)

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\* Members Count up to 9<sup>th</sup> November 2008



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## ***Program Summary: Emerging Solutions in Pain Section 14: Targeted Specialist Recruitment and Awareness Campaign***

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### **Program Overview**

MediCom will build an awareness campaign to expand current members and reach out to new members, as well as an adoption strategy to ensure that health care professionals are not only aware of *Emerging Solutions in Pain* but adopt it as their #1 source of education. MediCom plans to convert the <10 seconds users into engaged users with repeat visits and increased session lengths.

MediCom is proposing to actively recruit health care professionals in the field of pain management and addiction medicine to become members of the ESP online community to access a comprehensive array of ongoing education, resources, and tools through a series of targeted and focused awareness-building campaigns, comprised of three different components. MediCom has previously identified these as important in raising awareness among, and recruiting, key groups of health care professionals including physicians, pharmacists, nurses, physician assistants, residents, and fellows.

#### **1. *The 2009 Targeted Specialist Recruitment Campaigns***

MediCom is proposing to build a target recruitment campaign which includes blast email, fax campaigns, banner advertisements, and direct mail postcard campaigns to targeted specialist audiences of nurses, pharmacists, physician assistants and practitioners concerned with safe and effective opioid use.

##### **a. A Targeted Awareness Internet Banner Campaign**

Internet banners advertising the ESP initiatives will be placed on diverse medical association websites, such as (but are not limited to) the American Academy of Pain Management Nurses, the American Academy of Physical Medicine and Rehabilitation, the *Journal of Pain* and *Pain Medicine*.

Targeted awareness campaigns will be focused on the specialist audiences that are the primary intention of each program. As such, these campaigns will focus primarily on pain management physicians, addictionologists, nurses, pharmacists and allied health care professionals who specialize in or have an interest in pain management and/or addiction.

##### **b. The Blast and Fax Campaign**

MediCom is proposing to utilize a targeted, coordinated series of multimedia blast email and fax campaigns to actively recruit new ESP members and increase the website and other education initiatives utilization. General email and fax lists of relevant clinical audiences (within the targeted new audiences spectrum) will be purchased for use in promoting general awareness of the availability of the *Emerging Solutions in Pain* website, and the depth and breadth of the resources available on that site.

This blast and fax campaign will outline the *Emerging Solutions in Pain* initiatives, benefits of membership and information for accessing the ESP programs.



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## ***Program Summary: Emerging Solutions in Pain Section 14: Targeted Specialist Recruitment and Awareness Campaign***

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Each blast email campaign will consist of an HTML page branded with the ESP imagery, including colors and logo, and will include the following features:

- i. Embedded video of or text invitation from a clinical expert, encouraging the new member to join the online ESP community or announcing the launch of the new activity
- ii. Brief text description of the site and/or activity
- iii. Live link to the ESP website or to the specific program on the ESP website
- iv. Button for allowing the recipient to forward the email to a colleague
- v. Button for allowing the recipient to discuss their thoughts/suggestions on the content of ESP
- vi. Verbiage for unsubscribing to specific sections of ESP, for selecting their preferred method of communication (they may only want to receive an blast once a month on a specific topic) and opting out from future ESP email communications

The fax campaign will consist of an invitation to join the ESP community as well text descriptions of the EDP website and latest tools. A fax back joining form will also be included.

Metrics will be collected for each blast concerning delivery, opening, click-through and forwarding rates. Metrics for the fax campaign will include return faxes received. Analysis of these metrics will enable modification of subsequent blasts for optimal reach and effect.

- c. The 2009 Direct Mail Campaign  
 In addition to the Internet banners and blast emails, MediCom is proposing to create and coordinate a series of direct mail postcards to a target audience of 30,000 health care professionals who provide care to patients with chronic pain. The cards will be sent shortly after the website migration is complete to launch the new features in early April 2009, and will invite new members to join the ESP online community.



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## ***Program Summary: Emerging Solutions in Pain Section 14: Targeted Specialist Recruitment and Awareness Campaign***

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### **2. *The 2009 ESP Beacon Weekly Newsletter***

#### **The Beacon**

MediCom Worldwide, Inc. is proposing to continue the development, production and implementation of *The Beacon*, was an ESP-dedicated quarterly electronic newsletter supporting increased focus on new tools, resources and activities available through the ESP initiatives. *The Beacon* will be adapted to become a regular weekly update on all content posted onto ESP and the latest news in pain medicine. The primary purpose of this newsletter series is to encourage more routine use of the *Emerging Solutions in Pain* tools and resources by current and potential ESP members.

Through this HTML-based newsletter, subscribers will be exposed to highlights of new content, programs and resources available on the ESP website, thereby reinforcing the value offered by the initiatives, the ease of use of the ESP tools and resources, and the diverse range of educational and informational programs and activities available to ESP members. All content will be called out by a title or headline that will also function as a clickable link directly back to the full story on the ESP website. Content that will be highlighted include:

- a. Selected text from current clinical expert commentaries, journal article summaries, "In the News" stories and Ask the Expert columns
- b. Selected text from the 2009 Monograph series
- c. Announcements of ESP-sponsored live events, including the Meet the Experts Booth and live symposia
- d. Surveys of newsletter recipients for content, tool and resource suggestions
- e. Each section of text will contain a live link to the specific program on the ESP website
- f. Button for allowing the recipient to forward the email to a colleague
- g. Button for allowing the recipient to discuss their thoughts/suggestions on the content
- h. Verbiage for unsubscribing to specific sections of ESP, for selecting their preferred method of communication (they may only want to receive an blast once a month on a specific topic) and opting out from future ESP email communications

The benefits a weekly distribution includes:

- More consistent delivery of messages
- Subscribers will be updated weekly with new content posted within the last 7 days
- Increased utilization and readership

### **3. *The 2009 Emerging Solutions in Pain Scholarship Program for Residents, Fellows and Nurses***

MediCom is proposing continuation of the *Emerging Solutions in Pain* Scholarship Program, as an initiative that successfully extended the reach of ESP to a new target audience of residents, fellows and directors of medical school programs. This program is designed with multiple purposes:

- a. Grow the number of new ESP members
- b. Develop new thought leaders in the specialty of pain management and addiction management



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### **Program Summary: Emerging Solutions in Pain Section 14: Targeted Specialist Recruitment and Awareness Campaign**

- c. Introduce up-and-coming physicians and nurses to the pain management community and involve this group in the critical interface of pain and addiction
- d. Increase the pool of clinical expert contributors to ESP, through submission by the scholarship recipient of meeting and abstract summaries for publishing on the ESP website

In 2008, the ESP Scholarship Program achieved the following:

Meeting	Winner	Publications
2008 AAPM, 12-16 Feb, Orlando	Capt. Ivan Edwards, DO, MC USAFR, Resident, San Antonio, Texas	4 x Publication Reports of the AAPM 2 x Case Studies
2008 APS, 8-10 May, Tampa	Lauren Morris, DO, Fellow, New York, New York	3 x Publication Reports of the APS
2008 ICPCD, 29 Oct - 1 Nov, Philadelphia	Linda Garcia, MSN, RN, BC, Nurse, Worcester, MA	4 x Publication Reports of the ICPCD (in development)
2008 AAPM&R, 20-23 Nov, San Diego	Zachary Abbott, DO, Fellow, Denver, CO	TBD
2009 AAPMedicine	TBD	TBD

The proposed 2009 ESP Scholarship Program will include:

- 2009 APS, 7-9 May, San Diego, CA
- 2009 ASPMN (nurse), 12-15 Sep, Jacksonville, FL
- 2009 AATOD, 25-29 Apr, New York, NY
- 2009 AAPM&R, 22-25 Oct, Austin, TX

In this program, announcement of the scholarship availability will be posted on the ESP website, and through other ESP awareness initiatives. In addition, direct email blast campaigns will specifically target directors of medical school programs which include formal pain management education programs. To be considered for one of the four ESP scholarships, candidates must submit the following:

- a. Name, contact information and email address
- b. A brief biography or CV (100 words or less)
- c. A statement summarizing the candidate's experience in the field of pain management, or basis for interest in this field of medicine (200 words or less)
- d. A pain management or addiction medicine interesting case study to establish an ability of medical writing (400 words or less)
- e. A letter of recommendation from a senior clinician (one page or less)

Scholarship recipients will be selected following analysis of all submission packages through a numeric scoring system. Final selection will be based upon review of rating scores by a diverse group of staff from MediCom Worldwide, Inc. Scholarship recipients will receive registration fees, airfare, hotel accommodations and a small stipend. Recipients will be asked to write three or more abstracts of conference plenary sessions that will be posted on the ESP website.



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## Program Summary: *Emerging Solutions in Pain* Section 14: *Targeted Specialist Recruitment and Awareness Campaign*

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### Intended Audience

- The primary audience of the 2009 ESP Awareness and Adoption Campaign will include physicians, pharmacists, nurses, physician assistants, residents, fellows and other health care professionals who provide care to patients with chronic pain.
- In 2009, ESP will also expand the target audience to include:
  - More pain management physicians
  - Other new HCPs who:
    - Prescribe opioids
    - Influence prescribing
    - Impact patient management/outcomes
    - Require specialized content for optimal functioning

*Table: The target audiences for the ESP Awareness and Adoption Campaign*

Clinician Group	ESP Target Audience	Pharmacologic Decision Makers	Responsible for Pain Management
Pain specialists	Primary	Yes	Yes
Anesthesiologists	Primary	Yes	Yes
Addictionologists	Primary	Yes	Yes
Residents/fellows	Secondary	Yes	Yes
Pharmacists	Secondary	Yes	Yes
Nurses	Secondary	Yes (NPs)	Yes
PAs	Secondary	Yes	Yes
PCPs	No	Yes	Yes

### Format and Distribution

The 2009 *Emerging Solutions in Pain* Awareness Campaign will include, but is not limited to:

- (1) Banner advertisements, email blasts, faxes and direct mail
- (2) The ESP Scholarship will be announced on the *Emerging Solutions in Pain* website and through multiple email blast campaigns to appropriate target audiences.
- (3) *The Beacon* eNewsletter will be distributed to registered members of the *Emerging Solutions in Pain* community and other subscribers.

### Total Budget

The total budget to fund these activities is \$296,929.



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**Program Summary: Emerging Solutions in Pain**  
**Section 14: Targeted Specialist Recruitment and Awareness**  
**Campaign Budget**

<b>Cost Summary</b>	
<i>Targeted Specialist Recruitment Campaigns</i>	
<b>Approximate Total, Direct Expenses</b>	\$125,480.00
<b>Total, Indirect Expenses</b>	\$24,034.40
<b>Subtotal, Targeted Specialist Recruitment Campaigns</b>	\$149,514.40
<i>The Beacon Weekly e-Newsletter</i>	
<b>Approximate Total, Direct Expenses</b>	\$70,410.00
<b>Total, Indirect Expenses</b>	\$30,837.30
<b>Subtotal, The Beacon Weekly e-Newsletter</b>	\$101,247.30
<i>The ESP Scholarship Fund</i>	
<b>Approximate Total, Direct Expenses</b>	\$24,560.00
<b>Total, Indirect Expenses</b>	\$21,606.80
<b>Subtotal, The ESP Scholarship Fund</b>	\$46,166.80
<b>2009 ESP Targeted Specialist Recruitment and Awareness Campaigns</b>	<b>\$296,928.50</b>





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**Program Summary: Emerging Solutions in Pain**  
**Section 14: Targeted Specialist Recruitment and Awareness**  
**Campaign Budget**

<b>Detailed Budget Itemization: Recruitment Campaign</b>	
<i>Direct Expenses, Approximate</i>	Total
<b>Banner advertisements</b>	\$10,500.00
<b>Email list purchase, physicians: 16,000 quantity (1 purchase of 16,000 each)</b>	\$10,224.00
<b>Fax list purchase, physicians: 48,000 quantity (3 purchases of 16,000 each)</b>	\$14,055.00
<b>Email list purchase, nurses: 10,800 quantity (3 purchases of 3,600 each)</b>	\$5,850.00
<b>Fax list purchase, nurses: 9,450 quantity (3 purchases of 3,150 each)</b>	\$3,510.00
<b>Fax list purchase, pharmacists: 68,850 quantity (2 purchases of 34,425 each)</b>	\$9,370.00
<b>Blast email campaigns (4 total)</b>	
Design and layout	\$1,160.00
HTML programming	\$1,740.00
List management	\$1,740.00
Transmission fee	\$2,753.00
<b>Blast fax campaigns (8 total)</b>	
Design and layout	\$2,320.00
List management	\$3,480.00
Transmission fee	\$7,578.00
<b>PR news releases</b>	\$3,000.00
<b>Direct mail postcards; 30,000 quantity</b>	\$22,500.00
Includes printing, address application & mail services for 6 rounds of 5,000 each, targeting pain specialists	
<b>Postage; 30,000 quantity</b>	\$7,800.00
<b>Direct mail list purchase; 30,000 quantity</b>	\$8,700.00
<b>Graphic design / production services</b>	
Creation and subsequent adaptation of print advertisements	\$1,450.00
Creation and subsequent adaptation of banner advertisements	\$1,160.00
Programming of Flash-animations of banner advertisements	\$1,160.00
Design, typesetting and layout of direct mail postcard	\$2,320.00
List management	\$2,610.00
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$500.00
<b>Approximate Total, Direct Expenses</b>	\$125,480.00
<i>Indirect Expenses</i>	Total
<b>Project management</b>	
Coordination of internal teams	\$4,320.00
Coordination with third-party vendors	\$3,600.00
Preparation and coordination of status meetings/updates	\$900.00
<b>Medical / scientific services</b>	
Medical direction/account supervision	\$2,450.00
Copy writing	\$6,000.00
Proofreading	\$3,000.00
<b>Administrative and accounting fees</b>	\$3,764.40
<b>Total, Indirect Expenses</b>	\$24,034.40



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 Fax 215.337.0960

**Program Summary: Emerging Solutions in Pain**  
**Section 14: Targeted Specialist Recruitment and Awareness**  
**Campaign Budget**

<b>Detailed Budget Itemization: The Beacon Weekly e-Newsletter (47 issues total)</b>	
<i>Direct Expenses, Approximate</i>	Total
Graphic development/update of 2008 design	\$1,160.00
IT, programming services	
HTML programming	\$27,260.00
Review and maintenance of newsletter subscription lists	\$7,540.00
Transmission fees	\$33,450.00
Miscellaneous (phone, fax, non-fulfillment Fed Ex)	\$1,000.00
<b>Approximate Total, Direct Expenses</b>	<b>\$70,410.00</b>
<i>Indirect Expenses</i>	Total
<b>Project management</b>	
Coordination with internal teams	\$4,800.00
Preparation and coordination of status meetings/updates	\$1,800.00
<b>Content development</b>	
Medical direction/account management	\$5,600.00
Selection of highlights for weekly newsletter posting	\$3,600.00
Editing for newsletter posting	\$7,050.00
Proofreading	\$5,875.00
<b>Administrative and accounting fees</b>	<b>\$2,112.30</b>
<b>Total, Indirect Expenses</b>	<b>\$30,837.30</b>



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**Program Summary: Emerging Solutions in Pain**  
**Section 14: Targeted Specialist Recruitment and Awareness**  
**Campaign Budget**

<b>Detailed Budget Itemization: ESP Scholarship Fund</b>	
<i>Direct Expenses, Approximate</i>	Total
<b>ESP clinician scholarship, quantity: four</b>	\$20,000.00
Includes registration, travel and stipend for selected clinician to one national association meeting/congress	
<b>Scholarship-specific blast email campaigns (4 total)</b>	
Design and layout	\$1,160.00
HTML programming	\$1,740.00
List management	\$580.00
Transmission fee	\$80.00
<b>Miscellaneous (non-fulfillment shipping, faxes, etc.)</b>	\$1,000.00
<b>Approximate Total, Direct Expenses</b>	\$24,560.00
<i>Indirect Expenses</i>	Total
<b>Project management</b>	
Coordination of scholarship application campaign	\$1,800.00
Selection of scholarship awardees	\$3,600.00
Coordination with scholarship awardees	\$1,800.00
Coordination with internal teams	\$1,680.00
Preparation and coordination of status meetings/updates	\$900.00
<b>Medical/scientific services</b>	
Medical direction/account supervision	\$3,150.00
Creation of verbiage announcing scholarship fund, press releases other associated text	\$1,200.00
Review and edit to abstracts submitted by scholarship winners	\$4,000.00
Proofreading	\$1,000.00
<b>Data management</b>	\$1,740.00
<b>Administrative and accounting fees</b>	\$736.80
<b>Total, Indirect Expenses</b>	\$21,606.80



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## MediCom Worldwide, Inc.

### Section 15: Emerging Solutions in Pain Educational Initiative Policy Statements

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#### Conflict Resolution and Control of Content Statements

In accordance with the Accreditation Council for Continuing Education (ACCME) *Standards for Commercial Support: Standards to Ensure Independence in CME Activities* as well as the Accreditation Council of Pharmacy Education (ACPE) *Standards for Continuing Pharmacy Education: Standards for Commercial Support* it is the policy of MediCom Worldwide, Inc. to ensure balance, independence, objectivity and scientific rigor in all of its continuing medical education activities. MediCom Worldwide, Inc. requires everyone who is in a position to control the content of a CME, CNE or CPE accredited activity to disclose all relevant financial relationships with any commercial interest. This information is utilized to determine a) if a conflict exists, b) resolve the conflict by initiating a content validation process, and c) advise learners of this information. Any individual who refuses to or chooses not to disclose relevant financial relationships will be disqualified from participating as an instructor, planner or manager and cannot have control of or responsibility for the development, management, presentation or evaluation of a accredited activity certified by MediCom Worldwide, Inc.

MediCom Worldwide, Inc. has defined all those in position to control content as faculty, authors, presenters, planning committee members and all those internal staff who are in position to write, alter or impact the content of an activity certified for CME, CPE and or CNE. Disclosures received by MediCom from individuals in a position to control content are made transparent to learners prior to participating in all activities. MediCom Worldwide, Inc. discloses the following information to learners: a) the name of the individual, b) the name of the commercial interest(s), and c) the nature of the relationship the individual has with the commercial interest. MediCom Worldwide, Inc. also discloses to learners the name(s) of commercial interests supporting each CME, CNE, or CPE activity.

Should a conflict of interest be identified, a content validation process is initiated to ensure that the content or format of the activity and related materials will promote improvement in the quality of healthcare and not promote a specific proprietary business interest of a commercial interest. It is the policy of MediCom Worldwide, Inc. to conduct an unbiased review of all planned content for CME, CPE and or CNE activities certified for credit to ensure adherence to the ACCME, ACPE, and CNE content validation statements and to resolve any actual or perceived conflict of interest that exists. MediCom Worldwide, Inc. employs three primary metrics to validate content: a) fair balance, b) the scientific objectivity of studies mentioned in the materials or used as the basis for content, and 3) appropriateness of patient care recommendations made to the learner.

All faculty members receive instructions that communicate the MediCom Worldwide, Inc. standards of practice, specifically information concerning expectations related to content validation and safeguards against commercial bias. Individual presentations or initial drafts of a conflicted faculty member's content are reviewed by a MediCom Worldwide, Inc. clinical staff member. If there are concerns identified by the content validation process, feedback may be requested from the course director, program chair or independent expert.

MediCom Worldwide, Inc. is responsible for control of content and selection of presenters and moderators. The grantor agrees not to direct the content of the program nor will grantor be allowed access to review content at any stage of development. This CE activity is for scientific and educational purposes only and will not promote commercial interests or products directly or indirectly. As the ACCME/ACPE/CNE provider MediCom Worldwide, Inc. will be responsible for ensuring that all sponsored activities are planned and implemented in accordance with the ACCME Essential Areas and Policies and the ACPE Criteria for Quality.



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### **MediCom Worldwide, Inc.**

## **Section 15: Emerging Solutions in Pain Educational Initiative Policy Statements**

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MediCom Worldwide, Inc. and the grantor agree to:

- Abide by the ACCME Standards for Commercial Support of Continuing Medical Education
- Abide by the ACPE Criteria for Quality

In addition, the commercial supporter agrees to abide by all requirements of the PhRMA Code of Ethics and AMA Guidelines on gifts to physicians.

MediCom Worldwide, Inc. will ensure that the source of support from commercial interest either direct or in-kind is disclosed to the participants in program brochures, syllabi and other program support material. This disclosure will not include the use of trade name or product group message.

MediCom will ensure meaningful disclosure to the audience at the time of the program of (a) Grantor funding and (b) any significant relationship between MediCom and the Grantor or between individual speakers, moderators and the Grantor.

### **Signature Required for Grant Acceptance**

Joan Meyer  
President  
MediCom Worldwide, Inc.

### **Budget Reporting and Reconciliation**

- a. Funds should be in the form of an educational grant made payable to MediCom Worldwide, Inc.
- b. No other funds from Cephalon, Inc. will be paid to the program director, faculty, or others involved with the CE activity
- c. MediCom Worldwide, Inc. will furnish the grantor with documentation detailing the receipt and expenditure of the commercial support within 90 days of activity completion
- d. In the event of program cancellation and or providers inability to complete the activity as designed, provider agrees to return all unused grant funds to Cephalon. Provider will furnish Cephalon with documentation detailing any and all receipts of expenditures related to expense incurred up to program cancellation

### **Payment Structure**

50% due upon signing agreement:  
25% due upon completion of roundtable activities:  
Final 25% September 2009



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## **MediCom Worldwide, Inc.**

### **Section 15: Emerging Solutions in Pain Educational Initiative Policy Statements**

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#### **Activity Evaluation and Outcome Reporting**

MediCom Worldwide, Inc. requests that learners evaluate activities for potential presence of bias. In addition, MediCom utilizes proctors to evaluate live activities related to content validity and management of commercial support funds. The evaluation tool is also designed to pay specific attention to the following key elements:

- Patient treatment recommendations reflective of evidence-based recommendations
- Represent a standard of practice within the profession in the United States
- Contribute to overall improvements in patient care
- Knowledge growth
- Improvement in competence

The evaluation tool is designed to evaluate the studies and case presentations cited in the activity to ensure they are scientifically objective and conform to research principles generally accepted by the scientific community.

MediCom will employ a comprehensive strategy designed to measure outcomes at a variety of levels including those described by ACCME and described by the modified Kirkpatrick model.

### **Exhibit B** **ACTIQ Risk Management Program**

Provider is aware that ACTIQ® (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- ACTIQ is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- ACTIQ is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.
- ACTIQ is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

### **FENTORA Risk Management Program**

Provider is aware that FENTORA™ (fentanyl buccal tablet) [C-II] was approved subject to a Risk Minimization Action Plan (RiskMAP). The RiskMAP includes key safety messages that are essential to the safe use of this product. They are:

- FENTORA is indicated for the management of breakthrough pain in patients with cancer who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- FENTORA is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- No misuse of FENTORA should occur.
- Unintended (accidental) exposure to FENTORA should not occur.
- Patients considered opioid tolerant are those who are taking at least 60 mg oral morphine/day, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that FENTORA can be fatal to a child. Keep all units away from children and discard properly.
- FENTORA is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.





www.cephalon.com

Cephalon, Inc.  
41 Moores Road  
PO Box 4011  
Frazer, PA 19355  
Phone 610.344.0200  
Fax 610.344.0065

## INDEPENDENT EDUCATIONAL PROGRAM GRANT AGREEMENT

This Agreement is entered into as of this 18<sup>th</sup> day of October, 2011, by and between Cephalon ("Cephalon"), located at 41 Moores Road, Post Office Box 4011, Frazer, PA 19355, and MediCom Worldwide, Inc. ("Provider"), located at 101 Washington Street, Morrisville, PA 19067.

WHEREAS, Cephalon has reviewed Provider's grant request to support a medical education program ("Program"); and

WHEREAS, Cephalon has determined that the Program has the potential to address educational gaps; and

WHEREAS, it is the intent of the parties to ensure that the Program will be independent, objective, balanced, scientifically rigorous, and have reasonable expectations of meeting its educational objectives so that it will not be viewed by the United States Food and Drug Administration ("FDA") as promotional and that Cephalon will not be viewed as responsible for its content; and

WHEREAS, Cephalon agrees to provide support for the Program under the conditions set forth below.

NOW THEREFORE, Provider and Cephalon agree to the following terms under this Agreement:

1. Title of Program. The Educational Program is entitled "Effective Strategies in Managing Breakthrough Pain (008626)," and a copy of the grant request for the Program is attached hereto as Exhibit A.
2. The Program is:
  - ☒ certified (CE credits are offered); or
  - ☐ a non-certified independent program (where CE credits will not be offered).
3. Program Purpose. The Program is for scientific and educational purposes only, and is based on established bona fide and independently verifiable patient and/or practitioner needs or gaps in healthcare performance, and is not intended to promote a Cephalon product, directly or indirectly. The Program is not a repeat activity or endured version of a prior program.
4. Grant Support Arrangements.

Cephalon will provide support for the Program by means of an educational grant in the total amount of \$199,880.00. If the Program is canceled or terminated prior to completion by the Provider, Provider shall return the grant, or any unused portion thereof with full reconciliation, to Cephalon within thirty (30) days of such termination or cancellation. Provider shall have full responsibility for all funding arrangements of the



Program, including any funding to be provided to its Educational Partner. Payment terms of the grant shall be made in accordance with a schedule provide be Cephalon.

- (a) Upon notice from Cephalon, Provider shall provide Cephalon, within ninety (90) days, a detailed reconciliation that compares the grant proposal to the actual program (e.g., expenses, attendance levels, etc.) To the extent Cephalon has overpaid Provider, Provider shall provide a refund to Cephalon within sixty (60) days thereafter. Such detailed reconciliation information and documents shall be entered into Cephalon's web-based grants managements system at [www.cephalongrants.com](http://www.cephalongrants.com).
  - (b) Provider may not use funds provided by Cephalon to pay travel, lodging, honoraria or personal expenses for non-faculty attendees. Grant funds may be used to reduce the overall registration fees for attendees. Grant funds may not be used to purchase capital equipment or to provide general operational support for an institution. Funds for hospitality shall not be provided, except that funds may be used for modest meals or receptions that are held as part of the Program, but such events shall not compete with, nor take precedence over, educational events. The appropriateness of any reception shall be at the sole discretion of the Provider, and Provider shall have final decision-making authority in connection with any such activities.
  - (c) Funds may be used by the Provider to permit medical students, residents, fellows or other health care professionals in training to travel to and attend the Program; provided, however, that this is outlined in the approved grant proposal and that the selection of such students, residents or fellows who receive funds is made by either the academic or training institution, or, if by the Provider, such selection shall be made with the full concurrence of the academic or training institution.
5. Objectivity and Balance. Provider shall retain full responsibility for control of the content of the Program and shall ensure that the following requirements are met:
- (a) The Program material/content will be objective, balanced and free from commercial bias. All topics shall be treated in an impartial, unbiased, evidence-based manner. The title of the Program will fairly and accurately represent the scope of the presentation.
  - (b) Provider agrees that Cephalon shall not influence the content of the Program. Cephalon personnel will not attend content development meetings.
  - (c) Cephalon shall not review the Program for medical accuracy or completeness and the Provider and/or Educational Partner (if any) agree that they will not make such a request of Cephalon.



- (d) If a product marketed by Cephalon is the subject of discussion, the data will be objectively selected and presented, with an accurate reflection of favorable and unfavorable information about the product and shall also include a balanced discussion of prevailing information on alternative products and /or therapies.
  - (e) Provider represents that neither it nor the Educational Partner (if any) has either an open complaint or decision from the Accreditation Council for Continuing Medical Education ("ACCME") or the FDA that a program provided by the Provider or the Educational Partner failed to meet standards of independence, balance, objectivity, or scientific rigor at the time of signing this agreement. If a provider is notified of any such complaint or decision during the lifetime of the supported program/activity, the Provider will inform Cephalon within 30 days of notification.
- 6. RiskMAPs / REMS. Certain Cephalon products have an FDA approved Risk Management Action Plan (RiskMap) or Risk Evaluation and Mitigation Strategy (REMs). Furthermore, other products in the same therapeutic class may also have RiskMAPs/ REMS. Provider acknowledges that it is aware of the key safety messages in these RiskMAPs/ REMS, shall keep up-to-date with such information, and will present such information as it deems appropriate in the Program.
- 7. No Faculty Selection. Provider shall retain full responsibility for the selection of the presenters, authors, moderators, and/or other faculty (hereinafter referred to collectively as "Faculty"). Provider and/or Educational Partner (if any) shall not request recommendations for Faculty from Cephalon.
- 8. Data. Provider will ensure meaningful disclosure of limitations of data (e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion). Provider will require that Faculty disclose when a product is not approved in the United States for the use under discussion.
- 9. Question and Answer Session. To the extent the Program is a presentation, Provider will ensure meaningful opportunities for questioning by the audience.
- 10. Financial Relationships / Disclosure. Provider will ensure meaningful disclosure to the audience of support from Cephalon and all other supporters if applicable and any significant relationship between individual Faculty and Cephalon. All meaningful disclosure(s) shall also be made where appropriate including but not limited to, syllabi and enduring material.
- 11. Representations and Warranties. Provider represents that:
  - (a) Neither the Provider nor the Educational Partner, provides promotional or marketing services to Cephalon;
  - (b) If Provider or the Educational Partner has an affiliated company offering promotional or marketing services, Provider and/or Educational Partner



has instituted appropriate firewall controls and safeguards to ensure the Program remains independent, objective, balanced and scientifically rigorous. Firewall documents will be supplied by the Provider and/or Educational Partner and be approved by Cephalon.

- (c) Provider has determined that it is appropriate to use the Educational Partner in light of the requirements under this Agreement; and
  - (d) If Provider and/or Educational Partner employ a former Cephalon employee who worked at Cephalon at anytime during the most recent year, the information will be disclosed and a collective decision by the parties shall be made as to how to handle such situation to ensure that the Program is independent.
12. Invitations/Enduring Materials The Program audience will be selected by the Provider. The Provider shall be responsible for distributing materials about the Program, including invitations, reminder notices, and business reply cards that can be used by third parties to obtain any enduring Program material from the Provider. As soon as a date is finalized for a live event the Provider will notify Cephalon. For enduring material the Provider shall provide copies to Cephalon at the same time as first publication/distribution of such material.
  13. Ancillary Promotional Activities. To the extent the Program is a live presentation, no promotional activities or product advertisements will be permitted in the same room as, or in an oblique path to, the Program. If the Program is a teleconference or webcast, no product advertisements or promotional activities will be permitted immediately prior to, during, or immediately after the delivery of the Program. If the Program is in print format, no product advertisements or promotional materials will be interleaved within the pages of the Program. If the Program is made available electronically, no product advertisements or promotional materials will appear within the Program material or interleaved between computer windows or screens of the Program, all as stipulated in ACCME Guidelines.
  14. Compliance with Guidelines. Provider represents that the Program, regardless of whether it is certified or not, including development of the Program and Program materials, shall conform to the American Medical Association ("AMA") Guidelines on Gifts to Physicians, the AMA Ethical Opinion on Continuing Medical Education, the ACCME Standards for Commercial Support, the FDA December 3, 1997 Final Guidance for Industry-Supported Scientific and Educational Activities, and the Pharmaceutical Research and Manufacturers Association ("PhRMA") Code on Interactions with Healthcare Professionals.
  15. Logistical Status Reports. Provider and/or Educational Partner shall provide periodic reports to Cephalon regarding the management and logistics of Program components.
  16. Public Disclosure of Grant Payments. Provider and Partners acknowledge that Cephalon is required to publicly disclose certain terms of this grant agreement



including the identity of the recipient(s) of the grant, the nature of the activities performed by grant recipient(s), and the amount of the grant.

17. Miscellaneous.

- (a) No party shall use the other party's or its affiliates' name or trademarks for publicity or advertising purposes, except with the prior written consent of the other party.
- (b) To use the Cephalon logo, the Provider and/or Education Partner must contact the Cephalon Grants Coordinator who will supply the logo and correct use instructions.
- (c) Provider agrees to obtain all consents, authorizations, approvals and releases that may be necessary for the production of the Program and of any written materials prepared in connection therewith.

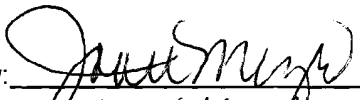
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- (d) No term, condition or other provision of any attachment or addendum to this Agreement shall supersede any term, condition or other provision of this Agreement, and with respect to any inconsistency or ambiguity, the Agreement shall control.

IN WITNESS WHEREOF, the parties, by their duly authorized representatives, agree to comply with all the terms and conditions of this Agreement.

**MEDICOM WORLDWIDE, INC.**


By:   
 Name: JOAN MAYER  
 Title: PRESIDENT

The above signatory is a duly authorized corporate officer of the IEP Provider.

Date:

Tax ID #:

**CEPHALON, INC.**

By:   
 Name: Robert Kaper, MD  
 Title: Vice President, Medical Affairs

Date: 10/28/11





Exhibit A  
Copy of Grant Request





101 Washington Street  
 Morrisville, Pennsylvania 19067  
 Phone 215.337.9991  
 Fax 215.337.0959

September 2, 2011

Cephalon

Dear Educational Grant Review Committee:

MediCom Worldwide, Inc. is pleased to submit the accompanying grant request to the Educational Grant Review Committee at Cephalon for an educational program for practitioners who treat patients with breakthrough pain. As an accredited provider of continuing medical education, MediCom Worldwide, Inc. recently completed a comprehensive needs assessment to identify the educational needs of practitioners and knowledge gaps surrounding the treatment of breakthrough pain.

MediCom Worldwide, Inc. is committed to delivering education that addresses gaps in health care professional education with the ultimate goal of improving patient care. We are therefore requesting funding for the development of an accredited online curriculum and live internet broadcast entitled *Effective Strategies in Managing Breakthrough Pain* to be hosted on *EmergingSolutionsinPain.com*.

The educational activities include (please see attached proposal for full description and rollout of activities):

1. Streaming Video Activities (3)
2. Live Internet Broadcast (1)
3. Practice Support Resources

The total budget to fund this activity is approximately \$199,880. Please refer to the detailed budget section of this proposal for complete grant funding details.

These scientific events will comply with all ACCME, FDA, AMA, and ACPE regulations for industry supported professional continuing education. MediCom Worldwide is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians, approved by the Accreditation Council for Pharmacy Education to provide pharmacy continuing education, and approved by the California State Board of Registered Nursing to provide nursing continuing education. Educational support will be acknowledged on the educational program in compliance with Accreditation Council for Continuing Medical Education (ACCME) Guidelines.

Thank you, in advance, for your consideration of this request.

Respectfully,

A handwritten signature in cursive script, appearing to read 'Joan Meyer'.

Joan Meyer, RN, MA  
 Executive Director, Continuing Education



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 Morrisville, Pennsylvania 19067  
 Phone 215.337.9991  
 Fax 215.337.0959  
 www.MedicalEd.com

## PROPOSAL SUMMARY

A comprehensive analysis of the educational needs of the physicians, pharmacists and nurses who treat patients with chronic pain has indicated a number of significant gaps and barriers among these clinicians related to the assessment, management and treatment approaches to patients who experience breakthrough pain (BTP). In order to cost-effectively and efficiently educate these health care professionals, MediCom Worldwide, Inc. is proposing to develop an accredited online curriculum utilizing a sequential series of focused Internet broadcasts entitled *Effective Strategies in Managing Breakthrough Pain*. This live Internet broadcast and its supporting resources will be posted on the Emerging Solutions in Pain website, to ensure that the >28,000 clinician members of this website are able to access, and benefit from, this educational curriculum.

Each activity in the series will feature a moderated presentation of data, as well as a case-based discussion between two clinical experts. Each activity will summarize key points as clinical pearls that support application of the knowledge presented in the clinical setting. Through a series of live question and answer sessions, clinicians will have the opportunity to interact directly with the faculty who presented the videos. In addition, an e-newsletter with frequently asked questions, as well as practice support resources based on the activities will reinforce learning and encourage further utilization of the education and information in clinical practice.

The following outline will be utilized to detail the full educational design and scope of this accredited series.

1. Educational Design
  - a. Streaming Video Activities (3)
  - b. Live Internet Broadcast (1)
  - c. Enduring Self-Study Curriculum
2. Activity Overview
  - a. Overview and Learning Objectives
  - b. Faculty
  - c. Accreditation Information
3. Practice Support Resources
  - a. e-Newsletter
  - b. Frequently Asked Questions (FAQs) Compendium
  - c. Practice Support Resources
4. Awareness and Recruitment
  - a. Target Audience
  - b. Blast e-Mail Campaigns to the Target Audience
5. Outcomes
  - a. Utilization Goals
  - b. Pre- and Post-Test Data
  - c. Evidence of Educational Efficacy
6. Appendix: Curriculum Delivery Method
7. Appendix: Example Outcomes Data



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## EDUCATIONAL DESIGN

The *Effective Strategies in Managing Breakthrough Pain* series has been designed to increase the knowledge and understanding of clinicians who treat patients with breakthrough pain (BTP). Through an interactive approach that utilizes streaming video-based modules, live interaction with clinical experts and tailored practice support resources, clinicians will be able to create an individualized curriculum based on their own unique needs and the needs of their practices. Please refer to Figure 1 for the educational design of the live portion of the series.

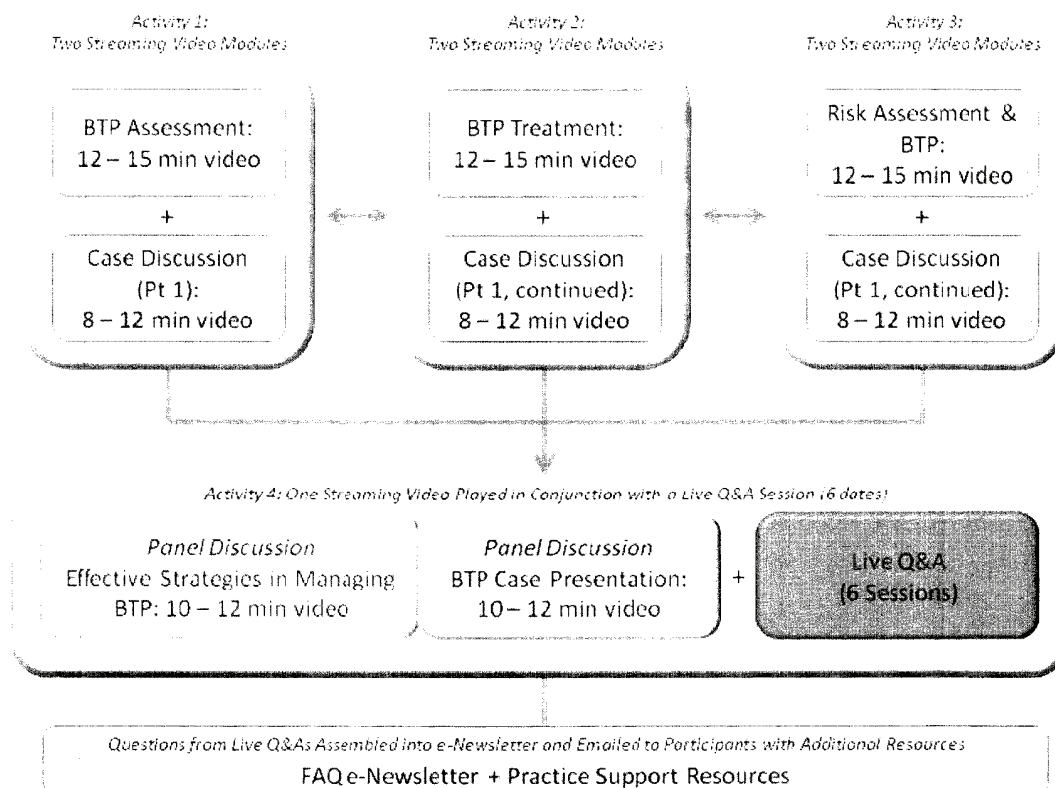


Figure 1, Educational Design of the *Effective Strategies in Managing Breakthrough Pain* Series

### Streaming Video Activities (3)

In the *Effective Strategies in Managing Breakthrough Pain* series, three activities will be accredited as stand-alone streaming videos, each addressing a topic relevant to a specific area of need in breakthrough pain. As indicated in Figure 1, above, these topics are:



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- Activity 1: Effective Assessment of Breakthrough Pain
- Activity 2: Individualized Approaches to the Treatment of Breakthrough Pain
- Activity 3: Elements of Safe Use and REMS in Breakthrough Pain

Each of the three streaming video activities will feature one clinical expert moderator and one clinical expert faculty member who will present data. Key points will be reinforced with animated graphics, charts and text; interactive discussion between the two faculty will reinforce key clinical points and increase audience engagement. Clinicians may view all activities, or only those that are relevant to their unique practice and educational needs. The streaming video activities may be viewed in any order, as well, to facilitate meeting individual needs, reinforced through preferred learning preferences.

In Activities 1, 2 and 3, information presentation will occur in two modules; both modules must be viewed to earn credit.

- In the first module of each activity, approximately 12 – 15 minutes in length, the two clinical experts will present and discuss data supporting the key learning objectives.
- In the second module of each activity, approximately 8 – 12 minutes in length, the clinical experts will discuss a case that exemplifies the key decision-making points discussed in the first module.
- To further reinforce key clinical points, the second module will include video footage of a patient with breakthrough pain, portrayed by an actor/actress. The same "patient" will be utilized in each activity in the *Effective Strategies in Managing Breakthrough Pain* series, with the case progressing in ways that are reflective of the key learning points of each activity. Continuation of the same patient throughout the activities will also demonstrate how the information presented can be applied in complex case progressions that may occur in actual clinical practice.
- The second module in each activity will summarize the key points and direct learners to the related practice support resources (see below) for further information and related resources.

Note that all three activities will be made available on the same date, to allow learners to combine activity viewing in a way that best meets their individual needs. All participants will be encouraged to participate in all three activities. Learners may also view the modules of any individual activity in separate user sessions, to facilitate participation by even those clinicians with severe time limitations; note that, to earn CE credit, both modules must be viewed. In addition, the 24/7 availability of the online activity will facilitate participation for those clinicians whose time is limited. Finally, to address diverse learner format preferences, all modules will be available as

- Streaming audio on ESP Radio for listening directly from either the mobile or desktop website
- Downloadable podcasts
- Text-based, printable PDFs



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### ***Live Internet Broadcast (1)***

The fourth activity in the *Effective Strategies in Managing Breakthrough Pain* series will be presented as a live Internet broadcast, in which learners will be able to submit questions to the faculty member(s) who presented each video, and listen to the answers live. The design of this activity will include the following:

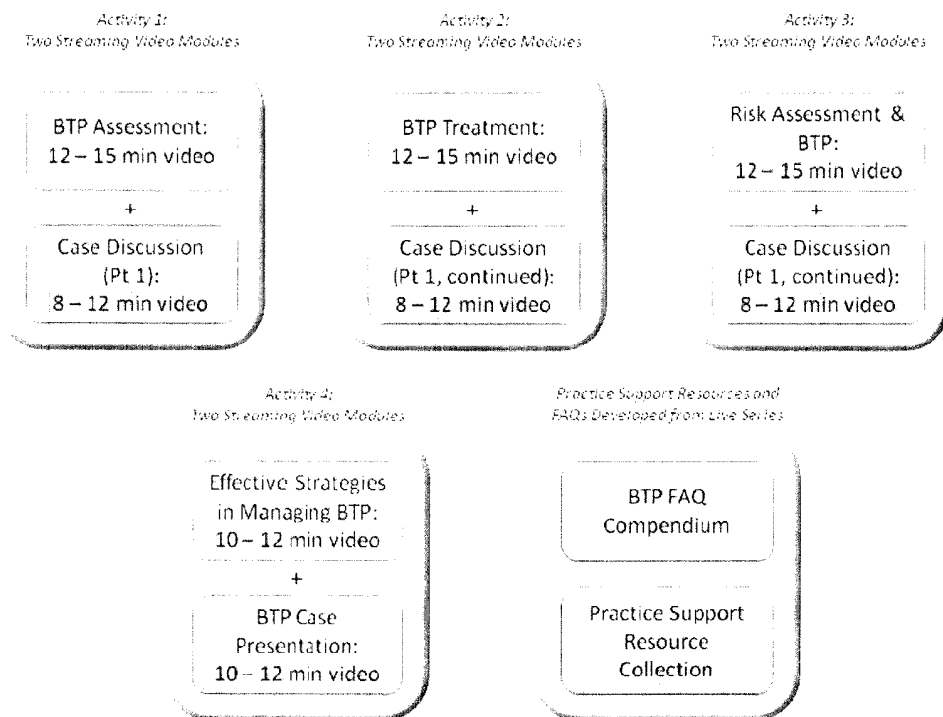
- Activity 4 will focus on Effective Strategies for Managing Breakthrough Pain; information presented in this activity will build upon the key learning points of the first three activities, to address the assessment, treatment and management of patients with breakthrough pain as part of a comprehensive and effective approach that supports improved quality of life and function in this patient population.
- Activity 4 will be similar in design and presentation as Activities 1, 2 and 3 (please refer to bullets in the section, above); the information presentation and case discussion will be presented as a streaming video in two modules, as well as case-based video footage.
- The presentation will occur by panel discussion, in which the clinical expert moderator from the first three activities will moderate a discussion between the three clinical expert faculty from Activities 1, 2 and 3.
- One six dates, on varying days of the week and at varying times, Activity 4 will be presented as a live Internet broadcast. During the broadcast, the two streaming video modules will be played sequentially, to form one video approximately 30 minutes in length; as the video is being broadcast, learners may submit questions to the faculty, which will be assembled into a queue. Immediately following the conclusion of the video portion of the broadcast, one of the three clinical expert faculty from the panel will be available for a live question and answer session, and will answer the questions submitted from the live audience.
- At the conclusion of the live Q&A sessions, all questions will be assembled into an e-newsletter that will be emailed to all participants as a follow-up and learning reinforcement. The e-newsletter will also include practice support resources developed as part of the *Effective Strategies in Managing Breakthrough Pain* series; please see below.

### ***Enduring Self-Study Curriculum***

Following the completion of the sixth date in the live Internet broadcast series, all four activities will be available as self-study streaming video activities; please refer to *Figure 2*, below.



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**Figure 2, Educational Design of the *Effective Strategies in Managing Breakthrough Pain Self-Study Curriculum***

Each activity will be able to viewed independently, and clinicians may view each activity in any order. Again, the use of two brief modules for each activity will facilitate participation by those clinicians with limited time; this format also reflects learning preferences of physician members of the Emerging Solutions in Pain website (please refer to Appendix A for data). All questions submitted through the live question and answer sessions will be assembled into the Breakthrough Pain FAQ Compendium, and all Practice Support Resources will be assembled into one collection. Links will be made throughout the *Effective Strategies in Managing Breakthrough Pain* self-study curriculum, encouraging learners to participate in all activities and to review all resources, to ensure a complete learning experience.

Finally, similar to Activities 1 - 3, the self-study version of Activity 4 will also be available in diverse learning formats, to accommodate individual preferences. Both modules in Activity 4 will therefore be available as

- Streaming audio on ESP Radio for listening directly from either the mobile or desktop website
- Downloadable podcasts
- Text-based, printable PDFs



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### ACTIVITY Overview and Learning Objectives

The agenda of *Effective Strategies in Managing Breakthrough Pain* series has been planned to create a curriculum that encourages and supports the integration of the key concepts in the assessment, management and treatment of BTP into clinical practice. Learning objectives have been developed that align with the gaps and barriers identified in the needs assessment, above.

Upon completion of each of the four activities in the series, practitioners should be able to satisfy each of the specific learning objectives associated with that activity. The learning objectives for *Effective Strategies in Managing Breakthrough Pain*, are summarized below.

*Table 1: Effective Strategies in Managing Breakthrough Pain Series: Topics, Gaps and Learning Objectives*

Video No.	Topic	Learning Objective	Learning Objective
1	Breakthrough Pain Assessment	Define and differentiate breakthrough pain	Formulate effective assessment techniques to assist in the diagnosis of breakthrough pain
2	Breakthrough Pain Treatment	Translate neurophysiologic mechanisms of BTP and how to correlate with pharmacokinetic profile of appropriate therapeutic options for maximized safety and efficacy	Define key principles of prescribing opioid analgesics for persistent and breakthrough pain including protocols for proper patient selection in determining treatment options
3	Effective Strategies to Minimize Risk	Integrate knowledge regarding risk stratification into treatment strategies of patients prescribed opioid therapy	Outline appropriate patient education including elements of safe use
4	Effective Strategies in Assessing and Managing BTP	Interpret recommendations for best-practice clinical application into current practice behaviors	Identify and incorporate opportunities within clinical practice setting to incorporate assessment, management and ongoing evaluation of breakthrough pain in chronic pain patients.





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## ACTIVITY OVERVIEW, CONTINUED

### Faculty

The online format of the educational series and the practice support resources will result in live and self-study activities that are both interactive and engaging. Based on this format, and the unique programming that will be utilized to develop the online video-based series, even faculty with limited time availability will be able to make significant contributions in the planning, development and execution of these activities and resources. Thus, as can be seen in *Table 2*, potential faculty include leading clinical experts and thought leaders in pain management and breakthrough pain.

*Table 2: Effective Strategies in Managing Breakthrough Pain: Potential Faculty*

Jeffrey Gudin, MD Director Pain Management Center Englewood Hospital and Medical Center Englewood, New Jersey	Russell Portenoy, MD Chairman, Department of Pain Medicine and Palliative Care Beth Israel Medical Center New York, N.Y.
Michael Brennan, MD The Pain Center of Fairfield Fairfield, CT	Steven Passik, PhD Professor of Psychiatry and Anesthesiology Vanderbilt University Medical Center Psychosomatic Medicine Nashville, TN
Sharon Weinstein, MD Director, Pain Medicine and Palliative Care Huntsman Cancer Institute Professor, Department of Anesthesiology Adjunct Associate Professor, Departments of Neurology and Internal Medicine (Oncology) University of Utah Salt Lake City, Utah	Paul Arnstein, RN, PhD Clinical Nurse Specialist for Pain Relief Massachusetts General Hospital Associate Professor MGH Institute for Health Professions Boston, Massachusetts



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## ACTIVITY OVERVIEW, CONTINUED

### ***Accreditation Information***

#### **CME Credit**

The activity will be planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME). MediCom Worldwide, Inc. is accredited by the ACCME to sponsor continuing medical education programs for physicians. MediCom Worldwide, Inc. will designate Activity 1, 2 and 3 for a maximum of 0.5 hours per Activity in category 1 credit towards the AMA Physician's Recognition Award. MediCom will designate Activity 4 for a maximum of 1.0 hour in category 1 credit towards the AMA Physician's Recognition Award.

Educational activities that are designated for continuing medical education have guidelines and requirements which to adhere. These programs will adhere to the ACCME Standards of Commercial Support, as well as all other applicable guidelines including FDA, OIG, and PhRMA CME credit for physicians by the Accreditation Council.

#### **CPE Credit**

MediCom Worldwide, Inc. is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing education. MediCom Worldwide, Inc. CE programs are developed in accordance with the "Criteria for Quality and Interpretive Guidelines" of the ACPE. For Activities 1, 2 and 3: each program is acceptable for 0.5 contact hours of continuing education credit. For Activity 4: this program is acceptable for 1.0 contact hour of continuing education credit.

#### **CNE Credit**

MediCom Worldwide, Inc. is approved by the California Board of Registered Nursing. MediCom Worldwide, Inc. designates Activity 4 for 1.0 contact hour.



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## ANCILLARY PRACTICE SUPPORT TOOLS

### ***e-Newsletter and FAQ Compendium***

To further reinforce learning and encourage application of the key points in the clinical practice setting, each of the questions submitted through the six live question and answer sessions, and faculty answers to those questions, will be collected and assembled into a Breakthrough Pain (BTP) FAQ Compendium. Following the final question and answer session, these FAQs and answers will be assembled into an e-Newsletter and emailed to all clinicians who participated in any activity within the series. The e-Newsletter will also include links to the Practice Support Resources, below, and links to further related resources on the Emerging Solutions in Pain website.

The BTP FAQ Compendium will also be posted on the Emerging Solutions in Pain website, with prominent announcement of availability in the "What's New" section of the ESP home page, as well as banner ads that will take users directly to these key resources.

### ***Practice Support Resource***

To support and reinforce practical utilization of the information presented in *Effective Strategies in Managing Breakthrough Pain*, one practice resource per Activity will be developed that is appropriate for supporting improved patient care in patients with breakthrough pain. While the list of final resources will be determined by the clinical expert faculty, examples that may be developed include:

- Patient checklists for communication optimization
- Patient diaries for recording side effects
- Assessment tools
- Point-of-care communication guides

Each practice support resource will be presented as a downloadable PDF, to facilitate ongoing use in the patient setting. Brief background and/or instructions will be included, as appropriate. All four practice support resources will be included in the e-Newsletter sent out to all series participants following completion of the final question and answer session, and will be posted as the series Practice Support Resource Collection on the Emerging Solutions in Pain website.



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## AWARENESS AND RECRUITMENT

### **Target Audience**

The target audience for the *Effective Strategies in Managing Breakthrough Pain* is comprised of physicians, nurses, pharmacists and other allied health care professionals who provide care to patients with breakthrough pain. In order to effectively reach these health care professionals, MediCom has conducted an analysis of this target audience, to effectively ensure focused development of tactics that will meet these clinicians' educational needs. Based on this analysis, MediCom has identified that the potential target audience includes approximately 14,000 physicians who provide care to patients experiencing breakthrough pain, in addition to the nurses, pharmacists and allied health care professionals who are members of the multidisciplinary team treating this patient cohort.

### **Blast e-Mail Campaigns to the Target Audience**

The current clinician membership of the Emerging Solutions in Pain website is comprised of more than 28,000 health care professionals who have registered as members, and provided contact specialty/degree information. Almost 9,000 of these members are physicians (MDs, DOs), with smaller numbers including nurse practitioners (NPs) and physician assistants (PAs); thus, a majority of the target audience of 14,000 will already be included in the Emerging Solutions in Pain membership.

To ensure the greatest possible reach of the *Effective Strategies in Managing Breakthrough Pain* series to the target audience, MediCom will supplement the ESP membership list with a targeted series of e-blasts to purchased lists of physicians. Awareness campaigns for the *Effective Strategies in Managing Breakthrough Pain* series will therefore include:

- Activity announcement e-blasts to a purchased list of community oncologists and pain medicine specialists. This list, which includes 73,000 physicians, will be purchased four times, such that potential learners will receive four invitations to participate in this activity at periodic times during its availability; a link to the activity will be embedded in the e-blast to facilitate access to the program and its ancillary practice support resources. A total of 292,000 e-blasts will be sent through this part of the awareness campaign.
- Activity announcement e-blasts to members of the Emerging Solutions in Pain community. The 23,000 members who subscribe to this service will receive four e-blast invitations to participate in this activity; similar to the e-blasts to the purchased lists, above, links will facilitate member access to the activity and its support resources. A total of 92,000 e-blasts will be sent through this part of the awareness campaign.
- Activity announcement fax-blasts to a purchased list of pharmacists. This list, which includes 47,000 pharmacists, will be purchased four times, such that potential learners will receive four invitations to participate in this activity at periodic times during the availability of the live Internet broadcast. A total of 188,000 fax-blasts will be sent through this part of the awareness campaign.
- Banner advertisement on the Emerging Solutions in Pain website, announcing availability of the activity to guests (non-members) and to members who do not subscribe to the ESP e-blast series; clicking on the banner will take the user directly to the activity
- Inclusion in The Beacon, ESP's monthly e-newsletter; four inclusions total.



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A summary of the *Effective Strategies in Managing Breakthrough Pain* awareness campaign is provided in Table 3, below.

Table 3: The Effective Strategies in Managing Breakthrough Pain Awareness Campaign

Audience Generation Initiative	Frequency	Total Reach of Initiative
E-blast series to purchased community oncology physician list	Four e-blasts; two at activity launch to announce availability of the live Internet broadcast dates, and two at 4 and 8 weeks after launch of the self-study activity series; 4 e-blasts total	73,000 oncology physicians per blast; 292,000 total
E-blast series to subscribing members of the Emerging Solutions in Pain community	Same frequency as above	Estimated average of 23,000 members per blast; 92,000 emails total
Fax-blast series to purchased pharmacist list	Four fax-blasts; three at activity launch to announce availability of the live Internet broadcast dates, and one 4 weeks after launch of the self-study activity series; 4 fax-blasts total	47,000 pharmacists per blast; 188,000 total
Banner advertisement on the Emerging Solutions in Pain website	Rotating banner on home page; banner availability: 12 months	
Inclusion in The Beacon, ESP's monthly e-newsletter	E-newsletter sent every month to 23,000 member subscribers; announcement in 4 e-blasts total	23,000 members per e-newsletter; 92,000 emails total

In addition, to ensure the greatest possible reach using the most cost-effective techniques, *Effective Strategies in Managing Breakthrough Pain* will be announced via the following methods:

- Twitter, with supportive information on Facebook and LinkedIn
- Identified partnership links
- Collaboration with associations



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## OUTCOMES

### Utilization Goals

The utilization goals for *Effective Strategies in Managing Breakthrough Pain* are provided in Table 4, below.

Table 4: Utilization Goals and Reach of the *Effective Strategies in Managing Breakthrough Pain*

Curriculum Component	Anticipated Series Attendance
The <i>Effective Strategies in Managing Breakthrough Pain</i> Accredited Internet Broadcast (4 streaming video activities)	Anticipated attendees 3,000 total health care professionals <ul style="list-style-type: none"> <li>• 1000 MD/DO</li> <li>• 1000 NPs/Nurses</li> <li>• 600 Pharmacists</li> <li>• 400 Others</li> </ul>
The <i>Effective Strategies in Managing Breakthrough Pain</i> Support Resources (e-Newsletter, FAQ Compendium, Resource Collection)	Anticipated views and downloads: 3,000 health care professionals <ul style="list-style-type: none"> <li>• 1,000 MD/DO</li> <li>• 500 NPs/Nurses</li> <li>• 750 Pharmacists</li> <li>• 750 Others</li> </ul>

### Outcome Measurement

Conducting educational outcomes studies to seek out data on effectiveness, knowledge gain, behavior change, and learner satisfaction is vital to provide feedback for continuous quality improvement.

MediCom Worldwide, Inc. is committed to measuring and assessing the educational outcomes of the proposed activities to ensure that they bring practical effectiveness to the learners who choose to participate in them. We believe that a consistent focus on measuring and enhancing the quality of education will ultimately improve the quality of care for patients.

MediCom will employ a comprehensive strategy designed to measure outcomes at a variety of levels including those required by ACCME and described by the 2009 Moore Scale. The following table describes the strategy and tactics used for analyzing the impact of the education and the outcomes achieved:

.

Strategy		Outcome achieved	
Strategy ID	Tactic	ACCME	MOORE
<b>Evaluation Form</b>			
<p>Utilize a comprehensive evaluation form to determine outcomes in several areas including:</p> <ul style="list-style-type: none"> <li>Satisfaction with the program</li> <li>Knowledge growth</li> <li>Competence improvement</li> <li>Needs determination for future education</li> </ul> <p>Evaluation form completion will be mandatory for all participants in the activity. CE certificate issuance will be driven by the receipt of a completed evaluation form.</p>	<p>To measure satisfaction of the participant with the activity, the participant will be asked to complete the following:</p> <ul style="list-style-type: none"> <li>Rate each speaker – 1 through 5 scale</li> <li>Rate achievement of learning objectives – 1 through 5 scale</li> <li>List any general comments about the program</li> </ul>	Satisfaction	One
	<p>To evaluate the improvements in knowledge and competency the attendees will be asked to rate their agreement with the following statements using a 5-point Likert scale:</p> <ul style="list-style-type: none"> <li>The program provided new information</li> <li>The information is applicable to their clinical practice</li> <li>The information learned will help improve their patients' outcomes</li> </ul>	Participation	Two
	<p>To determine if the activity created an intent to change behavior, each participant will be asked to complete the following:</p> <ul style="list-style-type: none"> <li>List 3 things that they will do upon returning to their practice</li> </ul>	Knowledge	Three
	<p>To help determine the need for additional education on the topic or a modification in future educational formats, the participant will be asked to complete the following:</p> <ul style="list-style-type: none"> <li>The educational approach was conducive to learning – list agreement using a 5-point Likert scale</li> <li>List the barriers to implementing the practice paradigms discussed</li> <li>List additional information or materials that would enhance the activity</li> </ul>	Competence	Four





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Strategy	Tactic	ACME	Moore
<p><b>Pre and Post Testing</b></p> <p>To determine if the participants in an activity had a change in competency, knowledge, and confidence, a pre- and post-test method.</p> <p>Each participant will be asked a series of questions immediately prior to the activity and immediately after the activity. Questions will be similar for the pre- and post-test.</p> <p>Goal of the questions will be to provide a measurement of changes in competency, knowledge, and confidence based on the learnings derived from the educational activity.</p>	<p>Test each participant pre- and post-activity</p> <p>Pre-activity questions will measure and establish a baseline in competency, confidence, and knowledge for each of the learning objectives by asking the participants the following three (3) questions:</p> <ol style="list-style-type: none"> <li>1. How important do you think (<i>insert key element based on learning objectives</i>) is in diagnosing/management/treating your patients with breakthrough pain</li> <li>2. How confident are you in implementing (<i>insert key element from first question</i>) with your patients with breakthrough pain?</li> <li>3. How often do you implement (<i>insert key element from first question</i>) with your patients with breakthrough pain?</li> </ol> <p>Post-activity questions will measure changes from baseline in competency, confidence, and knowledge for each of the learning objectives by asking the participants the following two (2) questions:</p> <ol style="list-style-type: none"> <li>1. Now that you have participated in the educational activity, how important do you think (<i>insert key element based on learning objectives</i>) is in diagnosing/management/treating your patients with breakthrough pain?</li> <li>2. Now that you have participated in the educational activity, how confident are you in implementing (<i>insert key element from first question</i>) with your patients with breakthrough pain?</li> </ol>	<p>Knowledge</p> <p>Competence</p>	<p>Three</p> <p>Four</p>



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***Evidence of Educational Efficacy: Demonstrated Ability to Impact Performance Using Case-based Learning***

MediCom has developed interactive, online curriculum-based educational activities for health care professionals across a diverse array of therapeutic areas and disease states for more than 10 years. This experience has translated into the proven ability to develop relevant, clinically-focused online programs, and to recruit effectively for these activities from among those clinicians with a demonstrated need for the information. *Table 5*, below, provides metrics for activity views and completions for two representative accredited activities from 2010 involving online case-based learning in a video format. Both activities were made available in streaming video format, with audio and text versions also available; both were accredited for CME, CNE and CPE credit.

*Table 5: Efficacy of MediCom's Online Activities*

Activity Number	Viewers	Completers
One	3,500	1,011
Two	3,300	817

In 2010, MediCom conducted a focused outcomes analysis concerning the efficacy of translating knowledge gained in an online environment to practice-based patient care using the two online video-based activities in *Table 5*. This outcomes study utilized case vignettes given to participants in the online activities, as well as to non-participants. The results of this comparative study were significant: **at least 137,643 patients seen by the 4,171 health care providers who participated in these and related online accredited activities were 30% more likely to receive evidence-based care than those seen by healthcare providers who did not participate in the activity.**

The results of this outcomes study were summarized in a poster presented at the 2010 PAINWeek conference; please refer to the Appendix for a full description of the study.



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## Grant Funding Request and Payment Structure

Total grant request amount is: \$199,880

## Budget Reporting and Reconciliation

### *Appropriate Use of Commercial Support*

- a. Funds should be in the form of an educational grant made payable to:  
 MediCom Worldwide, Inc.  
 101 Washington Street  
  
 Morrisville, PA 19067  
  
 Tax ID# 23-3063738
- b. No other funds from Cephalon will be paid to the program director, faculty, or others involved with the CE activity (additional honoraria, extra social events, etc).
- c. MediCom Worldwide, Inc. will furnish the commercial interest with documentation detailing the receipt and expenditure of the commercial support within 90 days of activity completion.

### ***Payment Structure***

95% due upon signing of agreement	\$189,886
5% due at posting of enduring material	\$ 9,994



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## APPENDIX: CURRICULUM DELIVERY METHOD

### *Website Description*

#### ***Emerging Solutions in Pain: Overview and Demographics***

*Emerging Solutions in Pain* (ESP) was launched in 2005 as a broad-based initiative employing an integrated communication approach to education and information dissemination. ESP's goal is to assist clinicians in managing the challenges of providing appropriate treatment to patients with chronic pain, while also minimizing the potential risk for opioid misuse, abuse, and diversion.

Since launch, ESP website has documented success in achieving its goals and mission:

- ESP membership has grown phenomenally since launch. The current membership is more than 28,000 health care professionals
  - Membership represents those clinicians who are willing to provide key identification data in order to obtain access to education, tools, and training
- ESP membership demographics includes all members of the multidisciplinary team, with physicians and nurses being the most represented. The ESP membership reflects a diverse spectrum of clinical specialties, including the following physician specialties
  - Pain management specialists
  - Anesthesiologists
  - Primary care physicians
  - Physical medicine and rehabilitation specialists
- In 2010, ESP had:
  - More than 284,350 unique user sessions
  - More than 770 unique user sessions daily
  - An average user session length of more than 8 minutes, 26 seconds
- ESP has been awarded both HONCode and Web Medica Acreditada (WMA) certification, the only two worldwide organizations certifying web sites adhering to the strictest guidelines and ethical standards of presenting credible and reliable information for health care professionals
- ESP has been recognized for both content and innovative design with numerous international awards
- ESP content has been rated highly in terms of usefulness (4.1), quality (4.1), change in clinical practices (3.8) and commitment to change (4.0)<sup>‡</sup>
- ESP educational activities have led to the following key changes in clinical practice: patient assessment (22.6%), patient monitoring (19.1%), documentation (12.2%), risk strategy (13.9%), pharmacological management (13.9%), and other (18.3%)<sup>¶</sup>

<sup>‡</sup>The numbers in brackets represents the average overall rating by ESP members to October 2010 where 5 = highest and 1 = lowest

<sup>¶</sup>Other – includes teaching, further research, and sharing with colleagues.

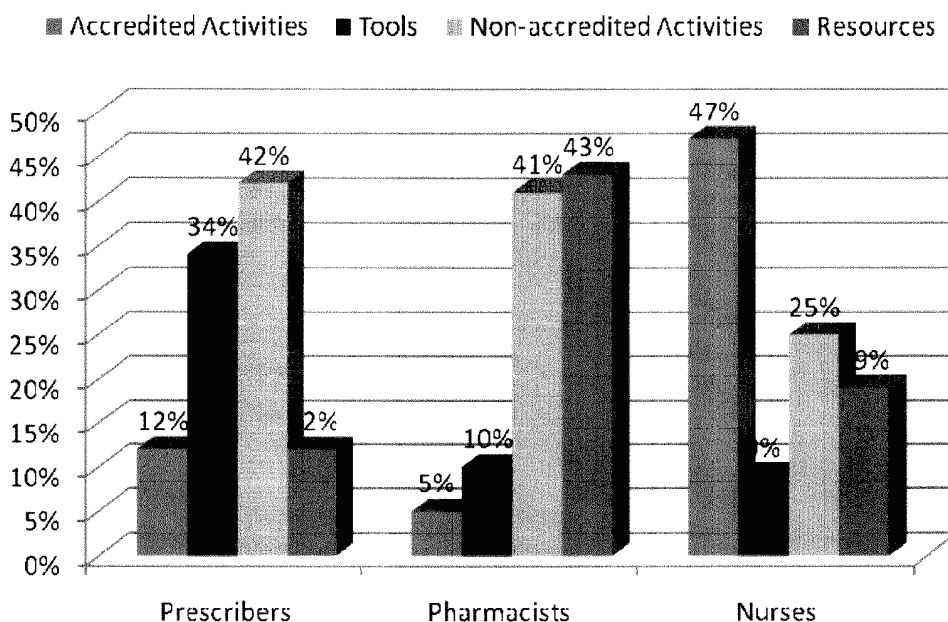


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### **Data Analysis: Patterns of Utilization and Metrics by Members of the Emerging Solutions in Pain Website**

The ESP website is built upon a structured Learning Management System (LMS) that facilitates accurate, rigorous and secure record-keeping and data maintenance of the accredited activities on the site. In addition, this infrastructure tracks views, downloads and access for every activity and resource on the ESP website, thereby allowing a comprehensive analysis of utilization of all of the education and resources available through this site.

In 2011, MediCom completed a comprehensive analysis of ESP utilization data for the 18-month period beginning January 1, 2010, and ending June 30, 2011. This analysis has provided significant insights into utilization patterns for clinician members of the ESP site, which have been specifically applied during the development of the educational design of the *Effective Strategies in Managing Breakthrough Pain* series.



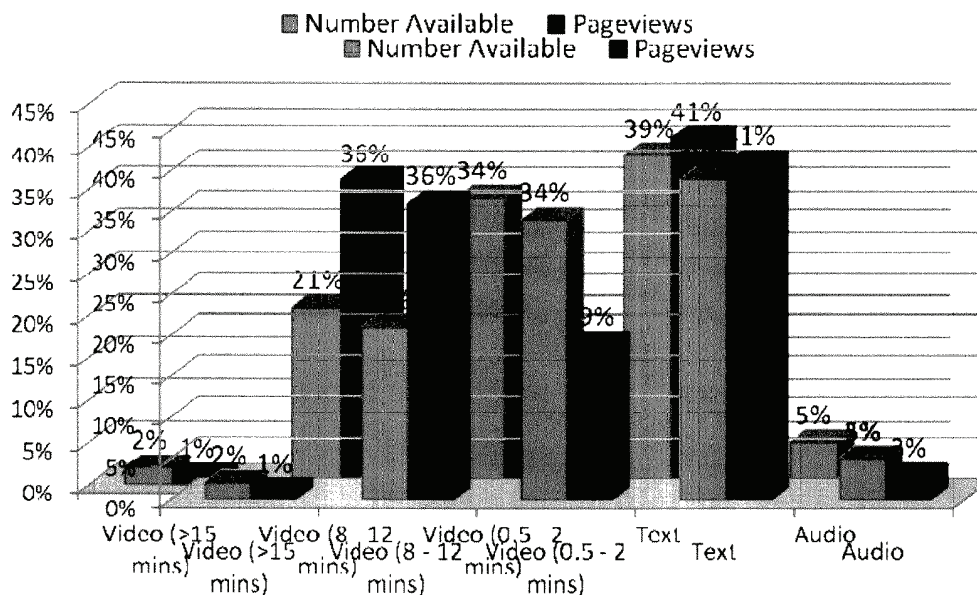
**Figure 3, Differential Content Access on the Emerging Solutions in Pain Website by Clinical Specialty**

As can be seen from the data in Figure 3, access of content on the ESP website differs by clinical specialty, with prescriber members accessing content that may either be applied directly to their practices ("Tools") or is educational in nature, but not of sufficient length to be accredited ("Non-accredited Activities"). However, other clinical specialties exhibit different clinical patterns; nurses, for example, primarily access accredited activities. Thus, the *Effective Strategies in Managing Breakthrough Pain* series has been designed to reflect as many of the educational needs and preferences of the target audience as possible. Specifically, the educational design of the streaming video activities includes the division of the educational content into two brief modules, to reflect the learning preferences of prescribers, while retaining accreditation and resources to reflect the needs of the multidisciplinary target audience.



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Finally, each module in the streaming video activities will range in length from 8 to 12 minutes per module. This reflects data specific to the preferred formats of physician members of ESP; please refer to Figure 4, below.



**Figure 4, Distribution of Format on ESP: Utilization by Physician Members**

Number of non-accredited educational activity items available: n = 321; number of pageviews, registered members only: 2,674

As can be seen from the data in Figure 4, physician members of the ESP website preferentially access videos that are 8 to 12 minutes in length, as compared to other video formats; this is demonstrated by the increased number of views, in relation to the number of these activities of this length available on the ESP website, and compared to other videos that are either longer or shorter.

Finally, this data also exemplifies the diversity of format preferences of physician members; to reflect this diversity, MediCom will create both text and audio formats of all activities in the *Effective Strategies in Managing Breakthrough Pain* series, to ensure that all members will be able to participate in these activities in their preferred learning format.





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## APPENDIX: EXAMPLE OUTCOMES DATA

### ***An Assessment of Internet-based (Emerging Solutions in Pain) CME Activities for Pain Physicians***

Bronwyn Boyes, PharmD\*, Joan Meyer, RN, MHA\*, Benjamin Whitfield†, Gregory Salinas†

\*MediCom Worldwide, Inc., 101 Washington Street, Morrisville, PA

†CE Outcomes, LLC, Birmingham, AL

#### *Background*

Physicians are increasingly utilizing the Internet, and in particular, trusted independent websites, as an essential component of obtaining professional information, as a source of continuing medical education (CME), and as a communication lifeline at the point of care. *Emerging Solutions in Pain* (ESP) was launched in 2005 with a leading cadre of experts in pain management and addiction medicine. ESP is a robust and multi award-winning ongoing educational initiative which provides an array of information, resources, tools, and case studies to the management of chronic pain. It aims to inform clinicians of methods of communication, ways in which risk of abuse may be measured, and how highlight and educate clinicians on the complexities surrounding to integrate these strategies into an individualized treatment plan. Membership is free to all health care professionals.

#### *Aim*

The purpose of this study was to determine the effectiveness of two Internet-based CME activities, *Assessment Strategies and Practical Approaches to Successful Monitoring of Chronic Pain*, and *Minimizing Risk and Improving Outcomes in Chronic Pain*, included on the educational initiative, *Emerging Solutions in Pain* (ESP). Both programs focused on the safe and effective treatment of chronic pain while minimizing the risks of misuse.

#### *Methods*

A post-activity assessment study was conducted 3-5 months after completion to determine the effectiveness of two CME activities on the practice patterns and knowledge of physicians who manage chronic pain patients. Effectiveness was measured using a case-based survey designed to assess whether the diagnostic and therapeutic choices of program participants were consistent with evidence-based content of the CME activities.

The survey was also administered to a demographically similar control group of physicians who did not participate in the educational program in order to assess differences in practice choices. The participant group was selected from a list of physicians completing the course and also agreeing to participate in future self-study activities. The control group was selected at random from the AMA Master File. The participant and control groups were matched on the following characteristics: physician specialty, degree, years in practice, whether or not direct patient care was their primary responsibility, and the number of patients seen per week with chronic pain.

CE Outcomes independently reviewed the educational objectives and content of ESP to define a series of key measurement indicators to frame case vignette questions, which were presented to participants and nonparticipants.





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### *Analysis*

Data were analyzed using frequencies, followed by T-tests to analyze the differences between the mean evidence-based responses of the 50 participant and the 50 nonparticipant physicians. Differences between the two groups were considered significant if the *P* value was  $\leq 0.15$ .

An effect size was calculated using the Cohen's *d* formula to determine the amount of difference between the evidence-based responses of the participants vs. nonparticipants. The calculation is expressed as a non-overlap percentage, or the percentage achieved by participants that was not reflected in the evidence-based responses of nonparticipants.

### *Results*

A total of 4,171 physicians (MDs/DOs) who practice in pain management seeing approximately 137,643 chronic pain patients participated in ESP CME activities over a 3-month period. Responses from 50 participant and 50 control nonparticipant primary care physicians (PCPs) and pain specialists were collected for analysis. Case vignettes were used to predict practice patterns and measure a physician's process of care in actual clinical practice.

### *Conclusion*

Physicians who participated in ESP CME activities are more likely to practice evidence-based care of chronic pain patients than those who did not participate in these activities, specifically: .

- Participants were more likely to recognize that a strategic precautionary approach to assessing a patient with moderate risk for aberrant behavior will reduce the likelihood of becoming a high-risk patient ( $P=.086$ ).
- Participants were more likely to start a patient with severe pain that is not controlled with acetaminophen and NSAIDs who demonstrates moderate risk for aberrant behavior on multimodal therapy ( $P=.059$ ).
- Participants were more likely to recognize that some over-the-counter medications cause a false-positive urine test and would assess a patient's OTC medications prior to stopping the patient's opioid therapy ( $P=.131$ ).
- Participants were more likely to recognize the need to utilize a standard risk assessment tool (such as the ORT or SOAPP) as the best approach to stratifying risk in a patient in the primary care setting ( $P=.06$ ).

The large effect size (30%) suggests that the ESP Internet-based CME programs offer effective, credible and high-impact education. These programs are available on-demand and in multiple formats to suit the learning preferences of physicians.

## Needs Assessment

### *Abstract*

Breakthrough pain (BTP) can occur in patients with chronic cancer or noncancer persistent pain. Although guidelines provide recommendations for treatment of BTP, the guidance is based on weak evidence and there are no specific guidelines or validated clinical survey instruments available to facilitate best-practice assessment of BTP in these populations. Recognition and differentiation by the practitioner of BTP from other subtypes of episodic pain is essential prior to the selection of an effective and safe treatment. Practitioners need improved methods of evaluating both the pain and the patient as well as an applied understanding of the necessary pharmacokinetics associated with analgesic drugs in order to obtain a safe and effective therapeutic response from the patient. Without treatment, BTP can exacerbate the patient's persistent pain, compromise function, and impact quality of life. Untreated or misdiagnosed BTP burdens the health care industry with additional and significant costs. Several practice gaps have been identified by researching the literature, professional association/society programs, survey data, and practitioner-self report. Educational needs exist for health care practitioners in the areas of assessment, treatment selection based on pharmacokinetics and pain characteristics, and monitoring of risks and benefits of treatment in the patient with BTP. In light of the lack of scientific support, additional translation of the guidelines by experts familiar with their use and knowledgeable about details of how best to customize treatment based on patient case requirements is suggested.

### *Introduction*

Breakthrough pain (BTP) is one component of cancer and/or chronic noncancer pain (CNCP). BTP has yet to be described using a universal and standard definition, but it is commonly considered to be moderate-to-severe episodic pain that occurs spontaneously, is transient in nature, and is independent from the patient's persistent background pain; pain that is usually well-controlled with the use of a prescribed routine regimen of opioid analgesics.[1-6,8,9] BTP is also different from acute pain which can arise from a secondary cause (ie, new illness or condition) and occurs in addition to the chronic persistent pain.[1-6,8,9]

Patients typically experience several episodes of BTP a day and in spite of its brief duration (ie, reaching maximum intensity within a median of 10 minutes and lasting for a median duration of 60 minutes), recurrent episodes of BTP exert a significant impact on the patient's health-related quality of life (HR-QOL).[6] Without proper assessment and effective treatment, BTP may eventually exacerbate the severity or intensity of the persistent chronic pain syndrome and diminish the patient's ability to function.[3-6,8]

There is a current lack of evidence which has led to weak formal guidance for the management of BTP. The latest guidance acknowledges the need for more well-designed studies to elucidate answers and recommendations in this area.[7,8] Until new data become available, assessment of BTP is considered one of the most important means to its recognition and treatment. BTP is frequently not recognized as such by many practitioners.[8] It may be mistaken for a number of other phenomena such as end-of-dose pain, pain as the result of inadequate or ineffective analgesic therapy, acute pain, or hyperalgesia. Some practitioners and patients may assume it is simply "normal" to have flares of pain accompany a persistent and painful condition. A majority of studies about BTP have been conducted in patients with cancer, leading to a misconception that BTP is only associated with cancer pain.[1,3,5,8] The fact is many patients with CNCP may also experience BTP.[1,6,7,9]

There has been an evolving understanding that BTP occurs irrespective of pain etiology and exists in patients irrespective of a cancer diagnosis. Clinicians need to be able to clearly differentiate BTP from other types of pain in order to provide effective treatment which will help to dispel the myth that episodic pain is a "normal" occurrence.[9,10] These goals are achieved by conducting a comprehensive patient assessment. Although there is an absence of a

dedicated and validated assessment tool specific for BTP in the clinical environment, assessment of pain may begin by using an array of pain assessment questionnaires (ie, Brief Pain Inventory) and patient evaluation surveys designed to assess functional status and quality of life (eg, Karnofsky Performance Status, FACT-G).[3,4,23] Assessment is typically conducted by engaging in a structured and comprehensive patient interview that includes questions about BTP intensity, number of episodes per day, types of pain, temporal features, precipitating factors, and pain predictability. The answers to these questions are also correlated to the patient's responses regarding the ability to function. Although the cause of BTP differs from patient to patient, at completion of the comprehensive assessment, the diagnosis of BTP is more easily identified.

As BTP is a condition specific to patients who are already prescribed to chronic opioid therapy (COT), additional and/or supplemental doses of opioid analgesic, commonly referred to as 'rescue' medication, are used to effectively manage BTP in most patients. Immediate-release, rapid-acting opioids, administered on an 'as-needed' basis, are the most commonly prescribed treatment for BTP in spite of little evidence to support their use as an optimal long-term treatment strategy for this patient population.[9,11] Short-acting oral opioids, such as morphine, may not be suitable for treating many types of BTP, as peak onset of effect may occur long after the BTP has spontaneously subsided.[11]

The formulations and characteristics of opioid drugs used to treat BTP differ significantly from those of long-acting, extended-release opioids.[12,13] Several different drug-development strategies have attempted to reduce side effects by utilizing anatomic barriers to drug distribution to provide different mechanisms of analgesia. These new delivery systems are

designed to provide a more effective management of breakthrough pain. [14] Clinicians need to contrast and compare characteristics associated with all opioid analgesics and become more familiar with the drugs by recognizing and differentiating their unique profiles in context with the characteristics of both the patient's persistent and BTP.[12-115]

Practitioners also need to monitor the patient for adverse effects, improvements in function, and decrease in number, severity or intensity of BTP episodes. As with the use of any controlled substance, practitioners also need to apply risk-reduction methods by assessing and monitoring the patient for aberrant drug-related behaviors, level of compliance, and therapeutic response.

#### ***Etiology of Chronic Pain and BTP – Does it Matter?***

Chronic pain results from tissue damage (nociceptive) or damage to the nerves or nervous system (neuropathic); it can stem from internal organs or cavity linings (visceral), or from the body's tissues (somatic). Mixed pain results from any number or combination of these types.[16] The reason for the damage to the tissue or nerves is of little consequence, as the resultant pain requires treatment, regardless of cause. Understanding the mechanism of pain is important to understanding its treatment, but in consideration of the edict that all pain be alleviated, cause is secondary to the need to treat.

#### ***Assessment of BTP – Definitely Matters***

BTP prevalence in patients with cancer is reported to range between 24%-95%, and a 63% prevalence of BTP has been reported in patients with CNCP.[17] It is critical for practitioners to have guidance in the process of BTP assessment and differentiation. Results from a 2010 study

demonstrated that nurses had difficulty defining BTP as a distinct pain subtype and were often unable to differentiate it from poorly controlled background pain.[18] Results from a physician study at a university in the northeast United States showed only 23% of respondents (21/91) were aware of the existence of pain management guidelines in which assessment of various types of pain is included.[19] The recently published IOM Report states “Pain assessment techniques must be valid and reliable and provide sensitivity, both with single and repeated measurements, and allow for the assessment of acute, chronic, persistent, and breakthrough pain.”[20]

- Survey self-reported learner-responses from more than 1,500 participants ( ie, MDs, PharmDs, PAs, Nurses, NPs) of an accredited MediCom educational activity which focused on BTP indicated that 92.2% would change practice as a result of this enduring activity and 92.5% were committed or above to making this change (based on the course content) for improved diagnosis and treatment of patients with BTP.

This intent may have been motivated by the fact that:[21]

- Prior to and after hearing the discussion in this educational activity, 42.5% and 88.8% respectively have a defined perception about breakthrough pain.
- Prior to or as a result of the discussion, 58.3% and 87.6% respectively have established an approach for assessing and treating breakthrough pain in all chronic pain patients.

Accurate assessment of BTP is dependent on effective communication between practitioner and patient. Although assessment instruments that have been designed for use in clinical trial research can be adapted for use in the clinic, they only provide unidimensional data which can undermine diagnostic confidence in regard to a determination of BTP. Additional assessment information must be obtained by conducting a thorough patient intake and interview; an interview that incorporates a list of multidimensional questions meant to elicit answers about essential criteria necessary to differentiate and diagnose BTP. It is equally important to recognize when the pain is not BTP to ensure the patient receives the most appropriate care. In the event of end-of-dose pain, drug tolerance, or hyperalgesia, the patient may require a new dose regimen or may need to have an alternate drug prescribed based on the interview findings. Without access to and application of assessment guidance, practitioners are at risk of failure to prevent, diagnose, and treat the patient with appropriate management of BTP.[17] The survey results suggest that guidance and consensus need to be presented and translated for use in the clinic to improve effective communication, assessment and differentiation of BTP, and to improve treatment of persistent pain to minimize frequency of BTP.

### ***Treatment of BTP – Customized Treatment Matters***

When BTP is diagnosed, treatment of the patient remains a challenge to most clinicians. It is not a simple matter of increasing the dose of long-acting opioid analgesic prescribed for the persistent pain, although that may be one strategy, but finding a solution often requires further investigation and consideration. Ideally, BTP therapy should provide rapid pain relief with an onset and duration of action that matches the timing of BTP. Increasing the dose may decrease the episodes of BTP, but may also increase unwanted side effects which may foster



noncompliance. Ensuring adequate treatment of persistent pain is a critical first-line element. If the persistent pain is not adequately controlled, BTP may not be diagnosed. If the patient is not currently prescribed a long-acting (LA) or extended-release (ER) opioid for the baseline pain, conversion from a short-acting opioid (SAO) to a LA/ER drug may be necessary. Chronic pain management guidelines recommend the use of LA/ER analgesics because they provide more consistent and prolonged plasma concentrations of drug compared with SAOs that tend to peak and trough, minimizing drug-serum fluctuations that could contribute to end-of-dose BTP or inadequate analgesic treatment.[15,22]

The underlying mechanism of BTP may be nociceptive, neuropathic or mixed.[23] Recognizing the difference among these varied types of BTP is essential to the selection of effective treatment. Opioids may not be as effective in the treatment of neuropathic pain as an alternative agent, such as an anticonvulsive or antidepressant drug.[24] Due to the multifactorial nature of BTP, therapeutic response is highly individualized. A drug that may not provide relief of BTP in one patient may provide excellent response in another individual.

In addition to understanding the basics of neurophysiology of pain, practitioners need to understand how to formulate a differential diagnosis. They need to know when the BTP is due to inadequate dosing of the opioid for persistent pain and when there is evidence of end-of-dose failure. Alternately, practitioners have to think about the possibility of hyperalgesia and understand the basis of central sensitization. They need to ask the following types of questions:

- Is the patient no longer obtaining pain relief from the chronic opioid regimen due to hyperstimulation of the receptors?

- Perhaps it is time to switch or rotate to another opioid or experiment with dose reduction?
- Does the BTP occur in response to a specific event or activity?
- Is the BTP event predictable, or does it arise without warning?

The answers to each of these questions will help to determine next steps. Oral opioids are a good choice for patients who can predict the onset of BTP and its duration, especially if it is tied to a specific activity or event (ie, taking a shower), but they are not a good treatment for spontaneous or idiopathic BTP. In the case of a patient who experiences incidental BTP in response to taking a shower, an oral opioid can be administered prior to the activity with time of analgesic onset synchronized with timing of the shower. This strategy allows the patient to shower without worrying about the onset of BTP. In the case of spontaneous BTP, the onset of action associated with oral opioids is delayed in comparison to the patient's need for immediate pain relief.[11,25]

Agents which possess an immediate or rapid onset are usually a better choice for a patient with rapid onset BTP. These newer and faster-acting synthetic opioid agents also possess a much higher dose equivalence compared to standard morphine. It is crucial for the practitioner to know that the immediate- and rapid-onset opioid drugs cannot be added to the drug regimen used to treat persistent pain without consideration of the total daily dose.[25] The patient and family or patient support network also needs to be educated on potential adverse effects as well as safe use and storage of the drug. Non-intentional overdose and accidental drug poisoning have been reported with the use of these newer agents.[26] In spite of the warning in the most recent American Pain Society (APS) and the American Academy of Pain

Medicine (AAPM) guidance document about the use of methadone for the treatment of BTP, the literature at large still discusses the use of methadone as a viable option for the treatment of BTP.[22] Methadone possesses its own characteristic pharmacokinetics and has been linked to prolonged cardiac QTc, arrhythmias, unintentional death, and drug poisoning.[22]

Practitioners need to be aware that the use of methadone for BTP is not advised and understand why its unique properties do not support its use for this indication. A recent study on sublingual methadone in small patient numbers of showed that it may be an effective, safe, and well tolerated option.[27]

The lack of available and robust evidence in the treatment of BTP presents a potential barrier to education. New guidelines outline treatment recommendations, but do so with the caveat of weak to minimal evidence used in their development.[22] In light of the lack of scientific support, additional translation of the guidelines by experts familiar with their use and knowledgeable about details of how best to customize treatment based on patient case requirements is suggested. As the demand for new clinical trials in the area of BTP increases, novel drug formulations and designs are becoming available. Practitioners need to understand the use and administration of these drugs and be able to identify criteria for their use in order to select appropriate patient candidates.

Patients echo the challenge of dealing with BTP and with their practitioners' inability to diagnose, treat, and communicate. A survey of 545 patients with cancer-related pain was released by the American Pain Foundation (APF) on January 28, 2010.[28] The report revealed that three out of four (75%) US adults with breakthrough cancer pain (BTcP) report that it is one of the most challenging aspects of having cancer. Fifty-three percent rated their pain as an 8, 9,

or 10 out of 10, with 10 being the worst pain imaginable. While 44% reported their pain was not adequately controlled. Almost all patients surveyed (91%) believed their quality of life would “greatly improve” if they could get their breakthrough cancer pain under control. To underscore the need for continuing education about this topic, more than half (52%) of patients surveyed stated their health care provider had described BTcP as “a normal side effect of cancer or its treatment.”[28]

Without effective treatment, the condition of BTP strains medical utilization and costs. Patients with untreated pain require additional care and utilize emergency services more frequently, which equates to a significant use of resources.[17] Several studies have all shown similar and significantly high cost data associated with the management of patients with BTP. An article published in the *American Journal of Managed Care* in 2008 summarized the findings of these studies, including findings from the largest study ever designed to measure the costs of BTP.[16,29]

*The BTP patients' (n=160) total cost per year for reported pain-related hospitalizations was \$1.7 million versus \$192,000 for non-BTP patients. BTP patients also reported more emergency department visits for pain (1.3 vs. 0.5 per year), resulting in greater estimated average cost per year for emergency department visits (\$84,000 vs. \$19,000). BTP patients reported more outpatient doctor visits per year for pain (4.2 vs 0.6), resulting in a greater cost per year for physician office visits (\$103,000 vs. \$7,000). BTP patients averaged higher total pain-related costs per year (\$12,000 vs. \$2,400). Examination of total pain-related costs for the entire sample revealed that BTP patients accounted for 90% of costs, and that these costs were primarily attributable to BTP-related hospitalizations of both direct and indirect costs associated with the management of patients with BTP.[29]*

***Monitoring of BTP – A Matter of Managing Risk***

After the practitioner has carefully considered the benefit-risk ratio when prescribing rescue medications for the treatment of BTP, the other side of the treatment ‘coin’ is to recognize and ensure the patient is able to function in response to the additional analgesic. The therapeutic goal of pain management is always to relieve pain without compromising function. Monitoring is a necessary component of patient management.[22,30]

Arriving at the optimal dose of medications for BTP is difficult and patient dependent. The analgesic may need to be titrated slowly in consideration of safety of the patient, accompanied by frequent and routine monitoring to determine levels of sedation, respiration, function, efficacy, and toxicity.[22] It is also important for the practitioner to keep other domains in mind during the monitoring process, such as fatigue, emotional distress, and social health to ensure continued or improved HR-QOL. Several generic health assessment tools are validated and available for this purpose, (eg, SF-36v2, EQ-5D, QWB-SA, HUI, and HALex).[31] Choice of which survey instrument may not be as crucial as understanding what the tool is used to measure, knowing how to use the tool, and how to accurately score the survey instrument and interpret the results.

Although no evidence exists on the risk of aberrant drug-related behavior in relation to the availability of medication prescribed for BTP, it is reasonable to assume that access to a short-acting drug may increase the risk of such behavior, especially in a patient who may already be assessed and stratified as high risk. A large retrospectively study published in January 2011, examining accumulated data from 5 clinical trials of patients taking daily opioids for CNCP ( $\geq 60$

mg/day oral morphine equivalent) and also prescribed immediate-release (IR) fentanyl buccal tablets (FBT) for breakthrough pain showed a relatively low incidence of drug abuse events and aberrant drug-related behaviors, perhaps due to the implementation of universal precautions and the controlled clinical study setting. However, overall, this was a large-scale study and the minimal numbers of problematic events relating to opioid use may suggest that such problems are of a lesser magnitude and significance than is commonly believed.[32] The management and monitoring of patients will usually depend on results derived from risk stratification. In low risk for aberrant drug-related behavior patients, a trial of a rescue opioid with routine follow-up and monitoring may be a reasonable strategy. In patients at higher risk, more frequent monitoring and follow-up is probably required.[29,34] Practitioners should always assess for aberrant drug-related behaviors and continue treatment toward meeting therapeutic goals, and reassess (as needed) to continually evaluate the relative benefits to risks for treatment navigation.[22,30]

Despite the fact that studies report low risk of abuse, misuse, and addiction associated with patients prescribed to long-term opioid therapy, risk of these conditions must always be considered.[31] It is not unimaginable for a patient who has tolerated long-term ER opioid therapy to experience euphoria in response to a newly prescribed, high-dose, IR opioid and want to use it outside the boundaries of the prescribed regimen. It may be considered a rare occurrence and improbable, but it should not be thought of as an impossibility. It is important to note that overdose potential must be seen as a separate but parallel phenomenon that can exist in the absence of abuse, diversion and addiction, and is not often accounted for through the use of survey results. Due to the prevalence of unintentional deaths associated with the use

of prescription opioid analgesics, several states have initiated prevention programs aimed at improving compliance and adherence regarding the patient's use of opioid drugs by both patient and prescriber (eg, North Carolina's 'Lazarus Project', Utah's 'Use Only As Directed' Program). Risk monitoring is an integral part of patient management, and guidance documents provide a road map of methods and survey instruments that may be used to achieve optimal management.[22,30,33,34]

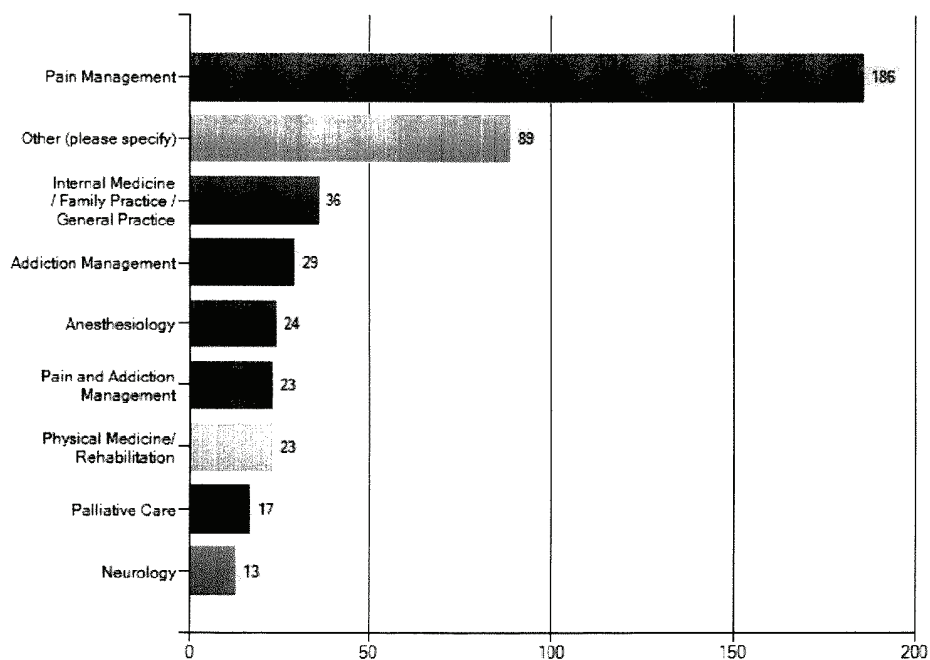
Monitoring requires clear communication between practitioner, patient and family, or patient network.[34] Empathetic, transparent, and direct communication combined with patient support education is considered paramount to successful, effective, and safe pain management. Alternately, insensitive communication and lack of communication or education may negatively affect the individual and family or support network, reduce treatment compliance, and increase health care utilization.[35]

#### ***Additional Support – Getting to the Heart of the Matter***

A pre-symposium survey, in collaboration with an American Pain Society symposium, was sent to registered clinicians to complete a brief survey about BTP. The survey participants (n=440) represented multiple disciplines as shown [21]:



Which of the following best describes the primary focus of your full-time clinical practice? Please select only ONE answer.



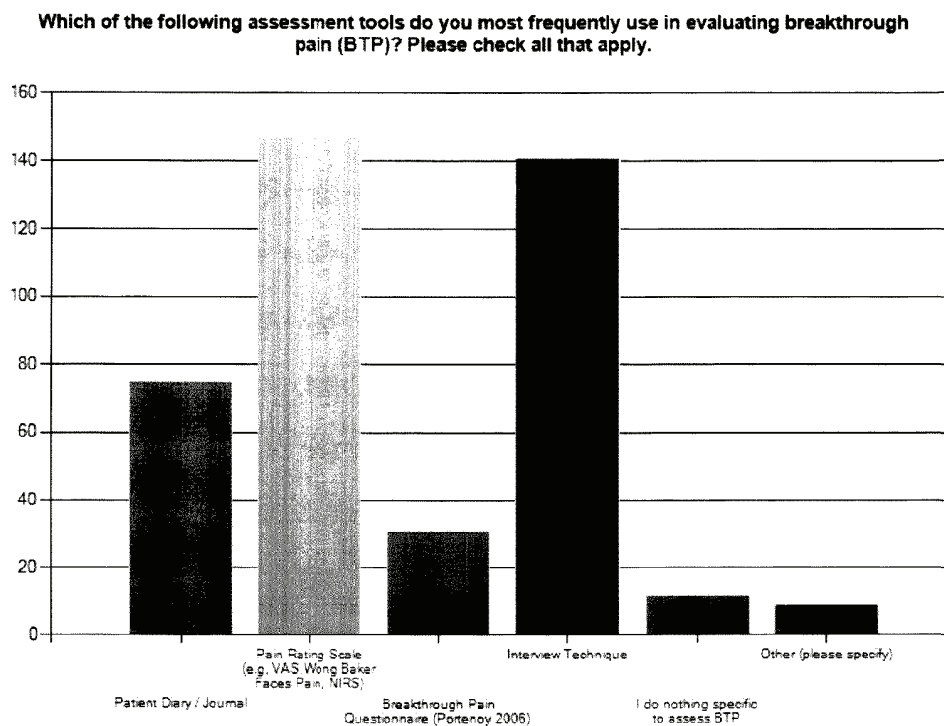
The majority represents private practice and community clinics and is directly involved with patient care (82%); approximately 83% have been practicing for more than five years. All see patients with chronic pain of both nonmalignant and malignant nature.

When asked to rate level of agreement with the following statements, responses varied among the survey responders, as shown [21]:

Please indicate your level of agreement relative to the statements below about patients on around-the-clock opioids for treatment of chronic non-cancer pain syndromes. Please select ONE response to each question from "Strongly Disagree" to "Strongly Agree."

Answer Options	Strongly Disagree	Disagree	Somewhat Disagree	No Opinion / Don't Know	Somewhat Agree	Agree	Strongly Agree
These patients should be assessed for intense flares of episodic pain when they do not complain.	7.3%	7.3%	9.1%	7.3%	15.5%	38.8%	14.7%
These patients should be treated for intense flares of episodic pain.	3.9%	2.6%	2.2%	4.7%	13.4%	38.4%	34.9%
These patients can experience intense flares of episodic pain that require treatment.	3.0%	1.7%	3.0%	3.9%	9.1%	35.8%	43.5%

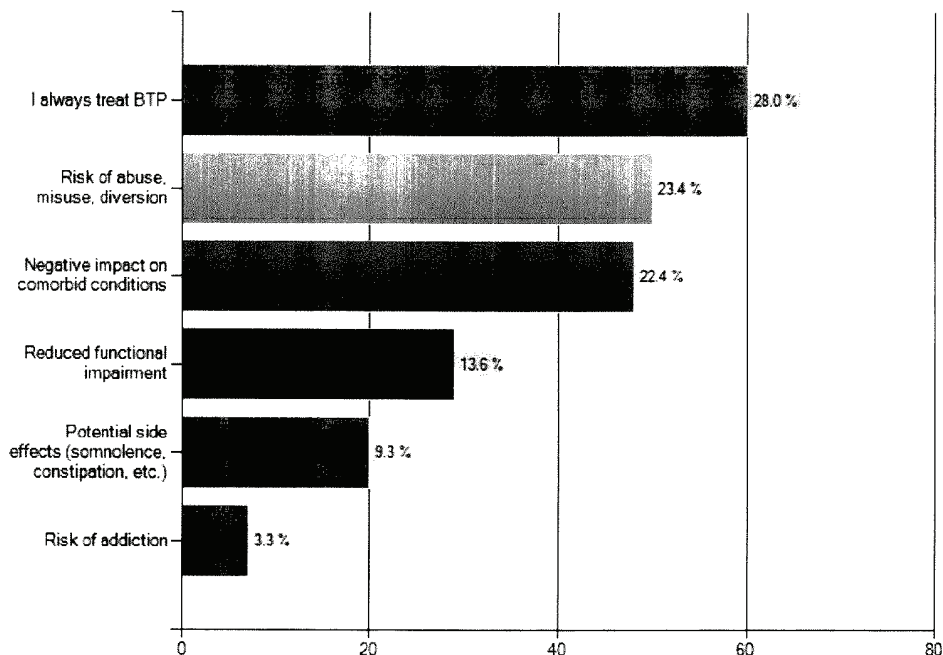
When asked how they currently and typically assess patients for BTP, responses varied and included [21]:



None of these assessment tools are validated for use in the assessment of BTP. They may be used to assess persistent pain, but further investigation is needed to determine if BTP is present. Additional guidance is recommended to improve assessment technique for the diagnosis of BTP.

When asked what one factor contributed most to their decision *not* to treat a patient for BTP, again, results varied, but factors surrounding abuse, misuse, and addiction predominated.[21]

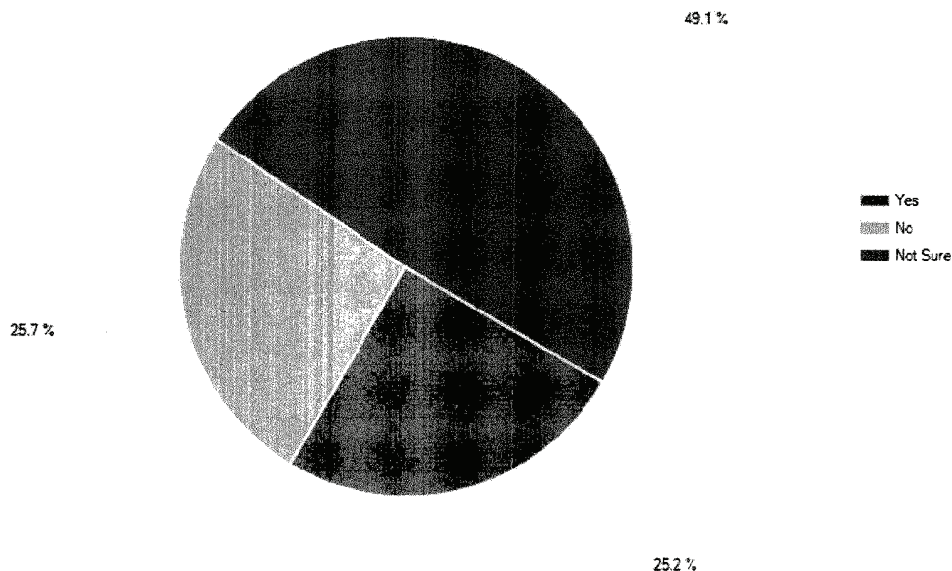
Which of following best describes the most important decision driver for you not to treat a diagnosed BTP patient? Please select only ONE answer.



Additional education is needed to demonstrate best practice assessment, prescribing, and monitoring to ensure a risk-averse practice and provide optimal therapy for patients with BTP.

When asked if BTP differed by evidence of scientific investigation in patients with and without cancer, respondents replied [21]:

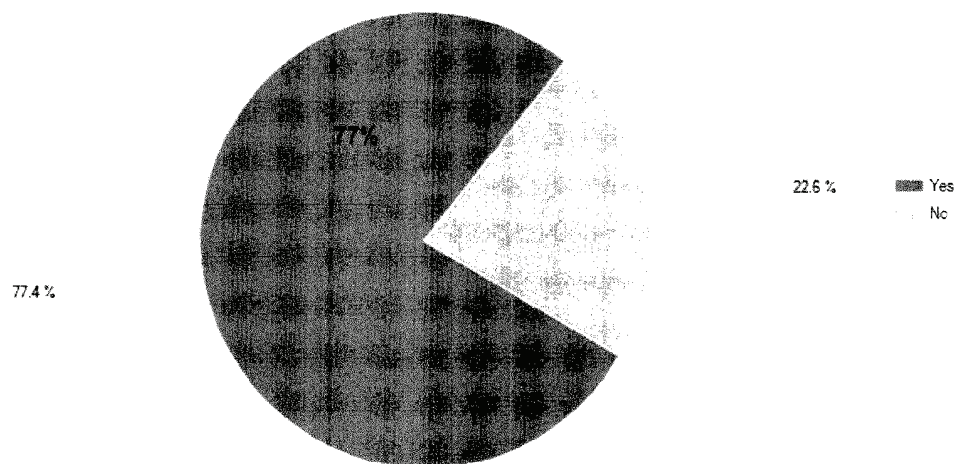
Is there scientific / clinical information that flares of pain intensity in patients with chronic non-malignant pain and cancer pain differ?



These results clearly indicate a need for continuing education about pain, and the origin of pain, in regard to neurophysiology. In fact, 15% of responders indicated they *do not* prescribe opioids for patients with BTP accompanied by noncancer chronic pain. Almost 35% indicated that the risk of abuse and misuse of the opioid is the primary reason why opioids are not prescribed for BTP in patients without cancer, and almost 20% believed there would be a negative impact on public health if indications were expanded to include the use of opioids for BTP in patients without cancer. These statistics demonstrate a significant need for education about risk minimization and the prevalence of abuse and misuse in this patient population.[21]

Finally, when asked if they prescribe rescue medication for patients with chronic noncancer pain who experience BTP, they indicated [21]:

Do you ever prescribe PRN analgesia to patients who also receive around-the-clock opioids?

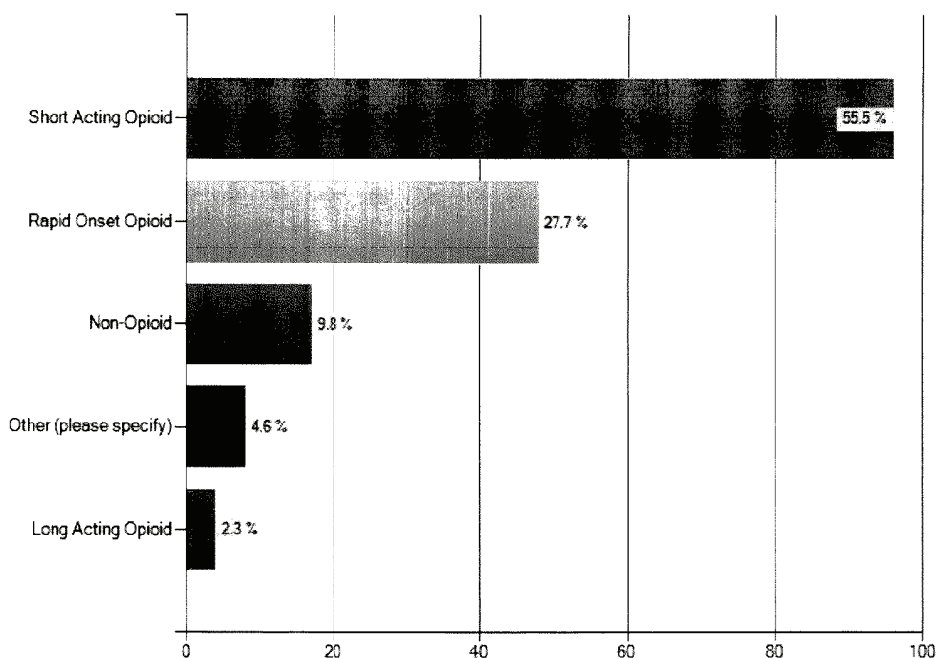


And when asked what type of medication was most frequently prescribed for BTP, responders indicated [21]:

9.4%

51.2%

Which of the following do you MOST often prescribe for intense flares of episodic pain or BTP in addition to around-the-clock opioids? Please select only ONE answer.



These results suggest practitioners need an improved understanding of pharmacokinetics in relationship to BTP.

Results from a second survey of 955 multispecialty practitioners conducted by MediCom Worldwide, Inc. further corroborated the APS survey findings. Survey responders, when asked, *If you could expand your current level of knowledge of 10 topics that would help you meet professional challenges and improve your personal practice relative to the effective management of pain, which would you study?* responded by included the following topics in the 'top 10' lineup: chronic nonmalignant pain (~35%); BTP (~25%); and unrelieved pain (23%).[21]

### Summary



In an environment where practitioners are lacking awareness of the clinical guidelines, BTP in patients with chronic pain is not differentiated, and frequently remains underdiagnosed and undertreated by health care practitioners. When BTP is diagnosed, practitioners may not always prescribe the most appropriate analgesic based on type and mechanism of pain matched to the drug's pharmacokinetic profile. This disconnect may be due to guidance recommendations that are not consistently applied in the clinical environment. Inadequate monitoring, poor communication, and lack of patient education on the part of the practitioner often results in poor clinical outcomes.

**Summary of practice gaps to be addressed in this educational activity:**

- Practitioners are mis- or underdiagnosing BTP in patients with chronic pain due to lack of assessment or use of inadequate assessment methods.
- Practitioners are not consistently relying on guidance recommendations when treating their patients who have BTP.
- Practitioners are undertreating or not treating patients who have BTP.
- Practitioners are not monitoring patients for response to opioid therapy per stated guidelines and are not providing adequate patient education

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Strategy #1	Tactic	Outcome Achieved	
		ACCME	Moore
<b>Evaluation Form</b>  Utilize a comprehensive evaluation form to determine outcomes in several areas including: <ul style="list-style-type: none"> <li>▪ Satisfaction with the program</li> <li>▪ Knowledge growth</li> <li>▪ Competence improvement</li> <li>▪ Needs determination for future education</li> </ul> Evaluation form completion will be mandatory for all participants in the activity. CE certificate issuance will be driven by the receipt of a completed evaluation form.	<p>To measure satisfaction of the participant with the activity, the participant will be asked to complete the following:</p> <ul style="list-style-type: none"> <li>▪ Rate each speaker – 1 through 5 scale</li> <li>▪ Rate achievement of learning objectives – 1 through 5 scale</li> <li>▪ List any general comments about the program</li> </ul> <p>To evaluate the improvements in knowledge and competency the attendees will be asked to rate their agreement with the following statements using a 5-point Likert scale:</p> <ul style="list-style-type: none"> <li>▪ The program provided new information</li> <li>▪ The information is applicable to their clinical practice</li> <li>▪ The information learned will help improve their patients' outcomes</li> </ul> <p>To determine if the activity created an intent to change behavior, each participant will be asked to complete the following:</p> <ul style="list-style-type: none"> <li>▪ List 3 things that they will do upon returning to their practice</li> </ul> <p>To help determine the need for additional education on the topic or a modification in future educational formats, the participant will be asked to complete the following:</p> <ul style="list-style-type: none"> <li>▪ The educational approach was conducive to learning – list agreement using a 5-point Likert scale</li> <li>▪ List the barriers to implementing the practice paradigms discussed</li> <li>▪ List additional information or materials that would enhance the activity</li> </ul>	Satisfaction    Participation   Knowledge   Competence	One   Two   Three   Four

Strategy #2	Tactic	ACCME	Moore
<p><b>Pre and Post Testing</b></p> <p>To determine if the participants in an activity had a change in competency, knowledge, and confidence, a pre- and post-test method.</p> <p>Each participant will be asked a series of questions immediately prior to the activity and immediately after the activity. Questions will be similar for the pre- and post-test.</p> <p>Goal of the questions will be to provide a measurement of changes in competency, knowledge, and confidence based on the learnings derived from the educational activity.</p>	<p>Test each participant pre- and post-activity</p> <p>Pre-activity questions will measure and establish a baseline in competency, confidence, and knowledge for each of the learning objectives by asking the participants the following three (3) questions:</p> <ol style="list-style-type: none"> <li>1. How important do you think (<i>insert key element based on learning objectives</i>) is in diagnosing/management/treating your patients with breakthrough pain</li> <li>2. How confident are you in implementing (<i>insert key element from first question</i>) with your patients with breakthrough pain?</li> <li>3. How often do you implement (<i>insert key element from first question</i>) with your patients with breakthrough pain?</li> </ol> <p>Post-activity questions will measure changes from baseline in competency, confidence, and knowledge for each of the learning objectives by asking the participants the following two (2) questions:</p> <ol style="list-style-type: none"> <li>1. Now that you have participated in the educational activity, how important do you think (<i>insert key element based on learning objectives</i>) is in diagnosing/management/treating your patients with breakthrough pain?</li> <li>2. Now that you have participated in the educational activity, how confident are you in implementing (<i>insert key element from first question</i>) with your patients with breakthrough pain?</li> </ol>	<p>Knowledge</p> <p>Competence</p>	<p>Three</p> <p>Four</p>

**Cephalon Budget Template**

<b>Budget Item</b>	<b>Cost</b>	<b>Comments</b>
Management Fee	\$ 16,500	Includes all project management, faculty coordination, medical direction and strategic management costs associated with the broadcasting of the accredited live webinar series and the accredited live streaming video series.
Editorial / Content Development Fee	\$ 19,840	Includes accredited slide development and review in conjunction with the clinical expert moderator, all faculty and the peer review team. All editorial, fact checking, references and transcriptions.
Creative / Graphic Design Fee	\$ 19,600	Includes all graphic and creative design services, slide template development, typesetting with graphic layouts and editorial review; recruitment.
Accreditation Fee	\$ 35,000	CME, CNE and CPE accreditation of 10 hour for live webinar and endured live webinar; and CME, CNE and CPE accreditation for 0.5 hour for each of three streaming videos in series.
Faculty Fee: Honoraria	\$ 20,700	Includes lead faculty/moderator (2), content development faculty (6), live webinar faculty (6) and clinical expert interviews (7).
Faculty Fee: Travel	\$ 300	Travel for faculty chair to studio filming
Faculty Fee: Lodging	\$ -	
Venue / Event Fee	\$ 28,100	Includes studio rental, internet feeds, Q-Cast system rentals for remote faculty, telephone bridging, conference call monitoring, moderation services and all A/V equipment with technical labor costs for live webinar series and streaming video series.
Association Fee	\$ -	
Website Hosting Fee	\$ 4,800	Hosting and co-location on Emerging Solutions in Pain for 12 months.
Audience Generation Fee	\$ 33,120	Banner and video advertisement campaign on Emerging Solutions in Pain, audience list purchases, multiple email and fax blast campaigns.
Educational Materials Production	\$ 8,200	Production of frequently asked questions PDF, downloadable slide deck, text based tools and PDF of practice support tools.
Shipping / Postage	\$ 650	All Fed Ex and shipping charges, phone and fax.
Outcomes Measurement Fees	\$ 6,570	Data management, data analysis and reporting.
Other	\$ 6,500	Includes all HTML programming and posting fees, incorporation into LMS and beta testing for the accredited live webinar series and the accredited live streaming video series.

**Total** **\$ 199,880**



## INDEPENDENT EDUCATIONAL PROGRAM GRANT AGREEMENT

This Agreement is entered into as of this 5<sup>th</sup> day of December, 2011 by and between Cephalon ("Cephalon"), located at 41 Moores Road, Post Office Box 4011, Frazer, PA 19355, and MediCom Worldwide, Inc. ("Provider") located at 101 Washington Street, Morrisville, PA 19067.

WHEREAS, Cephalon has reviewed Provider's grant request to support a medical education program ("Program"); and

WHEREAS, Cephalon has determined that the Program has the potential to address educational gaps; and

WHEREAS, it is the intent of the parties to ensure that the Program will be independent, objective, balanced, scientifically rigorous, and have reasonable expectations of meeting its educational objectives so that it will not be viewed by the United States Food and Drug Administration ("FDA") as promotional and that Cephalon will not be viewed as responsible for its content; and

WHEREAS, Cephalon agrees to provide support for the Program under the conditions set forth below.

NOW THEREFORE, Provider and Cephalon agree to the following terms under this Agreement:

1. Title of Program. The Educational Program is entitled "Conference Coverage, Live from APS 2012, 008896" and a copy of the grant request for the Program is attached hereto as Exhibit A.
2. The Program is:
  - ☒ certified (CE credits are offered); or
  - ☐ a non-certified independent program (where CE credits will not be offered).
3. Program Purpose. The Program is for scientific and educational purposes only, and is based on established bona fide and independently verifiable patient and/or practitioner needs or gaps in healthcare performance, and is not intended to promote a Cephalon product, directly or indirectly. The Program is not a repeat activity or endured version of a prior program.
4. Grant Support Arrangements.

Cephalon will provide support for the Program by means of an educational grant in the total amount of \$5,000.00. If the Program is canceled or terminated prior to completion by the Provider, Provider shall return the grant, or any unused portion thereof with full reconciliation, to Cephalon within thirty (30) days of such termination or cancellation. Provider shall have full responsibility for all funding arrangements of the



Program, including any funding to be provided to its Educational Partner. Payment terms of the grant shall be made in accordance with a schedule provide be Cephalon.

- (a) Upon notice from Cephalon, Provider shall provide Cephalon, within ninety (90) days, a detailed reconciliation that compares the grant proposal to the actual program (e.g., expenses, attendance levels, etc.) To the extent Cephalon has overpaid Provider, Provider shall provide a refund to Cephalon within sixty (60) days thereafter. Such detailed reconciliation information and documents shall be entered into Cephalon's web-based grants managements system at [www.cephalongrants.com](http://www.cephalongrants.com).
  - (b) Provider may not use funds provided by Cephalon to pay travel, lodging, honoraria or personal expenses for non-faculty attendees. Grant funds may be used to reduce the overall registration fees for attendees. Grant funds may not be used to purchase capital equipment or to provide general operational support for an institution. Funds for hospitality shall not be provided, except that funds may be used for modest meals or receptions that are held as part of the Program, but such events shall not compete with, nor take precedence over, educational events. The appropriateness of any reception shall be at the sole discretion of the Provider, and Provider shall have final decision-making authority in connection with any such activities.
  - (c) Funds may be used by the Provider to permit medical students, residents, fellows or other health care professionals in training to travel to and attend the Program; provided, however, that this is outlined in the approved grant proposal and that the selection of such students, residents or fellows who receive funds is made by either the academic or training institution, or, if by the Provider, such selection shall be made with the full concurrence of the academic or training institution.
5. Objectivity and Balance. Provider shall retain full responsibility for control of the content of the Program and shall ensure that the following requirements are met:
- (a) The Program material/content will be objective, balanced and free from commercial bias. All topics shall be treated in an impartial, unbiased, evidence-based manner. The title of the Program will fairly and accurately represent the scope of the presentation.
  - (b) Provider agrees that Cephalon shall not influence the content of the Program. Cephalon personnel will not attend content development meetings.
  - (c) Cephalon shall not review the Program for medical accuracy or completeness and the Provider and/or Educational Partner (if any) agree that they will not make such a request of Cephalon.

- (d) If a product marketed by Cephalon is the subject of discussion, the data will be objectively selected and presented, with an accurate reflection of favorable and unfavorable information about the product and shall also include a balanced discussion of prevailing information on alternative products and /or therapies.
  - (e) Provider represents that neither it nor the Educational Partner (if any) has either an open complaint or decision from the Accreditation Council for Continuing Medical Education ("ACCME") or the FDA that a program provided by the Provider or the Educational Partner failed to meet standards of independence, balance, objectivity, or scientific rigor at the time of signing this agreement. If a provider is notified of any such complaint or decision during the lifetime of the supported program/activity, the Provider will inform Cephalon within 30 days of notification.
- 6. RiskMAPs / REMS. Certain Cephalon products have an FDA approved Risk Management Action Plan (RiskMap) or Risk Evaluation and Mitigation Strategy (REMS). Furthermore, other products in the same therapeutic class may also have RiskMAPs/ REMS. Provider acknowledges that it is aware of the key safety messages in these RiskMAPs/ REMS, shall keep up-to-date with such information, and will present such information as it deems appropriate in the Program.
- 7. No Faculty Selection. Provider shall retain full responsibility for the selection of the presenters, authors, moderators, and/or other faculty (hereinafter referred to collectively as "Faculty"). Provider and/or Educational Partner (if any) shall not request recommendations for Faculty from Cephalon.
- 8. Data. Provider will ensure meaningful disclosure of limitations of data (e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion). Provider will require that Faculty disclose when a product is not approved in the United States for the use under discussion.
- 9. Question and Answer Session. To the extent the Program is a presentation, Provider will ensure meaningful opportunities for questioning by the audience.
- 10. Financial Relationships / Disclosure. Provider will ensure meaningful disclosure to the audience of support from Cephalon and all other supporters if applicable and any significant relationship between individual Faculty and Cephalon. All meaningful disclosure(s) shall also be made where appropriate including but not limited to, syllabi and enduring material.
- 11. Representations and Warranties. Provider represents that:
  - (a) Neither the Provider nor the Educational Partner, provides promotional or marketing services to Cephalon;
  - (b) If Provider or the Educational Partner has an affiliated company offering promotional or marketing services, Provider and/or Educational Partner

has instituted appropriate firewall controls and safeguards to ensure the Program remains independent, objective, balanced and scientifically rigorous. Firewall documents will be supplied by the Provider and/or Educational Partner and be approved by Cephalon.

- (c) Provider has determined that it is appropriate to use the Educational Partner in light of the requirements under this Agreement; and
  - (d) If Provider and/or Educational Partner employ a former Cephalon employee who worked at Cephalon at anytime during the most recent year, the information will be disclosed and a collective decision by the parties shall be made as to how to handle such situation to ensure that the Program is independent.
12. Invitations/Enduring Materials The Program audience will be selected by the Provider. The Provider shall be responsible for distributing materials about the Program, including invitations, reminder notices, and business reply cards that can be used by third parties to obtain any enduring Program material from the Provider. As soon as a date is finalized for a live event the Provider will notify Cephalon. For enduring material the Provider shall provide copies to Cephalon at the same time as first publication/distribution of such material.
  13. Ancillary Promotional Activities. To the extent the Program is a live presentation, no promotional activities or product advertisements will be permitted in the same room as, or in an obligate path to, the Program. If the Program is a teleconference or webcast, no product advertisements or promotional activities will be permitted immediately prior to, during, or immediately after the delivery of the Program. If the Program is in print format, no product advertisements or promotional materials will be interleaved within the pages of the Program. If the Program is made available electronically, no product advertisements or promotional materials will appear within the Program material or interleaved between computer windows or screens of the Program, all as stipulated in ACCME Guidelines.
  14. Compliance with Guidelines. Provider represents that the Program, regardless of whether it is certified or not, including development of the Program and Program materials, shall conform to the American Medical Association ("AMA") Guidelines on Gifts to Physicians, the AMA Ethical Opinion on Continuing Medical Education, the ACCME Standards for Commercial Support, the FDA December 3, 1997 Final Guidance for Industry-Supported Scientific and Educational Activities, and the Pharmaceutical Research and Manufacturers Association ("PhRMA") Code on Interactions with Healthcare Professionals.
  15. Logistical Status Reports. Provider and/or Educational Partner shall provide periodic reports to Cephalon regarding the management and logistics of Program components.
  16. Public Disclosure of Grant Payments. Provider and Partners acknowledge that Cephalon is required to publicly disclose certain terms of this grant agreement

including the identity of the recipient(s) of the grant, the nature of the activities performed by grant recipient(s), and the amount of the grant.

17. Miscellaneous.

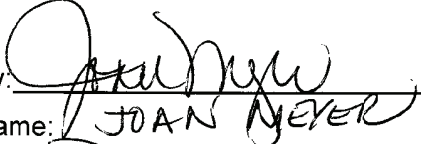
- (a) No party shall use the other party's or its affiliates' name or trademarks for publicity or advertising purposes, except with the prior written consent of the other party.
- (b) To use the Cephalon logo, the Provider and/or Education Partner must contact the Cephalon Grants Coordinator who will supply the logo and correct use instructions.
- (c) Provider agrees to obtain all consents, authorizations, approvals and releases that may be necessary for the production of the Program and of any written materials prepared in connection therewith.

[This Section is intentionally Left Blank]

- (d) No term, condition or other provision of any attachment or addendum to this Agreement shall supersede any term, condition or other provision of this Agreement, and with respect to any inconsistency or ambiguity, the Agreement shall control.

IN WITNESS WHEREOF, the parties, by their duly authorized representatives, agree to comply with all the terms and conditions of this Agreement.

**MEDICOM WORLDWIDE, INC.**

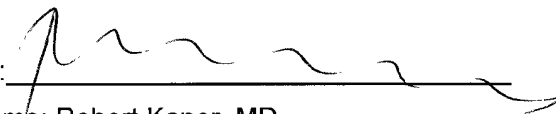
By:   
 Name: JOAN MEYER  
 Title: PRESIDENT

The above signatory is a duly authorized corporate officer of the IEP Provider.

Date: 12-8-11

Tax ID #: 23 3063738

**CEPHALON, INC.**

By:   
 Name: Robert Kaper, MD  
 Title: Vice President, Medical Affairs

Date: 12/07/11

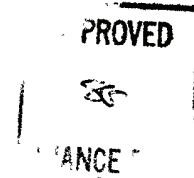


Exhibit A  
Copy of Grant Request



101 Washington Street  
Morrisville, Pennsylvania 19067  
Phone 215.337.9991  
Fax 215.337.0959

## ***Conference Coverage***

***Live from APS 2012  
Hosted on  
EmergingSolutionsinPain.com (ESP)***

***Submitted to:***

***Cephalon***

***November 8, 2011***





101 Washington Street  
Morrisville, Pennsylvania 19067  
Phone 215.337.9991  
Fax 215 337 0959

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101 Washington Street  
 Morrisville, Pennsylvania 19067  
 Phone 215.337.9991  
 Fax 215.337.0959

November 8, 2011

Cephalon

Dear Educational Grant Review Committee:

MediCom Worldwide, Inc. is pleased to submit the accompanying grant request to Cephalon Grant Committee to support an educational program for pain practitioners. As accredited providers of continuing medical education, MediCom Worldwide, Inc. recently completed a comprehensive needs assessment which highlighted the need for educational activities addressing educational needs of pain practitioners regarding safe opioid prescribing.

MediCom Worldwide, Inc. is committed to delivering education that addresses gaps in health care professional education with the ultimate goal of improving patient care. We are therefore requesting funding for the development and presentation of Meeting Highlights from the American Pain Society 31<sup>st</sup> Annual Scientific Meeting to American Pain Society (APS) delegates and members of the pain community. The Meeting Highlights will be in the format of video and available through EmergingSolutionsinPain.com (ESP) as updated information is available throughout the APS meeting.

The educational activities include: (Please see attached proposal for full description.)

- Meeting Highlights from APS 2012, May 16-19, 2012, Honolulu, Hawaii.

The total budget for this multi-supported activity is approximately \$75,700. The amount requested from Cephalon is \$5,000. Please refer to the detailed budget for complete grant funding details.

These scientific events will comply with all ACCME, FDA, AMA, and ACPE regulations for industry supported professional continuing education. MediCom Worldwide is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians, approved by the Accreditation Council for Pharmacy Education to provide pharmacy continuing education, and approved by the California State Board of Registered Nursing to provide nursing continuing education.

Educational support will be acknowledged on the educational program in compliance with Accreditation Council for Continuing Medical Education (ACCME) Guidelines.

Thank you, in advance, for your consideration of this request.

Respectfully,

A handwritten signature in cursive script, appearing to read 'Joan Meyer'.

Joan Meyer, RN, MA  
 Executive Director, Continuing Education



101 Washington Street  
Morrisville, Pennsylvania 19057  
Phone 215.337.9991  
Fax 215.337.0959

Conference Coverage  
Live from APS 2012

**NEEDS ASSESSMENT**

***Barriers to Effective Opioid Therapies in Moderate-to-Severe Pain Management***

The use of opioids for the treatment of moderate-to-severe chronic pain has been shown to be efficacious and has many endorsements from professional societies, associations, and clinical guidelines. [1-8]

Despite numerous therapeutic options in the pain management armamentarium, including drugs from a wide variety of pharmacologic classes as well as a variety of drug delivery routes and formulations (Table 1), a widespread issue of inadequate pain management remains a significant problem. The recent Institute of Medicine (IOM) report [9] highlighted that for many patients in the USA, treatment of pain remains inadequate despite concerted national efforts since the early 90s by organizations and associations such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Veteran's Health Administration, the American Pain Society, the American Pain Medicine Association, the American Pain Management Association, the American Chronic Pain Association, the American Pain Foundation and other professional societies to address this widespread issue of unsatisfactorily managed pain. [9-11]

**Table 1. Recommended drugs for persistent pain [2]**

<b>Nonopioid analgesics</b>
• Acetaminophen
• Salicylates (choline magnesium trisalicylate, salsalate)
• Cyclooxygenase-2 selective inhibitor NSAIDs (eg, celecoxib)
• NSAIDs (eg, naproxen, ibuprofen, diclofenac sodium, nabumetone, ketorolac)
<b>Opioids</b>
• Hydrocodone
• Oxycodone
• Morphine
• Hydromorphone
• Oxymorphone
• Fentanyl
• Tramadol
• Weak opioids (eg, codeine)
• Combination opioids (eg, +APAP)
<b>Adjuvant Agents</b>
• Tricyclic antidepressants (eg, desipramine, nortriptyline, amitriptyline)
• Other antidepressants (eg, duloxetine, venlafaxine, milnacipran)
• Anticonvulsants (eg, carbamazepine, gabapentin, pregabalin, lamotrigine)
• Antiarrhythmics (eg, mexiletine)
<b>Other Agents</b>
• Corticosteroids (eg, prednisone, methylprednisolone)
• Lidocaine (topical)

NSAIDs=nonsteroidal anti-inflammatory drugs; APAP=acetaminophen



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### Conference Coverage Live from APS 2012

Despite the increased attention on pain management and the publication of formal guidelines and standards for the management of pain, a significant number of patients continue to live daily with unacceptable levels of pain. [9-15]

The IOM report identified the following reasons for inadequate chronic pain management [9]:

- Uncertain diagnoses
- Societal stigma
- Lack of availability of effective treatments
- Inadequate patient and clinician knowledge about the best methods to manage pain

The increased awareness of the efficacy of opioids has resulted in a parallel increase in opioid prescribing. This in turn has led to prescription drug abuse becoming the nation's fastest-growing drug problem, and data from the National Survey on Drug Use and Health (NSDUH) reveals that:

- An estimated 5.3 million people aged 12 years or older currently use prescription pain drugs for nonmedical reasons
- More than 70% of people who abused prescription pain relievers accessed them from friends or relatives [16]

The growing public health problem and concerns of patient safety includes the risks of serious injury or death from accidental/unintentional overdose as well as misuse, abuse, addiction, and drug diversion.

Effective pain control in individuals with acute or chronic pain can be associated with a number of benefits, including an increased ability to work, improved function, and performing activities of daily living and an improved quality of life. The overall goal of therapy with analgesics is to find the minimum dose that adequately manages pain and enhances patient function while minimizing any unwanted adverse effects. [17] Considerable evidence indicates that opioids have a major role in the treatment of chronic pain of a nonmalignant origin. [18,19] Further, the American Pain Society (APS) and the American Academy of Pain Medicine (AAPM) commissioned a systematic review of the evidence on chronic opioid therapy for chronic noncancer pain and convened a multidisciplinary expert panel to review the evidence and formulate recommendations. [1] The resulting report advocates the benefit of chronic opioid therapy, but also recommends the application of risk-minimization techniques as preventive measures against potential exploitation, misappropriation, or abuse of these legally prescribed analgesics. [1]

Many physicians have a poor understanding of chronic pain or misunderstand the severity of their patients' condition. [9] This is often due to either an inaccurate assessment or an underestimation of the significance of their patients' personal experiences (Table 2). In particular, concerns about legal liability and fears regarding respiratory depression, tolerance, and addiction are common.

Many of these barriers to effective analgesia are thought to arise from unsubstantiated social or legal beliefs, or medical opinions that are not evidence based. [20]



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Conference Coverage  
Live from APS 2012

Patients have multiple concerns regarding ongoing use of opioid medications for pain management. Issues regarding tolerability, addiction or dependency, fears that increasing pain may indicate progressively worsening disease, being a "good" patient, and a desire for physicians to focus on treating the primary disease have all be cited as patient barriers to effective analgesia (**Table 2**). Difficulties in taking the medication and a lack of understanding about the medication have also been considered barriers. Factors related to the health care system can also present barriers to effective pain therapy (**Table 2**). These are primarily related to issues of cost, reimbursement, regulations, and availability.

**Table 2. Barriers to Effective Pain Management [20,21]**

<ul style="list-style-type: none"> <li>• Problems related to health care professionals <ul style="list-style-type: none"> <li>○ Inadequate knowledge of pain management</li> <li>○ Poor assessment of pain</li> <li>○ Concern about regulation of controlled substances</li> <li>○ Fear of patient addiction</li> <li>○ Concern about side effects of analgesics</li> <li>○ Concern about patients becoming tolerant to analgesics</li> <li>○ High prevalence of pain</li> <li>○ Pain management is a low priority</li> <li>○ Minimal capacity, resources and time</li> </ul> </li> </ul>
<ul style="list-style-type: none"> <li>• Problems related to patients <ul style="list-style-type: none"> <li>○ Reluctance to report pain</li> <li>○ Concern about distracting physicians from treatment of underlying disease</li> <li>○ Fear that pain means disease is worse</li> <li>○ Concern about not being a "good" patient</li> <li>○ Reluctance to take pain medications</li> <li>○ Fear of addiction or stigma of being thought of as an addict (may be more pronounced in minority patients)</li> <li>○ Worries about unmanageable side effects</li> <li>○ Concern about becoming tolerant to pain medications</li> <li>○ Poor adherence with the prescribed analgesic regimen</li> <li>○ Cultural attitudes</li> <li>○ Rural patients disadvantaged</li> <li>○ Inadequate patient education</li> </ul> </li> </ul>
<ul style="list-style-type: none"> <li>• Problems related to the health care system <ul style="list-style-type: none"> <li>○ Low priority given to cancer pain treatment</li> <li>○ Inadequate reimbursement</li> <li>○ The most appropriate treatment may not be reimbursed or may be too costly for patients and families</li> <li>○ Restrictive regulation of controlled substances</li> <li>○ Problems of availability of treatment or access to it</li> <li>○ Opioids unavailable in the patient's pharmacy</li> <li>○ Unaffordable medication</li> <li>○ Number of uninsured or underinsured</li> </ul> </li> </ul>



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**Knowledge and Practice Gaps**

There are numerous guidelines regarding the effective treatment of chronic pain. Despite this, there are many barriers to effective application of pain management that can be related to the patient, the physician, or the health care system. Increased awareness of potential barriers can allow clinicians to more effectively apply effective pain regimens. Adequate pain relief is a reasonable and reachable goal for patients once these identified barriers to achieving this goal are recognized, addressed, and overcome. Pain clinicians, in collaboration with well-educated patients, need to apply current knowledge regarding pain management to their daily practices to overcome these barriers.

**Role of Risk-Benefit Analyses in Opioid Therapy**

While the APS guidelines acknowledge the crucial role of chronic opioid therapy in the treatment of noncancer pain, these guidelines also emphasize these agents are associated with a number of adverse events and risks such as opioid abuse, addiction, and diversion. [1] The Food and Drug Administration (FDA) currently estimates that more than 33 million Americans age 12 and older misused extended-release and long-acting opioids during 2007 – up from 29 million just five years earlier, and that in 2006, nearly 50,000 emergency room visits were related to opioids. [22] Thus, the APS guidelines emphasize the need for proper patient selection that includes a benefit-to-harm evaluation that weighs the potential beneficial effects of chronic opioid therapy (ie, decreased pain and improved function) against the potential risks. The APS guidelines recommend the following regarding patient selection and risk stratification [1,23]:

1. Before initiating chronic opioid therapy, clinicians should conduct a history, physical examination and appropriate testing, including an assessment of risk of substance abuse, misuse, or addiction (strong recommendation, low-quality evidence).
2. Clinicians may consider a trial of chronic opioid therapy as an option if chronic noncancer pain is moderate or severe, pain is having an adverse impact on function or quality of life, and potential therapeutic benefits outweigh or are likely to outweigh potential harms (strong recommendation, low-quality evidence).
3. A benefit-to-harm evaluation including a history, physical examination, and appropriate diagnostic testing should be performed and documented before and on an ongoing basis during chronic opioid therapy (strong recommendation, low-quality evidence).

**Despite these recommendations, many clinicians have relatively undeveloped skills for performing risk stratification pertaining to outcomes associated with the abuse liability of opioids. [1]**

In a recent survey of clinicians regarding assessment strategies and practical approaches to successful monitoring of chronic pain, approximately 50% of respondents were unaware of the most effective techniques for curtailing drug abuse, misuse, and addiction. More interestingly, only 389/1009 respondents (39%) correctly identified appropriate patient selection as the most important focus of practice guidelines for opioid therapy for patients with moderate-to-severe chronic pain. [24] This data was reinforced by a recent online survey to almost 30,000 loyal pain clinician members of the *Emerging Solutions in Pain* (ESP) website about issues related to their beliefs and knowledge of the long-acting opioid Risk Evaluation and Mitigation Strategies (REMS) revealed that almost 13% do not routinely use any form of risk assessment screening. [25]





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Because of these concerns, the FDA announced a new risk reduction program – called REMS in April 2011 – for all extended-release and long-acting opioid medications. Key elements of this plan include [26]:

- Expansion of state-based prescription drug monitoring programs
- Recommending convenient and environmentally responsible ways to remove unused medications from homes
- Supporting education for patients and health care providers
- Reducing the number of “pill mills” and doctor-shopping through law enforcement

FDA Commissioner Margaret A. Hamburg, MD, noted that while “opioid drugs have benefit when used properly and are a necessary component of pain management for certain patients, they pose serious risks when used improperly – with serious negative consequences for individuals, families, and communities.” Dr. Hamburg asserted that, “The prescriber education component of this opioid REMS balances the need for continued access to these medications with stronger measures to reduce their risks.”

The REMS for long-acting opioids focuses primarily on educating doctors about proper pain management, patient selection and other requirements, and improving patient awareness about how to use these drugs safely. As part of the plan, the FDA wants companies to give patients education materials, including a medication guide that uses consumer-friendly language to explain safe use and disposal. Further, the FDA wants drug makers to work together to develop a single system for implementing REMS.

It is currently unknown what sort of opioid education program will be developed for prescribers, and only a matter of time before mandatory prescriber education on opioids tied to Drug Enforcement Administration (DEA) registration to prescribe controlled substances obtains congressional approval.

The results of the REMS survey [25] indicated that less than 70% correctly responded to knowledge questions related to REMS and opioid abuse, and 26% thought that the key element of REMS MOST necessary included the need for education initiatives for physicians and other care team members. Most responders felt that the REMS will have the most impact on prescribers (44%) or patients (24.6%), yet 34% had not read or heard about the FDA REMS elements, and 72% said that there is currently not enough information available to health care professionals about REMS. This was further reinforced by a recent symposium audience poll regarding which opioid formulations would be part of REMS where only 20% of an audience of 150 responded correctly [27]. Interestingly, 68% or 140 audience participants thought that the upcoming requirement of REMS to include mandatory education would cause prescribers to use this requirement as a way to “opt out” of writing for opioids [27].

### **Knowledge and Practice Gaps**

Clinicians have relatively underdeveloped skills for assessing the risks associated with opioid abuse liability (ie, misuse, abuse, addition, diversion) and the risk for opioid-related adverse events. Therefore, educational activities designed to improve these assessment skills has the potential to decrease the risk of opioid-related adverse events.





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Clinicians also require education on practical strategies to mitigate risks of adverse effects, misuse, abuse and diversion, as well as familiarization with recently enacted REMS requirements.

#### ***Appropriate Selection of Opioids***

Effective pain management includes the delivery of appropriate analgesia while reducing the risk of adverse events and preventing aberrant drug-related behaviors (eg, abuse/misuse). [23] There are a number of treatment options for patients with acute or chronic pain who require opioid therapy. Appropriate selection of an opioid formulation requires consideration of the clinical profile of the pain, the characteristics and route of administration, patient's previous medications, as well as the patients' potential risk for abuse/misuse. Opioids used for moderate-to-severe pain can be classified into various categories:

- Long-acting opioids (LAOs) including extended-release opioids which have a longer onset and longer duration of analgesia.
- Short-acting opioids (SAOs) have an onset of 30–45 minutes and a shorter duration of analgesia.
- Rapid-onset opioids (ROOs) have an onset of 15 minutes or less and a shorter duration of analgesia.

Extended-release (ER) formulations have advantages for patients who require continuous, around-the-clock analgesia for an extended period of time. This type of formulation is most appropriate for those who have relatively constant chronic pain. [17] A disadvantage of the ER formulation is that it is more difficult to titrate to specific levels of pain, particularly for those with fluctuating levels of pain. Fluctuating pain is a common feature of chronic pain syndromes such as low back pain and temporomandibular pain.

Because the onset of pain relief is slower with an ER formulation, there is the potential for patients to overdose if they use an ER product to treat acute pain because they may take an additional dose before the onset of effect occurs. Another disadvantage is that side effects are slower to dissipate with ER formulations. Thus, immediate-release formulations (with or without acetaminophen) are best for patients who require rapid onset of analgesia, those who have episodic increases in chronic pain intensity, and those with breakthrough pain. [29] Breakthrough pain is defined as a temporary flare in pain in persons with otherwise controlled chronic pain and is a common phenomenon, occurring in 50% to 90% of patients with malignant or nonmalignant chronic pain. [17] Thus, matching the formulation to the temporal variations in pain can optimize efficacy and minimize the risk of adverse events. [17]

Ongoing assessment which not only looks for stabilization but also progression to a goal of maximizing symptom relief and functionality while minimizing adverse effects should be the priority. The therapeutic strategy that guides the administration of chronic opioid therapy is opioid optimization. This should involve an ongoing process of assessment and monitoring, coupled with specialized knowledge which is aimed at selecting the best opioid medication for the individual patient. [28]

Certain characteristics of these drugs and their formulations can determine the potential for abuse and addictive behaviors among certain patients. [30] Opioid formulations can either



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employ an abuse-deterrent or tamper-resistant strategy. Abuse-deterrent formulations are those that contain substances that make the formulation less attractive to abusers. This typically includes the addition of an opioid receptor antagonist such as naloxone. [31] A tamper-resistant formulation is designed to be difficult to crush or dissolve, thus making chewing, snorting, or injecting the medication more difficult. [31]

In order to develop educational materials to guide the development of a strategy of opioid optimization, the medical literature indicates that there are many gaps in practitioner knowledge, skills, and behaviors that need to be addressed. There is very little material regarding the pharmacological differences between the various opioid medications, eg, comparing the varying effects and metabolic characteristics of such commonly used long-acting medications as morphine, oxycodone, hydromorphone, oxymorphone, and fentanyl. These drugs all have differing receptor and metabolic profiles which will determine differences in efficacy and adverse side effects. There is also a lack of knowledge among practitioners regarding differences in opioid formulations designed to prevent abuse or misdirection of medication.

Data collected at a recent symposium held in conjunction with the 22<sup>nd</sup> Annual Clinical Meeting of the AAPM revealed that more than 60% of the audience polled felt that they were less than confident that all of their chronic pain patients on ER or LA opioid formulations would have documentation of a standardized pain assessment and risk evaluation in each patient chart. [27]

#### ***Knowledge and Practice Gaps***

The type of drug, the route of delivery, and the formulation of opioids can affect efficacy, side effects, and abuse potential. Therefore, clinicians require a detailed knowledge of the pharmacology, pharmacokinetics, and formulations of various treatment options so that pain pharmacotherapy is optimized and abuse/misuse is minimized.



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### Activity Format and Structure

#### Program Overview

This activity is designed to provide a focused coverage of the 31<sup>st</sup> Annual Scientific Meeting of the American Pain Society. Using a format that focuses on the most significant developments from the meeting, plus post-meeting reviews of specific topics related to chronic non cancer pain. The rapid turnaround and posting of these reports ensure that readers can learn key data promptly after they are presented, while the post-meeting reviews offer expert commentary of the relevance of the latest findings in the context of current treatment practices. Our objective is to provide timely, relevant information for the practicing clinician with the goal of enhancing patient care in the area of chronic pain management.

Our use of opinion-leading faculty is an essential component of the coverage. Our expert physician moderator provides evaluation of the data and utilizing an interview format will discuss with the presenting faculty the likely contribution to patient management and practice.

Conference highlights will be available to the more than 30,000 members of the ESP website, and in addition coverage will be distributed to a target audience of approximately 6,200 including the attendees of the APS meeting as live clinician interviews are conducted.

#### How will the program benefit delegates?

ESP is proposing to provide dynamic and real-time updates to both the APS attendees and our target audience, through an on-the-floor HD video clinician interviews live from Honolulu, Hawaii which will:

- Alert meeting attendees that they may receive the meeting highlights through the ESP website and *ESP Radio*
- Allow attendees to download *ESP Mobile* to their 3G network-enabled phones
- Allow attendees to view the on-air interviews with the clinician thought leaders, live and in-person, at APS meeting or on the ESP website

This program would therefore benefit the following:

- APS delegates attending the 2012 APS meeting who were unable to attend all the sessions
- ESP members unable to attend the 2012 APS meeting
- 30,000 ESP members plus an additional distribution to approximately 5,000 clinicians who have indicated a need to increase their knowledge of pain management
- On-demand formats would enable clinicians to listen or view discussions from anywhere and at anytime

#### Target Audience

The primary audience of the Meeting Highlights from APS will be pain practitioners and other allied health care professionals who provide care to patients with acute or chronic pain. These include:

- Attendees of APS 2012 Meeting
- Members of ESP
- Target list of healthcare clinicians who have identified interest in ongoing education in pain management 5,000
- Subscribers to *ESP Mobile*
- Current listeners of *ESP Radio*
- Clinicians who have downloaded *ESP Mobile*





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### Learning Objectives

Upon completion of this activity, participants should be able to:

1. Apply recent data regarding safety and efficacy of current and novel approaches to chronic non cancer pain
2. Integrate recent communications, data, and educational plan related to the role of REMs in opioid management
3. Apply guidelines and best practice strategies in patient selection and treatment of chronic non cancer pain management

### Format and Awareness

**Meeting Highlights at APS 2012** will be HD video clinician interviews accessible via the *ESP* website and *ESP Radio* which can be also be accessed via *ESP Mobile* (a Smartphone application). The interview sessions will be archived on the *ESP* website for a period of one year to enable more health care participants to access the information presented.

### Audience Generation Activities

To date, more than 30,000 multidisciplinary, multispecialty providers have become members of the *ESP* site, with more than 284,000 unique user sessions in 2010. MediCom Worldwide will send an email to registered providers announcing the program on the *ESP* site.

### ESP BACKGROUND AND CASE STUDY

*Emerging Solutions in Pain (ESP)* was launched in 2005 as a broad-based initiative employing an integrated communication approach to education and information dissemination. *ESP*'s goal is to assist clinicians in managing the challenges of providing appropriate treatment to patients with chronic pain, while also minimizing the potential risk for opioid misuse, abuse, and diversion.

Since launch, *ESP* website has documented success in achieving its goals and mission:

- *ESP* membership has grown phenomenally since launch. The current membership is more than 30,000 health care professionals
  - Membership represents those clinicians who are willing to provide key identification data in order to obtain access to education, tools, and training
- *ESP* membership demographics includes all members of the multidisciplinary team, with physicians and nurses being the most represented. The *ESP* membership reflects a diverse spectrum of clinical specialties, including the following physician specialties:
  - Pain management specialists
  - Anesthesiologists
  - Primary care physicians
  - Physical medicine and rehabilitation specialists
- In 2010, *ESP* had:
  - More than 284,350 unique user sessions
  - More than 770 unique user sessions daily
  - An average user session length of more than 8 minutes, 26 seconds



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- In the first six months of 2011, ESP has continued to educate clinicians at a rate consistent with 2011. However, in the third quarter of 2011, ESP's access rate by clinicians has increased significantly. In the three month period of July 1 - September 30, 2011, ESP had:
  - More than 91,470 user sessions
  - More than 990 unique user sessions daily
  - An average user session length of more than 8 minutes, 29 seconds
- ESP has been awarded both HONCode and Web Medica Acreditada (WMA) certification, the only two worldwide organizations certifying web sites adhering to the strictest guidelines and ethical standards of presenting credible and reliable information for health care professionals
- ESP has been recognized for both content and innovative design with numerous international awards
- ESP content has been rated highly in terms of usefulness (4.1), quality (4.1), change in clinical practices (3.8) and commitment to change (4.0)<sup>‡</sup>
- ESP educational activities have led to the following key changes in clinical practice: patient assessment (22.6%), patient monitoring (19.1%), documentation (12.2%), risk strategy (13.9%), pharmacological management (13.9%), and other (18.3%)<sup>¶</sup>

### **ESP Mission Statement**

*Emerging Solutions in Pain (ESP)* is an ongoing educational initiative developed to address some of today's most critical issues in pain management. These issues involve balancing fundamental rights of patients and clinicians with the challenge of risk containment for opioid misuse, abuse and addiction associated with medical prescribing and use of controlled substances. Through evidence-based scientific data, validated tools, and the expertise of a cadre of leading pain and addiction medicine experts, the ESP program provides clinicians with guidance in the implementation of good practice management techniques. Site features and programs emphasize favorable interaction with regulatory and law enforcement agencies, as well as effective assessment, monitoring and documentation strategies; all of which contribute to the overall goal of optimizing outcomes for patients in pain.

### **Evidence of Efficacy: Online Educational Activities at the ESP Website**

In 2010, MediCom conducted a focused outcomes analysis concerning the efficacy of translating knowledge gained in an online environment to practice-based patient care. The 2010 *Emerging Solutions in Pain* outcomes study utilized case vignettes given to participants in online activities at the ESP website, as well as to non-participants who did not visit the ESP website. The results of this comparative study were significant: **'At least 137,643 patients with chronic pain seen by 4,171 health care providers who participated in *Emerging Solutions in Pain* are 30% more likely to receive evidence-based care than those seen by healthcare providers who did not participate in the activity, specifically in:**

- Treating a patient with chronic pain who is at moderate risk for aberrant behavior
- Recognizing the benefit of using a strategic precautionary approach to assessment and management of a patient with chronic pain
- Assessing a patient's OTC medications prior to stopping opioid therapy when the patient's urine drug screen is positive for methamphetamines

<sup>‡</sup>The numbers in brackets represents the average overall rating by ESP members to October 2010 where 5 = highest and 1 = lowest

<sup>¶</sup>Other – includes teaching, further research, and sharing with colleagues.





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- Utilizing risk assessment tools such as the Opioid Risk Tool (ORT) and the Screener and Opioid Assessment for Patients with Pain (SOAPP)"

The results of this outcomes study were presented as a poster at the 2010 PAINWeek meeting; see below for the complete abstract.

#### ***An Assessment of Internet-based (Emerging Solutions in Pain) CME Activities for Pain Physicians***

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#### ***Background***

Physicians are increasingly utilizing the Internet, and in particular, trusted independent websites, as an essential component of obtaining professional information, as a source of continuing medical education (CME), and as a communication lifeline at the point of care. *Emerging Solutions in Pain* (ESP) was launched in 2005 with a leading cadre of experts in pain management and addiction medicine. ESP is a robust and multi award-winning ongoing educational initiative which provides an array of information, resources, tools, and case studies to the management of chronic pain. It aims to inform clinicians of methods of communication, ways in which risk of abuse may be measured, and how highlight and educate clinicians on the complexities surrounding to integrate these strategies into an individualized treatment plan. Membership is free to all health care professionals.

#### ***Aim***

The purpose of this study was to determine the effectiveness of two Internet-based CME activities, *Assessment Strategies and Practical Approaches to Successful Monitoring of Chronic Pain*, and *Minimizing Risk and Improving Outcomes in Chronic Pain*, included on the educational initiative, *Emerging Solutions in Pain* (ESP). Both programs focused on the safe and effective treatment of chronic pain while minimizing the risks of misuse.

#### ***Methods***

A post-activity assessment study was conducted 3-5 months after completion to determine the effectiveness of two CME activities on the practice patterns and knowledge of physicians who manage chronic pain patients. Effectiveness was measured using a case-based survey designed to assess whether the diagnostic and therapeutic choices of program participants were consistent with evidence-based content of the CME activities.

The survey was also administered to a demographically similar control group of physicians who did not participate in the educational program in order to assess differences in practice choices. The participant group was selected from a list of physicians completing the course and also agreeing to participate in future self-study activities. The control group was selected at random from the AMA Master File. The participant and control groups were matched on the following characteristics: physician specialty, degree, years in practice, whether or not direct patient care was their primary responsibility, and the number of patients seen per week with chronic pain.

CE Outcomes independently reviewed the educational objectives and content of ESP to define a series of key measurement indicators to frame case vignette questions, which were presented to participants and nonparticipants.



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### *Analysis*

Data were analyzed using frequencies, followed by T-tests to analyze the differences between the mean evidence-based responses of the 50 participant and the 50 nonparticipant physicians. Differences between the two groups were considered significant if the *P* value was  $\leq 0.15$ .

An effect size was calculated using the Cohen's *d* formula to determine the amount of difference between the evidence-based responses of the participants vs. nonparticipants. The calculation is expressed as a non-overlap percentage, or the percentage achieved by participants that was not reflected in the evidence-based responses of nonparticipants.

### *Results*

A total of 4,171 physicians (MDs/DOs) who practice in pain management seeing approximately 137,643 chronic pain patients participated in ESP CME activities over a 3-month period. Responses from 50 participant and 50 control nonparticipant primary care physicians (PCPs) and pain specialists were collected for analysis. Case vignettes were used to predict practice patterns and measure a physician's process of care in actual clinical practice.

### *Conclusion*

Physicians who participated in ESP CME activities are more likely to practice evidence-based care of chronic pain patients than those who did not participate in these activities, specifically:

- Participants were more likely to recognize that a strategic precautionary approach to assessing a patient with moderate risk for aberrant behavior will reduce the likelihood of becoming a high-risk patient ( $P=.086$ ).
- Participants were more likely to start a patient with severe pain that is not controlled with acetaminophen and NSAIDs who demonstrates moderate risk for aberrant behavior on multimodal therapy ( $P=.059$ ).
- Participants were more likely to recognize that some over-the-counter medications cause a false-positive urine test and would assess a patient's OTC medications prior to stopping the patient's opioid therapy ( $P=.131$ ).
- Participants were more likely to recognize the need to utilize a standard risk assessment tool (such as the ORT or SOAPP) as the best approach to stratifying risk in a patient in the primary care setting ( $P=.06$ ).

The large effect size (30%) suggests that the ESP Internet-based CME programs offer effective, credible and high-impact education. These programs are available on-demand and in multiple formats to suit the learning preferences of physicians.



101 Washington Street  
Morrisville, Pennsylvania 19067  
Phone 215 337.9991  
Fax 215 337 0959

**Conference Coverage**  
**Live from APS 2012**

**Outcomes/Final Report**

The final report to be sent to you 90 days after this activity has been completed will include the following metrics and outcomes:

**Metric Measures:**

- Website User Sessions
- Smartphone User Sessions
- ESP Radio Sessions

**Outcome Measures:**

- L1 - Participation (Registrant Data);
- L2 - Satisfaction (Rate Level of Satisfaction);
- L3A - Declarative Knowledge (Learning Objectives Met);
- L4 - Competence (Plan to Make a Change);



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**Conference Coverage**  
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**Accreditation Information**

**CME Credit**

The activity will be planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME). MediCom Worldwide, Inc. is accredited by the ACCME to sponsor continuing medical education programs for physicians. MediCom Worldwide, Inc. will designate this educational activity for a maximum of 1.0 hours in category 1 credit towards the AMA Physician's Recognition Award, depending on the format type.

Educational activities that are designated for continuing medical education have guidelines and requirements which to adhere. These programs will adhere to the ACCME Standards of Commercial Support as well as all other applicable guidelines including FDA, OIG, and PhRMA CME credit for physicians by the Accreditation Council.

**CPE Credit**

MediCom Worldwide, Inc. is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing education. MediCom Worldwide, Inc. CE programs are developed in accordance with the "Criteria for Quality and Interpretive Guidelines" of the ACPE. This program is acceptable for 1.0 contact hours of continuing education credit

**CNE Credit**

MediCom Worldwide, Inc. is approved by the California Board of Registered Nursing. MediCom Worldwide, Inc. designates this activity for 1.0 contact hours.



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**Conference Coverage  
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**Grant Funding Request and Payment Structure**

The amount requested to fund this initiative is: \$5,000

**Budget Reporting and Reconciliation**

*Appropriate Use of Commercial Support*

A. Funds should be in the form of an educational grant made payable to:

MediCom Worldwide, Inc.  
101 Washington Street  
Morrisville, PA 19067  
Tax ID# 23-3063738

B. No other funds from Cephalon paid to the program director, faculty, or others involved with this activity (additional honoraria, extra social events, etc).

C. MediCom Worldwide, Inc. will furnish the commercial interest with documentation detailing the receipt and expenditure of the commercial support within 90 days of activity completion.

**Proposed Payment Structure**

- 100% due upon signing agreement



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Morrisville, Pennsylvania 19067  
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**Compliance and Conflicts of Interest**

**Firewall/Independence Statement**

MediCom Worldwide, Inc. (MediCom) is a privately held, independent, for-profit, medical education company with a Federal Tax Identification Number registered in the State of Pennsylvania and who maintains bank accounts, financial and employee reporting structures unaffiliated with any other entity.

MediCom is not owned by, part of, or controlled by any business entity that produces, markets, re-sells, distributes or otherwise participates in or profits from the distribution, promotion or sale of health care goods or services consumed by, or used on, patients.

MediCom is an accredited provider of education for medical, pharmacy and nursing professionals. MediCom is structured to provide CME programs to physicians that will advance health care practice and patient outcomes. Established in 1993, MediCom is accredited by the ACCME (Accreditation Council for Continuing Medical Education), ACPE (Accreditation Council for Pharmacy Education), and approved by the California Board of Registered Nursing to provide continuing education credits to nurses.

MediCom only provides continuing education for physicians, pharmacists, nurses, and other professional health care providers and does not provide promotional activities for any pharmaceutical and/or medical device manufacturing company.



101 Washington Street  
 Morrisville, Pennsylvania 19067  
 Phone 215 337 9991  
 Fax 215 337 0959

## Conference Coverage Live from APS 2012

**MediCom Worldwide, Inc.**  
[www.MediComWorldwide.com](http://www.MediComWorldwide.com)

Established in 1993, MediCom Worldwide, Inc. is a full-service, accredited, independent medical education company that has educated almost a million health care professionals through more than 800 diverse educational activities.

Central to our practice is the emphasis on compliant, scientifically rigorous, and performance-improving outcomes-based quality content, built on demonstrated educational gaps, together with cutting-edge technological delivery mechanisms in multiple formats that facilitate learner-centered education.

We support the CE needs of physicians, nurses, pharmacists, and other health care professionals, and we are CE-accredited to provide the following:

1. CME credit for physicians by Accreditation Council for Continuing Medical Education (ACCME) through March 2015
2. CPE credit for pharmacists by the Accreditation Council for Pharmacy Education (ACPE) through 2012
3. CNE credit for nurses by the California Board of Registered Nursing through 2013

We work closely with experts and a variety of key opinion leaders in our advisory committees in the development, delivery, and enhancement of our educational programs.

We at MediCom Worldwide, Inc. take pride in our advanced innovative concentration on adult learning principles and instructional design techniques that incorporate interactive, learner-centered, segmented methods of instruction.

MediCom Worldwide, Inc. is an independent medical education company dedicated to serving as a primary resource to health care professionals in providing state-of-the-art, evidence-based, fair and balanced activities to physicians and other allied health care professionals that will positively influence patient outcomes.





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Fax 215 337 0959

**Conference Coverage  
Live from APS 2012**

**Statement of Conflict Resolution and Disclosure**

In accordance with the ACCME *Standards for Commercial Support: Standards to Ensure Independence in CME Activities*, as well as the ACPE *Standards for Continuing Pharmacy Education: Standards for Commercial Support*, it is the policy of MediCom Worldwide, Inc. to ensure balance, independence, objectivity, and scientific rigor in all of its activities.

MediCom Worldwide, Inc. requires everyone who is in a position to control the content of a CME-, CNE-, or CPE-accredited activity to disclose all relevant financial relationships with any commercial interest. This information is utilized to: a) determine if a conflict exists, b) resolve the conflict by initiating a content validation process, and c) advise learners of this information. Any individual who refuses to or chooses not to disclose relevant financial relationships will be disqualified from participating as an instructor, planner, or manager and cannot have control of or responsibility for the development, management, presentation, or evaluation of an accredited activity certified by MediCom Worldwide, Inc. MediCom Worldwide, Inc. has defined all those in a position to control content as faculty, authors, presenters, planning committee members, and internal staff who are in a position to write, alter, or impact the content of an activity certified for CME, CPE, and/or CNE.

Disclosures received by MediCom Worldwide, Inc. from individuals in a position to control content are made transparent to learners prior to participating in all activities. MediCom Worldwide, Inc. discloses the following information to learners: a) the name of the individual, b) the name of the commercial interest(s), and c) the nature of the relationship that the individual has with the commercial interest. MediCom Worldwide, Inc. also discloses to learners the name(s) of commercial interests supporting each CME, CNE, and/or CPE activity.

Should a conflict of interest be identified, a content validation process is initiated to ensure that the content or format of the activity and related materials will promote improvement or quality in health care and not promote a specific proprietary business interest of a commercial entity. It is the policy of MediCom Worldwide, Inc. to conduct an unbiased review of all planned content for CME, CPE, and/or CNE activities certified for credit to ensure adherence to the ACCME, ACPE, and CNE content validation statements and to resolve any actual or perceived conflict of interest that exists. MediCom Worldwide, Inc. employs three primary metrics to validate content: a) fair balance, b) the scientific objectivity of studies mentioned in the materials or used as the basis for content, and c) appropriateness of patient care recommendations made to the learner.



101 Washington St, Suite 110  
Morrisville, PA 19067

07300Q.31  
Proposal Number: 11-431a

**Meeting Highlights from the 2012 APS Annual Scientific Meeting**  
September 6, 2011

<b>Cost Summary, Meeting Highlights</b>	
Approximate Total, Out-of-Pocket Expenses	\$ 47,750
Total, Time of Staff Expenses	\$ 27,950
<b>Meeting Highlights from the 2012 APS Annual Scientific Meeting</b>	<b>\$ 75,700</b>

<b>Detailed Budget Itemization</b>	
<b>Out-of-Pocket Expenses, Approximate</b>	<b>Total</b>
Exhibit space rental	\$ 5,000
Independent peer review (1 activity, 1.0 hour CME)	\$ 1,620
Faculty honoraria (5 faculty members)	\$ 3,750
Moderator honoraria (1 moderator)	\$ 3,000
<b>Moderator expenses</b>	
Air	\$ 800
Hotel (3 nights)	\$ 750
Ground transportation	\$ 100
OOP (3 days)	\$ 300
<b>MediCom expenses: 2 MCWW staff</b>	
Air	\$ 1,600
Hotel (4 nights)	\$ 2,000
Ground transportation (shared transportation)	\$ 100
OOP (4 days each)	\$ 400
<b>Meeting management staff expenses: 1 staff</b>	
Air	\$ 800
Hotel (4 nights)	\$ 1,000
Ground transportation (shared transportation)	\$ 100
OOP (4 days)	\$ 200
<b>Audio/visual services</b>	\$ 10,900
Includes all A/V services for filming of up to 5 clinical expert interviews on location at APS meeting; includes filming, studio set rental, electric charges, remote switching, Internet fees, equipment shipping and all on-site production services; on-site A/V management; travel for A/V staff member	
<b>Meeting highlights production</b>	\$ 6,800
Includes video interview and graphics editing; programming for posting on Emerging Solutions in Pain website; Q&A testing, posting of finished program	
<b>Hosting, maintenance and troubleshooting (12 months)</b>	\$ 1,800
<b>Recruitment</b>	\$ 4,100
Includes all labor, creative support services and transmission fees for development, programming and execution of banners and blast email campaign to members of the Emerging Solutions in Pain and MedicalEd websites	
<b>Data management</b>	\$ 680

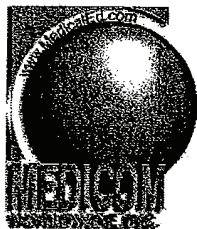


101 Washington St, Suite 110  
Morrisville, PA 19067

07300Q.32  
Proposal Number: 11-431a

**Meeting Highlights from the 2012 APS Annual Scientific Meeting**  
September 6, 2011

<b>Detailed Budget Itemization</b>	
<b>Out-of-Pocket Expenses, Approximate, continued</b>	<b>Total</b>
<b>Meeting management</b> Includes on-site meeting supervision, direction; venue coordination; travel coordination for faculty and staff; coordination of associated meeting logistics and client services management	\$ 1,700
<b>Miscellaneous (non-fulfillment shipping, faxes, FedEx, etc.)</b>	\$ 250
<b>Approximate Total, Out-of-Pocket Expenses</b>	<b>\$ 47,750</b>
<b>Time of Staff Expenses</b>	<b>Total</b>
<b>Project management</b> Strategic development, account management	\$ 4,000
Coordination with faculty	\$ 1,200
Coordination and supervision of internal teams	\$ 900
Preparation and coordination of status meetings/updates	\$ 600
<b>Medical services</b> Meeting highlights development, faculty identification and management	\$ 3,000
Copy writing	\$ 600
<b>Onsite management (2 staff members @ 3 days)</b>	\$ 7,200
<b>Accreditation for one hour of CME, CNE, CPE</b>	\$ 10,000
<b>Administrative and accounting fees</b>	\$ 450
<b>Total, Time of Staff Expenses</b>	<b>\$ 27,950</b>



March 8, 2001

P. Andrew Pyfer  
Product Manager  
Cephalon, Inc.  
145 Brandywine Parkway  
West Chester, PA 19380

Dear Mr. Pyfer:

The University of Wisconsin Medical School is accredited by the Accreditation council for continuing Medical Education to sponsor continuing medical education for physicians and MediCom is an ACPE-approved provider of pharmacy continuing education, as well as an approved provider of nursing continuing education through the California State Board of Registered Nursing.

A comprehensive needs assessment has identified interests of health care providers who manage patients suffering from pain. Based on this educational need, we are requesting an educational grant from Cephalon, Inc. to support the development and implementation of several continuing education activities on the subjects of effective pain management techniques and the changing guidelines to improve pain management. The budget to fund these activities is approximately \$691,200. Individual participant expenses will be covered under a separate agreement.

#### Proposed Educational Activities

Three Regional Symposia: conducted with renown faculty in the Northeastern, Western, and Southern U.S

Development and dissemination of a "Profiles in Pain Management" News letter for pain management specialists

Development and production of three self-study program materials in CD, audio tape formats

Development and implementation of a self-study "800" CE line

Procurement of Profiles in Pain Management URL

Design and technological development of Profiles in Pain Management web page

Adaptation and production of self-study programs offered via the Internet

These scientific activities, developed independently and presented live as symposia in three cities and then as enduring CME material in various formats, will comply with all ACCME, FDA, AMA, and ACPE regulations for industry-supported professional continuing education. The target audience for these activities are pain management specialists, oncologists and anesthesiologists.

As a supplement to our direct mail and web site announcement of these educational activities, we request Cephalon representatives to disseminate information regarding these programs to the medical community.

4599 Main Street  
Kingston, NJ 08528  
609-688-0065

1

However, the content of such information is the responsibility of the accredited provider and any such distribution will be solely as a supplement to provider's primary method of announcement and promotion.

Thank you, in advance, for your consideration of this request. Should you agree to provide funding for this project, Letters of Agreement will be forwarded to you as soon as possible.

Respectfully,

Joan Meyer RN, MA  
Director, Continuing Education


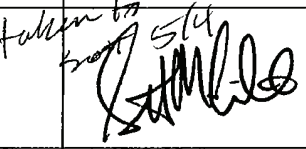
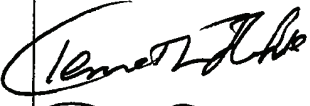
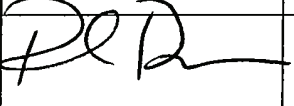
cc: Ann Bailey, University of Wisconsin Medical School

4599 Main Street  
Kingston, NJ 08528  
609-688-0065

## Cephalon Review of Education Grant

The attached Grant amount has been reviewed by members of the MEP team.

**Program Name:** Unrestricted Educational Grant: "Effective Pain Management Techniques and the Changing Guidelines to Improve Pain Management"

<u>Department</u>	<u>Name</u>	<u>Signature</u>	<u>Date</u>
Medical Affairs	Kiumars Vadieli	5/4 	5/10/01
Legal	Scott Melville	taken to Scott 5/4 	5/10/01
Regulatory	Ken White		5/10/01
Marketing	Andy Pyfer Lynne Brookes		5/4/01

Please return to Carrie Friday (x6532)  
after review & sign off.

Thank you

## MEDICAL EDUCATION AGREEMENT

As a condition of Cephalon, Inc.'s contribution of funds to support an independent medical education program (with or without CME credits), the Scientific and Educational Activity provider agrees to the following terms and conditions:

This Agreement ("Agreement") is entered into as of April 16, 2001 by and between Cephalon, Inc. ("Cephalon") and Medicom ("Provider") regarding a medical education program sponsored by Cephalon entitled "Effective Pain Management Techniques and the Changing Guidelines to Improve Pain Management". The parties' mutual objectives are to provide a balanced, independent, scientifically rigorous program to promote the education of attendees.

1. Statement of Purpose. This program is for scientific and educational purposes only and not to promote any commercial drug products.

2. Control of Content and Selection of Presenters and Moderators. The provider is ultimately responsible for the control of content and selection of presenters and moderators. Cephalon or its agents may respond to requests initiated by the provider for suggestions of presenters or sources of possible presenters. Cephalon will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Cephalon and speaker; and will provide this information in writing. Provider will seek suggestions from other sources, and will, in its sole discretion, select presenters and moderators.

3. Disclosure of Financial Relationships. Provider will direct speakers and moderators to disclose to the audience commercial support or funding or other significant financial relationships between the speakers and moderators and Cephalon and/or any other commercial company whose products are pertinent to the content of the presentation. Provider will disclose Cephalon's support at this program.

4. Involvement in Content. There will be no "scripting," emphasis, or influence on content by Cephalon or its agents. However, Cephalon may provide technical support to speakers, e.g., furnishing slides or data, upon their request.

5. Ancillary Promotional Activities. No promotional activities will be permitted in the same room as, or in the obligatory path to, the educational activity. No product advertisements will be permitted within the program or handouts.

6. Objectivity and Balance. Provider will advise presenters that data regarding Cephalon products (or competing products) are to be objectively selected and presented. Provider will provide the opportunity for speakers and the audience to discuss information, both favorable and unfavorable, about the product(s) and/or alternative treatments.



7. Limitations of Data. Provider will request the speakers, to the extent possible, to disclose limits on the data, e.g., that it involves ongoing research, interim analyses, preliminary data, or unsupported opinion.

8. Discussion of Unapproved Uses. Provider will request that presenters disclose when a product is not approved in the United States for the use under discussion.

9. Actiq® Risk Management Program. Provider is aware that Actiq (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- Actiq is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.*
- Actiq is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.

10. Opportunity for Debate. Provider will ensure opportunities for questioning by attendees and scientific debate with and between presenters.

11. Independence of Provider in the Use of Contributed Funds.

(a) funds should be in the form of an educational grant made payable to the provider organization.

(b) Provider must be advised of all other support by Cephalon of the CME activity (e.g., distributing brochures, preparing slides). If Provider disapproves of this activity, it shall promptly notify Cephalon.

(c) no other funds from Cephalon will be paid to the program director, faculty, or others involved with this CME activity, e.g., additional honoraria.

12. General.

(a) Cephalon agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.

(b) Provider agrees to: (1) abide by the ACCME Standards for Commercial Support of Continuing Medical Education; (2) acknowledge educational support from Cephalon in program brochures, syllabi, and other program materials; and (3) upon request, furnish Cephalon with a report concerning the expenditure of the funds provided by Cephalon.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

[PROVIDER]

CEPHALON, INC.

By: *Joan Meyer*  
Name: Joan Meyer  
Title: Director, Continuing Education

By: *Lynne M. Brookes*  
Name: Lynne M. Brookes  
Title: VP of Marketing





From the desk of...  
JOAN MEYER, RN, MA

2 Lavender Drive  
Princeton, NJ 08540

Phone 732-274-9495  
Outside NJ 800-408-4242  
Fax 732-274-2836  
Email Joan@MedicalEd.com

Carrie,  
Attached is your signed  
copy of the Medical Education  
agreement. Should you  
have any questions please  
do not hesitate to give me  
a call.

Sincerely,  
Joan Meyer



## MEDICAL EDUCATION AGREEMENT

As a condition of Cephalon, Inc.'s contribution of funds to support an independent medical education program (with or without CME credits), the Scientific and Educational Activity provider agrees to the following terms and conditions:

This Agreement ("Agreement") is entered into as of April 16, 2001 by and between Cephalon, Inc. ("Cephalon") and Medicom ("Provider") regarding a medical education program sponsored by Cephalon entitled "Effective Pain Management Techniques and the Changing Guidelines to Improve Pain Management". The parties' mutual objectives are to provide a balanced, independent, scientifically rigorous program to promote the education of attendees.

1. Statement of Purpose. This program is for scientific and educational purposes only and not to promote any commercial drug products.

2. Control of Content and Selection of Presenters and Moderators. The provider is ultimately responsible for the control of content and selection of presenters and moderators. Cephalon or its agents may respond to requests initiated by the provider for suggestions of presenters or sources of possible presenters. Cephalon will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Cephalon and speaker; and will provide this information in writing. Provider will seek suggestions from other sources, and will, in its sole discretion, select presenters and moderators.

3. Disclosure of Financial Relationships. Provider will direct speakers and moderators to disclose to the audience commercial support or funding or other significant financial relationships between the speakers and moderators and Cephalon and/or any other commercial company whose products are pertinent to the content of the presentation. Provider will disclose Cephalon's support at this program.

4. Involvement in Content. There will be no "scripting," emphasis, or influence on content by Cephalon or its agents. However, Cephalon may provide technical support to speakers, e.g., furnishing slides or data, upon their request.

5. Ancillary Promotional Activities. No promotional activities will be permitted in the same room as, or in the obligatory path to, the educational activity. No product advertisements will be permitted within the program or handouts.

6. Objectivity and Balance. Provider will advise presenters that data regarding Cephalon products (or competing products) are to be objectively selected and presented. Provider will provide the opportunity for speakers and the audience to discuss information, both favorable and unfavorable, about the product(s) and/or alternative treatments.

7. Limitations of Data. Provider will request the speakers, to the extent possible, to disclose limits on the data, e.g., that it involves ongoing research, interim analyses, preliminary data, or unsupported opinion.

8. Discussion of Unapproved Uses. Provider will request that presenters disclose when a product is not approved in the United States for the use under discussion.

9. Actiq® Risk Management Program. Provider is aware that Actiq (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- Actiq is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.*
- Actiq is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.

10. Opportunity for Debate. Provider will ensure opportunities for questioning by attendees and scientific debate with and between presenters.

11. Independence of Provider in the Use of Contributed Funds.

(a) funds should be in the form of an educational grant made payable to the provider organization.

(b) Provider must be advised of all other support by Cephalon of the CME activity (e.g., distributing brochures, preparing slides). If Provider disapproves of this activity, it shall promptly notify Cephalon.

(c) no other funds from Cephalon will be paid to the program director, faculty, or others involved with this CME activity, e.g., additional honoraria.

12. General.

(a) Cephalon agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.

(b) Provider agrees to: (1) abide by the ACCME Standards for Commercial Support of Continuing Medical Education; (2) acknowledge educational support from Cephalon in program brochures, syllabi, and other program materials; and (3) upon request, furnish Cephalon with a report concerning the expenditure of the funds provided by Cephalon.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

[PROVIDER]

CEPHALON, INC.

By: *Joan Meyer*  
Name: Joan Meyer  
Title: Director, Continuing Education

By: *Lynne M. Brookes*  
Name: Lynne M. Brookes  
Title: VP of Marketing

APPROVED  
*sm*  
LEGAL DEPT.





December 21, 2001

P. Andrew Pyfer  
Product Manager  
Cephalon, Inc.  
145 Brandywine Parkway  
West Chester, PA 19380

Dear Mr. Pyfer:

MediCom Worldwide is accredited by the Accreditation council for continuing Medical Education to sponsor continuing medical education for physicians and is an ACPE-approved provider of pharmacy continuing education, as well as an approved provider of nursing continuing education through the California State Board of Registered Nursing.

A comprehensive needs assessment has identified interests of health care providers who manage patients suffering from pain. Based on this educational need, we are requesting an educational grant from Cephalon, Inc. to support the development and implementation of several continuing education activities on the subjects of effective pain management techniques and the changing guidelines to improve pain management. The budget to fund these activities is approximately \$876,620.

Proposed Educational Activities

A series of educational lectures across the United States  
Production and dissemination of a News letter for pain management specialists  
Development and production of three self-study program materials in CD format  
Continuation of Pain Management web page  
Adaptation and production of self-study programs offered via the Internet  
A series of teleconference lectures across the United States

These scientific activities, developed independently and presented live as symposia in three cities and then as enduring CME material in various formats, will comply with all ACCME, FDA, AMA, and ACPE regulations for industry-supported professional continuing education. The target audience for these activities are pain management specialists, oncologists and anesthesiologists.

As a supplement to our direct mail and web site announcement of these educational activities, we request Cephalon representatives to disseminate information regarding these programs to the medical community.

However, the content of such information is the responsibility of the accredited provider and any such distribution will be solely as a supplement to provider's primary method of announcement and promotion.

101 Washington St.  
Morrisville, PA 19067  
215-337-9991

1

Thank you, in advance, for your consideration of this request. Should you agree to provide funding for this project, Letters of Agreement will be forwarded to you as soon as possible.

Respectfully,

A handwritten signature in cursive script, appearing to read "Joan Meyer".

Joan Meyer RN, MA  
Executive Director, Continuing Education



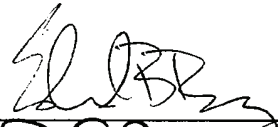
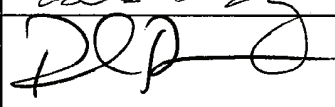
101 Washington St.  
Morrisville, PA 19067  
215-337-9991

## Cephalon Review of Education Grant

The attached Grant amount has been reviewed by members of the MEP team.

**Program Name:** Unrestricted Educational Grant:

Medicom - Educational Activities on Effective Pain Management  
Techniques and the Changing Guidelines to improve Pain Management

<u>Department</u>	<u>Name</u>	<u>Signature</u>	<u>Date</u>
Medical Affairs	Kiumars Vadieli		1-16-02
	Jess Amchin		1/21/02
Legal	Ed Berg		1/16/02
Marketing	Andy Pyfer		1/23/02
	Lynne Brookes		

Please return to Carrie Eastwick (x6532) upon completion of sign off –  
Thank you!!

Q1 438,310  
Q2 438,316  
Q0# C5125

## MEDICAL EDUCATION AGREEMENT

As a condition of Cephalon, Inc.'s contribution of funds to support an independent medical education program (with or without CME credits), the Scientific and Educational Activity provider agrees to the following terms and conditions:

This Agreement ("Agreement") is entered into as of December 21, 2001 by and between Cephalon, Inc. ("Cephalon") and MediCom Worldwide, Inc. ("Provider") regarding a series of medical education programs supported by Cephalon to be held throughout 2002. The parties' mutual objectives are to provide a balanced, independent, scientifically rigorous program to promote the education of attendees.

1. Statement of Purpose. This program is for scientific and educational purposes only and not to promote any commercial drug products.
2. Control of Content and Selection of Presenters and Moderators. The provider is ultimately responsible for the control of content and selection of presenters and moderators. Cephalon or its agents may respond to requests initiated by the provider for suggestions of presenters or sources of possible presenters. Cephalon will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Cephalon and speaker; and will provide this information in writing. Provider will seek suggestions from other sources, and will, in its sole discretion, select presenters and moderators.
3. Disclosure of Financial Relationships. Provider will direct speakers and moderators to disclose to the audience commercial support or funding or other significant financial relationships between the speakers and moderators and Cephalon and/or any other commercial company whose products are pertinent to the content of the presentation. Provider will disclose Cephalon's support at this program.
4. Involvement in Content. There will be no "scripting," emphasis, or influence on content by Cephalon or its agents. However, Cephalon may provide technical support to speakers, e.g., furnishing slides or data, upon their request.
5. Ancillary Promotional Activities. No promotional activities will be permitted in the same room as, or in the obligatory path to, the educational activity. No product advertisements will be permitted within the program or handouts.
6. Objectivity and Balance. Provider will advise presenters that data regarding Cephalon products (or competing products) are to be objectively selected and presented. Provider will provide the opportunity for speakers and the audience to discuss information, both favorable and unfavorable, about the product(s) and/or alternative treatments.
7. Limitations of Data. Provider will request the speakers, to the extent possible, to disclose limits on the data, e.g., that it involves ongoing research, interim analyses, preliminary data, or unsupported opinion.
8. Discussion of Unapproved Uses. Provider will request that presenters disclose when a product is not approved in the United States for the use under discussion.
9. Actiq® Risk Management Program. Provider is aware that Actiq (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:
  - Actiq is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.*

- Actiq is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.

10. Opportunity for Debate. Provider will ensure opportunities for questioning by attendees and scientific debate with and between presenters.

11. Independence of Provider in the Use of Contributed Funds.

(a) funds should be in the form of an educational grant made payable to the provider organization.

(b) Provider must be advised of all other support by Cephalon of the CME activity (e.g., distributing brochures, preparing slides). If Provider disapproves of this activity, it shall promptly notify Cephalon.

(c) no other funds from Cephalon will be paid to the program director, faculty, or others involved with this CME activity, e.g., additional honoraria.

12. General.

(a) Cephalon agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.

(b) Provider agrees to: (1) abide by the ACCME Standards for Commercial Support of Continuing Medical Education; (2) acknowledge educational support from Cephalon in program brochures, syllabi and other program materials; and (3) upon request, furnish Cephalon with a report concerning the expenditure of the funds provided by Cephalon.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

MEDICOM WORLDWIDE, INC.

CEPHALON, INC.

By: Joan Meyer  
 Name: Joan Meyer  
 Title: Executive Director, Cont. Ed

By: Lynne Brookes  
 Name: Lynne Brookes  
 Title: VP of Marketing

333 1/16/02



March 12, 2002

P. Andrew Pyfer  
Product Manager  
Cephalon, Inc.  
145 Brandywine Parkway  
West Chester, PA 19380

Dear Mr. Pyfer:

MediCom Worldwide is accredited by the Accreditation council for continuing Medical Education to sponsor continuing medical education for physicians and is an ACPE-approved provider of pharmacy continuing education, as well as an approved provider of nursing continuing education through the California State Board of Registered Nursing.

A comprehensive needs assessment has identified interests of health care providers who manage patients suffering from pain. Based on this educational need, we are requesting an educational grant from Cephalon, Inc. to support the development and implementation of a continuing education self-study activity on the subject of therapeutic options for the management of breakthrough pain. The budget to support this activity is approximately \$35,000.

Proposed Educational Activity

A CME self-study monograph based on relevant lectures and poster presentations at the upcoming APS meeting March 14-17, 2002.

This scientific activity, developed independently as an enduring CME self-study format, will comply with all ACCME, FDA, AMA, and ACPE regulations for industry-supported professional continuing education. The intended audience for this activity are pain management specialists, oncologists and anesthesiologists.

As a supplement to our direct mail announcements about this monograph, we request Cephalon representatives to disseminate information regarding these programs to the medical community.

However, the content of such information is the responsibility of the accredited provider and any such distribution will be solely as a supplement to provider's primary method of announcement and promotion.

Thank you, in advance, for your consideration of this request. Should you agree to provide funding for this project, Letters of Agreement will be forwarded to you as soon as possible.

Respectfully,

Joan Meyer RN, MA  
Executive Director, Continuing Education

101 Washington St.  
Morrisville, PA 19067  
215-337-9991

1

## MEDICAL EDUCATION AGREEMENT

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Morrisville, PA 19067  
215-337-9991

2



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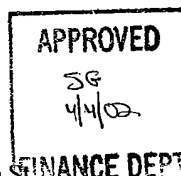
IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

MEDICOM WORLDWIDE, INC.

CEPHALON, INC.

By: *Joan Meyer*  
 Name: Joan Meyer  
 Title: Executive Director, Cont. Ed

By: *Lynne Brooks*  
 Name: Lynne Brooks  
 Title: VP of Marketing



101 Washington St  
 Morrisville, PA 19067  
 215-337-9991

3



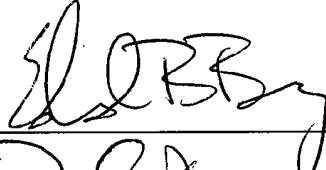
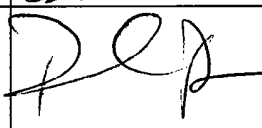
## Cephalon Review of Education Grant

The attached Grant amount has been reviewed by members of the MEP team.

**Program Name:** Unrestricted Educational Grant:

**Medicom –**

**A CME self-study monograph based on APS lectures/poster presentations**

<u>Department</u>	<u>Name</u>	<u>Signature</u>	<u>Date</u>
<b>Medical Affairs</b>	Kiumars Vadieli Jess Amchin <del>Susan Larijani</del>	 	3/21/02 4/1/02
<b>Legal</b>	Ed Berg		3/20/02
<b>Marketing</b>	Andy Pyfer Christine Wells Lynne Brookes		4/4/02

Please return to Carrie Eastwick (x6532) after review and sign off – thank you!!

A TRUE WATERMARK IS PRESENT IN THE PAPER • HOLD UP TO A LIGHT SOURCE TO VIEW

Cephalon, Inc.  
145 Brandywine Parkway  
West Chester, PA 19380

First Union  
National Bank

62-22/311

DATE

CHECK NO.

04/11/2002

00144838

Security Features  
Included


Thirty five thousand and no/100 \*\*\*\*\*

AMOUNT

\$35,000.00

PAY  
TO THE  
ORDER  
OF

MediCom Worldwide Inc  
101 Washington Ave  
Morrisville, PA 19067

  
*Charles A. Neuhart*  
AUTHORIZED SIGNATURE

MP

MP

⑈00144838⑈ ⑆031100225⑆ 2079950064057⑈

FACE OF DOCUMENT HAS A COLORED "VOID" BACKGROUND ON WHITE SECURITY PAPER

Cephalon, Inc.

145 Brandywine Parkway  
West Chester, PA 19380

04/11/2002

00144838

INVOICE NO.	DATE	DESCRIPTION	PAID AMOUNT	DISCOUNT	APPLIED AMOUNT
Med Ed Grant	'02 04/10/2002	VCH00045477	\$35,000.00		\$35,000.00

INTERNAL NO.	VENDOR #	VENDOR	TOTALS	TOTALS	TOTALS
463	MEDICOM00000	MediCom Worldwide Inc			\$35,000.00

07300U.S



## ACCOUNTS PAYABLE CHECK REQUEST



**PAYEE NAME:** MediCom Worldwide, Inc.

**ADDRESS:** 101 Washington St.  
Morrisville, PA 19067

**INVOICE NUMBER:**

**INVOICE DATE:**

**DUE DATE:** 4/12/2002

**P.O. NUMBER (if applicable):**

**DESCRIPTION:** Medical Education Grant for CME self-study monograph based on APS lectures/poster presentations

<u>G/L ACCOUNT NUMBER</u>	<u>DEPARTMENT</u>	<u>PROJECT</u>	<u>AMOUNT</u>
764000	63100	ACT00	\$ 35,000.00

**TOTAL: \$ 35,000.00**

Prepared By: Carrie Eastwick

Extension: 6532

Department Number: 63100

Approved By: \_\_\_\_\_

Print Approvers Name: Lynne Brookes

Approvers Title: VP of Marketing

*sent to acct. 4/9*

\*\*\*\*\* Mark here if the check is to be picked up by the preparer: ☒ \*\*\*\*\*

**Please note:** If there is any documentation to be mailed along with the payment, please attach a copy in addition to the copy for Accounting's records

Accounting Use Only:

Batch Number: \_\_\_\_\_

Voucher Number: \_\_\_\_\_

Entry Date: \_\_\_\_\_

4/5/2002

<b>3</b>	<b>WEIGHT</b>	<b>WEIGHT</b> ENTER "LTR" IF LETTER <div style="border: 1px solid black; padding: 5px; font-size: 1.5em;">Ltr</div>	<b>DIMENSIONAL WEIGHT</b> If Applicable	<b>SHIPPER'S COPY</b>	
	<b>4</b>	<b>TYPE OF SERVICE</b>	<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input checked="" type="checkbox"/> <b>NEXT DAY AIR</b>            For WORLDWIDE EXPRESS SHIPMENTS            Mark an "X" in this box if shipment only contains documents of no commercial value.         </div> <div style="width: 45%;"> <input type="checkbox"/> <b>EXPRESS (INTL)</b>  <input type="checkbox"/> <b>DOCUMENTS ONLY</b> </div> </div>		<b>CHARGES</b>
<b>5</b>		<b>OPTIONAL SERVICES</b>	<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input type="checkbox"/> <b>SATURDAY PICKUP</b> See instructions.           </div> <div style="width: 45%;"> <input type="checkbox"/> <b>SATURDAY DELIVERY</b> See instructions.           </div> </div>		\$ <u>          </u>
	<b>6</b>	<b>ADDITIONAL HANDLING CHARGE</b>	<input type="checkbox"/> <b>INSURED VALUE</b> Contents are automatically protected up to \$100. For insured value over \$100, see instructions.		\$ <u>          </u>
			<input type="checkbox"/> <b>C.O.D.</b> If C.O.D., enter amount to be collected and attach completed UPS C.O.D. tag to package.		\$ <u>          </u>
			<input type="checkbox"/> An Additional Handling Charge applies for certain items. See instructions.		\$ <u>          </u>
<b>7</b>	<b>TOTAL CHARGES</b>			\$ <u>          </u>	
	<b>METHOD OF PAYMENT</b>	<div style="display: flex; justify-content: space-between;"> <div style="width: 20%;"> <b>BILL SHIPPER</b>  <input checked="" type="checkbox"/> </div> <div style="width: 20%;"> <b>BILL RECEIVER</b>  <input type="checkbox"/> </div> <div style="width: 20%;"> <b>BILL THIRD PARTY</b>            DOMESTIC ONLY  <input type="checkbox"/> </div> <div style="width: 20%;"> <b>CREDIT CARD</b>  <input type="checkbox"/> </div> <div style="width: 20%;">           American Express            Diner's Club            Discover            MasterCard            Visa         </div> <div style="width: 20%;"> <b>CHECK</b>  <input type="checkbox"/> </div> </div> <div style="margin-top: 5px; font-size: 0.8em;"> <input type="checkbox"/> RECORD ACCOUNT NO. IN SECTION 8         </div>			
<b>8 RECEIVERS / THIRD PARTY'S UPS ACCT. NO. OR MAJOR CREDIT CARD NO.</b>				<b>EXPIRATION DATE</b> <div style="border: 1px solid black; height: 20px; width: 100%;"></div>	
<b>THIRD PARTY'S COMPANY NAME</b>					
<b>STREET ADDRESS</b>					
<b>CITY AND STATE</b>				<b>ZIP CODE</b>	
The shipper authorizes UPS to act as forwarding agent for export control and customs purposes. The shipper certifies that these commodities, technology or software were exported from the United States in accordance with the Export Administration Regulations. Overseen country to U.S. law is prohibited.					
<b>9</b>	<b>SHIPPER'S SIGNATURE</b> <span style="font-size: 1.5em; vertical-align: middle;">X</span> <span style="font-family: cursive; font-size: 1.2em; vertical-align: middle;">Ann Fashick</span>				
				<b>DATE OF SHIPMENT</b> <div style="font-size: 1.5em; font-family: cursive;">4/15/02</div>	
0101911202609 11:00 W					

## UPS WORLDWIDE EXPRESS TERMS AND CONDITIONS

United Parcel Service through its affiliates (the "carrier") is engaged in the international transportation of small packages in UPS Worldwide Express. Each package shall be considered a separate and distinct shipment.

**Commodities Handled and Restrictions upon Service**

The carrier offers transportation of general commodities, as usually defined, subject to the following restrictions:

(a) No service shall be rendered in the transportation of, and shippers are prohibited from shipping, articles of unusual value. Packages having a value of more than \$50,000 (U.S.) - \$500 (U.S.) for packages containing jewelry (not including costume jewelry) or packages shipped via a UPS Letter Center - are prohibited from being shipped and will not be accepted for transportation. The maximum value per package is \$50,000 (U.S.) except for packages containing jewelry (not including costume jewelry) of packages shipped via a UPS Letter Center, in which case the maximum value per package is \$500 (U.S.). The maximum liability per package assumed by UPS shall not exceed \$100 (U.S.) regardless of the purchase of insurance for protection in excess of \$100 (U.S.). The maximum liability per package assumed by the applicable insurance company shall not exceed \$50,000 (U.S.) (less \$100), except for packages containing jewelry (not including costume jewelry) or packages shipped via a UPS Letter Center, in which case the maximum liability assumed by the applicable insurance company shall not exceed \$500 (U.S.) (less \$100), regardless of the value in excess of the maximum.

(b) Refer to the applicable service guide for weight and size restrictions.

(c) No service shall be rendered in the transportation of any of the prohibited articles listed in the applicable service guide.

(d) The carrier does not provide a protective service for the transportation of perishable commodities or of commodities requiring protection from heat or cold. Such commodities will be accepted for transportation solely at the shipper's risk for damage, notwithstanding exposure to heat or cold.

**Prohibited by Law**

No service shall be rendered by the carrier in the transportation of any shipment which is prohibited by law or regulation of any federal, state, provincial, or local government in the origin or destination countries.

**Right of Inspection**

The carrier reserves the right to open and inspect any package tendered to it for transportation.

**Refusal of Packages**

The carrier reserves the right to refuse any package which by reason of the dangerous or any other character of its contents is liable in the judgment of the carrier, to soil, stain, or otherwise damage other merchandise or equipment, or which is economically or operationally impracticable to transport, or which is improperly packed or wrapped.

Packages must be so packed or wrapped as to pass the tests set forth in the International Safe Transit Association Procedure 1-A.

**Services Not Provided**

C.O.D., C.O. Tag, and Delivery Confirmation services are not provided for international shipments.

**Provisions for Customs Clearance**

The shipper must provide required documentation for customs clearance. By providing required documentation, the shipper certifies that all statements and information relating to exportation and importation are true and correct. Furthermore, the shipper understands that civil and criminal penalties, including forfeiture and sale may be imposed for making false or fraudulent statements, or for the violation of U.S. laws on exportation (see 18 U.S.C. Section 325, 22 U.S.C. Section 481, 18 U.S.C. Section 1001, and 50 U.S.C. App. 2410).

When a shipment is tendered to the carrier, the carrier is thereby appointed as the agent for performance of customs clearance, where required by law. The carrier is specified as the nominal consignee for the purpose of designating a customs broker to perform customs clearance. Local authorities may require documentation confirming that the carrier has been designated as the nominal consignee.

Customs penalties, storage charges, or other expenses incurred as a result of an action by Customs or failure by the shipper or consignee to provide proper documentation or to obtain a required license or permit will be charged to the consignee along with any applicable duty and tax. However, the shipper is liable for payment in the event of non-payment by the consignee. The carrier provides brokerage service at no additional charge for routine customs clearance of Express and Expedited shipments. Additional charges may apply for complex customs clearance procedures which include, but are not limited to, the following:

- Customs procedures involving a government agency other than Customs
- Customs Bonds
- Drawbacks
- Forms not involving more than five tariff lines
- Live Animals
- Marking Attendance
- Temporary Import Bonds (T.I.B.)

**Correction of Wrong Address**

If UPS is unable to deliver any package because of an incorrect address, UPS will make reasonable efforts, to be determined in its sole discretion, to secure the correct address. If the correct address is secured and found to be in the same destination country, the shipper will be notified of the correction, and an additional charge, as stated on the then current rate chart, will be assessed for delivery or attempted delivery to the correct address.

**Postal Code and Telephone Number**

The consignee's postal code, telephone number, and contact name are essential information. To ensure prompt delivery, shippers include postal code, telephone number, and contact name on the UPS Air Shipping Document.

**Delivery Attempts**

If the carrier is unable to make delivery of a shipment, a non-delivery notice will be left at the consignee's address stating that delivery has been attempted. Thereafter, a second, and, if necessary, a third attempt to deliver will be made without additional charge.

**Interruption of Service**

The carrier shall not be liable for any interruption of delivery service due to a cause beyond the carrier's control, or to strikes, lockouts, or labor disputes.

**Return of Undeliverable Packages**

Air shipments refused by consignees, or which for any other reason cannot be delivered, will be held and the shipper will be contacted for further instructions. The shipper will be responsible for payment of all other charges including, but not limited to, forwarding, disposal, or return air transportation charges, as well as any duty and tax, if applicable.

**Rates**

See the applicable rate chart in effect at the time of shipping for rates. Transportation charges, except the charge for UPS Letters, are based on the gross weight of the shipment or the dimension (volumetric) weight of the shipment, whichever is greater. Dimensional weight is based on the current International Air Transport Association (IATA) volumetric standard, which is subject to change without notice. When the dimensional weight of a shipment exceeds the actual weight, the shipment must be recorded on a UPS Waybill. Fractions of a pound will be increased to the next full pound.

**Payment for Service**

The carrier's credit terms require payment of all charges within seven (7) days after receipt of carrier's bill. When using a UPS Air Shipping Document, all UPS Worldwide Express shipments are prepaid and all charges must be paid by the shipper.

**Worldwide Express Service Guarantee**

The carrier guarantees on-schedule delivery of all UPS Worldwide Express Service shipments. In the event the carrier fails to complete delivery or attempt delivery within the carrier's time commitment, the carrier, at the carrier's option, will credit or refund the shipping charges to the payor upon request, subject to the following conditions:

- (a) The carrier's guaranteed delivery schedule has been obtained by contacting the carrier's Customer Service office.
  - (b) The package bears a properly completed UPS Air Shipping Document showing the consignee's correct name, deliverable address, and postal code.
  - (c) The shipment is tendered to the carrier during the carrier's published business hours.
  - (d) All applicable documentation required by the origin and/or destination country is completed and included with the shipment.
  - (e) The carrier is notified in writing or by telephone of a service failure within fifteen (15) calendar days from the date of scheduled delivery and is advised of the consignee's name and address, date of shipment, package weight, and the UPS Tracking Number.
- The guarantee does not apply to shipments which are delayed due to causes beyond the carrier's control including, but not limited to, the following: The unavailability or refusal of a person to accept delivery of the shipment; acts of God, public authorities acting with actual or apparent authority on the premises, acts or omissions of Customs or similar authorities; failure by the shipper or consignee to provide proper documentation, riots, strikes or other labor disputes, civil commotions, disruptions in air or ground transportation networks, such as weather phenomena, and natural disasters.

The carrier provides optional Saturday delivery to specific international destinations. Contact your UPS Customer Service office (1-800-782-7692) for destinations served and complete guarantee and time-in-transit details. The shipment must be recorded on a UPS Waybill to receive Saturday delivery.

**Responsibility for Loss or Damage**

Each UPS Letter or package is automatically protected by UPS against loss or damage up to a value of \$100. Unless a greater value is recorded in the insured value field as appropriate for the UPS shipping system used, the shipper agrees that the released value of each package or Letter is no greater than \$100, which is a reasonable value under the circumstances surrounding the transportation. UPS's maximum liability per package or Letter shall not exceed \$100, regardless of the purchase of insurance for protection in excess of \$100. If additional protection is desired, a shipper may purchase insurance for amounts in excess of \$100 by showing the full value in the insured value field, as appropriate for the UPS shipping system used. An insurance premium, as established by the insurer of the shipment, will be assessed for each additional \$100, or fraction thereof, of insured value in excess of \$100 up to the limits of insurance, and the shipper will be automatically covered as an additional insured under a shipper's interest insurance policy issued to UPS as the named insured, provided the shipper pays the additional charge. Insurance is not provided for UPS Prepaid Letters. For more information on the terms and conditions of this insurance, call 1-877-242-7930 to obtain an Excess Value Insurance brochure. Claims for loss of, or damage to, the shipper's property will be filed with UPS. Claims not made within six (6) months after delivery of the package, or in the case of non-delivery, within six (6) months after a reasonable time for delivery has elapsed, shall be deemed waived. The carrier shall not be liable for any special, incidental, or consequential damages.

All shipments are subject to the terms and conditions contained in the UPS Tariff, which can be found at [www.ups.com](http://www.ups.com).

THE RULES RELATING TO LIABILITY ESTABLISHED BY THE WARSAW CONVENTION AND ANY AMENDMENTS THERETO SHALL APPLY TO THE INTERNATIONAL CARRIAGE OF ANY SHIPMENT HEREUNDER INsofar AS THE SAME IS GOVERNED THEREBY.

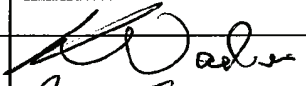

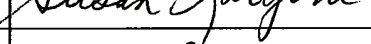
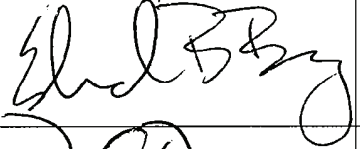

## Cephalon Review of Education Grant

The attached Grant amount has been reviewed by members of the MEP team.

**Program Name:** Unrestricted Educational Grant:

**Medicom Worldwide, Inc.**

**2003 Educational Activities for Pain Management**

<u>Department</u>	<u>Name</u>	<u>Signature</u>	<u>Date</u>
Medical Affairs	Kiumars Vadiel		4/7/03
	Jess Amchin		4/2/03
	Susan Larijani		4/2/03
Legal	Ed Berg		3/28/03
Marketing	Andy Pyfer Christine Wells Paula Castagno		4/8/03





January 23, 2003

P. Andrew Pyfer  
Product Director  
Cephalon, Inc.  
145 Brandywine Parkway  
West Chester, PA 19380

Dear Mr. Pyfer:

MediCom Worldwide is accredited by the Accreditation council for continuing Medical Education to sponsor continuing medical education for physicians and is an ACPE-approved provider of pharmacy continuing education, as well as an approved provider of nursing continuing education through the California State Board of Registered Nursing.

A comprehensive needs assessment has identified interests of health care providers who manage patients suffering from pain. Based on this educational need, we are requesting an educational grant from Cephalon, Inc. to support the development and implementation of several continuing education activities on the subjects of effective pain management techniques and the changing guidelines to improve pain management. The budget to fund these activities is approximately \$2,252,000.

Proposed Educational Activities for Pain Management

A series of approximately 300 CME lectures across the United States  
Establishment of a speaker bureau for clinical experts in pain management  
Development and implementation of a web-based speaker engagement system  
Development, production, and certification of CME slide content for five topics  
Development and production of CME slide kit on CD for faculty lectures  
Development, production, and implementation of web-based CME slide library for faculty

These scientific activities, will be developed independently and then adapted to enduring CME material in various formats, and will comply with all ACCME, FDA, AMA, and ACPE regulations for industry-supported professional continuing education. The target audience for these activities are pain management specialists, oncologists and anesthesiologists.

As a supplement to our direct mail and web site announcement of these educational activities, we request Cephalon representatives to disseminate information regarding these programs to the medical community.

However, the content of such information is the responsibility of the accredited provider and any such distribution will be solely as a supplement to provider's primary method of announcement and promotion.

101 Washington St.  
Morrisville, PA 19067  
215-337-9991

1

Thank you, in advance, for your consideration of this request. Should you agree to provide funding for this project, Letters of Agreement will be forwarded to you as soon as possible.

Respectfully,

A handwritten signature in cursive script, appearing to read "Joan Meyer".

Joan Meyer RN, MA  
Executive Director, Continuing Education

101 Washington St.  
Morrisville, PA 19067  
215-337-9991



## MEDICAL EDUCATION AGREEMENT

As a condition of Cephalon, Inc.'s contribution of funds to support a series of independent medical education programs (with CME credits), the Scientific and Educational Activity provider agrees to the following terms and conditions:

This Agreement ("Agreement") is entered into as of January 27, 2003, by and between Cephalon, Inc. ("Cephalon") and MediCom Worldwide, Inc. ("Provider") regarding a series of medical education programs supported by Cephalon to be held throughout 2003. The parties' mutual objectives are to provide a balanced, independent, scientifically rigorous program to promote the education of attendees. The amount of the educational grant requested is \$2,252,000.00.

1. Statement of Purpose. This program is for scientific and educational purposes only and not to promote any commercial drug products.

2. Control of Content and Selection of Presenters and Moderators. The provider is ultimately responsible for the control of content and selection of presenters and moderators. Cephalon or its agents may respond to requests initiated by the provider for suggestions of presenters or sources of possible presenters. Cephalon will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Cephalon and speaker; and will provide this information in writing. Provider will seek suggestions from other sources, and will, in its sole discretion, select presenters and moderators.

3. Disclosure of Financial Relationships. Provider will direct speakers and moderators to disclose to the audience commercial support or funding or other significant financial relationships between the speakers and moderators and Cephalon and/or any other commercial company whose products are pertinent to the content of the presentation. Provider will disclose Cephalon's support at this program.

4. Involvement in Content. There will be no "scripting," emphasis, or influence on content by Cephalon or its agents. However, Cephalon may provide technical support to speakers, e.g., furnishing slides or data, upon their request.

5. Ancillary Promotional Activities. No promotional activities will be permitted in the same room as, or in the obligatory path to, the educational activity. No product advertisements will be permitted within the program or handouts.

6. Objectivity and Balance. Provider will advise presenters that data regarding Cephalon products (or competing products) are to be objectively selected and presented. Provider will provide the opportunity for speakers and the audience to discuss information, both favorable and unfavorable, about the product(s) and/or alternative treatments.

7. Limitations of Data. Provider will request the speakers, to the extent possible, to disclose limits on the data, e.g., that it involves ongoing research, interim analyses, preliminary data, or unsupported opinion.

8. Discussion of Unapproved Uses. Provider will request that presenters disclose when a product is not approved in the United States for the use under discussion.

9. Actiq® Risk Management Program. Provider is aware that Actiq (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- Actiq is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.*
- Actiq is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.

10. Opportunity for Debate. Provider will ensure opportunities for questioning by attendees and scientific debate with and between presenters.

11. Independence of Provider in the Use of Contributed Funds.

(a) funds should be in the form of an educational grant made payable to the provider organization.

(b) Provider must be advised of all other support by Cephalon of the CME activity (e.g., distributing brochures, preparing slides). If Provider disapproves of this activity, it shall promptly notify Cephalon.

(c) no other funds from Cephalon will be paid to the program director, faculty, or others involved with this CME activity, e.g., additional honoraria.

12. General.

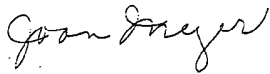
(a) Cephalon agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.

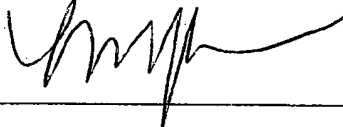
(b) Provider agrees to: (1) abide by the ACCME Standards for Commercial Support of Continuing Medical Education; (2) acknowledge educational support from Cephalon in program brochures, syllabi, and other program materials; and (3) upon request, furnish Cephalon with a report concerning the expenditure of the funds provided by Cephalon.

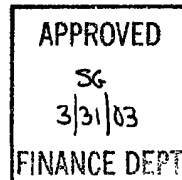
IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

MEDICOM WORLDWIDE, INC.  
INC.

CEPHALON,

By:   
Name: Joan Meyer  
Title: Executive Director, Cont. Ed  
Date: January 27, 2003

By:   
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_





145 BRANDYWINE PARKWAY  
WEST CHESTER, PENNSYLVANIA 19380  
(610) 344-0200  
FAX (610) 738-6311

## PURCHASE ORDER

No.

Show this Purchase Order Number  
on all correspondence, invoices,  
shipping papers and packages.

DIRECT ALL INVOICES TO ACCOUNTS PAYABLE DEPARTMENT

NOT VALID UNTIL A NUMBER IS ASSIGNED!

TODAY'S DATE

DATE REQUIRED

4/28/03

SHIP TO

CEPHALON, INC.

145 BRANDYWINE PARKWAY

WEST CHESTER, PA 19380

ATTN: Suzanne Richards  
ext 6532

Fax: 215-337-0960  
TO Medicom Worldwide, Inc.  
101 Washington Street  
Morrisville, PA 19067

QTY ORDERED	UNIT OF MEASURE	DEPT. CODE G/L ACCT.	PROJECT/ CAPITAL CODE	STOCK NO./DESCRIPTION	UNIT PRICE	TOTAL
86		631/ 7640	ACTQ	2003 Educational Activities for Pain Management  - Split Payment 1/2 Quarter 3 1/2 Quarter 4		1,502,000.00
ORDER PROCESSOR		DATE ORDERED		BUYER	SHIP VIA	TOTAL EXTENDED PRICE
				5/6/03		1,502,000.00

1. Please send one copy of your invoice.
2. Order is to be entered in accordance with prices, delivery and specifications shown above.
3. Notify us immediately if you are unable to ship as specified.

AUTHORIZED BY

Confidential

TEVA\_MDL\_A\_01850612

P-29481 \_ 00877



145 BRANDYWINE PARKWAY  
WEST CHESTER, PENNSYLVANIA 19380  
(610) 344-0200  
FAX (610) 738-6311

## PURCHASE ORDER

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DIRECT ALL INVOICES TO ACCOUNTS PAYABLE DEPARTMENT

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TODAY'S DATE

DATE REQUIRED

4/28/03

SHIP TO

CEPHALON, INC.

145 BRANDYWINE PARKWAY

WEST CHESTER, PA 19380

ATTN: Suzanne Richards  
ext. 6532

TO Fax: 215-337-0960  
Medicom Worldwide, Inc.  
101 Washington Street  
Morrisville, PA 19067

QTY ORDERED	UNIT OF MEASURE	DEPT. CODE G/L ACCT.	PROJECT/ CAPITAL CODE	STOCK NO./DESCRIPTION	UNIT PRICE	TOTAL
		6311 7640	ACTQ	2003 Educational Activities for Pain Management  - Split Payment 1/2 Quarter 3 1/2 Quarter 4		1,502,000.00
ORDER PROCESSOR		DATE ORDERED		BUYER	SHIP VIA	
					TOTAL EXTENDED PRICE	1,502,000.00

gave to B. Roche  
4/29/03

- Please send one copy of your invoice.
- Order is to be entered in accordance with prices, delivery and specifications shown above.
- Notify us immediately if you are unable to ship as specified.

AUTHORIZED BY



Q2 payment  
sent 5/1/03

A TRUE WATERMARK IS PRESENT IN THE PAPER • HOLD UP TO A LIGHT SOURCE TO VIEW

Cephalon, Inc.

145 Brandywine Parkway  
West Chester, PA 19380

First Union  
National Bank

02-27-011

DATE

CHECK NO.

04/25/2003

00152752

Seven hundred fifty thousand six hundred sixty seven and no/100 \*\*\*\*\*

PAY  
TO THE  
ORDER  
OF

MediCom Worldwide Inc  
101 Washington Ave  
Morrisville, PA 19067

\$750,667.00

*[Signature]*  
Charles A. Reinhardt III  
AUTHORIZED SIGNATURE

⑈00152752⑈ ⑆031100225⑆ 207995006405⑈

FACE OF DOCUMENT HAS A COLORED "VOID" BACKGROUND ON WHITE SECURITY PAPER

Cephalon, Inc.

145 Brandywine Parkway  
West Chester, PA 19380

04/25/2003

00152752

INVOICE NO	DATE	DESCRIPTION	PAID AMOUNT	DISCOUNT	APPLIED AMOUNT
2003-ED-AC-11111	04/22/2003	VCH00059465	\$750,667.00		\$750,667.00
INTERNAL NO.	VENDOR #	VENDOR	TOTALS	TOTALS	TOTALS
533	MEDICOM00000	MediCom Worldwide Inc			\$750,667.00



# ACCOUNTS PAYABLE CHECK REQUEST



**PAYEE NAME:** Medicom Worldwide, Inc.

**ADDRESS:** 101 Washington Street  
Morrisville, PA 19067

**INVOICE NUMBER:** n/a

**INVOICE DATE:** n/a

**DUE DATE:** n/a

**P.O. NUMBER (if applicable):**

**DESCRIPTION:** 2003 Educational Activities for Pain Management

<u>G/L ACCOUNT NUMBER</u>	<u>DEPARTMENT</u>	<u>PROJECT</u>	<u>AMOUNT</u>
7640	63100	ACTQ	\$ 750,667.00

**TOTAL: \$ 750,667.00**

Prepared By: Suzanne Richards

Extension: 6532

Department Number: 63100

Approved By: \_\_\_\_\_

Print Approvers Name: Bob Roche and Charlie Reinhart

Approvers Title: \_\_\_\_\_

*[Handwritten signatures and initials]*  
*SG Charles A. Reinhart III 4/17/03*

\*\*\*\*\* Mark here if the check is to be picked up by the preparer: ☒ \*\*\*\*\*

**Please note:** If there is any documentation to be mailed along with the payment, please attach a copy in addition to the copy for Accounting's records

Accounting Use Only:

Batch Number: \_\_\_\_\_

Voucher Number: \_\_\_\_\_

Entry Date: \_\_\_\_\_

4/16/2003



# ACCOUNTS PAYABLE CHECK REQUEST



**PAYEE NAME:** Medicom Worldwide Inc.

**ADDRESS:** 101 Washington Street  
Morrisville, PA 19067

**INVOICE NUMBER:** n/a

**INVOICE DATE:** n/a

**DUE DATE:** n/a

**P.O. NUMBER (if applicable):** n/a

**DESCRIPTION:** 2003 Educational Activities for Pain Management

<u>G/L ACCOUNT NUMBER</u>	<u>DEPARTMENT</u>	<u>PROJECT</u>	<u>AMOUNT</u>
7640	63100	ACTQ	\$ 2,252,000.00

**TOTAL: \$ 2,252,000.00**

Prepared By: Suzanne Richards

Extension: 6532

Department Number: 63100

Approved By: \_\_\_\_\_

Print Approvers Name:

Approvers Title:

\*\*\*\*\* Mark here if the check is to be picked up by the preparer: ☒ \*\*\*\*\*

**Please note:** If there is any documentation to be mailed along with the payment, please attach a copy in addition to the copy for Accounting's records

Accounting Use Only:

Batch Number: \_\_\_\_\_

Voucher Number: \_\_\_\_\_

Entry Date: \_\_\_\_\_

4/8/2003

**FedEx** *USA Airbill*  
Express
FedEx  
Tracking  
Number

8388 9629 2066

**1 From** Please print and press hard.

Date 5/1/03 Sender's FedEx Account Number 1161-3887-5

Sender's Name Suzanne Richards Phone (610) 344-0200

Company CEPHALON INC

Address 145 BRANDYWINE PKWY

City WEST CHESTER State PA ZIP 19380

**2 Your Internal Billing Reference** First 24 characters will appear on invoice. OPTIONAL

**3 To**

Recipient's Name Joan Meyer, RN Phone (215) 337-9991

Company MediCom Worldwide

Address 101 Washington Ave.

To "HOLD" at FedEx location, print FedEx address. We cannot deliver to P.O. boxes or P.O. ZIP codes.

Address \_\_\_\_\_

City Morrisville State PA ZIP 19067

**Try online shipping at [fedex.com](http://fedex.com)**

By using this Airbill you agree to the service conditions on the back of this Airbill and in our current Service Guide, including terms that limit our liability.

**Questions? Visit our Web site at [fedex.com](http://fedex.com)**  
or call 1.800.Go.FedEx® 800.463.3339.



**4a Express Package Service** Packages up to 150 lbs. Delivery commitment may be later in some areas.

☐ FedEx Priority Overnight Next business morning ☒ FedEx Standard Overnight Next business afternoon ☐ FedEx First Overnight Earliest next business morning delivery to select locations

☐ FedEx 2Day Second business day ☐ FedEx Express Saver Third business day

FedEx Envelope rate not available. Minimum charge: One-pound rate.

**4b Express Freight Service** Packages over 150 lbs. Delivery commitment may be later in some areas.

☐ FedEx 1Day Freight\* Next business day ☐ FedEx 2Day Freight Second business day ☐ FedEx 3Day Freight Third business day

\* Call for Confirmation.

**5 Packaging** \* Declared value limit \$500

☒ FedEx Envelope\* ☐ FedEx Pak\* Includes FedEx Small Pak, FedEx Large Pak, and FedEx Sturdy Pak ☐ Other

**6 Special Handling** Include FedEx address in Section 3.

☐ SATURDAY Delivery Available ONLY for FedEx Priority Overnight and FedEx 2Day to select ZIP codes ☐ HOLD Weekday at FedEx Location NOT Available for FedEx First Overnight ☐ HOLD Saturday at FedEx Location Available ONLY for FedEx Priority Overnight and FedEx 2Day to select locations

Does this shipment contain dangerous goods?  
One box must be checked.

☒ No ☐ Yes As per attached Shipper's Declaration ☐ Yes Shipper's Declaration not required ☐ Dry Ice Dry Ice, 9, UN 1845 x \_\_\_\_\_ kg

Dangerous Goods (including Dry Ice) cannot be shipped in FedEx packaging. ☐ Cargo Aircraft Only

**7 Payment Bill to:** Enter FedEx Acct. No. or Credit Card No. below.

☒ Sender Acct. No. in Section 1 will be billed. ☐ Recipient ☐ Third Party ☐ Credit Card ☐ Cash/Check

FedEx Acct. No. \_\_\_\_\_ Exp. Date \_\_\_\_\_

Total Packages	Total Weight	Total Declared Value†
		\$ .00

† Our liability is limited to \$100 unless you declare a higher value. See back for details. FedEx Use Only

**8 Release Signature** Sign to authorize delivery without obtaining signature.

*S. Richards*

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.

447

0238273755

SRS • Rev. Date 4/02 • Part #1576105 • ©1994-2002 FedEx • PRINTED IN U.S.A.

PULL AND RETAIN THIS COPY BEFORE AFFIXING TO THE PACKAGE.

07300V.12

## Terms And Conditions

**Definitions** On this Airbill, "we," "our," and "us" refer to Federal Express Corporation, its employees, and agents. "You" and "your" refer to the sender, its employees, and agents.

**Agreement To Terms** By giving us your package to deliver, you agree to all the terms on this Airbill and in our current Service Guide, which is available on request. You also agree to those terms on behalf of any third party with an interest in the package. If there is a conflict between the Service Guide and this Airbill, the Service Guide will control. No one is authorized to change the terms of our Agreement.

**Responsibility For Packaging And Completing Airbill** You are responsible for adequately packaging your goods and properly filling out this Airbill. If you omit the number of packages and/or weight per package, our billing will be based on our best estimate of the number of packages we received and/or an estimated "default" weight per package as determined by us.

**Responsibility For Payment** Even if you give us different payment instructions, you will always be primarily responsible for all delivery costs, as well as any cost we incur in either returning your package to you or warehousing it pending disposition.

### Limitations On Our Liability And Liabilities Not Assumed

- Our liability in connection with this shipment is limited to the lesser of your actual damages or \$100, unless you declare a higher value, pay an additional charge, and document your actual loss in a timely manner. You may pay an additional charge for each additional \$100 of declared value. The declared value does not constitute, nor do we provide, cargo liability insurance.
- In any event, we will not be liable for any damage, whether direct, incidental, special, or consequential in excess of the declared value of a shipment, whether or not Federal Express had knowledge that such damages might be incurred including but not limited to loss of income or profits.

### We won't be liable:

- for your acts or omissions, including but not limited to improper or insufficient packing, securing, marking, or addressing, or those of the recipient or anyone else with an interest in the package;
- if you or the recipient violates any of the terms of our Agreement.
- for loss or damage to shipments of prohibited items.
- for loss, damage, or delay caused by events we cannot control, including but not limited to acts of God, perils of the air, weather conditions, acts of public enemies, war, strikes, civil commotions, or acts of public authorities with actual or apparent authority.

### Declared Value Limits

- The highest declared value allowed for a FedEx Envelope and FedEx Pak shipment is \$500.
- For other shipments, the highest declared value allowed is \$50,000 unless your package contains items of extraordinary value, in which case the highest declared value allowed is \$500.
- Items of extraordinary value include shipments containing such items as artwork, jewelry, furs, precious metals, negotiable instruments, and other items listed in our Service Guide.
- You may send more than one package on this Airbill and fill in the total declared value for all packages, not to exceed the \$100, \$500, or \$50,000 per package limit described above. (Example: 5 packages can have a total declared value of up to \$250,000.) In that case, our liability is limited to the actual value of the package(s) lost or damaged, but may not exceed the maximum allowable declared value(s) or the total declared value, whichever is less. You are responsible for proving the actual loss or damage.

**Filing A Claim** YOU MUST MAKE ALL CLAIMS IN WRITING and notify us of your claim within strict time limits set out in the current Service Guide.

You may call our Customer Service department at 1.800.Go.FedEx® 800.463.3339 to report a claim; however, you must still file a timely written claim.

Within 90 days after you notify us of your claim, you must send us all the information you have about it. We aren't obligated to act on any claim until you have paid all transportation charges, and you may not deduct the amount of your claim from those charges.

If the recipient accepts your package without noting any damage on the delivery record, we will assume the package was delivered in good condition. For us to process your claim, you must make the original shipping cartons and packing available for inspection.

**Right To Inspect** We may, at our option, open and inspect your packages before or after you give them to us to deliver.

**Right Of Rejection** We reserve the right to reject a shipment when such shipment would be likely to cause delay or damage to other shipments, equipment, or personnel; or if the shipment is prohibited by law; or if the shipment would violate any terms of our Airbill or our current Service Guide.

**C.O.D. Services** C.O.D. SERVICE IS NOT AVAILABLE WITH THIS AIRBILL. If C.O.D. Service is required, please use a Federal Express C.O.D. Airbill.

**Air Transportation Tax Included** A federal excise tax when required by the Internal Revenue Code on the air transportation portion of this service, if any, is paid by us.

**Money-Back Guarantee** In the event of untimely delivery, Federal Express will, at your request and with some limitations, refund or credit all transportation charges. See current Service Guide for more information.

Part #157610 • Rev. 4/02

01/05/02

07300V.13





101 Washington Street  
Morrisville, PA 19067

Tel 215-337-9991  
800-408-4242  
Fax 215-337-0960

Website [www.MedicalEd.com](http://www.MedicalEd.com)

January 23, 2003

P. Andrew Pyfer  
Product Director  
Cephalon, Inc.  
145 Brandywine Parkway  
West Chester, PA 19380

Dear Mr. Pyfer:

MediCom Worldwide is accredited by the Accreditation council for continuing Medical Education to sponsor continuing medical education for physicians and is an ACPE-approved provider of pharmacy continuing education, as well as an approved provider of nursing continuing education through the California State Board of Registered Nursing.

A comprehensive needs assessment has identified interests of health care providers who manage patients suffering from pain. Based on this educational need, we are requesting an educational grant from Cephalon, Inc. to support the development and implementation of several continuing education activities on the subjects of effective pain management techniques and the changing guidelines to improve pain management. The budget to fund these activities is approximately \$134,375.00.

Proposed Educational Activity – AAPM 2003

Development, production, and submission of CME slide content to AAPM  
Development and production of CME slides for faculty lectures  
Coordination of faculty, content, meeting arrangements  
Travel/accommodations for faculty  
Design/production of invitations, posters, participant handouts  
Direct mail management, door-drops at hotels  
Premeeting registration  
Onsite meeting registration  
Onsite meeting management

This scientific activity, will be developed independently and will comply with all ACCME, FDA, AMA, and ACPE regulations for industry-supported professional continuing education. The target audience for these activities are pain management specialists and anesthesiologists.

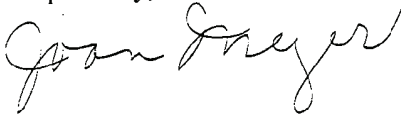
However, the content of such information is the responsibility of the accredited provider and any such distribution will be solely as a supplement to provider's primary method of announcement and promotion.

101 Washington St.  
Morrisville, PA 19067  
215-337-9991

1

Thank you, in advance, for your consideration of this request. Should you agree to provide funding for this project, Letters of Agreement will be forwarded to you as soon as possible.

Respectfully,

A handwritten signature in cursive script, appearing to read "Joan Meyer".

Joan Meyer RN, MA  
Executive Director, Continuing Education

101 Washington St.  
Morrisville, PA 19067  
215-337-9991



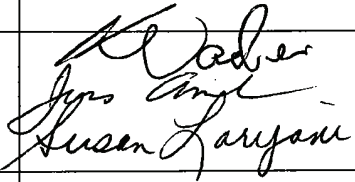
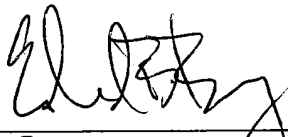

## Cephalon Review of Education Grant

The attached Grant amount has been reviewed by members of the MEP team.

**Program Name:** Unrestricted Educational Grant:

**Medicom Worldwide, Inc.**

**2003 Educational Activities for Pain Management**

<u>Department</u>	<u>Name</u>	<u>Signature</u>	<u>Date</u>
Medical Affairs	Kiumars Vadiiei Jess Amchin Susan Larijani		4-1-03 4/2/03 4/2/03
Legal	Ed Berg		3/28/03
Marketing	Andy Pyfer Christine Wells Paula Castagno		4/8/03



07300W.4

101 Washington Street  
Morrisville, PA 19067

Tel 215-337-9991  
800-408-4242  
Fax 215-337-0960

Website [www.MedicalEd.com](http://www.MedicalEd.com)

## MEDICAL EDUCATION AGREEMENT

As a condition of Cephalon, Inc.'s contribution of funds to support an independent medical education program (with CME credits), the Scientific and Educational Activity provider agrees to the following terms and conditions:

This Agreement ("Agreement") is entered into as of February 3, 2003 by and between Cephalon, Inc. ("Cephalon") and MediCom Worldwide, Inc. ("Provider") regarding a medical education program supported by Cephalon to be held at AAPM in 2003. The parties' mutual objectives are to provide a balanced, independent, scientifically rigorous program to promote the education of attendees. The amount of the educational grant requested is \$134,375.00.

1. Statement of Purpose. This program is for scientific and educational purposes only and not to promote any commercial drug products.
2. Control of Content and Selection of Presenters and Moderators. The provider is ultimately responsible for the control of content and selection of presenters and moderators. Cephalon or its agents may respond to requests initiated by the provider for suggestions of presenters or sources of possible presenters. Cephalon will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Cephalon and speaker; and will provide this information in writing. Provider will seek suggestions from other sources, and will, in its sole discretion, select presenters and moderators.
3. Disclosure of Financial Relationships. Provider will direct speakers and moderators to disclose to the audience commercial support or funding or other significant financial relationships between the speakers and moderators and Cephalon and/or any other commercial company whose products are pertinent to the content of the presentation. Provider will disclose Cephalon's support at this program.
4. Involvement in Content. There will be no "scripting," emphasis, or influence on content by Cephalon or its agents. However, Cephalon may provide technical support to speakers, e.g., furnishing slides or data, upon their request.
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7. Limitations of Data. Provider will request the speakers, to the extent possible, to disclose limits on the data, e.g., that it involves ongoing research, interim analyses, preliminary data, or unsupported opinion.

8. Discussion of Unapproved Uses. Provider will request that presenters disclose when a product is not approved in the United States for the use under discussion.

9. Actiq® Risk Management Program. Provider is aware that Actiq (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- Actiq is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- Actiq is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.

10. Opportunity for Debate. Provider will ensure opportunities for questioning by attendees and scientific debate with and between presenters.

11. Independence of Provider in the Use of Contributed Funds.

(a) funds should be in the form of an educational grant made payable to the provider organization.

(b) Provider must be advised of all other support by Cephalon of the CME activity (e.g., distributing brochures, preparing slides). If Provider disapproves of this activity, it shall promptly notify Cephalon.

(c) no other funds from Cephalon will be paid to the program director, faculty, or others involved with this CME activity, e.g., additional honoraria.

12. General.

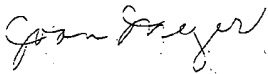
(a) Cephalon agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.

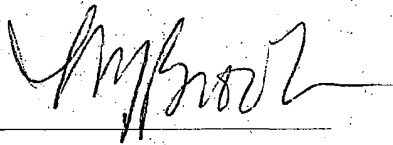
(b) Provider agrees to: (1) abide by the ACCME Standards for Commercial Support of Continuing Medical Education; (2) acknowledge educational support from Cephalon in program brochures, syllabi, and other program materials; and (3) upon request, furnish Cephalon with a report concerning the expenditure of the funds provided by Cephalon.

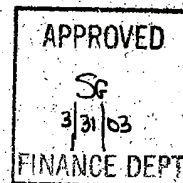
IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

MEDICOM WORLDWIDE, INC.

CEPHALON, INC.

By:   
Name: Joan Meyer  
Title: Executive Director, Cont. Ed  
Date: February 3, 2003

By:   
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_





A TRUE WATERMARK IS PRESENT IN THE PAPER • HOLD UP TO A LIGHT SOURCE TO VIEW

Cephalon, Inc.  
145 Brandywine Parkway  
West Chester, PA 19380

First Union  
National Bank

04/22/2003

DATE

CHECK NO.

04/25/2003

00152750

One hundred thirty four thousand three hundred seventy five and no/100 \*\*\*\*\*

AMOUNT

\$134,375.00

TO THE  
ORDER  
OF

MediCom Worldwide Inc  
101 Washington Ave  
Morrisville, PA 19067

*Charles A. Reinhardt*  
AUTHORIZED SIGNATURE

⑈00152750⑈ ⑆031100225⑆ 2079950064057⑈

FACE OF DOCUMENT HAS A COLORED "VOID" BACKGROUND ON WHITE SECURITY PAPER

Cephalon, Inc.

145 Brandywine Parkway  
West Chester, PA 19380

04/25/2003

00152750

INVOICE NO.	DATE	DESCRIPTION	PAID AMOUNT	DISCOUNT	APPLIED AMOUNT
AAFM 2003	04/22/2003	VCH0005946	\$134,375.00		\$134,375.00
INTERNAL NO.	VENDOR #	VENDOR	TOTALS	TOTALS	TOTALS
533	MEDICOM00000	MediCom Worldwide Inc			\$134,375.00



# ACCOUNTS PAYABLE CHECK REQUEST



**PAYEE NAME:** Medicom Worldwide Inc.

**ADDRESS:** 101 Washington Street  
Morrisville, PA 19067

**INVOICE NUMBER:** n/a

**INVOICE DATE:** n/a

**DUE DATE:** n/a

**P.O. NUMBER (if applicable):** n/a

**DESCRIPTION:** AAPM CME Symposia

<u>G/L ACCOUNT NUMBER</u>	<u>DEPARTMENT</u>	<u>PROJECT</u>	<u>AMOUNT</u>
7640	63100	ACTQ	\$ 134,375.00

**TOTAL:** \$ 134,375.00

Prepared By: Suzanne Richards

Extension: 6532

Department Number: 63100

Approved By: \_\_\_\_\_

Print Approvers Name:

Approvers Title:

*SG Charles A. Rembert III 4/17/03*

\*\*\*\*\* Mark here if the check is to be picked up by the preparer: ☒ \*\*\*\*\*

**Please note:** If there is any documentation to be mailed along with the payment, please attach a copy in addition to the copy for Accounting's records

Accounting Use Only:

Batch Number: \_\_\_\_\_

Voucher Number: \_\_\_\_\_

Entry Date: \_\_\_\_\_

4/8/2003



March 21, 2003

P. Andrew Pyfer  
Product Director  
Cephalon, Inc.  
145 Brandywine Parkway  
West Chester, PA 19380

Dear Mr. Pyfer:

MediCom Worldwide is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians and is an ACPE-approved provider of pharmacy continuing education, as well as an approved provider of nursing continuing education through the California State Board of Registered Nursing.

A comprehensive needs assessment has identified interests of health care providers who manage patients suffering from musculoskeletal pain. Based on this educational need, we are requesting an educational grant from Cephalon, Inc. to support the development and implementation of an education activity on the subject of the effective management of musculoskeletal. The budget to fund this activity is approximately \$125,468.

Proposed Educational Activity – AAPM & R 2003

Development, production, and submission of CME slide content to AAPM & R  
Development and production of CME slides for faculty lectures  
Coordination of faculty, content, meeting arrangements  
Travel/accommodations for faculty  
Design/production of invitations, posters, participant handouts  
Direct mail management, door-drops at hotels  
Premeeting registration  
Onsite meeting registration  
Onsite meeting management

This scientific activity, will be developed independently and will comply with all ACCME, FDA, and AMA regulations for industry-supported professional continuing education. The target audience for these activities are pain management specialists and physiatrists.

101 Washington St.  
Morrisville, PA 19067  
215-337-9991

1



However, the content of such information is the responsibility of the accredited provider and any such distribution will be solely as a supplement to provider's primary method of announcement and promotion.

Thank you, in advance, for your consideration of this request. Should you agree to provide funding for this project, Letters of Agreement must be signed as soon as possible.

Respectfully,

A handwritten signature in cursive script, appearing to read "Joan Meyer".

Joan Meyer RN, MA  
Executive Director, Continuing Education

101 Washington St.  
Morrisville, PA 19067  
215-337-9991

2

Policy Regarding  
Satellite CME Symposia and Non-CME Activities Held Concurrent with the  
AAPM&R Annual Assembly

## **Guidelines**

### **I. Direct Competition**

Satellite educational activities and non-CME activities must be offered during times allotted by the AAPM&R. It is recommended that these activities avoid conflicting with AAPM&R sponsored social events and programs. It is for this reason that identified time periods have been designated for satellite CME and non-CME activities. The AAPM&R has sole discretion to schedule all activities at the Annual Assembly.

### **II. CME Compliance**

The AAPM&R does **not** provide AMA-PRA Category 1 credit for satellite symposia. Those wishing to offer credit for their symposia must obtain credit from another accredited CME provider.

Any CME activities must be planned in accordance with ACCME *Essentials and Standards*. The AAPM&R requires that all CME symposia also be in compliance with the *Standards for Commercial Support of Continuing Medical Education* established by the ACCME. Providers of these activities are expected to meet the requirements established by ACCME.

### **III. Compliance with Opinion 8.061 of the AMA Code of Medical Ethics**

Satellite CME and non-CME activities must be in compliance with the AMA's Ethical Opinion on Gifts to Physicians from Industry. Although it is the responsibility of individual physicians to comply with this code, every effort should be made to ensure that attendees are not put in a situation that would be considered a violation of these guidelines.

### **IV. No Implied Endorsement**

Educational symposia and non-CME activities that have not been planned or sponsored by the AAPM&R are considered satellite events. Therefore, there can be no implication in any promotional materials, handouts, or enduring materials that they are planned, sponsored by, or are endorsed by the AAPM&R.

Those organizations or companies planning to purchase AAPM&R mailing lists or advertise in AAPM&R publications to promote their event must receive prior approval from the AAPM&R for any promotional materials used in connection with satellite CME symposia or non-CME activity. The AAPM&R reserves the right to decline advertising or requests for mailing labels for any reason at its sole discretion.

The AAPM&R recommends that employees of the sponsoring organization, any organization working with the sponsoring organization, activity organizer, and all agents be made aware of this policy. Violations of this policy may affect promotional efforts and eligibility for involvement with future AAPM&R meetings and conferences.

### **V. Independent Planning**

Policy Regarding  
Satellite CME Symposia and Non-CME Activities Held Concurrent with the  
AAPM&R Annual Assembly

All satellite CME and non-CME activities must be planned independently of AAPM&R activities. Organizers are solely responsible for making all appropriate financial arrangements for their activity. In addition, organizers and their agents are advised not to imply or represent to third parties (e.g., hotel staff, convention center personnel, etc.) that the activities they are planning are associated with the AAPM&R official meeting or events.

## VI. General Satellite CME and Non-CME Event Requirements

- In the event that a sponsor of a satellite event receives outside funding, the sponsor must have a Letter of Agreement with any granting (supporting) company, acknowledge support received from industry, and disclose CME faculty and sponsor relationships of potential participants with the manufacturers of any commercial products discussed in an educational session. ACCME *Standards* require written disclosure on conference materials, such as promotional pieces, and in the syllabus as well as at the beginning of each session.
- Once the satellite event has been approved, the CME provider and the commercial supporter(s) may not change. If the CME provider or the commercial supporter changes from what was approved on the application, approval of the event may be withdrawn and relevant fees forfeited by the applicant.
- As established by the ACCME *Standards for Commercial Support for Continuing Medical Education*, when an unlabeled use of a commercial product or an investigational use not yet approved for any purpose is discussed during an educational activity, the accredited sponsor must require the speaker to disclose that the product is not labeled for the use under discussion or that the product is still investigational. This disclosure should be given verbally during the event and in writing on syllabus materials.
- The following statement should be clearly and prominently displayed on the syllabus and on all printed material: "Continuing Medical Education (CME) credit for this event is not offered by AAPM&R."
- Volunteers designated by the chair of the AAPM&R Medical Education Committee may attend the CME symposia to audit compliance with this policy and to ensure that program content is free from bias.

## VII. Logistics

- A maximum of two morning (6-8am) and two evening (7-9pm) satellite events will be permitted each day during the Annual Assembly.
- Sponsors of satellite events may use the full time allotted or a reduced amount of time but may not exceed the scheduled time.
- Space for satellite events will be provided on a first come, first served basis and will only be assigned after the proposal is accepted by the AAPM&R.
- Sessions must be contained within the room assigned.
- All rooms will be set **theater style** unless a waiver is granted.
- Registration outside of the meeting room is limited to no more than two tables and must be prearranged with the AAPM&R.

Policy Regarding  
Satellite CME Symposia and Non-CME Activities Held Concurrent with the  
AAPM&R Annual Assembly

- Audiovisual requirements are the responsibility of the sponsor of the satellite event. Sponsors must use the A/V company contracted with the AAPM&R for the event.
- All food functions must occur within the assigned event schedule.
- All expenses associated with the event, including room set-up, clean up, food & beverage, A/V, electrical, telephone, shipping, etc. are the sole responsibility of the sponsor of the satellite event.
- Alternative sites may be selected by the sponsoring organization other than those offered by the AAPM&R. In that instance, the cost will be covered by the sponsoring organization, not the AAPM&R.
- When alternative sites are selected, scheduling of events must still follow the guidelines within this policy and the events must be held at the assigned times unless a waiver is applied for and approved.

#### VIII. Promotion

- The AAPM&R must review and approve all promotional materials produced in conjunction with the satellite activity (e.g. invitations, announcements, signs, flyers, Web site information).
- A minimum of five (5) business days is required for approval of promotional materials.
- Promotional materials should not be pre-printed prior to approval. It is not the responsibility of the AAPM&R to cover any costs associated with these materials if they have been pre-printed and not approved.
- A promotional flyer may be included in the attendee packet if it is approved and sent to the Annual Assembly host hotel/conference center in time for stuffing (exact dates and locations will be provided annually).
- A maximum of one (1) professionally made promotional sign will be allowed in a designated location in the registration area of the Annual Assembly. This sign must be removed immediately following the scheduled event.
- One (1) promotional sign may be placed outside the room in which the event will take place immediately prior to the event and must be removed immediately following the event.
- If the sponsoring organization is exhibiting in the Exhibit Hall, booth representatives may distribute invitations and other promotional material for the event at the booth.
- Room drops (placing promotional material under the doors of hotel guests) and hotel room marketing (arranging for pamphlets or other marketing materials to be placed in rooms) **are not permitted**.
- The AAPM&R logo **may not** be used on any promotional material.
- The use of the AAPM&R name or copyrighted material on any announcement, sign, publication, or other material requires prior written approval by AAPM&R.
- With approval from AAPM&R, promotional material may include the following statement, "This activity will be held during the AAPM&R Annual Assembly. It is not considered part of the official scientific program of the AAPM&R."
- At a minimum, all invitations and promotional materials must include the second sentence of the previous statement to be adapted as follows if the first sentence is not utilized, "This activity is not considered part of the official scientific program of the AAPM&R."

Policy Regarding  
Satellite CME Symposia and Non-CME Activities Held Concurrent with the  
AAPM&R Annual Assembly

**IX. Fees**

- The AAPM&R charges a fee of \$6,000 to hold a satellite event.
- The fee must be submitted along with the application form. This fee will not be deposited until after the event is approved. After this time, relevant cancellation policy applies (see below).
- The fee may be forfeited if the CME provider or commercial supporter(s) change after approval of the program.

**X. Benefits**

- This event offers a limited opportunity to provide a customized event marketed to over 2,500 psychiatrists in attendance.
- As an approved satellite program, the event will be listed in the onsite Official Program.
- Organizations accepted for a satellite program are eligible to receive one free pre-registrant mailing label set approximately four (4) weeks prior to the Annual Assembly. These are for a one-time use. Additional sets of pre-registration labels are available for purchase.
- Opportunity to post a sign in the registration area advertising the event.

**XI. Cancellation Policy**

- Once approved, the AAPM&R must be notified of the cancellation of a satellite event.
- If written notification of the cancellation of a satellite event is received by the AAPM&R 45 days prior to the Annual Assembly, a 75% refund will be issued.
- No refunds will be issued for events cancelled any time after the 45-day deadline.

**XII. Violations and Sanctions**

The AAPM&R, at its sole discretion, reserves the right to revoke privileges for future programs for any sponsoring organization, supporting organization, or activity organizer involved in planning a satellite CME symposium or non-CME activity that does not comply with the guidelines and requirements set forth in this policy.

Companies violating these guidelines and requirements may not be allowed involvement with any AAPM&R activities in the future. In addition, exhibiting companies providing grants to support a satellite activity agree that their company representatives and/or agents will adhere to these guidelines. Failure to do so may jeopardize future eligibility to exhibit with AAPM&R. All exhibitors are responsible for ensuring that their company representatives and/or agents adhere to all guidelines and requirements outlined herein and in the *AAPM&R Contract to Exhibit*.

**XIII. Application Process for Satellite CME Symposia and Non-CME Activities**

Proposals to schedule satellite CME symposia should be received by the Education and Research Department of the AAPM&R at least five (5) months prior to the date of the proposed event.

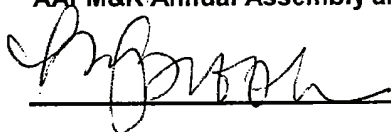
Policy Regarding  
Satellite CME Symposia and Non-CME Activities Held Concurrent with the  
AAPM&R Annual Assembly

In addition to assessing logistical and policy issues outlined above, the program content information provided on the application will be reviewed by appropriate AAPM&R committees and representatives to determine the program's ability to meet the educational needs of AAPM&R members. The application requires the following information:

- Rationale for holding the event
- Learning objectives for CME events
- Complete agenda
- Title for the event to be included in the Official Program
- Brief narrative description of the session that will be included in the Official Program
- Names of confirmed speakers
- Expected attendance
- Preferred time slot
- Contact information for accredited CME provider (if this is a CME event)
- Contact information of all commercial supporters of the event
- A copy of letters of agreement between commercial supporters and event organizers.
- Plan for how evaluations and CME credit will be distributed for CME events
- Sample evaluation form

Signatures of representatives from the funding organization and CME provider under the following statement

**"By signing this letter, we acknowledge that we have read the AAPM&R Policy Regarding Satellite CME Symposia and Non-CME Activities Held Concurrent with the AAPM&R Annual Assembly and agree to follow the policy as stated."**



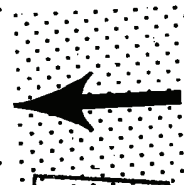
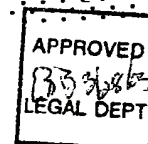
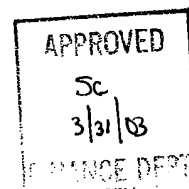
Cephalon Representative

4/9/03

Date

MediCom Worldwide, Inc. Representative

Date



## Cephalon Review of Education Grant

*Need signed agreement back*

The attached Grant amount has been reviewed by members of the MEP team.

**Program Name:** Unrestricted Educational Grant:

**Medicom Worldwide, Inc.**

**CME Program at the AAPM&R Convention**

<u>Department</u>	<u>Name</u>	<u>Signature</u>	<u>Date</u>
<b>Medical Affairs</b>	Kiumars Vadieli Jess Amchin Susan Larijani	<i>K Vadieli</i> <i>Jess Amchin</i> <i>Susan Larijani</i>	4-7-07 4/2/03 4/2/03
<b>Accounting</b>	Steve Girard		
<b>Legal</b>	Ed Berg	<i>Ed Berg</i>	3/28/03
<b>Marketing</b>	Andy Pyfer Paula Castagno Lynne Brookes	<i>Andy Pyfer</i>	4/8/03




**Cephalon**
**MEDICAL EDUCATION AGREEMENT**

As a condition of Cephalon, Inc.'s contribution of funds to support an independent medical education program (with or without CME credits), the Scientific and Educational Activity provider agrees to the following terms and conditions:

This Agreement ("Agreement") is entered into as of March 25, 2003, by and between Cephalon, Inc. ("Cephalon") and MediCom Worldwide, Inc. ("Provider") regarding a medical education program sponsored by Cephalon entitled "CME Program at the AAPM&R Convention 2003". The parties' mutual objectives are to provide a balanced, independent, scientifically rigorous program to promote the education of attendees.

1. Statement of Purpose. This program is for scientific and educational purposes only and not to promote any commercial drug products.

2. Control of Content and Selection of Presenters and Moderators. The provider is ultimately responsible for the control of content and selection of presenters and moderators. Cephalon or its agents may respond to requests initiated by the provider for suggestions of presenters or sources of possible presenters. Cephalon will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Cephalon and speaker; and will provide this information in writing. Provider will seek suggestions from other sources, and will, in its sole discretion, select presenters and moderators.

3. Disclosure of Financial Relationships. Provider will direct speakers and moderators to disclose to the audience commercial support or funding or other significant financial relationships between the speakers and moderators and Cephalon and/or any other commercial company whose products are pertinent to the content of the presentation. Provider will disclose Cephalon's support at this program.

4. Involvement in Content. There will be no "scripting," emphasis, or influence on content by Cephalon or its agents. However, Cephalon may provide technical support to speakers, e.g., furnishing slides or data, upon their request.

5. Ancillary Promotional Activities. No promotional activities will be permitted in the same room as, or in the obligatory path to, the educational activity. No product advertisements will be permitted within the program or handouts.

6. Objectivity and Balance. Provider will advise presenters that data regarding Cephalon products (or competing products) are to be objectively selected and presented. Provider will provide the opportunity for speakers and the audience to discuss information, both favorable and unfavorable, about the product(s) and/or alternative treatments.

7. Limitations of Data. Provider will request the speakers, to the extent possible, to disclose limits on the data, e.g., that it involves ongoing research, interim analyses, preliminary data, or unsupported opinion.

8. Discussion of Unapproved Uses. Provider will request that presenters disclose when a product is not approved in the United States for the use under discussion.

9. ACTIQ Risk Management Program. Provider is aware that ACTIQ® (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- ACTIQ is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- ACTIQ is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.

10. Opportunity for Debate. Provider will ensure opportunities for questioning by attendees and scientific debate with and between presenters.

11. Independence of Provider in the Use of Contributed Funds.

(a) funds should be in the form of an educational grant made payable to the provider organization.

(b) Provider must be advised of all other support by Cephalon of the CME activity (e.g., distributing brochures, preparing slides). If Provider disapproves of this activity, it shall promptly notify Cephalon.

(c) no other funds from Cephalon will be paid to the program director, faculty, or others involved with this CME activity, e.g., additional honoraria.

12. General.

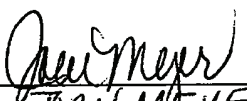
(a) Cephalon agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.

(b) Provider agrees to: (1) abide by the ACCME Standards for Commercial Support of Continuing Medical Education; (2) acknowledge educational support from Cephalon in program brochures, syllabi, and other program materials; and (3) upon request, furnish Cephalon with a report concerning the expenditure of the funds provided by Cephalon.

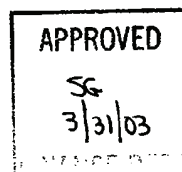
IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

MediCom Worldwide, Inc.

CEPHALON, INC.

By:   
Name: JOAN MEYER  
Title: Executive Director, Education

By:   
Name: Lynne Brookes  
Title: VP of Marketing





*JoD Ex'd*  
*4/10/03*

April 10, 2003

Joan Meyer RN, MA  
MediCom Worldwide, Inc.  
101 Washington Street  
Morrisville, PA 19067

Dear Ms. Meyer:

Enclosed please review our Unrestricted Educational Agreement for the support of a CME Program at the AAPM&R Convention. Please sign both of the original copies, return one to me at the address below, and keep the other copy for your files. I have also enclosed fully executed copies of three other agreements in support of 2003 Educational Activities for Pain Management. We have kept one copy of each for our files.

Please feel free to call me if you have any questions at 610-738-6532.

Sincerely,

A handwritten signature in cursive script that reads 'Suzanne Richards'.

Suzanne Richards  
Cephalon, Inc.

Return To:

Cephalon  
145 Brandywine Parkway  
West Chester, PA 19380  
Attn: Suzanne Richards

Enclosures

A TRUE WATERMARK IS PRESENT IN THE PAPER • HOLD UP TO A LIGHT SOURCE TO VIEW

Cephalon, Inc.

145 Brandywine Parkway  
West Chester, PA 19380First Union  
National Bank

02-22-111

DATE

CHECK NO.

04/25/2003

00152749

One hundred twenty five thousand four hundred sixty eight and no/100 \*\*\*\*\*

AMOUNT

\$125,468.00

TO THE  
ORDER  
OFMediCom Worldwide Inc  
101 Washington Ave  
Morrisville, PA 19067  
AUTHORIZED SIGNATURE

⑈00152749⑈ ⑆031100225⑆ 2079950064057⑈

FACE OF DOCUMENT HAS A COLORED "VOID" BACKGROUND ON WHITE SECURITY PAPER

Cephalon, Inc.

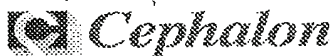
145 Brandywine Parkway  
West Chester, PA 19380

04/25/2003

00152749

INVOICE NO.	DATE	DESCRIPTION	PAID AMOUNT	DISCOUNT	APPLIED AMOUNT
APR 25 2003	04/22/2003	VCH00059462	\$125,468.00		\$125,468.00
INTERNAL NO.	VENDOR #	VENDOR	TOTALS	TOTALS	TOTALS
533	JMEDI000000	MediCom Worldwide Inc			\$125,468.00





# ACCOUNTS PAYABLE CHECK REQUEST



*Rec'd signed  
agreement  
4/22  
gave to  
legal*

**PAYEE NAME:** Medicom Worldwide Inc.

**ADDRESS:** 101 Washington Street  
Morrisville, PA 19067

**INVOICE NUMBER:** n/a

**INVOICE DATE:** n/a

**DUE DATE:** n/a

**P.O. NUMBER (if applicable):** n/a

**DESCRIPTION:** CME Programat the AAPM & R Convention

<u>G/L ACCOUNT NUMBER</u>	<u>DEPARTMENT</u>	<u>PROJECT</u>	<u>AMOUNT</u>
7640	63100	ACTQ	\$ 125,468.00

**TOTAL:** \$ 125,468.00

Prepared By: Suzanne Richards

Extension: 6532

Department Number: 63100

Approved By: \_\_\_\_\_

Print Approvers Name: \_\_\_\_\_

Approvers Title: *SG Charles A. Reinert III*

\*\*\*\*\* Mark here if the check is to be picked up by the preparer: ☒ \*\*\*\*\*

**Please note:** If there is any documentation to be mailed along with the payment, please attach a copy in addition to the copy for Accounting's records

Accounting Use Only:

Batch Number: _____
Voucher Number: _____
Entry Date: _____

4/8/2003

**FedEx** USA Airbill  
Express

 FedEx  
Tracking  
Number

8323 8968 3194

**1 From** Please print and press hard.

 Date 4/10/03 Sender's FedEx Account Number 1161-3887-5

 Sender's Name Suzanne Richards Phone (610) 344-0200

 Company CEPHALON INC

 Address 145 BRANDYWINE PKWY

Dept./Floor/Suite/Room

 City WEST CHESTER State PA ZIP 19380
**2 Your Internal Billing Reference**

First 34 characters will appear on invoice.

OPTIONAL

**3 To**

 Recipient's Name Joan Meyer Phone (215) 337-9991

 Company MediCom Worldwide

 Address 101 Washington Street

To "HOLD" at FedEx location, print FedEx address.

We cannot deliver to P.O. boxes or P.O. ZIP codes.

Address \_\_\_\_\_

Dept./Floor/Suite/Room

 City Morrisville State PA ZIP 19067

 Try online shipping at [fedex.com](http://fedex.com)

By using this Airbill you agree to the service conditions on the back of this Airbill and in our current Service Guide, including terms that limit our liability.

 Questions? Visit our Web site at [fedex.com](http://fedex.com)  
or call 1.800.Go.FedEx® 800.463.3339.

0202843636

 Sender's Copy  
0215

**4a Express Package Service**
☐ FedEx Priority Overnight  
Next business morning  
☒ FedEx Standard Overnight  
Next business afternoon  
☐ FedEx First Overnight  
Earliest next business morning  
delivery to select locations  
☐ FedEx 2Day  
Second business day  
☐ FedEx Express Saver  
Third business day  
 FedEx Envelope rate not available. Minimum charge: One-pound rate

Packages up to 150 lbs.

Delivery commitment may be later in some areas.

**4b Express Freight Service**

Packages over 150 lbs.

Delivery commitment may be later in some areas.

☐ FedEx 1Day Freight\*  
Next business day  
☐ FedEx 2Day Freight  
Second business day  
☐ FedEx 3Day Freight  
Third business day

\* Call for Confirmation:

**5 Packaging**

\* Declared value limit \$500

☒ FedEx Envelope\*  
☐ FedEx Pak\*  
Includes FedEx Small Pak, FedEx Large Pak, and FedEx Sturdy Pak  
☐ Other

**6 Special Handling**

Include FedEx address in Section 3.

☐ SATURDAY Delivery  
Available ONLY for  
FedEx Priority Overnight and  
FedEx 2Day to select ZIP codes  
☐ HOLD Weekday  
at FedEx Location  
NOT Available for  
FedEx First Overnight  
☐ HOLD Saturday  
at FedEx Location  
Available ONLY for  
FedEx Priority Overnight and  
FedEx 2Day to select locations

Does this shipment contain dangerous goods?

 One box must be checked.  
☒ No  
☐ Yes  
As per attached  
Shipper's Declaration  
☐ Yes  
Shipper's Declaration  
not required  
☐ Dry Ice  
Dry Ice, 9, UN 1845 x \_\_\_\_\_ kg  
☐ Cargo Aircraft Only

**7 Payment Bill to:**

Enter FedEx Acct. No. or Credit Card No. below.

☒ Sender  
Acct. No. in Section  
1 will be billed.  
☐ Recipient  
☐ Third Party  
☐ Credit Card  
☐ Cash/Check

 FedEx Acct. No.  
Credit Card No.

 Exp.  
Date

Total Packages	Total Weight	Total Declared Value*
		\$ .00

\* Our liability is limited to \$100 unless you declare a higher value. See back for details.

FedEx Use Only

**8 Release Signature**

Sign to authorize delivery without obtaining signature.

S. Richards

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.

447

SRS • Rev. Date 10/01 • Part #1578J05 • ©1994-2001 FedEx • PRINTED IN U.S.A.

PULL AND RETAIN THIS COPY BEFORE AFFIXING TO THE PACKAGE.

07300X.15



## Terms And Conditions

**Definitions** On this Airbill, "we," "our," and "us" refer to Federal Express Corporation, its employees, and agents. "You" and "your" refer to the sender, its employees, and agents.

**Agreement To Terms** By giving us your package to deliver, you agree to all the terms on this Airbill and in our current Service Guide, which is available on request. You also agree to those terms on behalf of any third party with an interest in the package. If there is a conflict between the Service Guide and this Airbill, the Service Guide will control. No one is authorized to change the terms of our Agreement.

**Responsibility For Packaging And Completing Airbill** You are responsible for adequately packaging your goods and properly filling out this Airbill. If you omit the number of packages and/or weight per package, our billing will be based on our best estimate of the number of packages we received and/or an estimated "default" weight per package as determined by us.

**Responsibility For Payment** Even if you give us different payment instructions, you will always be primarily responsible for all delivery costs, as well as any cost we incur in either returning your package to you or warehousing it pending disposition.

### Limitations On Our Liability And Liabilities Not Assumed

- Our liability in connection with this shipment is limited to the lesser of your actual damages or \$100, unless you declare a higher value, pay an additional charge, and document your actual loss in a timely manner. You may pay an additional charge for each additional \$100 of declared value. The declared value does not constitute, nor do we provide, cargo liability insurance.
- In any event, we will not be liable for any damage, whether direct, incidental, special, or consequential in excess of the declared value of a shipment, whether or not Federal Express had knowledge that such damages might be incurred including but not limited to loss of income or profits.

### We won't be liable:

- for your acts or omissions, including but not limited to improper or insufficient packing, securing, marking, or addressing, or those of the recipient or anyone else with an interest in the package.
- if you or the recipient violates any of the terms of our Agreement.
- for loss or damage to shipments of prohibited items.
- for loss, damage, or delay caused by events we cannot control, including but not limited to acts of God, perils of the air, weather conditions, acts of public enemies, war, strikes, civil commotions, or acts of public authorities with actual or apparent authority.

### Declared Value Limits

- The highest declared value allowed for a FedEx Envelope and FedEx Pak shipment is \$500.
- For other shipments, the highest declared value allowed is \$50,000 unless your package contains items of extraordinary value, in which case the highest declared value allowed is \$500.
- Items of extraordinary value include shipments containing such items as artwork, jewelry, furs, precious metals, negotiable instruments, and other items listed in our Service Guide.
- You may send more than one package on this Airbill and fill in the total declared value for all packages, not to exceed the \$100, \$500, or \$50,000 per package limit described above. (Example: 5 packages can have a total declared value of up to \$250,000.) In that case, our liability is limited to the actual value of the package(s) lost or damaged, but may not exceed the maximum allowable declared value(s) or the total declared value, whichever is less. You are responsible for proving the actual loss or damage.

**Filing A Claim** YOU MUST MAKE ALL CLAIMS IN WRITING and notify us of your claim within strict time limits set out in the current Service Guide.

You may call our Customer Service department at 1.800.Go.FedEx® 800.463.3339 to report a claim; however, you must still file a timely written claim.

Within 90 days after you notify us of your claim, you must send us all the information you have about it. We aren't obligated to act on any claim until you have paid all transportation charges, and you may not deduct the amount of your claim from those charges.

If the recipient accepts your package without noting any damage on the delivery record, we will assume the package was delivered in good condition. For us to process your claim, you must make the original shipping cartons and packing available for inspection.

**Right To Inspect** We may, at our option, open and inspect your packages before or after you give them to us to deliver.

**Right Of Rejection** We reserve the right to reject a shipment when such shipment would be likely to cause delay or damage to other shipments, equipment, or personnel; or if the shipment is prohibited by law; or if the shipment would violate any terms of our Airbill or our current Service Guide.

**C.O.D. Services** C.O.D. SERVICE IS NOT AVAILABLE WITH THIS AIRBILL. If C.O.D. Service is required, please use a Federal Express C.O.D. Airbill.

**Air Transportation Tax Included** A federal excise tax when required by the Internal Revenue Code on the air transportation portion of this service, if any, is paid by us.

**Money-Back Guarantee** In the event of untimely delivery, Federal Express will, at your request and with some limitations, refund or credit all transportation charges. See current Service Guide for more information.



## 2004 MEDICAL EDUCATION AGREEMENT V CME LECTURE SERIES

As a condition of Cephalon, Inc's contribution of funds to support a series of independent medical education programs (with CME, CPE, and CNE credits), the Scientific and Educational Activity provider agrees to the following terms and conditions:

This Agreement ("Agreement") is entered into as of December 12, 2003 by and between Cephalon, Inc. ("Cephalon") and MediCom Worldwide, Inc. ("Provider") regarding a series of 350 educational lectures and 30 symposia supported by Cephalon to be held during 2004. The parties' mutual objectives are to provide balanced, independent, scientifically rigorous lectures to promote the education of attendees. The amount of the educational grant requested is \$4,368,980.

1. Statement of Purpose. This program is for scientific and educational purposes only and not to promote any commercial drug products.

2. Control of Content and Selection of Presenters and Moderators. The provider is ultimately responsible for the control of content and selection of presenters and moderators. Cephalon or its agents may respond to requests initiated by the provider for suggestions of presenters or sources of possible presenters. Cephalon will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Cephalon and speaker; and will provide this information in writing. Provider will seek suggestions from other sources, and will, in its sole discretion, select presenters and moderators.

3. Disclosure of Financial Relationships. Provider will direct speakers and moderators to disclose to the audience commercial support or funding or other significant financial relationships between the speakers and moderators and Cephalon and/or any other commercial company whose products are pertinent to the content of the presentation. Provider will disclose Cephalon's support at this program.

4. Involvement in Content. There will be no "scripting," emphasis, or influence on content by Cephalon or its agents. However, Cephalon may provide technical support to speakers, e.g., furnishing slides or data, upon their request.

5. Ancillary Promotional Activities. No promotional activities will be permitted in the same room as, or in the obligatory path to, the educational activity. No product advertisements will be permitted within the program or handouts.

6. Objectivity and Balance. Provider will advise presenters that data regarding Cephalon products (or competing products) are to be objectively selected and presented. Provider will provide the opportunity for speakers and the audience to discuss information, both favorable and unfavorable, about the product(s) and/or alternative treatments.

7. Limitations of Data. Provider will request the speakers, to the extent possible, to disclose limits on the data, e.g., that it involves ongoing research, interim analyses, preliminary data, or unsupported opinion.

8. Discussion of Unapproved Uses. Provider will request that presenters disclose when a product is not approved in the United States for the use under discussion.

9. Actiq® Risk Management Program. Provider is aware that Actiq (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- Actiq is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- Actiq is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.

10. Opportunity for Debate. Provider will ensure opportunities for questioning by attendees and scientific debate with and between presenters.

11. Independence of Provider in the Use of Contributed Funds.

(a) funds should be in the form of an educational grant made payable to the provider organization.

(b) Provider must be advised of all other support by Cephalon of the CME activity (e.g., distributing brochures, preparing slides). If Provider disapproves of this activity, it shall promptly notify Cephalon.

(c) no other funds from Cephalon will be paid to the program director, faculty, or others involved with this CME activity, e.g., additional honoraria.

12. General.

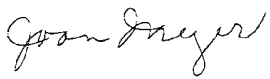
(a) Cephalon agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.

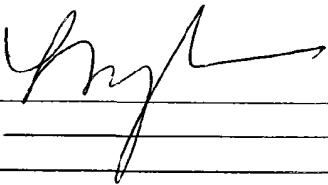
(b) Provider agrees to: (1) abide by the ACCME Standards for Commercial Support of Continuing Medical Education; (2) acknowledge educational support from Cephalon in program brochures, syllabi, and other program materials; and (3) upon request, furnish Cephalon with a report concerning the expenditure of the funds provided by Cephalon.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

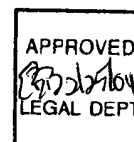
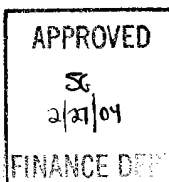
MEDICOM WORLDWIDE, INC.

CEPHALON, INC.

By:   
 Name: Joan Meyer  
 Title: Executive Director, Cont. Ed  
 Date: December 12, 2003

By:   
 Name: \_\_\_\_\_  
 Title: \_\_\_\_\_  
 Date: \_\_\_\_\_

**SIGN I**





## 2004 MEDICAL EDUCATION AGREEMENT II

As a condition of Cephalon, Inc's contribution of funds to support a series of independent medical education programs (with CME, CPE, and CNE credits), the Scientific and Educational Activity provider agrees to the following terms and conditions:

This Agreement ("Agreement") is entered into as of December 12, 2003 by and between Cephalon, Inc. ("Cephalon") and MediCom Worldwide, Inc. ("Provider") regarding a CME satellite symposium at AAPM & R developed and held by MediCom Worldwide, Inc. and supported by Cephalon to be held in 2004. The parties' mutual objectives are to provide a balanced, independent, scientifically rigorous program to promote the education of attendees. The amount of the educational grant requested is \$135,000.

1. Statement of Purpose. This program is for scientific and educational purposes only and not to promote any commercial drug products.

2. Control of Content and Selection of Presenters and Moderators. The provider is ultimately responsible for the control of content and selection of presenters and moderators. Cephalon or its agents may respond to requests initiated by the provider for suggestions of presenters or sources of possible presenters. Cephalon will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Cephalon and speaker; and will provide this information in writing. Provider will seek suggestions from other sources, and will, in its sole discretion, select presenters and moderators.

3. Disclosure of Financial Relationships. Provider will direct speakers and moderators to disclose to the audience commercial support or funding or other significant financial relationships between the speakers and moderators and Cephalon and/or any other commercial company whose products are pertinent to the content of the presentation. Provider will disclose Cephalon's support at this program.

4. Involvement in Content. There will be no "scripting," emphasis, or influence on content by Cephalon or its agents. However, Cephalon may provide technical support to speakers, e.g., furnishing slides or data, upon their request.

5. Ancillary Promotional Activities. No promotional activities will be permitted in the same room as, or in the obligatory path to, the educational activity. No product advertisements will be permitted within the program or handouts.

6. Objectivity and Balance. Provider will advise presenters that data regarding Cephalon products (or competing products) are to be objectively selected and presented. Provider will provide the opportunity for speakers and the audience to discuss information, both favorable and unfavorable, about the product(s) and/or alternative treatments.

7. Limitations of Data. Provider will request the speakers, to the extent possible, to disclose limits on the data, e.g., that it involves ongoing research, interim analyses, preliminary data, or unsupported opinion.

8. Discussion of Unapproved Uses. Provider will request that presenters disclose when a product is not approved in the United States for the use under discussion.

9. Actiq® Risk Management Program. Provider is aware that Actiq (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- Actiq is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
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- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.

10. Opportunity for Debate. Provider will ensure opportunities for questioning by attendees and scientific debate with and between presenters.

11. Independence of Provider in the Use of Contributed Funds.

(a) funds should be in the form of an educational grant made payable to the provider organization.

(b) Provider must be advised of all other support by Cephalon of the CME activity (e.g., distributing brochures, preparing slides). If Provider disapproves of this activity, it shall promptly notify Cephalon.



(c) no other funds from Cephalon will be paid to the program director, faculty, or others involved with this CME activity, e.g., additional honoraria.

## 12. General.

(a) Cephalon agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.

(b) Provider agrees to: (1) abide by the ACCME Standards for Commercial Support of Continuing Medical Education; (2) acknowledge educational support from Cephalon in program brochures, syllabi, and other program materials; and (3) upon request, furnish Cephalon with a report concerning the expenditure of the funds provided by Cephalon.

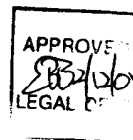
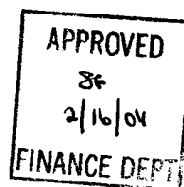
IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

MEDICOM WORLDWIDE, INC.

CEPHALON, INC.

By: *Joan Meyer*  
 Name: Joan Meyer  
 Title: Executive Director, Cont. Ed  
 Date: December 12, 2003

By: *[Signature]*  
 Name: \_\_\_\_\_  
 Title: \_\_\_\_\_  
 Date: \_\_\_\_\_



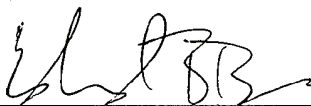
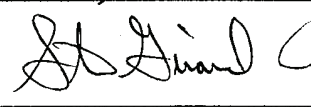



**Cephalon Review of Education Grant**

The attached Grant amount has been reviewed by members of the MEP team.

**Program Name:** Unrestricted Educational Grant:

**Medicom Worldwide, Inc.**  
**CME Teleconference Series**

<u>Department</u>	<u>Name</u>	<u>Signature</u>	<u>Date</u>
<b>Legal</b>	Ed Berg		2/12/04
<b>Accounting</b>	Steve Girard		2/16/04
<b>Marketing</b>	Paula Castagno Andy Pyfer		2/20/04



December 12, 2003

P. Andrew Pyfer  
Product Director  
Cephalon, Inc.  
145 Brandywine Parkway  
West Chester, PA 19380

Dear Mr. Pyfer:

MediCom Worldwide is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians and by the Accreditation Council for Pharmacy Education to sponsor continuing education for pharmacists, as well as an approved provider of nursing continuing education through the California State Board of Registered Nursing.

A comprehensive needs assessment has identified interests of health care providers who manage patients suffering from pain. Based on this educational need, we are requesting an educational grant from Cephalon, Inc. to support the development and implementation of several continuing education activities on the subjects of effective pain management techniques and the changing guidelines to improve pain management. The budget to fund these teleconference activities is approximately \$150,000.

Proposed Educational Activities for Pain Management

- Development, production, and implementation of a CME teleconference series on the appropriate dosing and administration of fentanyl.

This teleconference project will be conducted in two venues. The first venue will be exclusive to 21 locations the Southeast region of the U.S. followed by a roll-out to 79 additional sites nationally.

These scientific activities, will be developed independently and will comply with all ACCME, FDA, AMA, and ACPE regulations for industry-supported professional continuing education. The target audience for these activities are pain management specialists, oncologists and anesthesiologists, and other healthcare practitioners interested in pain management education.

As a supplement to our direct mail and web site announcement of these educational activities, we request Cephalon representatives to disseminate information regarding these programs to the medical community.

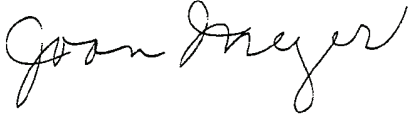
However, the content of such information is the responsibility of the accredited provider and any such distribution will be solely as a supplement to provider's primary method of announcement and promotion.

101 Washington St.  
Morrisville, PA 19067  
215-337-9991

1

Thank you, in advance, for your consideration of this request. Should you agree to provide funding for this project, Letters of Agreement will be forwarded to you as soon as possible.

Respectfully,

A handwritten signature in cursive script, reading "Joan Meyer".

Joan Meyer RN, MA  
Executive Director, Continuing Education

101 Washington St.  
Morrisville, PA 19067  
215-337-9991



## 2004 MEDICAL EDUCATION AGREEMENT IV

As a condition of Cephalon, Inc.'s contribution of funds to support a series of independent medical education programs (with CME, CPE, and CNE credits), the Scientific and Educational Activity provider agrees to the following terms and conditions:

This Agreement ("Agreement") is entered into as of December 12, 2003 by and between Cephalon, Inc. ("Cephalon") and MediCom Worldwide, Inc. ("Provider") regarding a series of educational teleconferences supported by Cephalon to be held during 2004. The parties' mutual objectives are to provide a balanced, independent, scientifically rigorous lecture to promote the education of attendees. The amount of the educational grant requested is \$150,000.

1. Statement of Purpose. This program is for scientific and educational purposes only and not to promote any commercial drug products.
2. Control of Content and Selection of Presenters and Moderators. The provider is ultimately responsible for the control of content and selection of presenters and moderators. Cephalon or its agents may respond to requests initiated by the provider for suggestions of presenters or sources of possible presenters. Cephalon will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Cephalon and speaker; and will provide this information in writing. Provider will seek suggestions from other sources, and will, in its sole discretion, select presenters and moderators.
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- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.

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(c) no other funds from Cephalon will be paid to the program director, faculty, or others involved with this CME activity, e.g., additional honoraria.

## 12. General.

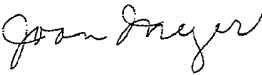
(a) Cephalon agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.

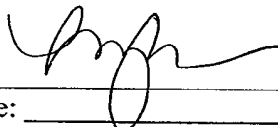
(b) Provider agrees to: (1) abide by the ACCME Standards for Commercial Support of Continuing Medical Education; (2) acknowledge educational support from Cephalon in program brochures, syllabi, and other program materials; and (3) upon request, furnish Cephalon with a report concerning the expenditure of the funds provided by Cephalon.

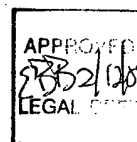
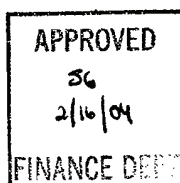
IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

MEDICOM WORLDWIDE, INC.

CEPHALON, INC.

By:   
 Name: Joan Meyer  
 Title: Executive Director, Cont. Ed  
 Date: December 12, 2003

By:   
 Name: \_\_\_\_\_  
 Title: \_\_\_\_\_  
 Date: \_\_\_\_\_





Terrence Terifay  
Cephalon, Inc  
145 Brandywine Parkway  
West Chester, PA 19380

Dear Mr. Terifay:

As an accredited provider of continuing medical education for physicians, pharmacists and nurses, MediCom Worldwide, Inc. has recently completed a comprehensive needs assessment to identify the educational needs of clinicians who provide care to patients with chronic pain. This needs assessment was compiled from the following sources:

- Advisory panel of clinical experts
- Survey of past participant feedback
- Literature searches

Based on the identified educational need, MediCom is requesting an educational grant from Cephalon Inc. to support the development and production of a live educational event that will take place at PRI MED EAST in Boston, Oct 2004.

This live activity will be reproduced as a self-study activity developed jointly with Medscape and presented via a online multimedia adaptation of the live event. This activity will comply with all ACCME, FDA, AMA, and ACPE regulations for industry-supported professional continuing education. The televised healthcast format allows health care professionals across the nation to conveniently participate in this activity from their own home, office, hospital, or clinic.

The budget to fund this activity is approximately \$247,350.00

Thank you, in advance, for your consideration of this request. Should you agree to provide funding for this project, Letters of Agreement will be forwarded to you as soon as possible.

Respectfully,

Joan Meyer  
Executive Director, Continuing Education

*2 part talk (CME)*  
*- BTP*  
*- Abuse / Addiction*





2-Jul-04

## PROPOSAL #04-082

PRI-MED 2004 - PRI MED EAST

Cephalon, Inc

Grant Request: \$247,350.00

PRI MED EASTPriMed Administrative Fee

\$ 20,000.00

MediCom Project ManagementMeeting and Faculty Coordination  
Design and graphics\$ 30,000.00  
\$ 3,500.00CME Approval/CertificatesReview/Approval  
Certificates @ 250  
Adaption of content for enduring material\$ 5,000.00  
\$ 2,250.00  
\$7,500MediCom On-site Symposium Management 2 Symposia

\$800/day per 2 staff - 1.5 days ea.

\$ 2,400.00

MediCom Expenses

Air Travel	\$	800.00
Hotel & Room Tax	\$	600.00
Meals	\$	100.00
Out of Pocket	\$	50.00
Ground Transport	\$	100.00
Misc., shipping, FedEx	\$	500.00
Printing of Evaluation forms	\$	300.00
Production of Support Material/Handouts	\$	6,250.00
Posters	\$	800.00
Catering; food/beverage for 250	\$	25,000.00
A/V services and digital recording	\$	3,500.00

Faculty Expenses

Honoraria	Two faculty per meeting	\$	5,000.00
Airfare	2	\$	1,600.00
Hotel	2	\$	700.00
Meals		\$	100.00
Ground transportation airport limo to/from		\$	300.00

MediCom Service Charges

Overall Project Management / Accounting \$ 15,000.00

Medicom subtotal

**Projected Total** \$ **131,350.00**Enduring Material Adaptation  
Medscape

\$116,000.00

Total Grant Request

\$ **247,350.00**



2-Jul-04

## PROPOSAL #04-082

PRI-MED 2004 - PRI MED EAST

Cephalon, Inc

Grant Request: \$247,350.00

PRI MED EASTPriMed Administrative Fee

\$ 20,000.00

MediCom Project Management

Meeting and Faculty Coordination	\$	30,000.00
Design and graphics	\$	3,500.00

CME Approval/Certificates

Review/Approval	\$	5,000.00
Certificates @ 250	\$	2,250.00
Adaption of content for enduring material		\$7,500

MediCom On-site Symposium Management 2 Symposia

\$800/day per 2 staff - 1.5 days ea.	\$	2,400.00
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MediCom Expenses

Air Travel	\$	800.00
Hotel & Room Tax	\$	600.00
Meals	\$	100.00
Out of Pocket	\$	50.00
Ground Transport	\$	100.00
Misc., shipping, FedEx	\$	500.00
Printing of Evaluation forms	\$	300.00
Production of Support Material/Handouts	\$	6,250.00
Posters	\$	800.00
Catering; food/beverage for 250	\$	25,000.00
A/V services and digital recording	\$	3,500.00

Faculty Expenses

Honoraria Two faculty per meeting	\$	5,000.00
Airfare 2	\$	1,600.00
Hotel 2	\$	700.00
Meals	\$	100.00
Ground transportation airport limo to/from	\$	300.00

MediCom Service Charges

Overall Project Management / Accounting	\$	15,000.00
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Medicom subtotal

<b>Projected Total</b>	<b>\$</b>	<b>131,350.00</b>
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Enduring Material Adaptation

Medscape		\$116,000.00
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Total Grant Request

<b>\$</b>	<b>247,350.00</b>
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**EDUCATIONAL GRANT DRAFT REQUEST**

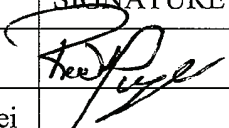
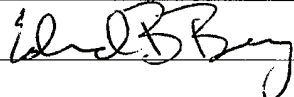
The attached material has been reviewed and is approved:

Payee: Medicom Worldwide, Inc.

Amount: \$247,350

Type of Program: "Treatment of Chronic Pain in the Primary Care Setting" Symposium  
to be presented at PRI MED EAST in Boston, October 31, 2004

Submitted for Review: 7/29/04

DEPARTMENT	NAME	SIGNATURE	DATE
Scientific Communications	Rod Hughes		7-29-04
Medical Affairs	Kiumars Vadieli		
Legal & Government	Ed Berg		7/29/04

Return to: Suzanne Richards, ext. 86532

MediCom Worldwide, Inc.  
LETTER OF AGREEMENT

07300BB.5

*Regarding Terms, Conditions and Purposes of an Educational Grant*

Among MediCom Worldwide, Inc. (The Sponsor), WebMD, Inc., ("Medscape") and Cephalon, Inc (the Commercial Supporter / Grantor). Cephalon, Inc has agreed to provide, an unrestricted grant in the amount of **247,350** in support of the educational activities as outlined below. MediCom Worldwide, Inc. agrees to disburse the grant funds specific to the development and implementation of the Internet activity directly to Medscape.

**Title of CME Activity:** Treatment of Chronic Pain in the Primary Care Setting

**Proposed Date:** Live event: October 31, 2004; Internet Posting date :November 15, 2004

**Location:** Live symposia to take place in conjunction with National Conference "Pri Med East"  
Boston, MA. Medscape to adapt live activity for self study format via internet

**Commercial Supporter:** Cephalon, Inc.

**Address:** 145 Brandywine West Chester, PA 19380

**Telephone:** 610-738-6517

**Contact:** Terry Terifay

**Type of Grant:** Unrestricted Grant:

**Distribution of funds:**

Total Grant: \$247,350

- MediCom Worldwide, Inc. \$131,350
- Medscape: \$116,000

**Sponsor:** MediCom Worldwide, Inc.

**Telephone:** 215-337-9991

**Fax:** 215-337-0959

**Contact:** Joan Meyer

**WebMD, Inc., ("Medscape")**

**Address:** 224 W. 30<sup>th</sup> Street, New York, NY 10001

**Telephone:** 212-624-3891

**Contact:** Sarah Speer

**CONDITIONS**

1. **Statement of Purpose:** program is for scientific and educational purposes only and will not promote the Grantor's products, directly or indirectly.
2. **Control of Contents & Selection of Presenters & Moderators:** MediCom Worldwide, Inc. is responsible for control of content of the activity and selection of presenters and moderators. The Grantor agrees not to direct the content of the activity or to influence the MediCom Worldwide, Inc. and Medscape with regard to content. The Grantor, or its agents, will respond only to MediCom Worldwide, Inc./Medscape initiated requests for suggestions of presenters or sources of potential presenters. MediCom Worldwide, Inc. and Medscape will record the role of Grantor, or its agents, in suggesting presenters; will seek suggestions from other sources; and will make selection of presenter(s) based on balance and independence.
3. **Disclosure of Financial Relationships.** MediCom Worldwide, Inc. will ensure disclosure to the audience of (a) program funding and (b) any significant relationship between MediCom Worldwide, Inc., and the commercial supporter or between individual speakers or moderators and the commercial supporter.
3. **Role of the Medscape:** Medscape may act as the representative for MediCom Worldwide, Inc. in the overall management of this activity and in day-to-day communications with the parties associated with this activity, including faculty and the Grantor.

4. **Disclosure of Financial Relationships:** MediCom Worldwide, Inc. will ensure meaningful disclosure to audience, at the time of the program, of (a) Grantor funding and (b) any significant relationship between MediCom Worldwide, Inc., Medscape and the Grantor or between individual speakers or moderators and the Grantor and/or Medscape.
5. **Involvement in Content:** There will be no "scripting," emphasis, or direction of content by the Grantor or its agents.
6. **Ancillary Promotional Activities:** No promotional activities will be permitted in the same room or oblique path as the educational activity. No product advertisements will be permitted in the program room.
7. **Objectivity & Balance:** MediCom Worldwide, Inc. will make every effort to ensure that the Grantor's products (or competing products) are objectively selected and presented, with favorable and unfavorable information and balanced discussion of prevailing information on the product(s) and/or alternative treatments.
8. **Limitations on Data:** MediCom Worldwide, Inc. will ensure, to the extent possible, meaningful disclosure of limitations on data, e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion.
9. **Discussion of Unapproved Uses:** MediCom Worldwide, Inc. will require that presenters disclose when a product is not approved in the United States for the use under discussion.
10. **Opportunities for Debate:** MediCom Worldwide, Inc. will ensure meaningful opportunities for questioning or scientific debate.
11. **Independence of MediCom Worldwide, Inc. and Medscape in the Use of Contributed Funds:**
  - a. Funds should be in the form of an educational grant made payable to MediCom Worldwide, Inc.
  - b. All other support associated with the CME activity (e.g., distributing brochures, preparing slides, etc.) must be given with the full knowledge and approval of the MediCom Worldwide, Inc.
  - c. No other funds from Cephalon, Inc. will be paid to the program director, faculty, or others involved with the CME activity (additional honoraria, extra social events, etc.).

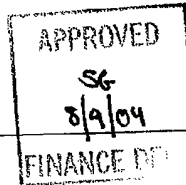
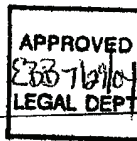
Cephalon, Inc. agrees to abide by all requirements of the ACCME Essential Areas and Policies related to commercial support of continuing medical education.

MediCom Worldwide, Inc. and Medscape agree to: 1) abide by the ACCME Essential Areas and Policies relating to commercial support of continuing medical education; 2) **abide by the Food and Drug Administration Policy Statement on Industry Supported Scientific and Educational Activities** 3) acknowledge educational support from Cephalon, Inc in program brochures, syllabi, and other program materials; and 4) furnish Cephalon, Inc. a report concerning the expenditure of the funds provided.

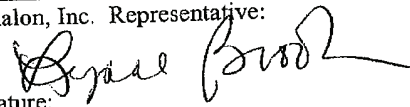
Payee: MediCom Worldwide, Inc.

In Care Of: Joan Meyer  
Address 101 Washington St  
Morrisville, PA 19067

Tax ID. # 233063738



Cephalon, Inc. Representative:

Signature: 


Date:

Medscape Representative:

Signature:

Date:

MediCom Worldwide, Inc. Representative: Joan Meyer

Signature: 

Date: 7/21/04

2/00

07300BB.8

**PRI-MED****Symposia Contract**

Industry Supported Symposia, to be held in conjunction with the Pri-Med Conference &amp; Exhibitions.

Organizing Company: MEDICOM WORLDWIDE, INC. Education Sponsor: MEDICOM WORLDWIDE, INC.  
 (Program Management / Execution) (Accreditor)  
 Commercial Supporter: CEPHALON Program Topic: CITRONIC PAIN  
 (Grantor)  
 Conference & Exhibition Location(s): Please indicate all regions for which this contract will apply:

- Pri-Med South: April 1-4, 2004\*  
Ft. Lauderdale, FL
- Pri-Med West: May 12-15, 2004\*  
Anaheim, CA
- Pri-Med Mid-West: June 16-19, 2004\*  
Rosemont, IL
- Pri-Med East: October 28-31, 2004\*  
Boston, MA (dates subject to change)
- Pri-Med Mid-Atlantic: November 17-20, 2004\*  
Washington, DC

\*Pre-Conference Symposia Days are held one day prior to the opening of the 3-Day Conference &amp; Exhibition

**Symposium Fee:** \$20,000 for Breakfast, Mid-Morning, Lunch, and Afternoon time slots  
 \$26,000 for Dinner slots

The commercial supporter wishes to provide support for the named continuing medical education activity by means of an unrestricted educational grant. Payments of grant monies shall be allocated to each region: \$2,000 deposit of total grant monies due at time of application. Remaining balance shall be due approximately 7 months prior to each Conference. Please see payment schedule below:

**REMIT PAYMENT TO:**

**Mailing Address:** Pri-Med  
 c/o MJC Communications  
 PO Box 380072  
 Boston, MA 02241-0872

**Overnight Address:** Pri-Med  
 c/o MJC Communications  
 Symposia Marketing Specialist  
 380 Stuart Street  
 Boston, MA 02116  
 (617) 406-4000

PAYMENT SCHEDULE	PRI-MED SOUTH	PRI-MED WEST	PRI-MED MID-WEST	PRI-MED EAST	PRI-MED MID-ATLANTIC
Balance Due as Pri-Med	Upon Acceptance	Upon Acceptance	Upon Acceptance	April 16, 2004	May 7, 2004

**Pri-Med's Responsibilities**

- Provide a session room in the Convention Center or in a Conference Hotel.
- Provide basic Audio/Visual needs including: one LCD projector, screen(s), podium and wired lavallere microphone, sound for the room.
- Determine room set and session capacity.
- Market all approved symposium programs.
- Provide quality assurance services through the Pri-Med Institute.
- Manage the entire registration process including pre-registration and on-site registration.
- Provide the Organizing Company with bi-weekly pre-registration updates.
- Provide ExpoCard readers to electronically record symposium attendance on-site.
- Provide the Organizing Company with a list of pre-registrants and a list of actual session attendees.
- Provide (2) Temporary Staff Personnel to assist for the duration of a symposium. Temporary Staff will assist with on-site registration along with any additional needs the Organizing Company might have including but not limited to: syllabus distribution and survey collection.
- Assign (2) Pri-Med staff members to oversee the registration process and manage the ticket holder and non-ticket holder wait lines.
- Provide a shared office for all Organizing Companies to conduct informal speaker slide reviews, make phone calls, and store syllabus materials.

**Organizing Company / Sponsoring Institution's Responsibilities**

- Create educational content for the symposium and coordinate all aspects of the CME program which include but are not limited to:
  - Secure CME accreditation and ensure compliance with ACCME guidelines.
  - Ensure neither Harvard Medical School nor the Partnering Institution, in the specified region, is the accrediting institution. See Conditions for a listing of partnering institutions.
  - Secure speakers / moderators, ensure their affiliations are not with Harvard Medical School or the Partnering Institution in the region, and obtain approval from Pri-Med. See Conditions for a listing of partnering institutions.
  - Submit symposium content to the Pri-Med Institute for quality review and feedback. See Conditions for further details.
  - Create, print, and ship all syllabus material.
  - Distribute education certificates.
- Provide all requested program information, by the determined deadlines, for inclusion on the web site, in the Full Conference Brochure, Symposium Overview, and Conference Directory. Information received after the deadline may not be included.
- Design a 3½" x 9½" black and white advertisement to be included in the Conference Directory.
- Create (2) 22" x 28" promotional signs to be displayed on the Symposium Wall and outside the assigned session room.
- (Optional) Create additional 22" x 28" promotional signage to display in the Convention Center and/or Conference Hotels.
- Manage all on-site operations, with the exception of registration, including but not limited to: speaker requests, food and beverage service, audio visual, and syllabus distribution.
- Place required food and beverage orders directly with the Convention Center, comply with Pri-Med's food & beverage guidelines, and incur all associated costs.
- Place all audio visual requests, in addition to the standard set, directly with the Official Conference Vendor.
- Monitor pre-registration attendance figures and contact Pri-Med regarding additional promotional options as necessary.



07300BB.9

**CONDITIONS**

- Statement of Purpose:** This CME activity is for scientific and educational purposes only and will not promote the Commercial Supporter's products, directly or indirectly.
- Control of Content and Selection of Presenters and Moderators:** Sponsor is responsible for control of content and selection of presenters and moderators. The Commercial Supporter agrees not to direct the content of the program. The Commercial Supporter, or its agents, will respond only to Sponsor-initiated requests for suggestions of presenters or sources of possible presenters. The Commercial Supporter will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Commercial Supporter and speakers, and will provide this information in writing. Sponsor will record role of Commercial Supporter, or its agents, in suggesting presenter(s), will seek suggestions from other sources, and will make selection of presenter(s) based on balance and independence.
- Involvement in Content:** There will be no "scripting," emphasis, or direction of content by the Commercial Supporter or its agents.
- Objectivity & Balance:** Sponsor will make every effort to insure that data regarding the Commercial Supporter's products (or competing products) are objectively selected and presented, with favorable and unfavorable information and balanced discussion of prevailing information on the product(s) and/or alternative treatments.
- Limitations on Data:** Sponsor will ensure that data regarding the Commercial Supporter's products (or competing products) are objectively selected and presented, with favorable and unfavorable information and balanced discussion of prevailing information on the product(s) and/or alternative treatments.
- Discussion of Unapproved Uses:** Sponsor will require that presenters disclose when a product is not approved in the United States for the use under discussion.
- Disclosure of Financial Relationships:** Sponsor will ensure meaningful disclosure to the audience, at the time of the program, of (a) Commercial Supporter funding and (b) any significant relationship between the Sponsor and the Commercial Supporter or between individual speakers or moderators and the Commercial Supporter.
- Opportunities for Debate:** Sponsor will ensure meaningful opportunities for questions or scientific debate.
- Role of the Pri-Med Institute:** The Pri-Med Institute, which is accredited by the ACCME to provide continuing medical education for physicians, will quality-review sponsored activities. The content provider agrees to submit all requested program materials to the Pri-Med Institute for review 6-weeks prior to the activity and conducts its work under rules and regulations as stipulated by the ACCME.
- Speaker & Accreditation Restrictions:** Symposium Programs, in the specified regions, may not be accredited by Harvard Medical School or the partnering institution and speakers/moderators may not be affiliated with Harvard Medical School or the partnering institutions. Partnering Institutions include: *South:* University of Miami School of Medicine, *West:* David Geffen School of Medicine at UCLA, *Mid-West:* Northwestern University Feinberg School of Medicine, *East:* No partnering institution, and *Mid-Atlantic:* Johns Hopkins University School of Medicine.
- Published Information:** An organizing company shall not modify the symposium title or session information once it has been submitted to Pri-Med and published.
- Ancillary Promotional Activities:** No promotional activities will be permitted in the same room or oblique path as the educational activity. No product advertisement will be permitted in the program room. No promotion of the educational activity and/or promotional signage will be permitted in an exhibit booth. No literature may be distributed in the public space or by means of plastic literature holders secured to signage. No independent promotional mailings will be permitted unless otherwise approved by Pri-Med. Promotional Signage will be permitted in the public space provided it adheres to the 22"x28" size specifications and limit (1) sign per level in the Convention Center and (1) sign per Hotel. An Organizing Company will ensure a minimum of (2) 22"x28" signs are created and shipped to the Center for display on the Symposium Wall and outside the session room.
- Enduring Materials:** An Organizing Company shall notify Pri-Med if the symposium, being held in conjunction, will be audio recorded, video recorded, or published. adhere to Pri-Med's distribution guidelines, and ensure that the Pri-Med brand is not identifiable or referenced in the reproduction.
- Exhibit Space:** Most supporting companies have a presence on the exhibit floor, holding a minimum of 400 square feet of exhibit space. This presence is strongly encouraged.
- Room Set & Capacity:** An organizing company is committed to the room set determined by Pri-Med and set alterations are prohibited. An organizing company is committed to the session capacity pre-determined by Pri-Med and must be equally flexible in accommodating additional on-site attendees, upon Pri-Med's request, on the Pre-Conference Symposia Day.
- Photography:** Pri-Med reserves the right to photograph the audience and speakers while a symposium is in session.
- Cancellation by Commercial Supporter:** The Payee shall receive a 50% refund of the total symposium fee (less the \$2,000 application deposit) if notification of cancellation is received in writing on or before the Cancellation Deadline. If a program is cancelled after the deadline, a refund will not be issued. Pri-Med will deduct (\$5) priority points, and reserves the right to prohibit participation in symposia at future meetings. The 2004 cancellation deadlines are as follows:  
*South:* September 19, 2003      *West:* October 31, 2003      *Mid-West:* December 5, 2003      *Mid-Atlantic:* April 16, 2004      *East:* May 7, 2004
- Cancellation by Pri-Med:** In the event that the premises in which the Conference & Exhibition is or is to be conducted shall become, in the sole discretion of Management, unfit for occupancy, or in the event the holding of the Conference & Exhibition or the performance of Management under the contract (of which these Rules and Regulations are a part) are substantially or materially interfered with by virtue of any cause or causes not reasonably within the control of Management, said contract and/or the Conference & Exhibition (or any part thereof) may be terminated by Management. Management shall not be responsible for delays, damage, loss, increased costs or other unfavorable conditions arising by virtue of cause or causes not reasonably within the control of Management. If Management terminates said contract and/or Conference & Exhibition (or any part thereof) as aforesaid, then Management may retain such part of a payee's symposium fee as shall be required to recompense it for expenses incurred up to the time such contingency shall have occurred, and there shall be no further liability on the part of either party. For purposes hereof, the phrase "cause or causes not reasonably within the control of Management" shall include, but shall not be limited to, fire; casualty; flood; epidemic; earthquake; explosion or accident; blockage; embargo; inclement weather; governmental restraints; restraints or orders of civil defense or military authorities; act of public enemy; riot or civil disturbance; strike, lockout, boycott or other labor disturbances; inability to secure sufficient labor; technical or other personnel failure; impairment or lack of adequate transportation facilities; inability to obtain, condemnation, requisition or commandeering of necessary supplies or equipment; local, state, or federal laws, ordinances, rules, orders, decrees, or regulations where legislative, executive or judicial, and whether constitutional or unconstitutional; or Acts of God.

	<b>JOAN MEYER</b>	<b>AGREED</b>	<b>7-26-04</b>
Organizing Company	Print Full Name	Signature	Date
	<b>Lynne Brookos</b>	<b>Lynne Brookos</b>	<b>8/15/04</b>
Commercial Supporter	Print Full Name	Signature	Date
	<b>JOAN MEYER</b>	<b>Joan Meyer</b>	<b>7-26-04</b>
Educational Sponsor	Print Full Name	Signature	Date
Pri-Med	Print Full Name	Signature	Date
(For Pri-Med Use Only)	Assignment	(Pri-Med is an M/C Communications Company)	Investment

**APPROVED**  
**SEP 8/15/04**  
**LEGAL DEPT**

07300BB.10

From: Origin ID: (610)738-6532  
Suzanne Richards  
CEPHALON  
145 BRANDYWINE PARKWAY  
  
WEST CHESTER, PA 19380



Ship Date: 16AUG04  
Actual Wgt: 1 LB  
System#: 2402709/NET1850  
Account#: S \*\*\*\*\*

REF: 631



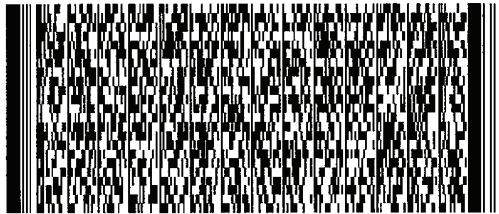
Delivery Address Bar Code

SHIP TO: (215)337-9991

BILL SENDER

Joan Meyer  
Medicom  
101 Washington Street

Morrisville, PA 19067



\*\* 2DAY \*\*

WED

Deliver By:  
18AUG04

TRK# 7907 3383 1558

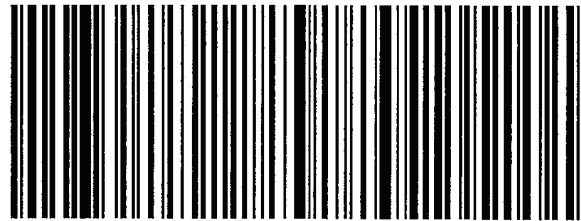
FORM  
0201

PHL

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19067 -PA-US

17 NXXA



Shipping Label: Your shipment is complete

1. Use the 'Print' feature from your browser to send this page to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

**Warning: Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and could result in additional billing charges, along with the cancellation of your FedEx account number.**

Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com. FedEx will not be responsible for any claim in excess of \$100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of \$100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is \$500, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see current FedEx Service Guide.

[https://www.fedex.com/cgi-bin/ship\\_it/unity/1DiRt0CdUw4JfYv4AgQt2EdZz6BfXt0AhQ...](https://www.fedex.com/cgi-bin/ship_it/unity/1DiRt0CdUw4JfYv4AgQt2EdZz6BfXt0AhQ...) 8/16/2004

Confidential

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P-29481 \_ 00929



**2004 MEDICAL EDUCATION AGREEMENT V  
CME LECTURE SERIES  
Amendment**

This Amendment ("Amendment") is entered into as of July 20, 2004. This will serve to amend certain terms and conditions of the 2004 Medical Education Agreement V (the "Agreement") between MediCom Worldwide, Inc. ("Provider") and Cephalon, Inc ("Commercial Supporter") entered into and signed March 8, 2004.

The Agreement identified a need to develop and execute a series of live medical education activities focusing on topics related to chronic pain management and approved for CME, CPE and CNE continuing education credits.

The series was designed to execute 350 (1.0 hours per) live educational lecture activities scheduled in 2004 throughout the United States and a series of 30 (3.0 hours per) live symposia activities scheduled in specifically identified regions in the United States.

As a result of ongoing Provider management review and process improvement initiatives, Provider is requesting an amendment to the scope of the original grant request which will result in a decrease in the total number of activities to be executed throughout 2004. Provider will execute a total of 214 live activities as part of this agreement. In so doing the grant request will be amended as follows:

<b>Approved total grant request:</b>	<b>\$4,368,980.00</b>
<b>Amended total grant request:</b>	<b>\$2,611,472.00</b>
<b>Invoiced and paid to date:</b>	<b>\$2,184,500.00</b>
<b>Invoice and final payment:</b>	<b>\$426,972</b>

All other terms and conditions of the original Agreement not specifically changed herein remain in full force and effect.

IN WITNESS WHEREOF, the parties hereto have executed this Amendment as of the day and year first written above.

MediCom Worldwide, Inc.

Signature: Joan Meyer

Name: Joan Meyer

Title: Executive Director

Date: July 20, 2004

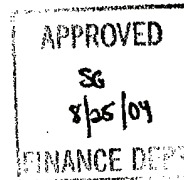
Cephalon, Inc

Signature: [Signature]

Name: Lynne Brookes

Title: V. P. of Marketing

Date: 8/16/04

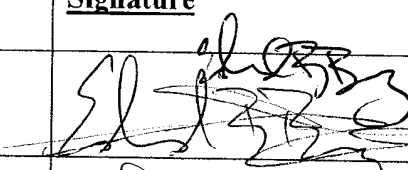
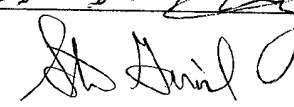



**Cephalon Review of Education Grant**

The attached Grant amount has been reviewed by members of the MEP team.

**Program Name:** Unrestricted Educational Grant:

**Medicom Worldwide, Inc.**  
**National CME Lectures and Symposia**

<u>Department</u>	<u>Name</u>	<u>Signature</u>	<u>Date</u>
Legal	Ed Berg		2/25/04
Accounting	Steve Girard		2/27/04
Marketing	Paula Castagno Andy Pyfer		2/25/04



December 12, 2003

P. Andrew Pyfer  
Product Director  
Cephalon, Inc.  
145 Brandywine Parkway  
West Chester, PA 19380

Dear Mr. Pyfer:

MediCom Worldwide is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians and by the Accreditation Council for Pharmacy Education to sponsor continuing education for pharmacists, as well as an approved provider of nursing continuing education through the California State Board of Registered Nursing.

A comprehensive needs assessment has identified interests of health care providers who manage patients suffering from pain. Based on this educational need, we are requesting an educational grant from Cephalon, Inc. to support the development and implementation of several continuing education activities on the subjects of effective pain management techniques and the changing guidelines to improve pain management. The budget to fund these activities is approximately \$4,368,980.

Proposed Educational Activities for Pain Management

A series of approximately 350 one-hour CME lectures across the United States  
A series of 30 half-day (4 CME credit hrs.) symposia strategically held across the US  
Continuation of the CEP speaker lecture bureau for invited clinical experts in pain management  
Development, production, and certification of CME slide content for four identified topics  
Continuation of access to MediCom's proprietary CEP web-based CME slide library for faculty

These scientific activities, will be developed independently and will comply with all ACCME, FDA, AMA, and ACPE regulations for industry-supported professional continuing education. The target audiences for these activities are pain management specialists, oncologists and anesthesiologists, nurses, pharmacists and those other healthcare professionals interested in pain management education.

As a supplement to our direct mail and web site announcement of these educational activities, we request Cephalon representatives to disseminate information regarding these programs to the medical community.

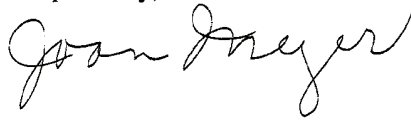
However, the content of such information is the responsibility of the accredited provider and any such distribution will be solely as a supplement to provider's primary method of announcement and promotion.

101 Washington St.  
Morrisville, PA 19067  
215-337-9991

1

Thank you, in advance, for your consideration of this request. Should you agree to provide funding for this project, Letters of Agreement will be forwarded to you as soon as possible.

Respectfully,

A handwritten signature in cursive script, appearing to read "Joan Meyer".

Joan Meyer RN, MA  
Executive Director, Continuing Education

101 Washington St.  
Morrisville, PA 19067  
215-337-9991





## 2004 MEDICAL EDUCATION AGREEMENT V CME LECTURE SERIES

As a condition of Cephalon, Inc's contribution of funds to support a series of independent medical education programs (with CME, CPE, and CNE credits), the Scientific and Educational Activity provider agrees to the following terms and conditions:

This Agreement ("Agreement") is entered into as of December 12, 2003 by and between Cephalon, Inc. ("Cephalon") and MediCom Worldwide, Inc. ("Provider") regarding a series of 350 educational lectures and 30 symposia supported by Cephalon to be held during 2004. The parties' mutual objectives are to provide balanced, independent, scientifically rigorous lectures to promote the education of attendees. The amount of the educational grant requested is \$4,368,980.

1. Statement of Purpose. This program is for scientific and educational purposes only and not to promote any commercial drug products.

2. Control of Content and Selection of Presenters and Moderators. The provider is ultimately responsible for the control of content and selection of presenters and moderators. Cephalon or its agents may respond to requests initiated by the provider for suggestions of presenters or sources of possible presenters. Cephalon will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Cephalon and speaker; and will provide this information in writing. Provider will seek suggestions from other sources, and will, in its sole discretion, select presenters and moderators.

3. Disclosure of Financial Relationships. Provider will direct speakers and moderators to disclose to the audience commercial support or funding or other significant financial relationships between the speakers and moderators and Cephalon and/or any other commercial company whose products are pertinent to the content of the presentation. Provider will disclose Cephalon's support at this program.

4. Involvement in Content. There will be no "scripting," emphasis, or influence on content by Cephalon or its agents. However, Cephalon may provide technical support to speakers, e.g., furnishing slides or data, upon their request.

5. Ancillary Promotional Activities. No promotional activities will be permitted in the same room as, or in the obligatory path to, the educational activity. No product advertisements will be permitted within the program or handouts.

6. Objectivity and Balance. Provider will advise presenters that data regarding Cephalon products (or competing products) are to be objectively selected and presented. Provider will provide the opportunity for speakers and the audience to discuss information, both favorable and unfavorable, about the product(s) and/or alternative treatments.

7. Limitations of Data. Provider will request the speakers, to the extent possible, to disclose limits on the data, e.g., that it involves ongoing research, interim analyses, preliminary data, or unsupported opinion.

8. Discussion of Unapproved Uses. Provider will request that presenters disclose when a product is not approved in the United States for the use under discussion.

9. Actiq® Risk Management Program. Provider is aware that Actiq (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- Actiq is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.*
- Actiq is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.

10. Opportunity for Debate. Provider will ensure opportunities for questioning by attendees and scientific debate with and between presenters.

11. Independence of Provider in the Use of Contributed Funds.

(a) funds should be in the form of an educational grant made payable to the provider organization.

(b) Provider must be advised of all other support by Cephalon of the CME activity (e.g., distributing brochures, preparing slides). If Provider disapproves of this activity, it shall promptly notify Cephalon.

(c) no other funds from Cephalon will be paid to the program director, faculty, or others involved with this CME activity, e.g., additional honoraria.

## 12. General.

(a) Cephalon agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.

(b) Provider agrees to: (1) abide by the ACCME Standards for Commercial Support of Continuing Medical Education; (2) acknowledge educational support from Cephalon in program brochures, syllabi, and other program materials; and (3) upon request, furnish Cephalon with a report concerning the expenditure of the funds provided by Cephalon.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

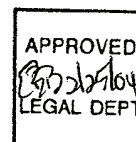
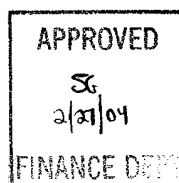
MEDICOM WORLDWIDE, INC.

CEPHALON, INC.

By: Joan Meyer  
 Name: Joan Meyer  
 Title: Executive Director, Cont. Ed  
 Date: December 12, 2003

By: [Signature]  
 Name: \_\_\_\_\_  
 Title: \_\_\_\_\_  
 Date: \_\_\_\_\_

**SIGN I**



From: Origin ID: (610)738-6532  
Suzanne Richards  
CEPHALON  
145 BRANDYWINE PARKWAY  
  
WEST CHESTER, PA 19380



Ship Date: 26AUG04  
Actual Wgt: 1 LB  
System#: 2402709/NET1850  
Account#: S \*\*\*\*\*

REF: 631



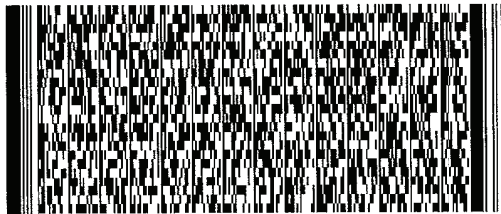
Delivery Address Bar Code

SHIP TO: (215)337-9991

BILL SENDER

Joan Meyer  
Medicom  
101 Washington Street

Morrisville, PA 19067



STANDARD OVERNIGHT

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Deliver By:  
27AUG04

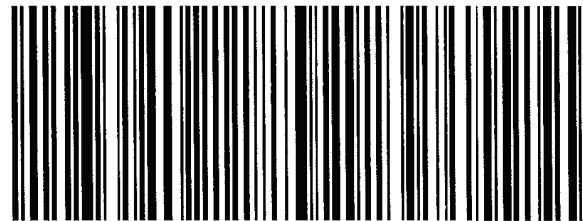
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19067 -PA-US

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Shipping Label: Your shipment is complete

1. Use the 'Print' feature from your browser to send this page to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

**Warning: Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and could result in additional billing charges, along with the cancellation of your FedEx account number.**

Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com. FedEx will not be responsible for any claim in excess of \$100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of \$100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is \$500, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see current FedEx Service Guide.

From: SUZANNE RICHARDS (610)738-6532  
CEPHALON  
145 BRANDYWINE PARKWAY  
WEST CHESTER, PA, 19380

REVENUE BARCODE

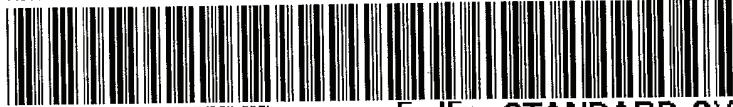


FedEx.

To: Lynn Sturgis (215)337-9991  
Medicom Worldwide  
101 Washington Street  
Morrisville, PA, 19067

SHIP DATE: 08MAR04  
WEIGHT: 1 LBS

Ref: 631



DELIVERY ADDRESS BARCODE(FEDEX-EDR)

TRK # 7905 7210 3285 52PM

FedEx STANDARD OVERNIGHT

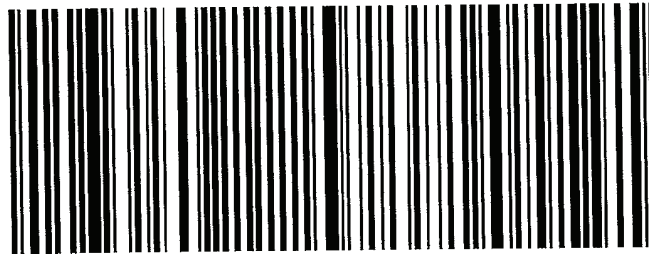
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19067-PA-US

17 NXXA

TUE  
A2

Deliver by:  
09MAR04



## Shipping Label: Your shipment is complete

1. Use the 'Print' feature from your browser to send this page to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

**Warning: Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and could result in additional billing charges, along with the cancellation of your FedEx account number.**

Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on [fedex.com](http://fedex.com). FedEx will not be responsible for any claim in excess of \$100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of \$100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is \$500, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see current FedEx Service Guide.



4700 W. Lake Avenue  
Glenview, IL 60025-1485  
847/375-4731 Fax 877/734-8750  
E-mail: [aapm@amctec.com](mailto:aapm@amctec.com)  
Web site: <http://www.painmed.org/>

August 3, 2004

Sent via E-Mail: [joan@medicaled.com](mailto:joan@medicaled.com)

Ms. Joan Meyer  
Medicom  
101 Washington Street  
Morrisville, PA 19067

RE: Cephalon, Inc.

Dear Ms. Meyer:

I am pleased to inform you that the 2005 Annual Meeting Program Committee of the American Academy of Pain Medicine (AAPM) has approved the proposal that you submitted, in concept, for a commercially supported symposium at the AAPM's 21<sup>st</sup> Annual Meeting. We request additional information by August 10. Please submit the title of each talk and suggested speakers for each talk. The AAPM Program Committee is responsible for reviewing proposals and all materials for these programs. The committee reviewed your proposal at its July meeting and based on the content of the proposed program, which the committee feels is timely and relevant to AAPM members' practices, and the qualifications of the proposed speakers, the committee has approved the program for further development. We ask that you abide by the AAPM Guidelines for Commercially Supported Symposia, a copy of which is enclosed.

The lunch symposium "A Blueprint for Successful Opioid Pain Management: Providing Care While Preventing Misuse and Diversion" will be held on Saturday, February 26, 2005 from 12:15 –1:45 p.m.

We will need you to provide us with a confirmed program schedule and complete contact information for all speakers including name, credentials, facility, facility city/state, mailing address, phone, fax, email, and a short program synopsis for the brochure. This information should be submitted electronically via email attachment. During this process, please be aware that the Program Planning Committee will be responsible for final approval and has the authority and responsibility to make additional recommendations regarding content, faculty, etc. In order to meet our deadlines for brochure copy, etc., we ask that you complete preparation of the above materials by **August 17**. Your cooperation in regard to compliance will be appreciated.

Enclosed is the letter of agreement regarding the use of funds for continuing medical education activities and an invoice for the educational grant. Please sign and return a copy of the letter of agreement along with payment to my attention no later than October 4, 2004. Recognition of your support of the annual meeting and this session will begin in the registration brochure that will be distributed to 25,000 medical professionals. Please send all information to [kchecea@amctec.com](mailto:kchecea@amctec.com). Should you have any questions regarding any of these materials, please feel free to contact me at 847/375-4765.

Sincerely,

Kathryn M. Checea  
Director of Professional Relations

Enclosure: AAPM Guidelines for Commercially Supported Symposia  
Letter of agreement  
Invoice

cc: Dean Robinson, Cephalon, Inc. - [drobinso@cephalon.com](mailto:drobinso@cephalon.com)

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**EDUCATIONAL GRANT DRAFT REQUEST**

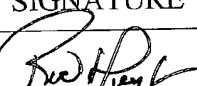
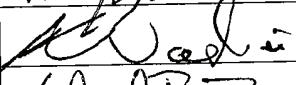
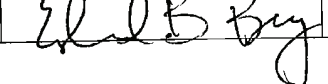
The attached material has been reviewed and is approved:

Payee: American Academy of Pain Medicine

Amount: \$50,000 ~~171,750.00~~

Type of Program: Commercially Supported Symposium – AAPM 21<sup>st</sup> Annual Meeting

Submitted for Review: 8/12/04

DEPARTMENT	NAME	SIGNATURE	DATE
Scientific Communications	Rod Hughes		8.12.04
Medical Affairs	Kiumars Vadieli		8/12/04
Legal & Government	Ed Berg		8/12/04

Return to: Suzanne Richards, ext. 86532





MediCom Worldwide, Inc.  
**LETTER OF AGREEMENT**

### *Regarding Terms, Conditions and Purposes of an Educational Grant*

The American Academy of Pain. (The Sponsor), MediCom Worldwide, Inc. (The Joint Sponsor) and Cephalon, Inc (the Commercial Supporter / Grantor).

Cephalon, Inc agrees to provide to MediCom Worldwide, Inc. an unrestricted grant in the amount of \$171,750.00 in support of the educational activities as outlined below. MediCom Worldwide, Inc. agrees to disburse the grant funds to develop and implement this activity as outlined in coordination with the American Academy of Pain Medicine.

**Title of CME Activity: A Blueprint for Successful Opioid Management: Providing Care While Preventing Misuse and Diversion**

Date: February 26, 2005

**Location:** The annual AAPM conference Palm Springs, CA

Commercial Supporter: Cephalon, Inc

Address: 145 Brandywine West Chester, PA 19380

Telephone: 610-738-6517

Contact: Terrence Terifay  
Rod Hughes

Type of Grant: Unrestricted Grant: X

**Restricted Grant (specification listed below)**

Amount of Grant: MediCom Worldwide, Inc. \$171,750.00

Sponsor: The American Academy of Pain Medicine  
MediCom Worldwide, Inc.

**Telephone: 215-337-9991**

Fax: 215-337-0959 Contact: Joan Meyer

Joint Sponsor: MediCom Worldwide, Inc.  
Address: 101 Washington St. Morrisville, PA

## CONDITIONS

1. **Statement of Purpose:** program is for scientific and educational purposes only and will not promote the Grantor's products, directly or indirectly.
2. **Control of Contents & Selection of Presenters & Moderators:** MediCom Worldwide, Inc. and AAPM are responsible for control of content and selection of presenters and moderators. The Grantor agrees not to direct the content of the program or to influence the Joint Sponsors with regard to content. The Grantor, or its agents, will respond only to MediCom Worldwide, Inc initiated requests for suggestions of presenters or sources of potential presenters. The Grantor will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Grantor and speaker, and will provide this information in writing. The Joint Sponsors will record the role of Grantor, or its agents, in suggesting presenters; will seek suggestions from other sources; and will make selection of presenter(s) based on balance and independence.
3. **Role of the Joint Sponsor:** As a Joint Sponsor, MediCom Worldwide, Inc. may act as the representative for AAPM. in the overall management of this activity and in day-to-day communications with the parties associated with this activity, including faculty and the Grantor.

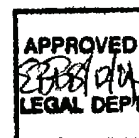
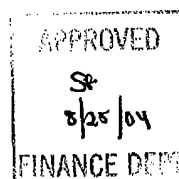
4. **Disclosure of Financial Relationships:** MediCom Worldwide, Inc. and AAPSPM will ensure meaningful disclosure to audience, at the time of the program, of (a) Grantor funding and (b) any significant relationship between MediCom Worldwide, Inc., AAPM and the Grantor or between individual speakers or moderators and the Grantor and/or AAPM.
5. **Involvement in Content:** There will be no "scripting," emphasis, or direction of content by the Grantor or its agents.
6. **Ancillary Promotional Activities:** No promotional activities will be permitted in the same room or obligate path as the educational activity. No product advertisements will be permitted in the program room.
7. **Objectivity & Balance:** MediCom Worldwide, Inc. and AAPM will make every effort to ensure that the Grantor's products (or competing products) are objectively selected and presented, with favorable and unfavorable information and balanced discussion of prevailing information on the product(s) and/or alternative treatments.
8. **Limitations on Data:** MediCom Worldwide, Inc. and AAPM will ensure, to the extent possible, meaningful disclosure of limitations on data, e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion.
9. **Discussion of Unapproved Uses:** MediCom Worldwide, Inc. and AAPM will require that presenters disclose when a product is not approved in the United States for the use under discussion.
10. **Opportunities for Debate:** MediCom Worldwide, Inc. and AAPM will ensure meaningful opportunities for questioning or scientific debate.
11. **Independence of the Joint Sponsors in the Use of Contributed Funds:**
  - a. Funds should be in the form of an educational grant made payable to MediCom Worldwide, Inc.
  - b. All other support associated with the CME activity (e.g., distributing brochures, preparing slides, etc.) must be given with the full knowledge and approval of the Joint Sponsors.
  - c. No other funds from Cephalon, Inc. will be paid to the program director, faculty, or others involved with the CME activity (additional honoraria, extra social events, etc.).

Cephalon, Inc. agrees to abide by all requirements of the ACCME Essential Areas and Policies related to commercial support of continuing medical education.

MediCom Worldwide, Inc. and AAPM agree to: 1) abide by the ACCME Essential Areas and Policies relating to commercial support of continuing medical education; 2) acknowledge educational support from Cephalon, Inc in program brochures, syllabi, and other program materials; and 3) furnish Cephalon, Inc and MediCom Worldwide, Inc. a report concerning the expenditure of the funds provided.

**Payment Terms:**

One-third of projected costs due upon signing of agreement  
 One-third of project costs are due mid project  
 Final third of project costs due upon completion



Cephalon, Inc. Representative:

Signature:

A handwritten signature in black ink, appearing to be "R. J. ...".

Date:

MediCom Worldwide, Inc. Representative: Joan Meyer

Signature:

A handwritten signature in black ink, appearing to be "Joan Meyer".

Date: August 6, 2004

**American Academy of Pain Medicine Agreement for Commercial Support of CME Activities, continued.**

The Company agrees to: (1) abide by all requirements of the ACCME *Standards for Commercial Support of Continuing Medical Education* as stipulated above and (2) abide by the AAPM Guidelines for Commercial Support of CME Activities.

AAPM agrees to: (1) abide by the ACCME *Standards for Commercial Support of Continuing Medical Education*; (2) acknowledge educational support from the Company in program brochures, syllabi, and all other program materials, and (3) upon request, furnish the Company with a report concerning the expenditure of the funds provided.

The following represents full and accurate disclosure of all contributions provided by the Company for this continuing education activity.

**AGREED**

CME Activity: Commercially Supported Symposia

Location/program description: AAPM 21st Annual Meeting – Wyndham Palm Springs & Convention Center, Palm Springs, California

Activity dates: February 24-27, 2005

Unrestricted Educational Grant and/or administrative fee made payable to the American Academy of Pain Medicine in the amount of: **\$ 50,000.00**. AAPM will use this grant to underwrite the specific expenses for this activity as identified in the AAPM Guidelines for Commercial Support.

**Company**

Commercial Supporter Company Name: Cephalon, Inc.

Commercial Company Representative or Agent Name: \_\_\_\_\_

Title: \_\_\_\_\_

Signature: [Signature] Date: \_\_\_\_\_

American Academy of Pain Medicine

Department Director or Designee Name: Kathy Checea

Title: Director of Professional Relations

Signature: [Signature] Date: 8/3/04

Communications Company/Third Party (if applicable)

Organization name: MEDICOM WORLDWIDE, INC

Address: 101 WASHINGTON ST MORRISVILLE, PA 19067

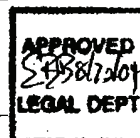
Representative or Agent Name: JOAN MEYER

Title: EXEC. DIRECTOR

Phone number: 215 337-9991 Fax: 215 337-0959 Email: Joan@MedicalEd.com

Signature: [Signature] Date: 8-6-04

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Cephalon, Inc.

145 Brandywine Parkway  
West Chester, PA 19380

09/17/2004 00166110

INVOICE NO.	DATE	DESCRIPTION	PAID AMOUNT	DISCOUNT	APPLIED AMOUNT
AAPM sponsor	09/08/2004	VCH00085110	\$171,750.00		\$171,750.00

INTERNAL NO.	VENDOR #	VENDOR	TOTALS	TOTALS	TOTALS
644	MEDICOM00000	MediCom Worldwide Inc			\$171,750.00



# ACCOUNTS PAYABLE CHECK REQUEST



**PAYEE NAME:** Medicom Worldwide, Inc.

**ADDRESS:** 101 Washington Street  
Morrisville, PA 19067

**INVOICE NUMBER:** n/a

**INVOICE DATE:** n/a

**DUE DATE:** ASAP

**P.O. NUMBER (if applicable):** n/a

**DESCRIPTION:** Sponsorship of AAPM Symposium

<u>G/L ACCOUNT NUMBER</u>	<u>DEPARTMENT</u>	<u>PROJECT</u>	<u>AMOUNT</u>
7640	631	ACTQ	\$ <del>171,775.00</del> 171,750.00

**TOTAL:** \$ ~~171,775.00~~ 171,750.00

Prepared By: Suzanne Richards  
 Extension: 86532  
 Department Number: 631

Approved By: \_\_\_\_\_  
 Print Approvers Name: Bob Roche / Charlie Reinhart

Approvers Title: \_\_\_\_\_

\*\*\*\*\* Mark here if the check is to be picked up by the preparer: ☒ \*\*\*\*\*

**Please note:** If there is any documentation to be mailed along with the payment, please attach a copy in addition to the copy for Accounting's records

Accounting Use Only:

Batch Number: _____
Voucher Number: _____
Entry Date: _____

8/26/2004

From: Origin ID: (610)738-6532  
Suzanne Richards  
CEPHALON  
145 BRANDYWINE PARKWAY  
  
WEST CHESTER, PA 19380



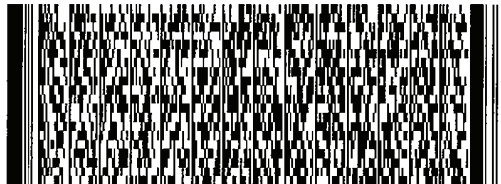
CLS0825040504

SHIP TO: (215)337-9991

BILL SENDER

Joan Meyer  
Medicom  
101 Washington Street

Morrisville, PA 19067



Ship Date: 23SEP04  
Actual Wgt: 1 LB  
System#: 2402709/INET1900  
Account#: S \*\*\*\*\*

REF: 631



Delivery Address Bar Code

STANDARD OVERNIGHT

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Deliver By:  
24SEP04

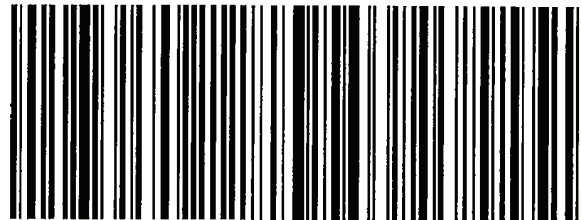
TRK# 7920 9667 1370

FORM  
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Rod Hughes, PhD  
Cephalon, Inc.  
145 Brandywine Parkway  
West Chester, PA 19380

August 24, 2004

Dear Dr. Hughes:

MediCom Worldwide, Inc. is accredited by the Accreditation Council for continuing Medical Education to sponsor continuing medical education for physicians and by the Accreditation council for Pharmacy Education to sponsor continuing education for pharmacists, as well as an approved provider of nursing continuing education through the California State Board of Registered Nursing.

As an accredited provider of continuing education, MediCom Worldwide, Inc. has recently completed a comprehensive needs assessment to identify the educational needs of clinicians who provide care to patients with chronic pain. Based on this educational need, we are requesting an educational grant from Cephalon, Inc. to support the continuing development of educational resources to be utilized by the Clinical Experts in Pain Faculty. The budget to fund this activity is approximately \$300,000.

Medical Education Forum

*The 2004 medical education forum is proposed to review and enhance current educational content utilized by the Clinical Experts in Pain in the delivery of accredited activities coordinated through MediCom Worldwide, Inc. MediCom purposes to work in conjunction with identified educational advisors in the review of current educational modules as well as recommend content updates in the specified topic areas of Chronic Pain Management and Issues of Abuse and Diversion. Topic content will be created and produced as both power point images as well as images available on the CEP slide library. MediCom will utilize this content in the development and coordination of a series of 250 live peer-to-peer educational activities to be scheduled throughout 2005.*

This scientific activity will be developed independently and will comply with all ACCME, FDA, AMA, OIG, and ACPE regulations for industry-supported professional continuing education.

Thank you, in advance, for your consideration of this request. Should you agree to provide funding for this project, Letters of Agreement will be forwarded to you as soon as possible.

Respectfully,

Joan Meyer  
Executive Director  
Continuing Education



**EDUCATIONAL GRANT DRAFT REQUEST**

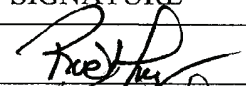

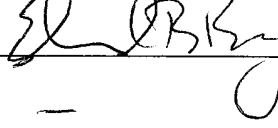
The attached material has been reviewed and is approved:

Payee: Medicom Worldwide

Amount: \$300,000

Type of Program: Development and Management of a Clinical Experts in Pain Faculty Meeting.

Submitted for Review: 8/26/04

DEPARTMENT	NAME	SIGNATURE	DATE
Scientific Communications	Rod Hughes		8.26.04
Medical Affairs	Kiumars Vadieli		8/26/04
Legal & Government	Ed Berg		8/26/04

Return to: Suzanne Richards, ext. 86532

## MediCom WORLDWIDE, Inc.

### Educational Grant Letter of Agreement

Between Cephalon, Inc 145 Brandywine Parkway West Chester, PA and MediCom Worldwide, Inc. ("Provider") 101 Washington St Morrisville, PA.

Title of Program:

**2004 Medical Education Forum**

Date, Location & Time of Program:

November 12-14, 2004

Key Biscayne, FL

Provider has requested support for the above-named Program in the form of an educational grant in the amount of \$300,000.00 It is the intent of this Agreement to ensure that the Program is conducted in a manner consistent with the Food and Drug Administration's Policy Statement on Industry Supported Scientific and Educational Activities, AMA Guidelines on Gifts to Physicians, and the Accreditation Counsel for Continuing Medical Education (ACCME)

To that end, *PROVIDER*, *Cephalon, Inc* agree as follows:

1. **Statement of Purpose:** The Program is for scientific and educational purposes only and is not intended to promote a *Cephalon, Inc.* product directly or indirectly.
2. **Control of Content & Selection of Presenters & Moderators:** The provider is ultimately responsible for the control of content and selection of presenters and moderators. *Cephalon, Inc.* agrees not to direct the content of the program. *Cephalon, Inc.* or its agents, may respond to requests initiated by Provider for suggestions of presenters or sources of possible presenters. *Cephalon, Inc.*, or its agents will suggest more than one name (if possible); will provide speaker qualification; will disclose financial or other relationships between *Cephalon, Inc.*, and speaker; and will provide this information in writing. Provider will, in its sole discretion, select presenters and moderators.
3. **Disclosure of Financial Relationships:** Provider will direct speakers and moderators to disclose to the audience commercial support or funding or other significant financial relationships between the speakers and moderators and *Cephalon Inc.*, and/or any other commercial company whose products are pertinent to the content of the presentation. Disclosure shall be made in writing in all instances when that is possible. Should disclosure occur verbally, such disclosure must be verified by written documentation in the activity file. Provider will disclose *Cephalon, Inc.* support at this program.

4. **Involvement in Content:** There will be no "scripting," emphasis, or direction of content by *Cephalon, Inc.* or its agents.
5. **Ancillary Promotional Activities:** No promotional activities will be permitted in the same room or obligate path to the educational activity. No product advertisement will be permitted within the program or handout. Provider reserves the right to monitor, unannounced, any presentation to insure that standards are being met. The cost of such monitoring shall be the responsibility of *Cephalon, Inc.*
6. **Objectivity & Balance:** Provider will make every effort to ensure that data regarding *Cephalon, Inc.* products (or competing products) are objectively selected and presented, with favorable and unfavorable information and balance discussion of prevailing information on the product(s) and/or alternative treatments. Provider will provide the opportunity for speakers and the audience to discuss information, both favorable and unfavorable, about the product(s) and/or alternative treatments.
7. **Limitations on Data:** Provider will request the speakers, to the extent possible, to disclose limits on the data, e.g., that it involves ongoing research, interim analyses, preliminary data, or unsupported opinion.
8. **Discussion of Unapproved Uses:** Provider will require that presenters disclose when any product mentioned during the program is not approved in the United States for the use under discussion or is still investigational.
9. **Opportunities for Debate:** Provider will ensure meaningful opportunities for questioning by attendees and scientific debate with and between presenters.
10. No party shall use the other party's or its affiliate's name or trademarks for publicity or advertising purposes without the prior written consent of the other party.
11. **Structure of Grant and Use of Funds:** Funds should be in the form of an educational grant made payable to the provider organization (MediCom Worldwide, Inc.). No other funds from *Cephalon, Inc.* will be paid to the program director, faculty, or others involved with the program. Grant funds shall not be used to pay travel, lodging, registration fees, honoraria, or personal expenses for non-faculty attendees. At the conclusion of the program, the Provider agrees to deliver to *Cephalon, Inc.* a report concerning the expenditure of the funds provided. *The grant amount is based upon current estimates. The Provider requests that Cephalon, Inc. provide additional grant funds if costs for faculty expense exceed estimates. If the Provider anticipates that additional grant funding may be required, the Provider will seek the approval of Cephalon, Inc. prior to exceeding the agreed upon grant amount. Any additional grant funds approved in this manner will be provided under the terms of this agreement.*

12. **Regulatory Authority:** *Provider agrees to abide by the ACCME Standards for Commercial Support of Continuing Medical Education. Provider will acknowledge educational support from Cephalon, Inc. in program brochures, syllabi, and other program material Cephalon, Inc. agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.*

Payee: MediCom Worldwide, Inc.

In Care Of: Joan Meyer  
Address 101 Washington St  
Morrisville, PA 19067

Tax ID. # 233063738

IN WITNESS WHEREOF, the parties have executed this Agreement as of the last of the respective dates below.

Provider: Name (Print) Joan Meyer

Signature

Title Executive Director

Date: August 24, 2004

Cephalon, Inc

Name (Print) \_\_\_\_\_

Signature \_\_\_\_\_

Title \_\_\_\_\_

Date: \_\_\_\_\_





145 BRANDYWINE PARKWAY  
WEST CHESTER, PENNSYLVANIA 19380  
(610) 344-0200  
FAX (610) 738-6311

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No.

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on all correspondence, invoices,  
shipping papers and packages.

NOT VALID UNTIL A NUMBER IS ASSIGNED!

TODAY'S DATE

9/7/04

DATE REQUIRED

SHIP TO

CEPHALON, INC.

145 BRANDYWINE PARKWAY

WEST CHESTER, PA 19380

ATTN: Suzanne Richards  
Ext. 86532

DIRECT ALL INVOICES TO ACCOUNTS PAYABLE DEPARTMENT

TO  
Medicon Worldwide  
101 Washington Street  
Morrisville, PA 19067  
FAX # 215-337-0960

QTY ORDERED	UNIT OF MEASURE	DEPT. CODE G/L ACCT.	PROJECT/ CAPITAL CODE	STOCK NO./DESCRIPTION	UNIT PRICE	TOTAL
		631/ 7640	ACTQ	Clinical Experts in Pain Faculty Meeting  Gave to Bob 9/7/04		300,000.00
ORDER PROCESSOR		DATE ORDERED		BUYER	SHIP VIA	
TOTAL EXTENDED PRICE						300,000.00

1. Please send one copy of your invoice.
2. Order is to be entered in accordance with prices, delivery and specifications shown above.
3. Notify us immediately if you are unable to ship as specified.

AUTHORIZED BY

*Lynne Brookes*  
PRINT NAME

From: Origin ID: (610)738-6532  
Suzanne Richards  
CEPHALON  
145 BRANDYWINE PARKWAY  
WEST CHESTER, PA 19380



Ship Date: 07SEP04  
Actual Wgt: 1 LB  
System#: 2402709/INET1850  
Account#: S \*\*\*\*\*

REF: 631



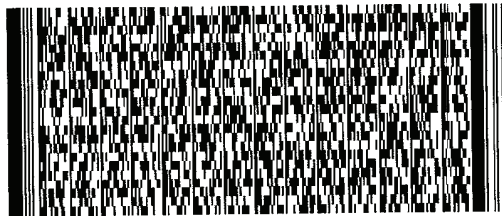
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SHIP TO: (215)337-9991

BILL SENDER

Joan Meyer  
Medicom  
101 Washington Street

Morrisville, PA 19067



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WED

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08SEP04

TRK# 7919 2695 3717

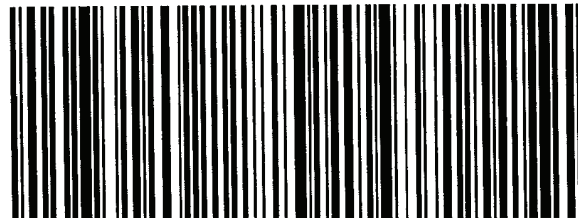
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## EDUCATIONAL GRANT DRAFT REQUEST

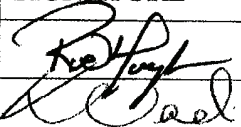
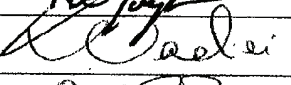
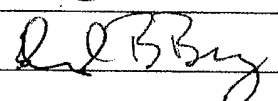
The attached material has been reviewed and is approved:

Payee: Medicom Worldwide

Amount: \$2,921,000

Type of Program: Clinical Dialogues in Pain Management Program

Submitted for Review: 8/26/04

DEPARTMENT	NAME	SIGNATURE	DATE
Scientific Communications	Rod Hughes		8.26.04
Medical Affairs	Kiumars Vadieli		8/26/04
Legal & Government	Ed Berg		8/26/04

Return to: Suzanne Richards, ext. 86532

- 1) Milestone payments to be tied to performance requirements in contract.
- 2) Consider adding options to terminate based upon physician assessment as to value of program



## MediCom WORLDWIDE, Inc.

### Educational Grant Letter of Agreement

Between Cephalon, Inc 145 Brandywine Parkway West Chester, PA and MediCom Worldwide, Inc. ("Provider") 101 Washington St Morrisville, PA.

**Title of Program:**

Clinical Dialogues in Pain Management

**Date, Location & Time of Program:**

Series of live peer-to-peer one-hour educational activities scheduled throughout the US. Series will be divided as follows:

Series I will consist of approx 125 activities scheduled from January – June 2005

Series II will consist of approx 125 activities scheduled from July – December 2005

Provider has requested support for the above-named Program in the form of an educational grant in the amount of \$2,920,847. It is the intent of this Agreement to ensure that the Program is conducted in a manner consistent with the Food and Drug Administration's Policy Statement on Industry Supported Scientific and Educational Activities, AMA Guidelines on Gifts to Physicians, and the Accreditation Counsel for Continuing Medical Education (ACCME)

To that end, *PROVIDER*, *Cephalon, Inc* agree as follows:

1. **Statement of Purpose:** The Program is for scientific and educational purposes only and is not intended to promote a *Cephalon, Inc.* product directly or indirectly.
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12/99

4. **Involvement in Content:** There will be no “scripting,” emphasis, or direction of content by *Cephalon, Inc.* or its agents.
5. **Ancillary Promotional Activities:** No promotional activities will be permitted in the same room or obligate path to the educational activity. No product advertisement will be permitted within the program or handout. Provider reserves the right to monitor, unannounced, any presentation to insure that standards are being met. The cost of such monitoring shall be the responsibility of *Cephalon, Inc.*
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12/99 2

12. **Regulatory Authority:** *Provider agrees to abide by the ACCME Standards for Commercial Support of Continuing Medical Education. Provider will acknowledge educational support from Cephalon, Inc. in program brochures, syllabi, and other program material Cephalon, Inc. agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.*

Payee: MediCom Worldwide, Inc.

In Care Of: Joan Meyer  
Address 101 Washington St  
Morrisville, PA 19067

Tax ID. # 233063738

**Payment Terms:**

25% of project costs are due January 1, 2005

25 % of project costs are due April 1, 2005

25% of project costs are due June 1, 2005

Final 25 % of project costs are due upon completion

IN WITNESS WHEREOF, the parties have executed this Agreement as of the last of the respective dates below.

Provider: Name (Print) Joan Meyer  
Signature *Joan Meyer*  
Title Executive Director  
Date: August 25, 2004

Cephalon, Inc Name (Print) Lynne Brookes  
Signature *Lynne Brookes*  
Title V.P. of Marketing  
Date: 9/14/04





# Pain Management Peer-to-Peer Live Meetings

Clinical Dialogues<sup>SM</sup>  
in Pain Management

*Prepared for*  
Cephalon, Inc.

August 25, 2004

2005

**MediCom Worldwide, Inc.**

CME  
Proposal

MediCom Worldwide, Inc.  
*Clinical Dialogues<sup>SM</sup> in Pain Management*

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Rod Hughes, PhD  
 Cephalon, Inc  
 145 Brandywine Parkway  
 West Chester, PA 19380

Dear Dr. Hughes:

As an accredited provider of continuing medical education for physicians, pharmacists and nurses, MediCom Worldwide has recently completed a comprehensive needs assessment to identify the educational needs of clinicians who provide care to patients with chronic pain. This needs assessment was compiled from the following sources:

- Comprehensive discussions with MediCom's advisory panel
- Survey of healthcare professional currently practicing in the area of pain management
- Literature searches

Based on the identified educational need, MediCom is requesting an educational grant from Cephalon, Inc. to support the development and implementation of a series of 250 live peer-to-peer educational activities that will take place during 2005. These activities will focus on strategies for improving the assessment and treatment in patients with chronic pain with special attention to abuse and addiction issues. The budget to fund these activities is approximately \$2,920,847.00; please refer to the detailed budget section of this proposal for complete grant funding details.

These scientific events will comply with all ACCME, FDA, AMA, and ACPE regulations for industry supported professional continuing education. MediCom Worldwide is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians, approved by the Accreditation Council for Pharmacy Education to provide pharmacy continuing education, and approved by the California State Board of Registered Nursing to provide nursing continuing education.

As a supplement to our direct mail and web site announcement of these educational activities, we request the assistance of Cephalon, Inc in the dissemination of information regarding these programs to the medical community. The content of such information, however, is the responsibility of MediCom as the accredited provider, and any such distribution will be solely as a supplement to MediCom's primary method of announcement and promotion.

Thank you, in advance, for your consideration of this request. Should you agree to provide funding for this project, Letters of Agreement will be forwarded to you as soon as possible.

Respectfully,

A handwritten signature in cursive script, appearing to read "Joan Meyer".

Joan Meyer RN, MA  
 Executive Director, Continuing Education

MediCom Worldwide, Inc. • 101 Washington Street • Morrisville, PA 19067  
 215-337-9991

Page 2

MediCom Worldwide, Inc.  
*Clinical Dialogues<sup>SM</sup> in Pain Management*

**SUMMARY**



**Program Summary**

MediCom is proposing to enhance the knowledge of health care professionals who provide care to patients with chronic pain by implementing a series of live peer-to-peer educational activities that will be led by a clinical expert in the field of pain management. These activities will be held in 250 venues throughout the US in 2005.

**Title:**

**Dialogues in Pain Management**

**Topic:**

1. Chronic Pain Management: Establishing New Paradigms
2. Chronic Pain Management: A Focus in the Issues of Abuse and Diversion

**CE Provider:**

MediCom Worldwide is a fully accredited provider of:

- CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each activity will be approved for a maximum of one category 1 credit toward the AMA Physician's Recognition Award
- CPE credit for pharmacists by the Accreditation Council for Pharmacy Education. Each activity will be approved for 1.0 (0.1CEU) for Continuing Pharmacy Education
- CNE credit for nurses by the California State Board of Registered Nursing. Each activity will be approved for 1.0 Contact Hours.

**Format:**

A series of live peer-to-peer activities scheduled in 250 cities throughout the US

**Total Budget:**

\$2,920,847



MediCom Worldwide, Inc.  
*Clinical Dialogues<sup>SM</sup> in Pain Management*  
**NEEDS ASSESSMENT**



### **Needs Assessment**

To prepare physicians, pharmacists, nurses and allied healthcare professionals to diagnose and treat chronic pain, these activities will focus on the pathophysiology of pain and the concept of balanced analgesia, a new paradigm and the physiologic peaks of breakthrough pain and persistent pain. We will also address the risks and benefits of short acting opioids in the treatment of this pain. In addition, we will provide a separate educational module specific to the ongoing need to provide accurate information regarding the issues, and fears associated with abuse and diversion in pain management.

Consultation with our pain management clinical advisors, analysis of surveys of healthcare professionals, and a review of the literature revealed a ongoing educational need in the field of pain management, regarding the balance between achieving clinical goals for pain reduction and managing the legal issues surrounding the use of opioids. To address this educational need, MediCom proposes a series of live peer-to-peer activities, which will efficiently utilize the advantages of live didactic lectures followed by interaction with a leading clinical expert.

Overall, the needs assessment revealed that:

- Chronic pain negatively impacts patients' quality of life and functionality
- Misconceptions on the part of patients, clinicians, the health care system, and society may act as barriers to the optimal treatment of chronic pain
- Opioids are powerful and effective analgesics for alleviating pain; however, some clinicians are hesitant to prescribe them out of concern for legal ramifications and addiction potential

### **Consultation with Clinical Advisors**

During this educational advisory panel meeting, faculty discussed ideas, concerns, and considerations for effective pain management. Focusing on opioid prescribing, the faculty discussed assessment of pain, monitoring, regulatory issues, and risk reduction.

#### **Major issues covered:**

- Physicians' fear of prescribing opioids
- Malpractice related to undertreatment
- Effects of California's pain management initiative
- Impact of conservative opioid prescribing on patient well-being
- Recognizing potential for abuse and addiction
- Potential solutions for dealing with aberrant behavior in patients taking opioids
- Monitoring patients on opioid therapy, including the role of pharmacists, urine screens, tracking prescriptions
- Common and conflicting goals of law enforcement and medicine with respect to pain management
- Issuance of guidelines for pain management by national organizations
- Review of recent criminal cases of diversion

**Conclusions:**

- A sense of fear and apprehension regarding prescribing opioids exists in the medical community and affects all types of health care professionals
- This fear has a negative impact on patient care, and thus one goal must be to "allay some of those fears"
- Changing attitude and behavior regarding the treatment of pain continues to be a significant challenge
- Risks must be managed and balanced to protect not on the health care professional and the patient, but also society
- Best practices must be developed for managing pain appropriately and effectively
- A network of all types of health care professionals, including primary care physicians, psychologists, addictionologists, is needed to bring about national change
- Pharmacists are a crucial constituent and must be included in any educational endeavor that strives to improve current approaches to pain management

**Survey of HealthCare Professionals**

Results are based on feedback from completed needs assessments and evaluation forms obtained from a total of 6,332 clinicians in 2003-2004. This data revealed that 90% of clinicians cited a continuing educational need in one or more of the following areas. The top five topics of interest identified were

- o *Acute pain management in the patient on chronic opioids for chronic pain*
- o *How to identify risk factors associated with potential drug abuse*
- o *Regulatory and legal issues to be aware of in treating pain patients*
- o *Management of addicted patients*
- o *Best practices for chronic non malignant pain treatment*
- o *Treating the side effects of opiates*

**Literature Review**

Chronic, nonmalignant pain is a devastating problem that accompanies many injuries and disease states; when undertreated, it can be physically, socially, mentally and economically devastating. While increasing numbers of clinicians are recognizing that chronic pain is a true medical problem that must be addressed, pain remains a prevalent problem for too many patients: an international survey conducted across 14 countries reported that 22% of patients presenting in the primary care setting report unrelieved pain. In the United States alone, 83 million people cite pain as a significant factor in their lives, and more than 26% of nursing home residents indicate that they experience pain on a daily basis.<sup>1-4</sup> As chronic pain is such a prevalent and pervasive problem, primary care clinicians are often the first health care professionals to address chronic pain when it occurs in their patients. Indeed, the primary care clinician is often in a unique position to both identify and successfully treat many common causes of chronic pain, including low back pain: a recent study published in the *Journal of Pain Symptom Management* analyzed a patient population consisting of 209 adults in 12 separate family practices. In this group, 44% of patients experienced lumbar or low back pain; other common causes of pain included joint disease/arthritis (33%), and headache/migraine (28%) pain.<sup>5</sup> The many challenges of treating chronic pain are exemplified by low back pain: it is

estimated that as many as 20% of the population report back pain each year, and that at some point in their lives, 80% will have low back pain severe enough to result in absence from work. Underscoring the significance of back pain, approximately 50% of working-age people experience back pain symptoms each year.<sup>1-4</sup>

Extensive clinical studies have demonstrated that, as pain increases, quality of life proportionally decreases.<sup>6</sup> This reduction in quality of life is due to a number of factors: unrelieved pain results in compromised physical ability, leading to detrimental effects on overall function, health, and well-being,<sup>7</sup> and finally, to a reduced ability to participate in activities of daily living (ADLs). Moreover, the psychological consequences of unrelieved chronic pain are significant: many patients experience feelings of helplessness and uselessness, leading to dysphoria and fatigue, and for some, the creation of a "pain personality". The end result of unrelieved chronic pain can be an individual who is unable to maintain meaningful, significant personal relationships, to sustain steady employment, and to function within the normal expectations of daily living.

Improving functionality, therefore, must be one of the key treatment goals for any patient experiencing chronic pain. Some clinical experts have suggested that the most effective method for improving functionality is the utilization of a multidimensional, or multimodal,<sup>8</sup> approach, reinforcing the critical need to evaluate and address all components of the pain experience. This includes not only pharmacotherapy, but a physical performance assessment, cognitive and behavioral therapy, and quality of life determinations, as well.<sup>9</sup> A long-term therapeutic regimen that effectively treats chronic pain, thereby improving functionality, includes an accurate assessment, identification of the underlying source of the pain and the pain intensity, and a careful orchestration of both analgesics and adjunctive therapy. While some subset of patients will find pain relief early in therapy, many patients with chronic pain will experience extensive trials of progressively stronger medications, as initial pharmacotherapies may fail to result in significant analgesia. The psychological burden of unrelieved pain can be immense: more than 28% of these patients believe that there is no solution to their chronic pain, and less than half of these believe that their physician completely understands the impact of pain on their lives.<sup>4,10</sup>

Up to 86 percent of Americans suffering from chronic pain experience breakthrough pain, even when the persistent pain is well managed yet it is often misunderstood aspect of chronic pain that requires a tailored strategy for care. Breakthrough pain treatment is a multiple step process, beginning with patient assessment. For many patients with unrelieved chronic pain, opioids are an instrumental component of the analgesic armamentarium. As a class, opioids have proven efficacy, not only in providing meaningful pain relief to many patients, but also in improving functionality. Opioids offer pharmacologic advantages through the availability of diverse formulations and doses that provide significant flexibility when tailoring a therapeutic regimen for the chronic pain patient.

Additional advantages of the opioids include not only longer acting modalities and options for managing breakthrough pain, but also minimal and/or predictable adverse events, and fewer interactions with other commonly prescribed drugs. Moreover, opioids are not associated with end organ damage. Many clinicians, however, continue to express reticence over prescribing opioids; this is especially true in the primary care setting, where a lack of knowledge about opioids, negative attitudes toward prescribing opioids, regulatory concerns and concerns over long-term safety and durability of

response may combine to create major barriers to the effective utilization of opioids and, therefore, to pain relief.<sup>11,12</sup> Clearly, education is required to address clinician concerns over opioid use that may result in underutilization of these important analgesic agents. In addition to addressing class objections that include regulatory concerns over prescribing opioids, however, health care professionals who provide care to patients with chronic pain must also understand the differences between the agents in this class. These include not only pharmacokinetic and pharmacodynamic differences between the opioids themselves, but also differences resulting from varied formulations and delivery systems.

Clinical experience has revealed that, for many patients, opioids are an effective therapeutic option, and their use, combined with the aggressive management of side effects, results in improvement in overall functionality and quality of life.<sup>14</sup> Thus, when chronic pain patients are assessed and assigned therapy on an individual basis, and when clinicians understand the full range of therapeutic options, including the diversity among opioids, meaningful differences in pain relief become an achievable goal for many patients living with unrelieved chronic pain.

## References

1. Gureje O, Von Korff M, Simon GE, Gater R. Persistent pain and well-being: a World Health Organization Study in Primary Care. *JAMA*. 1998;280(2):147-151.
2. Rosomoff HL, Rosomoff RS. Low back pain. Evaluation and management in the primary care setting. *Med Clin North Am*. 1999;83:643-662.
3. Won A, Lapane K, Gambassi G, Bernabei R, Mor V, Lipsitz LA. Correlates and management of nonmalignant pain in the nursing home. SAGE Study Group. Systematic Assessment of Geriatric drug use via Epidemiology. *J Am Geriatr Soc*. 1999;47(8):936-942.
4. Pain Factsheet. Accessed December 9, 2003 at: [www.arthritis.org/conditions/speakingofpain/factsheet.asp](http://www.arthritis.org/conditions/speakingofpain/factsheet.asp).
5. Adams NJ, Plane MB, Fleming MF, Mundt MP, Saunders LA, Stauffacher EA. Opioids and the treatment of chronic pain in a primary care sample. *J Pain Symptom Manage*. 2001;22:791-796.
6. Katz N. The impact of pain management on quality of life. *J Pain Symptom Manage*. 2002;24(1 Suppl):S38-47.
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9. Barkin RL, et al. Management of Chronic Pain: Part II. *Disease-a-Month*. Mosby; 1996;42(8):460-502.
10. Donovan MI, Evers K, Jacobs P, Mandleblatt S. When there is no benchmark: designing a primary care-based chronic pain management program from the scientific basis up. *J Pain Symptom Manage*. 1999;18:38-48.
11. Glajchen, M. Chronic pain: treatment barriers and strategies for clinical practice. *J Am Board Fam Pract*. 2001;14(3):211-218.
12. Portenoy RK. Opioids therapy for chronic nonmalignant pain: clinician's perspective. *J Law Med Ethics*. 1996;24:296-309.

MediCom Worldwide, Inc.  
*Clinical Dialogues<sup>SM</sup> in Pain Management*  
**PROGRAM OVERVIEW**



**Intended Audience**

This *Clinical Dialogues<sup>SM</sup> in Pain Management* series is intended for physicians, pharmacists, nurses, and allied health care professionals who provide care to patients with pain.

**Post-Activity Feedback**

Course evaluation forms will be required of all participants who seek to receive continuing education credit. MediCom will summarize the information collected from these forms in a formal report to evaluate program effectiveness.

Participants will evaluate the following as *excellent, good, fair, or poor*:

1. Overall content
2. Faculty teaching effectiveness
3. Format
4. Audio / visual quality

Participants will also respond to the following questions:

1. How well did the program achieve its educational objectives?
2. Do you feel that the program material was useful and practice-oriented?
3. Do you feel that the information provided in this educational activity will aid in improving patient care in your practice?
4. Do you feel that fair balance was maintained for all therapeutic options?
5. Would you participate in future educational activities?

**Request for Sponsor Support**

MediCom will announce and promote the live activities primarily through direct mail and advertisement on [www.MedicalEd.com](http://www.MedicalEd.com).

As a supplement to the primary methods indicated above, MediCom may request the assistance of Cephalon, Inc in the dissemination of information regarding these programs to the medical community. The content of such information, however, is the responsibility of MediCom as the accredited provider, and any such distribution will be solely as a supplement to MediCom's primary method of announcement and promotion.





MediCom Worldwide, Inc.  
 101 Washington Street  
 Morrisville, Pennsylvania 19067

Proposal Number: 05-014a  
 Date: August 25, 2004

*Clinical Dialogues in Pain Management*  
**2005 Pain Management Peer-to-Peer Live Meetings**  
**Projected Budget Estimate**

<i>Program Parameters</i>	
Number of dinner meetings	250
Faculty presenter per activity	1
Health care professional attendees per meeting	15
Direct mail invitations to health care professionals	500

<i>Cost Summary</i>	
Approximate Total, Direct Expenses	\$ 2,027,625
Total, Indirect Expenses	\$ 893,222
<b>Cost of 2005 Peer-to-Peer Dinner Meeting Series Program</b>	<b>\$ 2,920,847</b>

Approval Signature \_\_\_\_\_

Date \_\_\_\_\_

**Note: no work may begin until MediCom receives, via email or fax, this approval with signature and date**



MediCom Worldwide, Inc.  
101 Washington Street  
Morrisville, Pennsylvania 19067

Proposal Number: 05-014a  
Date: August 25, 2004

*Clinical Dialogues in Pain Management*  
**2005 Pain Management Peer-to-Peer Live Meetings**  
**Projected Budget Estimate**

**Detailed Budget Itemization**

<b>Direct Expenses, Approximate</b>	
<b>Direct mail invitations, mail services, postage</b>	\$ 118,125
Personalized invitations to be mailed to every potential participant; includes printing, assembly, mail services and postage. Postage estimated at \$0.37 per direct mail piece	
<b>Direct mail list purchase</b>	\$ 15,750
<b>Print materials</b>	\$ 25,000
Includes printing of shell materials for adaptation and use in individualized dinner meeting kits for every meeting; dinner meeting kits to include accreditation information, speaker biographical and disclosure information, agenda, and handout materials, where appropriate	
<b>Speaker honoraria</b>	\$ 625,000
<b>Speaker travel (air, OOP, hotel)</b>	\$ 300,000
<b>Ground transportation</b>	\$ 50,000
<b>Catering</b>	\$ 468,750
<b>Audio/visual services</b>	\$ 137,500
<b>Onsite CME coordination</b>	\$ 262,500
<b>Shipping/Fed Ex</b>	\$ 25,000
<b>Approximate Total, Direct Expenses</b>	
	\$ 2,027,625

<b>Indirect Expenses</b>	
<b>Program development</b>	\$ 100,000
Includes all labor associated with initial program set-up and development, including creation of text for print support materials, graphic design, typesetting and layout of all support materials, and development and creation of final program appearance	
<b>Meeting management</b>	\$ 250,000
Includes coordination with faculty for content, dates, travel and all other program details	
<b>Accreditation of program for CME, CPE, CNE</b>	\$ 25,000
<b>Continuing Education participant certificates</b>	\$ 56,000
<b>Administrative and accounting fees</b>	\$ 196,690
<b>Project management</b>	\$ 265,532
<b>Total, Indirect Expenses</b>	
	\$ 993,222



MediCom Worldwide, Inc.  
*Clinical Dialogues<sup>SM</sup> in Oncology*

**PAYMENT SCHEDULE**



**Payment Terms:**

One-third of project costs are due upon signing of letter of agreement  
One-third of project costs are due mid project  
One-third of project costs are due upon completion and reconciliation



MediCom Worldwide, Inc.  
 101 Washington Street  
 Morrisville, Pennsylvania 19067

Proposal Number: 05-014a  
 Date: August 25, 2004

*Clinical Dialogues in Pain Management*  
**2005 Pain Management Peer-to-Peer Live Meetings**  
*Projected Budget Estimate*

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Approval Signature \_\_\_\_\_

Date \_\_\_\_\_

**Note: no work may begin until MediCom receives, via email or fax, this approval with signature and date**



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101 Washington Street  
Morrisville, Pennsylvania 19067

Proposal Number: 05-014a

Date: August 25, 2004

*Clinical Dialogues in Pain Management*  
**2005 Pain Management Peer-to-Peer Live Meetings**  
***Projected Budget Estimate***

*Detailed Budget Itemization*

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MediCom Worldwide, Inc.  
*Clinical Dialogues<sup>SM</sup> in Oncology*

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One-third of project costs are due mid project

One-third of project costs are due upon completion and reconciliation

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CEPHALON  
145 BRANDYWINE PARKWAY  
  
WEST CHESTER, PA 19380



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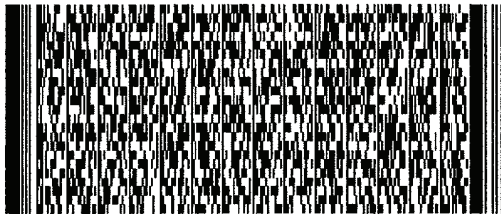


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Joan Meyer  
Medicom  
101 Washington Street  
  
Morrisville, PA 19067



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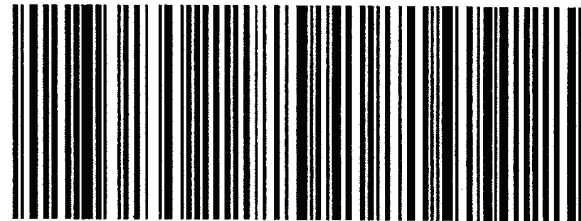
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Dr. Rod Hughes  
Cephalon, Inc.  
145 Brandywine Parkway  
West Chester, PA 19380

November 15, 2004

Dear Dr. Hughes:

MediCom Worldwide, Inc. is accredited by the Accreditation Council for continuing Medical Education to sponsor continuing medical education for physicians and by the Accreditation council for Pharmacy Education to sponsor continuing education for pharmacists, as well as an approved provider of nursing continuing education through the California State Board of Registered Nursing.

A comprehensive needs assessment has been completed and has identified a ongoing need and interest of health care providers who manage patients suffering from chronic pain to enhance their knowledge and understanding of pain treatment as it relates specifically to breakthrough pain. Based on this educational need, we are requesting an educational grant from Cephalon, Inc. to support the development of a educational symposia to take place in conjunction with the American Pain Society meeting in 2005. The budget to fund this activity is approximately \$191,725.00. The target audience for this activity will be pain care specialist participating in the overall scientific session.

This scientific activity will be developed independently and will comply with all ACCME, FDA, AMA, OIG, and ACPE regulations for industry-supported professional continuing education.

Thank you, in advance, for your consideration of this request. Should you agree to provide funding for this project, Letters of Agreement will be forwarded to you as soon as possible.

Respectfully,

Joan Meyer  
Executive Director  
Continuing Education

**2005 APS Satellite Symposium**  
**Job #P05-003a**

**Title Options:**

1. The Building Blocks of Breakthrough Pain Treatment: **Assessment, Believe, Communication, Diagnosis, Effective Treatment**

**Preferred Time of Presentation:**

Breakfast

**Learning Objectives:**

1. Define the concept of breakthrough pain.
2. Compare and contrast current assessment tools that rate patient pain levels, activities of daily living and quality of life.
3. Identify questions and communication techniques that are designed to improve patient/physician dialogue.
4. Outline the pharmacology and physiologic role of opioid medications in the treatment of pain.

**Agenda:**

- 1) Introduction
  - a) Definition of breakthrough pain (BTP)
  - b) Impact of BTP
    - i) 86% of Americans suffering from chronic pain experience BTP
    - ii) Limitations on activities
    - iii) Increased hospital, ER, and physician visits; increased costs by 500%
- 2) Assessment Tools
  - a) TARGET chronic pain assessment
  - b) ECOG activity tool
  - c) Substance abuse & diversion assessment tool
- 3) Enhancing the Patient/Physician Partnership
  - a) Communication Skills
    - i) Common vocabulary and definitions
    - ii) Dialog-conducive questions
- 4) Conceptual Approach to Treatment
- 5) The Evolutionary Steps
  - a) Physiology of Nociception and Pain Perception



- b) BTP and Impact on QoL
- c) BTP Characteristics and Pharmacology

**Description:**

Breakthrough pain (BTP) is a unique type of pain that must be assessed and treated differentially from chronic pain. The “building blocks” of an effective strategy for BTP management begin with assessment tools that address both chronic pain and BTP. A second building block is establishing an effective communication strategy with the patient, who may lack a fundamental understanding of pain management terms and concepts. Final building blocks include diagnosis and treatment. Clinicians must recognize that the pathophysiology of BTP is different from that of chronic pain, and must, therefore, be differentially diagnosed and treated, to provide effective long-term analgesia.

**Mechanism of Participant Evaluation to be Used:**

Written evaluation

**Mechanism of Provider CME Credit:**

Written evaluation

**Name and Address of Organization Providing CME Credit for this Program:**

MediCom Worldwide, Inc.  
101 Washington Street  
Morrisville, PA 19067

**Accredited Provider Contact:**

Joan Meyer. 800-408-4242 ext. 129, [jmeyer@medicaled.com](mailto:jmeyer@medicaled.com)

**Name of Organization Providing Logistical/Meeting Support:**

MediCom Worldwide, Inc.

**Communications Company/Meeting Planner Contact:**

Diane Evans, 800-408-4242 ext. 133, [devans@medicaled.com](mailto:devans@medicaled.com)

**Corporate member:**

Cephalon, Inc.

Facutly: **Jeff Gudin, MD**  
**Gary Wright, MD**  
**Paul Spector, MD**  
**Daniel Bennett, MD**



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Dr. Rod Hughes  
Cephalon, Inc.  
145 Brandywine Parkway  
West Chester, PA 19380

November 15, 2004

Dear Dr. Hughes:

MediCom Worldwide, Inc. is accredited by the Accreditation Council for continuing Medical Education to sponsor continuing medical education for physicians and by the Accreditation council for Pharmacy Education to sponsor continuing education for pharmacists, as well as an approved provider of nursing continuing education through the California State Board of Registered Nursing.

A comprehensive needs assessment has been completed and has identified a ongoing need and interest of health care providers who manage patients suffering from chronic pain to enhance their knowledge and understanding of pain treatment as it relates specifically to breakthrough pain. Based on this educational need, we are requesting an educational grant from Cephalon, Inc. to support the development of a educational symposia to take place in conjunction with the American Pain Society meeting in 2005. The budget to fund this activity is approximately \$191,725.00. The target audience for this activity will be pain care specialist participating in the overall scientific session.

This scientific activity will be developed independently and will comply with all ACCME, FDA, AMA, OIG, and ACPE regulations for industry-supported professional continuing education.

Thank you, in advance, for your consideration of this request. Should you agree to provide funding for this project, Letters of Agreement will be forwarded to you as soon as possible.

Respectfully,

Joan Meyer  
Executive Director  
Continuing Education

**2005 APS Satellite Symposium**  
**Job #P05-003a**

**Title Options:**

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- b) BTP and Impact on QoL
- c) BTP Characteristics and Pharmacology

**Description:**

Breakthrough pain (BTP) is a unique type of pain that must be assessed and treated differentially from chronic pain. The “building blocks” of an effective strategy for BTP management begin with assessment tools that address both chronic pain and BTP. A second building block is establishing an effective communication strategy with the patient, who may lack a fundamental understanding of pain management terms and concepts. Final building blocks include diagnosis and treatment. Clinicians must recognize that the pathophysiology of BTP is different from that of chronic pain, and must, therefore, be differentially diagnosed and treated, to provide effective long-term analgesia.

**Mechanism of Participant Evaluation to be Used:**

Written evaluation

**Mechanism of Provider CME Credit:**

Written evaluation

**Name and Address of Organization Providing CME Credit for this Program:**

MediCom Worldwide, Inc.  
101 Washington Street  
Morrisville, PA 19067

**Accredited Provider Contact:**

Joan Meyer. 800-408-4242 ext. 129, [jmeyer@medicaled.com](mailto:jmeyer@medicaled.com)

**Name of Organization Providing Logistical/Meeting Support:**

MediCom Worldwide, Inc.

**Communications Company/Meeting Planner Contact:**

Diane Evans, 800-408-4242 ext. 133, [devans@medicaled.com](mailto:devans@medicaled.com)

**Corporate member:**

Cephalon, Inc.

Facutly: **Jeff Gudin, MD**  
**Gary Wright, MD**  
**Paul Spector, MD**  
**Daniel Bennett, MD**



Dr. Rod Hughes  
Cephalon, Inc.  
145 Brandywine Parkway  
West Chester, PA 19380

October 13, 2004

Dear Dr. Hughes:

MediCom Worldwide, Inc. is accredited by the Accreditation Council for continuing Medical Education to sponsor continuing medical education for physicians and by the Accreditation council for Pharmacy Education to sponsor continuing education for pharmacists, as well as an approved provider of nursing continuing education through the California State Board of Registered Nursing.

A comprehensive needs assessment has been completed and has identified a ongoing need and interest of health care providers who manage patients suffering from chronic pain to enhance their knowledge and understanding of pain treatment as it relates specifically to breakthrough pain. Based on this educational need, we are requesting an educational grant from Cephalon, Inc. to support the development of a educational symposia to take place in conjunction with the American Pain Society meeting in 2005. The budget to fund this activity is approximately \$191,725.00. The target audience for this activity will be pain care specialist participating in the overall scientific session.

This scientific activity will be developed independently and will comply with all ACCME, FDA, AMA, OIG, and ACPE regulations for industry-supported professional continuing education.

Thank you, in advance, for your consideration of this request. Should you agree to provide funding for this project, Letters of Agreement will be forwarded to you as soon as possible.

Respectfully,

Joan Meyer  
Executive Director  
Continuing Education

## MediCom WORLDWIDE, Inc.

### Educational Grant Letter of Agreement

Between Cephalon, Inc 145 Brandywine Parkway West Chester, PA and MediCom Worldwide, Inc. ("Provider") 101 Washington St Morrisville, PA.

Title of Program:  
The Building Blocks of Breakthrough Pain Treatment

Date, Location & Time of Program:  
Friday April 1, 2002  
7:00 – 8:30 AM  
Boston, MA

Provider has requested support for the above-named Program in the form of an educational grant in the amount of \$191,725. It is the intent of this Agreement to ensure that the Program is conducted in a manner consistent with the Food and Drug Administration's Policy Statement on Industry Supported Scientific and Educational Activities, AMA Guidelines on Gifts to Physicians, and the Accreditation Counsel for Continuing Medical Education (ACCME)

To that end, *PROVIDER*, *Cephalon, Inc* agree as follows:

1. **Statement of Purpose:** The Program is for scientific and educational purposes only and is not intended to promote a *Cephalon, Inc.* product directly or indirectly.
2. **Control of Content & Selection of Presenters & Moderators:** The provider is ultimately responsible for the control of content and selection of presenters and moderators. *Cephalon, Inc.* agrees not to direct the content of the program. *Cephalon, Inc.* or its agents, may respond to requests initiated by Provider for suggestions of presenters or sources of possible presenters. *Cephalon, Inc.*, or its agents will suggest more than one name (if possible); will provide speaker qualification; will disclose financial or other relationships between *Cephalon, Inc.*, and speaker; and will provide this information in writing. Provider will, in its sole discretion, select presenters and moderators.
3. **Disclosure of Financial Relationships:** Provider will direct speakers and moderators to disclose to the audience commercial support or funding or other significant financial relationships between the speakers and moderators and *Cephalon Inc.*, and/or any other commercial company whose products are pertinent to the content of the presentation. Disclosure shall be made in writing in all instances when that is possible. Should disclosure occur verbally, such disclosure must be verified by written documentation in the activity file. Provider will disclose *Cephalon, Inc.* support at this program.

4. **Involvement in Content:** There will be no "scripting," emphasis, or direction of content by *Cephalon, Inc.* or its agents.
5. **Ancillary Promotional Activities:** No promotional activities will be permitted in the same room or obligate path to the educational activity. No product advertisement will be permitted within the program or handout. Provider reserves the right to monitor, unannounced, any presentation to insure that standards are being met. The cost of such monitoring shall be the responsibility of *Cephalon, Inc.*
6. **Objectivity & Balance:** Provider will make every effort to ensure that data regarding *Cephalon, Inc.* products (or competing products) are objectively selected and presented, with favorable and unfavorable information and balance discussion of prevailing information on the product(s) and/or alternative treatments. Provider will provide the opportunity for speakers and the audience to discuss information, both favorable and unfavorable, about the product(s) and/or alternative treatments.
7. **Limitations on Data:** Provider will request the speakers, to the extent possible, to disclose limits on the data, e.g., that it involves ongoing research, interim analyses, preliminary data, or unsupported opinion.
8. **Discussion of Unapproved Uses:** Provider will require that presenters disclose when any product mentioned during the program is not approved in the United States for the use under discussion or is still investigational.
9. **Opportunities for Debate:** Provider will ensure meaningful opportunities for questioning by attendees and scientific debate with and between presenters.
10. No party shall use the other party's or its affiliate's name or trademarks for publicity or advertising purposes without the prior written consent of the other party.
11. **Structure of Grant and Use of Funds:** Funds should be in the form of an educational grant made payable to the provider organization (MediCom Worldwide, Inc.). No other funds from *Cephalon, Inc.* will be paid to the program director, faculty, or others involved with the program. Grant funds shall not be used to pay travel, lodging, registration fees, honoraria, or personal expenses for non-faculty attendees. At the conclusion of the program, the Provider agrees to deliver to *Cephalon, Inc.* a report concerning the expenditure of the funds provided.
12. **Regulatory Authority:** Provider agrees to abide by the ACCME Standards for Commercial Support of Continuing Medical Education. Provider will acknowledge educational support from *Cephalon, Inc.* in program brochures, syllabi, and other program material *Cephalon, Inc.* agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.



Payee: MediCom Worldwide, Inc.

In Care Of: Joan Meyer  
Address 101 Washington St  
Morrisville, PA 19067

Tax ID. # 233063738

IN WITNESS WHEREOF, the parties have executed this Agreement as of the last of the respective dates below.

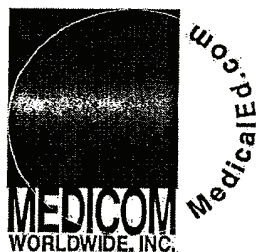
Provider: Name (Print) Joan Meyer  
Signature *Joan Meyer*  
Title Executive Director  
Date: October 13, 2004

Cephalon, Inc

Name (Print) \_\_\_\_\_  
Signature \_\_\_\_\_  
Title \_\_\_\_\_  
Date: \_\_\_\_\_



2005 APS  
Boston, MA  
April 1, 2005



**APS 2005 SYMPOSIUM**  
**PROJECTED BUDGET**

**TOPIC: Breakthrough Pain**

**FACULTY** Four

**Grant Request: \$191,725.00**

**APS FEE**

**Budget**

**\$ 40,000.00**

**MediCom PreMeeting Coordination, Registration**

**\$ 35,000.00**

**Print Design, Production**

**Design**

**\$ 2,500.00**

**Direct Mail ~# 3,000 incl \$.37 postage**

**\$ 5,100.00**

**Posters # 3**

**\$ 2,400.00**

**Handouts # 300**

**\$ 5,000.00**

**Door Drops/Exhibit Ad**

**\$ 12,000.00**

**MediCom On-site Symposium Management**

**\$ 3,200.00**

**Food & Beverage Catering 300**

**\$ 24,000.00**

**MediCom Expenses**

**Air Travel**

**\$ 1,600.00**

**Out of Pocket**

**\$ 75.00**

**Hotel**

**\$ 1,600.00**

**Meals**

**\$ 300.00**

**Ground Transport**

**\$ 200.00**

**Misc. (Fed Ex)**

**\$ 750.00**

**A/V**

**\$ 8,000.00**

**CME Approval/Certificates**

**Review/Approval**

**\$ 10,000.00**

**Faculty Expenses**

**Honorarium**

**\$ 10,000.00**

**T & A**

**\$ 8,000.00**

**Administration / Service Charges/Account Management**

**\$ 22,000.00**

**TOTAL MEDICOM GRANT REQUEST**

**\$ 191,725.00**

**2005 APS Satellite Symposium**  
**Job #P05-003a**

**Title Options:**

1. The Building Blocks of Breakthrough Pain Treatment: **Assessment, Believe, Communication, Diagnosis, Effective Treatment**

**Preferred Time of Presentation:**  
 Breakfast

**Learning Objectives:**

1. Define the concept of breakthrough pain.
2. Compare and contrast current assessment tools that rate patient pain levels, activities of daily living and quality of life.
3. Identify questions and communication techniques that are designed to improve patient/physician dialogue.
4. Outline the pharmacology and physiologic role of short-acting pain medications.

**Agenda:**

- 1) Introduction
  - a) Definition of breakthrough pain (BTP)
  - b) Impact of BTP
    - i) 86% of Americans suffering from chronic pain experience BTP
    - ii) Limitations on activities
    - iii) Increased hospital, ER, and physician visits; increased costs by 500%
- 2) Assessment Tools
  - a) TARGET chronic pain assessment
  - b) ECOG activity tool
  - c) Substance abuse & diversion assessment tool
- 3) Enhancing the Patient/Physician Partnership
  - a) Communication Skills
    - i) Common vocabulary and definitions
    - ii) Dialog-conducive questions
- 4) Conceptual Approach to Treatment
- 5) The Evolutionary Steps
  - a) Physiology of Nociception and Pain Perception

- b) BTP and Impact on QoL
- c) BTP Characteristics and Pharmacology

**Description:**

Breakthrough pain (BTP) is a unique type of pain that must be assessed and treated differentially from chronic pain. The “building blocks” of an effective strategy for BTP management begin with assessment tools that address both chronic pain and BTP. A second building block is establishing an effective communication strategy with the patient, who may lack a fundamental understanding of pain management terms and concepts. Final building blocks include diagnosis and treatment. Clinicians must recognize that the pathophysiology of BTP is different from that of chronic pain, and must, therefore, be differentially diagnosed and treated, to provide effective long-term analgesia.

**Mechanism of Participant Evaluation to be Used:**

Written evaluation

**Mechanism of Provider CME Credit:**

Written evaluation

**Name and Address of Organization Providing CME Credit for this Program:**

MediCom Worldwide, Inc.  
101 Washington Street  
Morrisville, PA 19067

**Accredited Provider Contact:**

Joan Meyer, 800-408-4242 ext. 129, [jmeyer@medicaled.com](mailto:jmeyer@medicaled.com)

**Name of Organization Providing Logistical/Meeting Support:**

MediCom Worldwide, Inc.

**Communications Company/Meeting Planner Contact:**

Diane Evans, 800-408-4242 ext. 133, [devans@medicaled.com](mailto:devans@medicaled.com)

**Corporate member:**

Cephalon, Inc.

Facutly: Jeff Gudin, MD  
Gary Wright, MD  
Paul Spector, MD  
Daniel Bennett, MD

**American Pain Society  
Agreement for Commercial Support of CME Activities**

It is the policy of the American Pain Society that all continuing medical education activities, offering CME credit, fully conform to the Accreditation Council for Continuing Medical Education (ACCME) *Essentials and Guidelines for Accreditation of Sponsors of Continuing Medical Education* and *Standards for Commercial Support and Enduring Materials* (copies of both documents are on file in our Education Offices and are available to commercial supporters). This agreement is intended to define and document our responsibilities as a sponsor of continuing medical education for physicians and those of a commercial supporter (hereafter known as the Company) of those activities, and to define terms and conditions under which commercial funding will be accepted and utilized in support of the continuing education activity named below.

The commercially supporting company and American Pain Society agree to the following terms and conditions:

1. **Statement of Purpose:** This program is for scientific and educational purposes and will not promote the products of the Company, either directly or indirectly.
2. **Responsibility:** As an accredited sponsor, APS shall hold full responsibility for the identification of CME needs, determination of objectives, methods, materials, delivery, budget, and evaluation of the activity independent of commercial influence, support or preference.
3. **Control of Content and Selection of Presenters and Moderators:** APS is responsible for control of content and selection of presenters and moderators. The Company agrees not to direct the content of the program. If requested, the Company, or its agents, will respond only to APS initiated requests for suggestions of presenters or sources of possible presenters. In this case, the company will suggest more than one name; will provide speaker qualifications; will disclose financial or other relationships between the Company and the speaker(s), and will provide this information in writing. APS will recognize any suggestions made and will seek suggestions from other sources as well. The Scientific Program Committee will make speaker and topic selections based on balance, independence and its set of criteria.
4. **Exhibit Placement:** The Company agrees that exhibit placement shall not be a condition of support for this activity.
5. **Disclosure of Financial Relationships:** APS will ensure meaningful disclosure to the audience at the time of the program, of (a) company support; and, (b) any significant relationship between APS and the Company or between individual speakers or moderators and the Company.
6. **Ancillary Promotional Activities:** No promotional activities will be permitted in the same room as the educational activity. No product advertisements will be permitted in the program room.
7. **Objectivity and Balance:** APS will make every effort to ensure that data regarding the Company's products (or competing products) are objectively selected and presented, with favorable and unfavorable information and balanced discussion of prevailing information on the product(s) and/or alternative treatment modalities.
8. **Limitations on Data:** APS will ensure, to the extent possible, meaningful disclosure of limitations on data, (e.g., ongoing research, interim analysis, preliminary data, or unsupported opinion).
9. **Discussion of Unapproved Uses:** APS will require that presenters disclose when a product is not approved in the United States for the use under discussion.
10. **Opportunities for Debate:** APS will ensure meaningful opportunities for questioning or scientific debate.
11. **Independence of APS in the use of Contributed Funds:**
  - funds should be in the form of an unrestricted educational grant made payable to APS.
  - all other support associated with this CME activity (e.g., distributing brochures, preparing slides, printing handouts, distributing handouts, utilizing additional evaluation forms from those used by APS), must be given with the full knowledge and approval of American Pain Society.
  - no other funds from the Company will be paid to the program director, faculty, or others involved with the CME activity (additional honoraria, extra social events, etc.).

The Company agrees to abide by all requirements of the ACCME *Standards for Commercial Support of Continuing Medical Education* as stipulated above. We agree to: (1) abide by the ACCME *Standards for Commercial Support of Continuing Medical Education*; (2) acknowledge educational support from the Company in program brochures, syllabi, and all other program materials, and (3) upon request, furnish the Company with a report concerning the expenditure of the funds provided.

**American Pain Society Agreement for Commercial Support of CME Activities Cont.**

The following represents full and accurate disclosure of all contributions provided by the Company for this continuing education activity.

**AGREED**

CME Activity: 2005 APS 24th Annual Scientific Meeting – Corporate Satellite Symposia  
Diamond Level Support

Location: Boston, MA

Dates: March 30-April 2, 2005

Unrestricted Educational Grant and/or administrative fee made payable to American Pain Society in the amount of: \$40,000. The APS will use this grant to underwrite the specific expenses for this activity, which may include travel, hotel, per diem, honorarium and printing expenses. The unrestricted educational grant may also be used to underwrite other aspects of the Scientific Meeting.

Commercial Supporter Company Name: Cephalon, Inc.

Commercial Company Representative or Agent Name: \_\_\_\_\_

Title: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

American Pain Society Representative:

Department Director or Designee Name: Kathryn Checea

Title: National Director of Professional Relations

Signature: \_\_\_\_\_

*Kathryn M. Checea*

Date: 9/23/04

Course Director or Designee Name: Ruth Tiernan

Title: Director of Education

Signature: \_\_\_\_\_

*Ruth Tiernan*

Date: 9/23/04

K:\APS\Sales\SPONSORS\Agreement.doc Created on 09/20/99 3:44 PM

## MediCom WORLDWIDE, Inc.

### Educational Grant Letter of Agreement

Between Cephalon, Inc 145 Brandywine Parkway West Chester, PA and MediCom Worldwide, Inc. ("Provider") 101 Washington St Morrisville, PA.

Title of Program:

The Building Blocks of Breakthrough Pain Treatment

Date, Location & Time of Program:

Friday April 1, 2002

7:00 – 8: 30 AM

Boston, MA

Provider has requested support for the above-named Program in the form of an educational grant in the amount of \$191,725. It is the intent of this Agreement to ensure that the Program is conducted in a manner consistent with the Food and Drug Administration's Policy Statement on Industry Supported Scientific and Educational Activities, AMA Guidelines on Gifts to Physicians, and the Accreditation Counsel for Continuing Medical Education (ACCME)

To that end, *PROVIDER*, *Cephalon, Inc* agree as follows:

1. **Statement of Purpose:** The Program is for scientific and educational purposes only and is not intended to promote a *Cephalon, Inc.* product directly or indirectly.
2. **Control of Content & Selection of Presenters & Moderators:** The provider is ultimately responsible for the control of content and selection of presenters and moderators. *Cephalon, Inc.* agrees not to direct the content of the program. *Cephalon, Inc.* or its agents, may respond to requests initiated by Provider for suggestions of presenters or sources of possible presenters. *Cephalon, Inc.*, or its agents will suggest more than one name (if possible); will provide speaker qualification; will disclose financial or other relationships between *Cephalon, Inc.*, and speaker; and will provide this information in writing. Provider will, in its sole discretion, select presenters and moderators.
3. **Disclosure of Financial Relationships:** Provider will direct speakers and moderators to disclose to the audience commercial support or funding or other significant financial relationships between the speakers and moderators and *Cephalon Inc.*, and/or any other commercial company whose products are pertinent to the content of the presentation. Disclosure shall be made in writing in all instances when that is possible. Should disclosure occur verbally, such disclosure must be verified by written documentation in the activity file. Provider will disclose *Cephalon, Inc.* support at this program.



4. **Involvement in Content:** There will be no “scripting,” emphasis, or direction of content by *Cephalon, Inc.* or its agents.
5. **Ancillary Promotional Activities:** No promotional activities will be permitted in the same room or obligate path to the educational activity. No product advertisement will be permitted within the program or handout. Provider reserves the right to monitor, unannounced, any presentation to insure that standards are being met. The cost of such monitoring shall be the responsibility of *Cephalon, Inc.*
6. **Objectivity & Balance:** Provider will make every effort to ensure that data regarding *Cephalon, Inc.* products (or competing products) are objectively selected and presented, with favorable and unfavorable information and balance discussion of prevailing information on the product(s) and/or alternative treatments. Provider will provide the opportunity for speakers and the audience to discuss information, both favorable and unfavorable, about the product(s) and/or alternative treatments.
7. **Limitations on Data:** Provider will request the speakers, to the extent possible, to disclose limits on the data, e.g., that it involves ongoing research, interim analyses, preliminary data, or unsupported opinion.
8. **Discussion of Unapproved Uses:** Provider will require that presenters disclose when any product mentioned during the program is not approved in the United States for the use under discussion or is still investigational.
9. **Opportunities for Debate:** Provider will ensure meaningful opportunities for questioning by attendees and scientific debate with and between presenters.
10. No party shall use the other party’s or its affiliate’s name or trademarks for publicity or advertising purposes without the prior written consent of the other party.
11. **Structure of Grant and Use of Funds:** Funds should be in the form of an educational grant made payable to the provider organization (MediCom Worldwide, Inc.). No other funds from *Cephalon, Inc.* will be paid to the program director, faculty, or others involved with the program. Grant funds shall not be used to pay travel, lodging, registration fees, honoraria, or personal expenses for non-faculty attendees. At the conclusion of the program, the Provider agrees to deliver to *Cephalon, Inc.* a report concerning the expenditure of the funds provided.
12. **Regulatory Authority:** Provider agrees to abide by the ACCME Standards for Commercial Support of Continuing Medical Education. Provider will acknowledge educational support from *Cephalon, Inc.* in program brochures, syllabi, and other program material *Cephalon, Inc.* agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.

Payee: MediCom Worldwide, Inc.

In Care Of: Joan Meyer  
Address 101 Washington St  
Morrisville, PA 19067

Tax ID. # 233063738

IN WITNESS WHEREOF, the parties have executed this Agreement as of the last of the respective dates below.

Provider:

Name (Print) Joan Meyer

Signature

Title

Date:

Executive Director

October 13, 2004

Cephalon, Inc

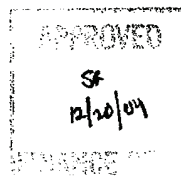
Name (Print)

Signature

Title

Date:

Lynne Brookes  
[Signature]  
V.P. Marketing  
12/7/04



**EDUCATIONAL GRANT DRAFT REQUEST**


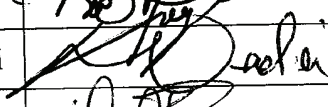
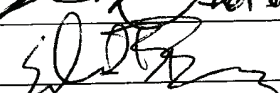
The attached material has been reviewed and is approved:

Payee: Medicom Worldwide, Inc.

Amount: \$191,725

Type of Program: 2005 APS Symposium: "The Building Blocks of BTP Treatment: Assessment, Believe, Communicate, Diagnosis, Effective Treatment"

Submitted for Review: November 18, 2004

DEPARTMENT	NAME	SIGNATURE	DATE
Scientific Communications	Rod Hughes		11-29-04
Medical Affairs	Kiumars Vadiei		12/3/04
Legal & Government	Ed Berg		12-1-04

Return to: Suzanne Richards, ext. 86532

Cephalon, Inc.

145 Brandywine Parkway  
West Chester, PA 19380

01/14/2005

00169649

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INVOICE NO.	DATE	DESCRIPTION	PAID AMOUNT	DISCOUNT	APPLIED AMOUNT
GRANT	11/18/2004	VCH00092132	\$191,725.00		\$191,725.00

INTERNAL NO.	VENDOR #	VENDOR	TOTALS	TOTALS	TOTALS
680	MEDICOM00000	MediCom Worldwide Inc			\$191,725.00



# ACCOUNTS PAYABLE CHECK REQUEST



*Save to Steve  
1/10/05*

**PAYEE NAME:** Medicom Worldwide, Inc.

**ADDRESS:** 101 Washington Street  
Morrisville, PA 19067

**INVOICE NUMBER:** n/a

**INVOICE DATE:** n/a

**DUE DATE:** n/a

**P.O. NUMBER (if applicable):** n/a

**DESCRIPTION:** Med Ed Grant for APS Symposium "The Building Blocks of BTP Treatment"

<u>G/L ACCOUNT NUMBER</u>	<u>DEPARTMENT</u>	<u>PROJECT</u>	<u>AMOUNT</u>
7640	631	ACTQ	\$ 191,725.00

**TOTAL:** \$ 191,725.00

Prepared By: Suzanne Richards

Extension: 86532

Department Number: 631

Approved By: \_\_\_\_\_

Print Approvers Name: Lynne Brookes

Approvers Title: Vice President, Marketing

\*\*\*\*\* Mark here if the check is to be picked up by the preparer: ☒ \*\*\*\*\*

**Please note:** If there is any documentation to be mailed along with the payment, please attach a copy in addition to the copy for Accounting's records

Accounting Use Only:

Batch Number: \_\_\_\_\_

Voucher Number: \_\_\_\_\_

Entry Date: \_\_\_\_\_

1/5/2005

From: Origin ID: (610)738-6532  
Suzanne Richards  
CEPHALON  
145 BRANDYWINE PARKWAY  
  
WEST CHESTER, PA 19380



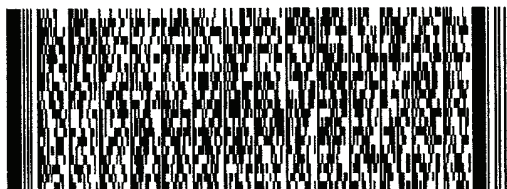
CL809140405/06

SHIP TO: (215)337-9991

BILL SENDER

Joan Meyer  
Medicom  
101 Washington Street

Morrisville, PA 19067



Ship Date: 21JAN05  
Actual Wgt: 1 LB  
System#: 2402709/INET2000  
Account#: S \*\*\*\*\*

REF: 631



Delivery Address Bar Code

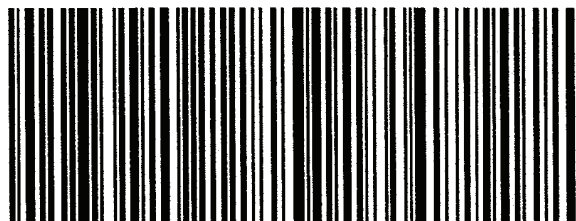
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24JAN05

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FORM  
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19067 -PA-US

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From: Origin ID: (610)738-6532  
Suzanne Richards  
CEPHALON  
145 BRANDYWINE PARKWAY  
  
WEST CHESTER, PA 19380

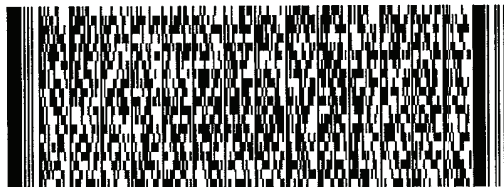


CLS0914040506

SHIP TO: (215)337-9991

BILL SENDER

**Joan Meyer**  
**Medicom**  
**101 Washington Street**

**Morrisville, PA 19067**

Ship Date: 05JAN05  
Actual Wgt: 1 LB  
System#: 2402709/INET2000  
Account#: S \*\*\*\*\*

REF: 631



Delivery Address Bar Code

**STANDARD OVERNIGHT****THU**Deliver By:  
06JAN05

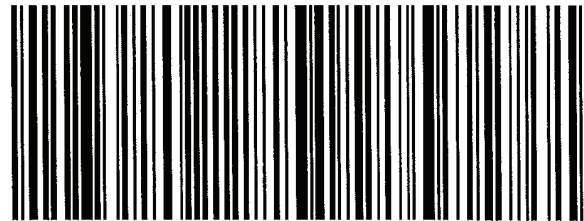
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Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com. FedEx will not be responsible for any claim in excess of \$100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of \$100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is \$500, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see current FedEx Service Guide.





145 Brandywine Parkway • West Chester, PA • 610.738.6532 • 610.738.6641f

## Fax

TO: Joan Meyer  
COMPANY: Medicom  
FAX: 215-337-0960  
FROM: Suzanne Richards  
DATE: 12/7/04  
PAGES (including  
cover sheet):  
COMMENTS: APS Grant

THE INFORMATION CONTAINED IN THIS FAX MESSAGE IS INTENDED ONLY FOR THE PERSONAL AND CONFIDENTIAL USE OF THE RECIPIENT(S) NAMED ABOVE AND BELONGS TO CEPHALON, INC.

This message may contain information that is privileged, confidential and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient, or an agent responsible for delivering it to the intended recipient, you are hereby notified that you have received this document in error and that any review, dissemination, distribution, or copying of this message is strictly prohibited. If you have received this communication in error, please notify us immediately by telephone, and return the original message to us by mail. Thank you.

MEDICOM - AAPM&R 10/05



# Current Practices and Future Perspectives in the Management of Chronic Pain

*Development and Implementation  
of a Satellite Symposium at the  
AAPM&R 2005 Annual Assembly*

*Prepared for*

**Edward Hoey**

Cephalon, Inc.

April 26, 2005

**MediCom Worldwide, Inc.**

**CME**  
**Proposal**

A stylized graphic of a caduceus (a staff with two snakes entwined and wings at the top) and a hand holding a pen, positioned over the word 'Proposal'.

MediCom Worldwide, Inc.

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Mr. Edward Hoey  
Cephalon, Inc.  
41 Moores Road  
Frazer, PA 19355

Dear Mr. Hoey:

As an accredited provider of continuing medical education for physicians, pharmacists and nurses, MediCom Worldwide has recently completed a comprehensive needs assessment to identify the educational needs of clinicians in physical medicine and rehabilitation practices to diagnose and treat chronic pain and improve functionality in their patient population.

Based on the identified educational need, MediCom is requesting an educational grant from Cephalon, Inc. to support the development and implementation of a live satellite symposium at the 66<sup>th</sup> American Academy of Physical Medicine and Rehabilitation (AAPM&R) Annual Assembly.

These activities will focus on strategies for improving the treatment in patients with chronic pain in the rehabilitative setting. The budget to fund these activities is approximately \$154,750.00. Please refer to the detailed budget section of this proposal for complete grant funding details.

These scientific events will comply with all ACCME, FDA, AMA, and ACPE regulations for industry supported professional continuing education. MediCom Worldwide is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians, approved by the Accreditation Council for Pharmacy Education to provide pharmacy continuing education, and approved by the California State Board of Registered Nursing to provide nursing continuing education.

Thank you, in advance, for your consideration of this request. Should you agree to provide funding for this project, Letters of Agreement will be forwarded to you as soon as possible.

Respectfully,

A handwritten signature in cursive script, appearing to read "Joan Meyer".

Joan Meyer RN, MA  
Executive Director, Continuing Education

MediCom Worldwide, Inc. • 101 Washington Street • Morrisville, PA 19067  
215-337-9991

Page 2

## MediCom Worldwide, Inc.

## PROGRAM SUMMARY

**Program Summary**

MediCom is proposing to coordinate the program development and implementation of a live satellite symposium at the 66th American Academy of Physical Medicine and Rehabilitation (AAPM&R) Annual Assembly, October 27-30, 2005, to be held in Philadelphia, Pennsylvania.

**Title:** Current Practices and Future Perspectives in the Management of Chronic Pain

**Topic:** The decade that began January 1, 2001 has been declared by Congress as the Decade of Pain Control and Research. By establishing this awareness of the need for care of people with pain, the goal of private and public sectors efforts is to improve the state of pain care research, education, and clinical care by the year 2010.

This symposium will provide an update on the status of the Decade of Pain Control and Research to include an overview of the developments since the decade began, the key issues of current therapies, and the opportunities for improved pain management as a goal by the decade's end. The Faculty presentations will cover detailed discussion of the physiology of pain, types of pain, including types of breakthrough pain, and pharmacologic therapies utilized in pain management in order to allow for improved restoration of function through rehabilitation. The impact of pain as a barrier in rehabilitation and alternative approaches to managing pain in the rehabilitative setting will also be addressed.

Presentation topics and faculty members were selected based on suggestions made by Thought Leaders in pain management including Drs. Scott Fishman, Richard Payne and Russell Portenoy.

**Presentation Topics (Learning Objectives):**

- Chairman update on Decade of Pain
- Identify recent therapeutic advances for patients with chronic pain.
- Discuss the impact of pain as a barrier in rehabilitation.
- Identify emerging therapeutics used to improve restoration of function by managing chronic and breakthrough pain.
- Outline alternative approaches to managing pain in the rehabilitative setting.



**Proposed Faculty Suggestions:**

Daniel B. Carr, MD  
 Medical Director, Pain Management Program  
 Professor of Pain Research  
 Departments of Anesthesia and Medicine  
 New England Medical Center  
 Boston, Massachusetts

John F. Dombrowski, MD  
 Interim Director  
 Pain Management Center  
 Georgetown University Hospital  
 Washington, DC

Michel Y. Dubois, MD  
 Director, Pain Management Center  
 Professor, Department of Anesthesiology  
 New York University Medical Center  
 New York, New York

John T. Farrar, MD  
 Adjunct Assistant Professor of Epidemiology  
 Department of Biostatistics and Epidemiology  
 Adjunct Assistant Professor of Anesthesia  
 Department of Anesthesia  
 University of Pennsylvania School of Medicine  
 Philadelphia, Pennsylvania

Bill McCarberg, MD  
 Director, Chronic Pain Management Program  
 Kaiser Permanente  
 San Diego, California

Edwin A. Salsitz, MD  
 Medical Director of Office-Based Opioid Therapy  
 Department of Medicine  
 Beth Israel Medical Center  
 New York, New York

Steven P. Stanos, DO  
 Medical Director  
 Chronic Pain Care Center  
 Rehabilitation Institute of Chicago  
 Instructor, Physical Medicine and Rehabilitation  
 Northwestern University Medical School  
 Chicago, Illinois



- CE Provider:** MediCom Worldwide is a fully accredited provider of:
- CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each activity will be approved for a maximum of 1.5 category 1 credit toward the AMA Physician's Recognition Award
  - CPE credit for pharmacists by the Accreditation Council for Pharmacy Education. Each activity will be approved for 1.0 (0.1CEU) for Continuing Pharmacy Education
  - CNE credit for nurses by the California State Board of Registered Nursing. Each activity will be approved for 1.0 Contact Hours.
- Format:** Live satellite symposia to be offered in conjunction with AAPM&R 66<sup>th</sup> Annual Assembly.
- Total Budget:** \$154,750.00

MediCom Worldwide, Inc.

## NEEDS ASSESSMENT



### Needs Assessment

Chronic pain is the third leading cause of physical impairment in the United States, preceded by cancer and heart disease. Affecting 80 million Americans, chronic pain is often a barrier in rehabilitation settings where clinicians strive to restore function in their patients.<sup>1</sup>

Enhanced knowledge of pain assessment and available therapies is necessary for clinicians in physical medicine and rehabilitation to appropriately manage pain and help patients overcome functional limitations. An understanding of recent and emerging therapeutic advances, as well as alternative approaches to pain management can help these clinicians. Education is required to optimize the assessment and management of pain through the enhanced understanding of these therapeutic strategies.

To address this educational need, MediCom proposes to enhance the knowledge of this audience whose focus is to restore function in the patients they care for with acute and chronic pain, and breakthrough pain. The live satellite symposia will include presentation of three didactic lectures followed by question and answer session with these leading clinical experts.

### Literature Review

The congressional declaration of this present decade as the "Decade of Pain Control and Research" and the acknowledgement in January 2001 by the Joint Commission of Healthcare Organizations of pain as the fifth vital sign" reflects the significance of this public health issue in the United States. The cost to the health care system, and the devastating effect on the patients' quality of life are important issues when considering the magnitude of this problem. Pain is the number one cause of adult disability in the United States, affecting one in three people—about 50 million Americans<sup>2</sup> The mechanisms of underlying pain symptoms, especially chronic and neuropathic pain have been the topic of research and has increased the understanding of the function of the neurological system over the last few years.<sup>3</sup> Treatment can be less than optimal for pain and a continued need to help patients effectively manage the type pain they are experiencing is one of the many hopeful outcomes for this decade and beyond.

Clinicians who provide rehabilitative services help patients to achieve an optimal level of functioning, self-care, self-responsibility, independence, and quality-of-life. Achieving the patient's optimal level of functioning includes providing rehabilitative services, which aim to minimize symptoms, exacerbation of chronic illnesses, impairments, and disabilities. Assessment of the patient's physical, cognitive, behavioral, communicate, emotional, and social status identifies factors that may affect attainment of rehabilitative goals. Some problems may include developmental disabilities, physical impairments and disabilities, and pain interfering with optimal level of function or participation in rehabilitation.<sup>4</sup> According to a recent study published in the *American Journal of Physical Medicine & Rehabilitation*, "Rehabilitation Hospital Staff Knowledge and Attitudes Regarding Pain", no previously published studies exist that document pain-related knowledge, attitudes, or educational needs of clinical staff in a rehabilitative hospital.

The purpose of this study was to obtain information to aid in the development of an institutional pain care improvement plan. Results of the survey showed that rehabilitation hospital staff rates their own lack of education about pain management as one of the chief barriers to effective pain management. This lack of education may ultimately lead to undermining the rehabilitative process for patients who do not benefit from proper pain management.<sup>5</sup>

In the rehabilitative setting, clinicians need to address a variety of types of pain experienced by patients. Chronic, nonmalignant pain is a pernicious problem that is often concomitant with many injuries and disease states. Under treated, chronic pain can be a physical, social, mental, and economic burden on patients especially for those whose functionality is already compromised. Chronic pain can have an adverse impact on physical and psychosocial functioning and exacerbate impairments already present due to a chronic, disabling condition. The impact of chronic pain in neurorehabilitation populations requires continued research to truly understand the need for effective interventions to manage pain and disability for these patients.<sup>6</sup> In addition to chronic pain, patients in this population experience breakthrough pain, a common phenomenon in the pain clinic and in the general medical and surgical patient population.<sup>7,8</sup> Types of breakthrough pain include incident, idiopathic and end of dose pain. It is usually associated with moderate to severe pain and may be a predictor of poor response to treatment with routine pharmacotherapy. Breakthrough pain is a marker for both functional impairment and psychological distress. Clinical considerations include pain intensity, frequency, and duration. Breakthrough pain occurs in many settings including hospitals, hospice, nursing homes, emergency rooms, home care, and in rehabilitative settings. Improved pain control is important for all patients. In the rehabilitative setting, it is especially important to help patients overcome the obstacle of pain, which could hinder restoration of function.

#### References

1. <http://www.aapmr.org/condtreat/pain/fibro.htm> (accessed April 2005).
2. Prevalence of Chronic Pain and Migraine, U.S. Pharmacist, Vol. No. 30:03 Posted 3/21/05.
3. Harden RN. Neurologist. 2005 Mar;11(2):111-122.
4. Pain as the 5<sup>th</sup> Vital Sign: Take 5, Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Standards Related to the Assessment and Treatment of Pain, VA Trainee Pocket Card, [http://www.va.gov/oaa/pocketcard/section6\\_jcaho.asp](http://www.va.gov/oaa/pocketcard/section6_jcaho.asp) (accessed April 2005).
5. Am J Phys Med Rehabil. 2003 Jan;82(1):65-8 Rehabilitation hospital staff knowledge and attitudes regarding pain. Loder E, Witkower A, McAlary P, Huhta M, Matarrazzo J. Pain and Headache Management Programs, Spaulding Rehabilitation Hospital, Boston, Massachusetts 02114, USA.
6. Benrad-Larson LM, Wegener ST. NeuroRehabilitation. 2000;14(3):127-137.
7. Taylor D, Chun SY, Renking J, Stegman M, Webster LR. Breakthrough pain in patients with chronic noncancer pain: Impact on quality of life and the effects of oral transmucosal fentanyl citrate. Presented at the 2<sup>nd</sup> Joint Meeting of the American Pain Society and Canadian Pain Society, Vancouver, BC, Canada, May 6-9, 2004.
8. Svendsen KB, Anderson S, Arnason S, Arner S, et al. Breakthrough pain in malignant and non-malignant diseases: a review of prevalence, characteristics and mechanisms. Eur J Pain. 2005 Apr;9(2):195-206.

MediCom Worldwide, Inc.

## PROGRAM OVERVIEW



### Intended Audience

This *Current Practices and Future Perspectives in the Management of Chronic Pain* series is intended for physiatrists, residents, and allied health care professionals in physical medicine and rehabilitation practices.

### Post-Activity Feedback

Course evaluation forms will be required of all participants who seek to receive continuing education credit. MediCom will summarize the information collected from these forms in a formal report to evaluate program effectiveness.

Participants will evaluate the following as *excellent*, *good*, *fair*, or *poor*.

1. Overall content
2. Faculty teaching effectiveness
3. Format
4. Audio / visual quality

Participants will also respond to the following questions:

1. How well did the program achieve its educational objectives?
2. Do you feel that the program material was useful and practice-oriented?
3. Do you feel that the information provided in this educational activity will aid in improving patient care in your practice?
4. Do you feel that fair balance was maintained for all therapeutic options?
5. Would you participate in future educational activities?



MediCom Worldwide, Inc.  
 101 Washington Street  
 Morrisville, Pennsylvania 19067

Date: April 25, 2005  
 Job Number M00573

*Clinical Dialogues in Pain Management*  
**2005 AAPM&R Satellite Symposium**  
*Projected Budget Estimate*

<b>Program Parameters</b>	
Topic	1
Faculty	3
Symposium Attendees	275
Direct mail invitations to health care professionals	2500
Supplemental save-the-date cards for secondary recruitment	2000

<b>Cost Summary</b>	
Approximate Total, Direct Expenses	\$ 77,425
Total, Indirect Expenses	\$ 77,325
<b>Cost of 2005 AAPM&amp;R Satellite Symposium</b>	<b>\$ 154,750</b>

Approval Signature

Date

**Note: no work may begin until MediCom receives, via email or fax, this approval with signature and date**



MediCom Worldwide, Inc.  
101 Washington Street  
Morrisville, Pennsylvania 19067

Date: April 25, 2005  
Job Number M00573

*Clinical Dialogues in Pain Management*  
**2005 AAPM&R Satellite Symposium**  
**Projected Budget Estimate**

<b>Direct Expenses; Approximate</b>	
<b>AAPM&amp;R Fee</b>	\$ 10,000
<b>Direct mail invitations, mail services, postage</b>	\$ 5,000
Direct mail invitations, mailed to registered meeting attendees; includes printing, assembly, mail services and postage. Postage estimated at \$0.37 per direct mail piece	
<b>Direct mail list purchase</b>	
<b>Supplemental invitations for secondary recruitment</b>	\$ 2,500
Includes printing of save-the-date cards for use by association as secondary recruitment materials	
<b>Invitation door-drop/advertisement fee</b>	\$ 3,000
<b>Participant handouts</b>	\$ 4,800
Includes printing of participant workbook; will include accreditation information, speaker biographical and disclosure information, agenda, and symposium graphics <i>Color slides</i>	
<b>Posters; quantity: 3 ; 2 scroll signs; tent cards; podium sign</b>	\$ 2,400
<b>Faculty expenses</b>	
Honoraria	\$ 8,000
Travel	\$ 2,700
Accommodations	\$ 1,500
Ground transportation	\$ 600
<b>Catering</b>	\$ 27,500
<b>Audio/visual services</b>	\$ 8,000
<b>MediCom expenses</b>	
Air travel (Local no air expense)	
Accommodations (Local no expense)	
Meals (includes faculty dinner)	\$ 500
Ground transportation	\$ 250
OOP	\$ 75
<b>Shipping/Fed Ex</b>	\$ 350
<b>Miscellaneous</b>	\$ 250
<b>Approximate Total, Meeting Management Direct Expenses</b>	<b>\$ 77,425</b>

<b>Indirect Expenses</b>	
<b>MediCom pre-meeting coordination, registration</b>	\$ 35,000
Includes faculty recruitment, content coordination, medical writing, editing, site negotiation and coordination; database development and management	
<b>MediCom on-site symposium registration, two MediCom staff</b>	\$ 3,200
<b>Graphic design</b>	\$ 2,500
<b>Accreditation of program for CME, CPE, CNE</b>	\$ 10,000
<b>Continuing Education participant certificates</b>	\$ 4,125
<b>Administrative and accounting fees</b>	\$ 9,500
<b>Project management</b>	\$ 13,000
<b>Total, Indirect Expenses</b>	<b>\$ 77,325</b>

## MediCom Worldwide, Inc.

### Educational Grant Letter of Agreement

Between Cephalon, Inc. 41 Moores Road Frazer, PA 19355 and MediCom Worldwide, Inc. ("Provider") 101 Washington St. Morrisville, PA 19067.

**Title of Program:**

Live Symposia to take place at AAPM&R Conference

**Date, Location & Time of Program:**

October 2005

Philadelphia, PA

Provider has requested support for the above-named Program in the form of an educational grant in the amount of \$154,750. It is the intent of this Agreement to ensure that the Program is conducted in a manner consistent with the Food and Drug Administration's Policy Statement on Industry Supported Scientific and Educational Activities, AMA Guidelines on Gifts to Physicians, and the Accreditation Counsel for Continuing Medical Education (ACCME)

To that end, *PROVIDER, Cephalon, Inc.* agree as follows:

1. **Statement of Purpose:** The Program is for scientific and educational purposes only and is not intended to promote a *Cephalon, Inc.* product directly or indirectly.
2. **Control of Content & Selection of Presenters & Moderators:** The provider is ultimately responsible for the control of content and selection of presenters and moderators. *Cephalon, Inc.* agrees not to direct the content of the program. *Cephalon, Inc.* or its agents, may respond to requests initiated by Provider for suggestions of presenters or sources of possible presenters. *Cephalon, Inc.*, or its agents will suggest more than one name (if possible); will provide speaker qualification; will disclose financial or other relationships between *Cephalon, Inc.*, and speaker; and will provide this information in writing. Provider will, in its sole discretion, select presenters and moderators.
3. **Disclosure of Financial Relationships:** Provider will direct speakers and moderators to disclose to the audience commercial support or funding or other significant financial relationships between the speakers and moderators and *Cephalon Inc.*, and/or any other commercial company whose products are pertinent to the content of the presentation. Disclosure shall be made in writing in all instances when that is possible. Should disclosure occur verbally, such disclosure must be verified by written documentation in the activity file. Provider will disclose *Cephalon, Inc.* support at this program.



4. **Involvement in Content:** There will be no "scripting," emphasis, or direction of content by *Cephalon, Inc.* or its agents.
5. **Ancillary Promotional Activities:** No promotional activities will be permitted in the same room or obligate path to the educational activity. No product advertisement will be permitted within the program or handout. Provider reserves the right to monitor, unannounced, any presentation to insure that standards are being met. The cost of such monitoring shall be the responsibility of *Cephalon, Inc.*
6. **Objectivity & Balance:** Provider will make every effort to ensure that data regarding *Cephalon, Inc.* products (or competing products) are objectively selected and presented, with favorable and unfavorable information and balance discussion of prevailing information on the product(s) and/or alternative treatments. Provider will provide the opportunity for speakers and the audience to discuss information, both favorable and unfavorable, about the product(s) and/or alternative treatments.
7. **Limitations on Data:** Provider will request the speakers, to the extent possible, to disclose limits on the data, e.g., that it involves ongoing research, interim analyses, preliminary data, or unsupported opinion.
8. **Discussion of Unapproved Uses:** Provider will require that presenters disclose when any product mentioned during the program is not approved in the United States for the use under discussion or is still investigational.
9. **Opportunities for Debate:** Provider will ensure meaningful opportunities for questioning by attendees and scientific debate with and between presenters.
10. No party shall use the other party's or its affiliate's name or trademarks for publicity or advertising purposes without the prior written consent of the other party.
11. **Structure of Grant and Use of Funds:** Funds should be in the form of an educational grant made payable to the provider organization (MediCom Worldwide, Inc.). No other funds from *Cephalon, Inc.* will be paid to the program director, faculty, or others involved with the program. Grant funds shall not be used to pay travel, lodging, registration fees, honoraria, or personal expenses for non-faculty attendees. At the conclusion of the program, the Provider agrees to deliver to *Cephalon, Inc.* a report concerning the expenditure of the funds provided.
12. **Regulatory Authority:** Provider agrees to abide by the ACCME Standards for Commercial Support of Continuing Medical Education. Provider will acknowledge educational support from *Cephalon, Inc.* in program brochures, syllabi, and other program material *Cephalon, Inc.* agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.

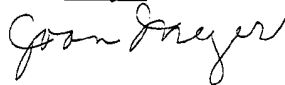
Payee: MediCom Worldwide, Inc..

12/99 2

In Care Of: Joan Meyer  
Address 101 Washington St  
Morrisville, PA 19067

Tax ID. # 233063738

IN WITNESS WHEREOF, the parties have executed this Agreement as of the last of the respective dates below.

Provider: Name (Print) Joan Meyer  
Signature   
Title Executive Director  
Date: April 25, 2005

Cephalon, Inc. Name (Print) \_\_\_\_\_  
Signature \_\_\_\_\_  
Title \_\_\_\_\_  
Date: \_\_\_\_\_



Mr. Edward Hoey  
Cephalon, Inc.  
41 Moores Road  
Frazer, PA 19355

Dear Mr. Hoey:

As an accredited provider of continuing medical education for physicians, pharmacists and nurses, MediCom Worldwide has recently completed a comprehensive needs assessment to identify the educational needs of clinicians in physical medicine and rehabilitation practices to diagnose and treat chronic pain and improve functionality in their patient population.

Based on the identified educational need, MediCom is requesting an educational grant from Cephalon, Inc. to support the development and implementation of a live satellite symposium at the 66<sup>th</sup> American Academy of Physical Medicine and Rehabilitation (AAPM&R) Annual Assembly.

These activities will focus on strategies for improving the treatment in patients with chronic pain in the rehabilitative setting. The budget to fund these activities is approximately \$154,750.00. Please refer to the detailed budget section of this proposal for complete grant funding details.

These scientific events will comply with all ACCME, FDA, AMA, and ACPE regulations for industry supported professional continuing education. MediCom Worldwide is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians, approved by the Accreditation Council for Pharmacy Education to provide pharmacy continuing education, and approved by the California State Board of Registered Nursing to provide nursing continuing education.

Thank you, in advance, for your consideration of this request. Should you agree to provide funding for this project, Letters of Agreement will be forwarded to you as soon as possible.

Respectfully,

A handwritten signature in cursive script, appearing to read "Joan Meyer".

Joan Meyer RN, MA  
Executive Director, Continuing Education

MediCom Worldwide, Inc. • 101 Washington Street • Morrisville, PA 19067  
215-337-9991



MediCom Worldwide, Inc.  
 101 Washington Street  
 Morrisville, Pennsylvania 19067

Date: April 25, 2005  
 Job Number M00573

*Clinical Dialogues in Pain Management*  
**2005 AAPM&R Satellite Symposium**  
*Projected Budget Estimate*

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Approval Signature \_\_\_\_\_

Date \_\_\_\_\_

**Note: no work may begin until MediCom receives, via email or fax, this approval with signature and date**



MediCom Worldwide, Inc.  
101 Washington Street  
Morrisville, Pennsylvania 19067

Date: April 25, 2005  
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	\$ 77,325



Cephalon, Inc.  
41 Moores Road  
P.O. Box 4011  
Frazer, PA 19355

October 5, 2005

Joan Meyer RN, MA  
Executive Director Continuing Education  
MediCom Worldwide, Inc.  
101 Washington Street  
Morrisville PA 19067

Re: Revised Letter of Agreement (LOA) for live symposium for AAPM & R 66<sup>th</sup> annual meeting.

Dear Ms Meyer,

Enclosed please find a revised copy of MediCom Worldwide's Medical Education Agreement for a live symposium to take place at the AAPM & R conference being held October 27, 2005 in Philadelphia, PA. This new Letter of Agreement (LOA) is being sent to you, per your request, after your communication from the AAPMR in which they expressed concerns about the ACTIQ (oral transmucosal fentanyl citrate) [C-II] Risk Management Program language contained in the original. To satisfy this concern we have agreed to make an exception in this instance and provide the new LOA with the ACTIQ language removed.

Please be assured that we are in no way encouraging anyone to include ACTIQ in the program, however if it is, the following language is meant to ensure that those physicians responsible for developing content are aware of some important aspects of the ACTIQ Risk Management Program (RMP). The RMP includes safety messages that are essential to the safe use of this product. They are:

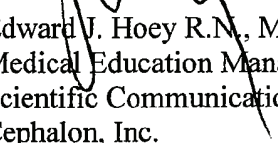
- ACTIQ is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- ACTIQ is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.
- ACTIQ is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.



Cephalon, Inc.  
41 Moores Road  
P.O. Box 4011  
Frazer, PA 19355

If you have any questions, please feel free to contact me at 610-883-5505.

Sincerely,



Edward J. Hoey R.N., MBA  
Medical Education Manager – Pain Medicine  
Scientific Communications  
Cephalon, Inc.

Enclosure:  
MediCom Worldwide, Inc. Educational Grant Letter of Agreement



## MediCom WORLDWIDE, Inc.

### Educational Grant Letter of Agreement

Between Cephalon, Inc 41 Moores Road Frazer, PA 19355 and MediCom Worldwide, Inc. ("Provider") 101 Washington St. Morrisville, PA 19067.

Title of Program:

Live Symposia to take place at AAPM&R Conference

Date, Location & Time of Program:

Oct 2005

Philadelphia, PA

Provider has requested support for the above-named Program in the form of an educational grant in the amount of \$154,750. It is the intent of this Agreement to ensure that the Program is conducted in a manner consistent with the Food and Drug Administration's Policy Statement on Industry Supported Scientific and Educational Activities, AMA Guidelines on Gifts to Physicians, and the Accreditation Counsel for Continuing Medical Education (ACCME)

To that end, *PROVIDER*, *Cephalon, Inc* agree as follows:

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12/99

4. **Involvement in Content:** There will be no “scripting,” emphasis, or direction of content by *Cephalon, Inc.* or its agents.
5. **Ancillary Promotional Activities:** No promotional activities will be permitted in the same room or obligate path to the educational activity. No product advertisement will be permitted within the program or handout. Provider reserves the right to monitor, unannounced, any presentation to insure that standards are being met. The cost of such monitoring shall be the responsibility of *Cephalon, Inc.*
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9. **Opportunities for Debate:** Provider will ensure meaningful opportunities for questioning by attendees and scientific debate with and between presenters.
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12. **Regulatory Authority:** Provider agrees to abide by the ACCME Standards for Commercial Support of Continuing Medical Education. Provider will acknowledge educational support from *Cephalon, Inc.* in program brochures, syllabi, and other program material *Cephalon, Inc.* agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.

Payee: MediCom Worldwide, Inc.

In Care Of: Joan Meyer  
Address 101 Washington St  
Morrisville, PA 19067

Tax ID. # 233063738

IN WITNESS WHEREOF, the parties have executed this Agreement as of the last of the respective dates below.

Provider: Name (Print) Joan Meyer

Signature

Title

Date:

Executive Director

April 25, 2005

Cephalon, Inc

Name (Print)

Signature

Title

Date:

Rod Hughes

Vice President Scientific Communications



**EDUCATIONAL GRANT DRAFT REQUEST**



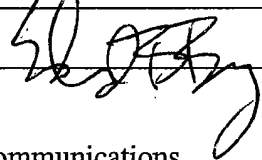
The attached material has been reviewed and is approved:

Payee: MediCom Worldwide

Amount: \$154,750

Type of Program: American Academy of Physical Medicine and Rehabilitation Annual Assembly

Submitted for Review: June 20, 2005

DEPARTMENT	NAME	SIGNATURE	DATE
Scientific Communications	Rod Hughes		6-27-05
Medical Affairs	Kiumars Vadieli		6/27/05
Legal & Government	Ed Berg		6/27/05

Return to: Candice McCarthy 35663 -- Scientific Communications



Edward J. Hoey  
Medical Education Manager - Pain Medicine  
Scientific Communications

---

6/17/05

Rod

Attached is a grant proposal for  
the upcoming AAPM+R meeting  
being held in Phila Oct 27-30, 2005.

I would request the Grant Review  
committee approve this proposal to  
help address the most educational  
needs of this group based off  
the needs assessment.

Respectfully

Ed



## MEDICAL EDUCATION AGREEMENT

As a condition of Cephalon, Inc.'s contribution of funds to support an independent medical education program (with or without CME credits), the Scientific and Educational Activity provider agrees to the following terms and conditions:

This Agreement ("Agreement") is entered into as of June 27, 2005 by and between Cephalon, Inc. ("Cephalon") and MediCom Worldwide, Inc. ("Provider") regarding a medical education program sponsored by Cephalon entitled "Current Practices and Future Perspectives in the Management of Chronic Pain" to be held from October 27-30, 2005. The parties' mutual objectives are to provide a balanced, independent, scientifically rigorous program to promote the education of attendees.

1. Statement of Purpose. This program is for scientific and educational purposes only and not to promote any commercial drug products.
2. Control of Content and Selection of Presenters and Moderators. The provider is ultimately responsible for the control of content and selection of presenters and moderators. Cephalon or its agents may respond to requests initiated by the provider for suggestions of presenters or sources of possible presenters. Cephalon will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Cephalon and speaker; and will provide this information in writing. Provider will seek suggestions from other sources, and will, in its sole discretion, select presenters and moderators.
3. Disclosure of Financial Relationships. Provider will direct speakers and moderators to disclose to the audience commercial support or funding or other significant financial relationships between the speakers and moderators and Cephalon and/or any other commercial company whose products are pertinent to the content of the presentation. Provider will disclose Cephalon's support at this program.
4. Involvement in Content. There will be no "scripting," emphasis, or influence on content by Cephalon or its agents. However, Cephalon may provide technical support to speakers, e.g., furnishing slides or data, upon their request.
5. Ancillary Promotional Activities. No promotional activities will be permitted in the same room as, or in the obligatory path to, the educational activity. No product advertisements will be permitted within the program or handouts.
6. Objectivity and Balance. Provider will advise presenters that data regarding Cephalon products (or competing products) are to be objectively selected and presented. Provider will provide the opportunity for speakers and the audience to discuss information, both favorable and unfavorable, about the product(s) and/or alternative treatments.



7. Limitations of Data. Provider will request the speakers, to the extent possible, to disclose limits on the data, e.g., that it involves ongoing research, interim analyses, preliminary data, or unsupported opinion.

8. Discussion of Unapproved Uses. Provider will request that presenters disclose when a product is not approved in the United States for the use under discussion.

9. ACTIQ Risk Management Program. Provider is aware that ACTIQ® (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- ACTIQ is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- ACTIQ is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.
- ACTIQ is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

10. Opportunity for Debate. Provider will ensure opportunities for questioning by attendees and scientific debate with and between presenters.

11. Independence of Provider in the Use of Contributed Funds.

(a) funds should be in the form of an educational grant made payable to the provider organization.

(b) Provider must be advised of all other support by Cephalon of the CME activity (e.g., distributing brochures, preparing slides). If Provider disapproves of this activity, it shall promptly notify Cephalon.

(c) no other funds from Cephalon will be paid to the program director, faculty, or others involved with this CME activity, e.g., additional honoraria.

12. General.



(a) Cephalon agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.

(b) Provider agrees to: (1) abide by the ACCME Standards for Commercial Support of Continuing Medical Education; (2) acknowledge educational support from Cephalon in program brochures, syllabi, and other program materials; and (3) upon request, furnish Cephalon with a report concerning the expenditure of the funds provided by Cephalon.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

MEDICOM WORLDWIDE, INC.

CEPHALON, INC.

By: *Joan Meyer*  
Name: JOAN MEYER  
Title: Executive Director

By: *Rod Hughes*  
Name: Rod Hughes  
Title: Vice President Scientific Communications





# ACCOUNTS PAYABLE CHECK REQUEST



**PAYEE NAME:** MediCom Worldwide

**ADDRESS:** 101 Washington Street  
Morrisville, PA 19067

**INVOICE NUMBER:** 10103102

**INVOICE DATE:** 6/29/2005

**DUE DATE:** upon receipt

**P.O. NUMBER (if applicable):**

**DESCRIPTION:** Medical Education grant for live symposia in conjunction with AAPM&R  
to be held October 2005

**COPY**

**G/L ACCOUNT NUMBER**

**DEPARTMENT**

440

**PROJECT**

Educational Grant  
payment

**AMOUNT**

154,750.00

**TOTAL:**

**\$154,750.00**

Prepared By: Candice McCarthy  
Extension: 35663  
Department Number: 440

Approved By: Rod Hughes, PhD

Print Approvers Name: Vice President Scientific Communications

Approvers Title:

\*\*\*\*\* Mark here if the check is to be picked up by the preparer: ☐ \*\*\*\*\*

**Please note:** If there is any documentation to be mailed along with the payment,  
please attach a copy in addition to the copy for Accounting's records

Accounting Use Only:

Batch Number: \_\_\_\_\_  
Voucher Number: \_\_\_\_\_  
Entry Date: \_\_\_\_\_

6/29/2005

MEDICOM WORLDWIDE, INC.

101 WASHINGTON STREET  
MORRISVILLE, PA 19067**Invoice**

Date	Invoice #
6/29/2005	10103102

<b>Bill To</b>
Cephalon, Inc. Attention: Candice McCarthy 41 Moores Road Frazer, PA 19355 Fax: 610-883-5578

P.O. No.	Terms	Project
	UPON RECEIPT	03-XXX-F-002-M00573

Quantity	Description	Rate	Amount
	LIVE SYMPOSIA IN CONJUNCTION WITH AAPM&R TO BE HELD OCT 2005 PHILADELPHIA, PA  <i>Paid 6/30/05 (Crystal Report) (in worksheet)</i>	154,750.00	154,750.00

Thank you.  
Federal Tax ID 23-3063738.**Total**

\$154,750.00

**Confidential**

TEVA\_MDL\_A\_01852820

P-29481 \_ 01028

**EDUCATIONAL GRANT APPROVAL FORM**

The attached material has been reviewed and is approved:

Payee: MediCom Worldwide Inc

Amount: 366,210

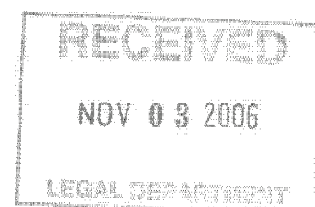
Type of Program: ASPMN symposium and eduring materials

Submitted for Review: 10/26/06

DEPARTMENT	NAME	SIGNATURE	DATE
Scientific Communications	Rod Hughes	<i>R Hughes</i>	11-8-06
Medical Affairs	Kiumars Vadieli	<i>K Vadieli</i>	11/13/06
Legal & Government	Eric Siegel	<i>E Siegel</i>	11-8-06

Please Return to: Kimber Titus 86766 – Scientific Communications

*Suz Steczak 86537*



**EDUCATIONAL GRANT REQUEST**  
(Scientific Communications Sign-off Sheet)

Submission to Committee Date: 10/26/06 Grant Tracking # 404 Amount: \$ 366,210

NOTE: •Submission must be 30 days prior to program date

•Grant Tracking # if applicable

•Grant request must be submitted on provider letterhead

Educational Provider Name: MediCom Worldwide Inc

Accredited (CME/CE) ☒ Yes

Street Address: 101 Washington St.

City: Morrisville

State: PA

Zip: 19067

Program title: ASPMN symposium and enduring materials

Start Date: March 1, 2006 - Oct. 31, 2008

Location: \_\_\_\_\_

Is Cephalon the only sponsor of program: ☒ Yes ☐ No ☐ Unknown

Type of Program (choose all that apply): ☒ Nat'l Symposia ☐ Teleconference ☒ Print

☐ Grand Rounds ☒ Website ☒ DVD/CD-ROM 

☐ Regional or Local Meeting ☐ Other: \_\_\_\_\_

Will Grant Support Enduring Materials: ☒ Yes ☐ No

Was Cephalon Involved in the Grant Request to Date? ☐ Yes ☒ No

If Yes, describe: \_\_\_\_\_

Will Cephalon have future Involvement? ☐ Yes ☒ No

If Yes, describe: \_\_\_\_\_

Manager Signature: \_\_\_\_\_

Print Name: \_\_\_\_\_

Bhaval Shah Bell, Ph.D.

Director/Sr. Director Signature: \_\_\_\_\_

Print Name: \_\_\_\_\_

Jacqui Brooks, M.D.

GRANT COMMITTEE APPROVAL ☐ Yes ☐ No Date: \_\_\_\_\_

If no, state reason: \_\_\_\_\_

For Budgetary Purposes Only - Product: (Check One)

☒ Actiq ☐ Gabitril ☐ Provigil ☐ Trisenox ☐ Vivitrol ☐ Other: \_\_\_\_\_



Cephalon, Inc.  
41 Moores Road  
Frazer, PA 19355  
tel 610.344.0200  
fax 610.344.0065  
www.cephalon.com

## Memo

---

To: Legal Department – Archives  
From: Kimber Titus x86766  
Date: December 7, 2006  
Re: Fully-Executed Agreement(s) for Archiving in Central Files

I have attached hereto a fully executed agreement for archiving in Central Files.

I have completed the checklist below in preparation for archiving in Central Files:

- ☒ An authorized Cephalon officer has signed the agreement(s) (at the level of Vice President or above. If this is a CDA, a Director or Senior Director may be authorized to sign if a valid Delegation of Authority to sign CDAs is on file in the Legal Department).
- ☒ The agreement(s) is fully executed by both parties and both original signatures are attached.
- ☒ The signature page contains the Legal Department approval stamp, which signifies that the agreement(s) was routed to Legal for review and approval prior to signature.

Thank you!



www.cephalon.com

Cephalon, Inc.  
 41 Moores Road  
 P.O. Box 4011  
 Frazer, PA 19355  
 Phone 810/344-0200  
 Fax 810/344-0065

## INDEPENDENT EDUCATIONAL PROGRAM ("IEP") GRANT AGREEMENT

This Agreement is entered into as of this 20th day of November, 2006 by and between Cephalon ("Cephalon"), located at 41 Moores Road, Post Office Box 4011, Frazer, PA 19355, and MediCom Worldwide, Inc. ("IEP Provider") located at 101 Washington Street, Morrisville, PA 19067.

WHEREAS, Cephalon has reviewed IEP Provider's grant request to support a medical education program ("Program"); and

WHEREAS, Cephalon has determined that the Program has the potential to significantly further medical knowledge and improve patient care; and

WHEREAS, it is the intent of the parties to ensure that the Program will be independent, objective, balanced and scientifically rigorous, so that it will not be viewed by the United States Food and Drug Administration ("FDA") as promotional and that Cephalon will not be viewed as responsible for its content; and

WHEREAS, Cephalon agrees to provide funding for the Program under the conditions set forth below.

NOW THEREFORE, IEP Provider and Cephalon agree to the following terms under this Agreement:

1. Title of Program. The IEP is entitled, ASPMN Symposium and Enduring Materials and a copy of the grant request for the Program is attached hereto as Exhibit A.
2. Type of Program. The Program is:
  - ☒ accredited (e.g., continuing medical education or "CME"); or
  - ☐ an independent program where CE credits will not be offered.
3. IEP Provider. The IEP Provider is the following type of entity:
  - ☒ Accredited continuing medical education provider
  - ☐ University/Hospital
  - ☐ Professional Organization
  - ☐ Medical Education Company
4. Educational Partner. The IEP Provider ☐ shall ☒ shall not use a third party that will provide assistance in support of the Program ("Educational Partner").





5. Educational Components. The expected components of the Program (e.g., number of live meetings, CD ROM, web-based, etc.) are as follows:

- (a) Live symposia;
- (b) Internet based activity hosted by Medscape;
- (c) CD-ROM based on live footage accredited as a supplement in ASPMN Journal;

6. Program Purpose. The Program is for scientific and educational purposes only and is not intended to promote a Cephalon product directly or indirectly. The Program is not a repeat performance of a prior program.

7. Grant Amount Funding Arrangements.

- (a) Cephalon will provide support for the Program by means of an educational grant in the total amount of \$366,210. If the Program is canceled or terminated prior to completion, IEP Provider shall return the grant, or any unused portion thereof, to Cephalon within thirty (30) days of such termination or cancellation. IEP Provider shall have full responsibility for all funding arrangements of the Program, including any funding to be provided to IEP Provider's Educational Partner. Payment of the grant shall be made in accordance with a schedule agreed to by the parties. All payments due hereunder shall be made by Cephalon within forty-five (45) days of its receipt of an invoice for same, provided IEP Provider is in compliance with the terms of this Agreement.
- (b) Within thirty (30) days of completion of the Program, IEP Provider shall provide Cephalon with a detailed reconciliation of actual out-of-pocket expenses incurred, and to the extent Cephalon has overpaid IEP Provider for same, IEP Provider shall provide a refund to Cephalon within thirty (30) days thereafter. Such detailed reconciliation shall be forwarded to Cephalon at the address above to the attention of Rod J Hughes, Ph.D., Vice President, Scientific Communications.
- (c) IEP Provider may not use funds provided by Cephalon to pay travel, lodging, honoraria or personal expenses for non-faculty attendees. Grant funds may be used to reduce the overall registration fees for attendees. Grant funds may not be used to purchase capital equipment or to provide general operational support for an institution. Funds for hospitality shall not be provided except that funds may be used for modest meals or receptions that are held as part of the Program, but such events shall not compete with nor take precedence over educational events. The appropriateness of any reception shall be at the sole discretion of the IEP Provider, and IEP Provider shall have final decision making authority in connection with any such activities.
- (d) Funds may be used by the IEP Provider to permit medical students, residents, fellows or other health care professionals in training to travel to



and attend the Program; provided, however, that the selection of such students, residents or fellows who receive funds is made by either the academic or training institution or, if by the IEP Provider, such selection shall be made with the full concurrence of the academic or training institution.

- (e) In accordance with the Accreditation Council for Continuing Medical Education ("ACCME") Standards and to assist Cephalon in complying with its internal auditing procedures, IEP Provider agrees to verify the manner in which the grant is used. Accordingly, within thirty (30) days following a request from Cephalon, IEP Provider shall provide to Cephalon:

- i. A written statement verifying that the Program occurred, and
- ii. An itemized list of expenditures supported by the grant.

- 8. Objectivity and Balance. IEP Provider shall retain full responsibility for control of the content of the Program and shall ensure that the following requirements are met:

- (a) The Program material/information will be objective, balanced and free from commercial bias. All topics shall be treated in an impartial, unbiased manner. All discussions shall include a range of views about each class of drug and disease treatment options. Information shall not unfairly represent a spectrum of views favoring a product or class of products marketed by Cephalon or any other company. The title of the Program will fairly and accurately represent the scope of the presentation.

- (b) IEP Provider agrees that neither Cephalon nor its agents shall control the content of the Program. IEP Provider agrees that there will be no scripting, targeting of points for emphasis, or other activities by Cephalon or its agents that are designed to influence the content of the Program. If requested in writing by the IEP Provider, medical/scientific representatives from Cephalon may attend content development meetings or other planning meetings, for the purpose of addressing any scientific inaccuracies they observe. Personnel from Cephalon must not discuss or in any way attempt to control (either during the meeting or at breaks or meals), the content of the program. An appropriate medical/scientific representative from Cephalon may provide a presentation at a content development meeting at the request of the provider, or may respond to specific questions at such meeting regarding the results of a Cephalon-sponsored research study, provided the information presented conforms to the generally accepted standards of experimental design, data collection and analysis, and provided any presentation is accompanied by a detailed outline of the presentation, which can be used by the IEP Provider/Educational Partner to confirm the scientific objectivity of the presentation.





- (c) If the IEP Provider, in its sole discretion, requests a Cephalon medical representative to review the Program for medical accuracy and completeness, Cephalon will comply with such request. The parties acknowledge there is no obligation or any condition requiring IEP Provider to make such a request. Any such request must be made after the Program materials are fully developed and such request must be made by the IEP Provider only to a Cephalon medical representative that has responsibility for the therapeutic area that will be covered by the Program. IEP Provider will not ask any marketing or sales representatives at Cephalon to comment on the material. All final decisions regarding whether to modify the material based on any comments provided by the Cephalon medical representative shall be in the sole discretion of IEP Provider.
  - (d) If a product marketed by Cephalon is the subject of discussion, the data will be objectively selected and presented, with an accurate reflection of favorable and unfavorable information about the product and shall also include a balanced discussion of prevailing information on alternative products and /or therapies.
  - (e) Any suggestions of superiority of one product or treatment over another will be supported by the body of available data, and will not result from selective presentation or emphasis on data favorable to particular treatment.
  - (f) IEP Provider represents that neither it nor the Educational Partner (if any) has either an open complaint or decision from the ACCME or the Food and Drug Administration that a program provided by the IEP Provider or the Educational Partner failed to meet standards of independence, balance, objectivity, or scientific rigor.
9. Risk Minimization Action Plan. Cephalon provides the following Risk Minimization Action Plan ("RiskMAP") information to all IEP Providers. Neither Cephalon nor its agents shall influence or control whether a product marketed by Cephalon is the subject of discussion. A RiskMAP is a strategic safety program designed to meet specific goals and objectives in minimizing known risks of a product while preserving its benefits. Any product marketed by Cephalon that is approved with a RiskMAP, and the key safety-related health outcomes outlined in that RiskMAP, are listed in Exhibit B. IEP Provider agrees that it is aware of the RiskMAP(s) and the key safety messages.
10. Faculty Selection. IEP Provider shall retain full responsibility for the selection of the presenters, authors, moderators, and/or other faculty (hereinafter referred to collectively as "Faculty"). Cephalon, through its Scientific Communications Department, may respond only to IEP Provider-initiated, written requests (or requests from the Educational Partner) for suggestions of Faculty or sources of possible Faculty. In response to such requests at least three (3) names will be suggested (if possible) for each open position and this information will be provided in writing. IEP Provider will record the role of Cephalon in suggesting



Faculty; will seek suggestions from other sources; and will make its selection of Faculty based on objective criteria. IEP Provider shall not be obligated to request or accept such assistance from Cephalon or its agents as a condition of receiving the educational grant hereunder.

11. Disclosures. IEP Provider will ensure meaningful disclosure of limitations of data (e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion). IEP Provider will require that Faculty disclose when a product is not approved in the United States for the use under discussion.
12. Question and Answer Session. To the extent the Program is a presentation, IEP Provider will ensure meaningful opportunities for questioning by the audience.
13. Financial Relationships. IEP Provider will ensure meaningful disclosure to the audience of Cephalon funding and any significant relationship between individual Faculty and Cephalon. All meaningful disclosure(s) shall also be made in any written materials, including but not limited to announcements, brochures, syllabi and enduring material. Disclosures shall not mention product trade names.
14. Metrics/Copies of Program Material.
  - (a) IEP Provider and/or Educational Partner shall provide certain outcome measurements and metrics to Cephalon as requested by the Scientific Communications Department. Such metrics shall be provided either after the conclusion of a single live event or monthly for a year-long accredited program and may at Cephalon's request include the number of program participants, number of certifications, assessment of the program and faculty, and demonstration of learning by program participants.
  - (b) After the Program has occurred, IEP Provider shall provide Cephalon with 5 copies of all Program materials in CD ROM or electronic format and 20 copies in print format.
15. Representations and Warranties. IEP Provider represents that:
  - (a) Neither it nor the Educational Partner, if any, provides marketing, advertising, public relations, market research, medical education services or other consulting services (e.g., support for advisory boards) to any other department within Cephalon ("Marketing Activities");
  - (b) If IEP Provider or the Educational Partner has an affiliated company that provides Marketing Activities to Cephalon, IEP Provider has instituted appropriate controls and safeguards to ensure the Program (i) remains independent, objective, balanced and scientifically rigorous, (ii) is not intended to promote a Cephalon product directly or indirectly, and (iii) is not in any way biased due to the affiliated company's relationship with Cephalon;





- (c) IEP has determined that it is appropriate to use the Educational Partner in light of the requirements under this Agreement; and
  - (d) If IEP Provider or its Educational Partner employs a former Cephalon employee who worked at Cephalon anytime during the most recent year and who had marketing responsibility in the therapeutic area that will be covered by the Program, then that former employee will not have any role in the planning, development or delivery of the Program.
- 16. Invitations/Enduring Materials. The Program audience will be selected by the IEP Provider. The IEP Provider shall be responsible for distributing materials about the Program, including invitations, reminder notices, and business reply cards that can be used by third parties to obtain any enduring Program material from the IEP Provider. Notwithstanding the foregoing, IEP Provider hereby authorizes and requires Cephalon to distribute a subset of business reply cards that can be used by third parties to obtain the enduring Program material from the IEP Provider. The business reply cards must be developed or approved by the IEP Provider.]
- 17. Ancillary Promotional Activities. To the extent the Program is a live presentation, no promotional activities or product advertisements will be permitted in the same room as or in an oblique path to the Program. If the Program is a teleconference or webcast, no product advertisements or promotional activities will be permitted immediately prior to, during, or immediately after the delivery of the Program. If the Program is in print format, no product advertisements or promotional materials will be interleaved within the pages of the Program. If the Program is made available electronically, no product advertisements or promotional materials will appear within the Program material or interleaved between computer windows or screens of the Program
- 18. Compliance with Guidelines. IEP Provider represents that the Program, including development of the Program and Program materials, shall conform to the American Medical Association ("AMA") Guidelines on Gifts to Physicians, the AMA Ethical Opinion on Continuing Medical Education, the ACCME Standards for Commercial Support, the FDA December 3, 1997 Final Guidance for Industry-Supported Scientific and Educational Activities, and the Pharmaceutical Research and Manufacturers Association ("PhRMA") Code on Interactions with Healthcare Professionals.
- 19. Logistical Status Reports. IEP Provider and/or Educational Partner shall provide periodic reports to Cephalon regarding the management and logistics of program components.
- 20. Miscellaneous.
  - (a) No party shall use the other party's or its affiliates' name or trademarks for publicity or advertising purposes, except with the prior written consent of the other party.



- (b) IEP Provider agrees to obtain all consents, authorizations, approvals and releases that may be necessary for the production of the Program and of any written materials prepared in connection therewith. IEP Provider agrees to indemnify Cephalon with respect to any claims, actions or demands, including reasonable attorneys' fees that may arise in any manner out of IEP Provider's failure to secure such consents, authorizations, approvals or releases.
- (c) No term, condition or other provision of any attachment or addendum to this Agreement shall supersede any term, condition or other provision of this Agreement and with respect to any inconsistency or ambiguity, the Agreement shall control.

IN WITNESS WHEREOF, the parties, by their duly authorized representatives, agree to comply with all the terms and conditions of this Agreement.

**MEDICOM WORLDWIDE, INC.**

By: *Joan Meyer*  
 Name: *Joan Meyer*  
 Title: *Executive Director  
Continuing Education*  
 The above signatory is a duly authorized corporate officer of the IEP Provider.

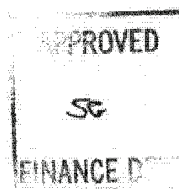
Date: *12/6/2006*

Tax ID #: *23-3063738*

**CEPHALON, INC.**

By: *RJH*  
 Name: *Rod J. Hughes, Ph.D.*  
 Title: Vice President, Scientific Communications

Date:



MediCom Worldwide, Inc.

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Confidential

Page 1





October 10, 2006

Bhaval Shah-Bell, PhD  
Cephalon, Inc.  
41 Moores Road  
Frazer, PA 19355

Dear Dr. Shah-Bell:

As an accredited provider of continuing education for nurses, MediCom Worldwide, Inc. has recently completed a comprehensive needs assessment to identify the educational needs of professional nurses who provide care to patients for ongoing pain management. This needs assessment was compiled from the following sources:

- Expert Opinion
- Needs Assessment Survey
- Past Participant Feedback
- Environment Scan including literature search

Based on the identified educational need, MediCom is requesting an educational grant from Cephalon, Inc to support the development of a live symposium in conjunction with the American Society of Pain Management Nurses scheduled to be held in March of 2007 in Dallas, Texas. In addition to the live program MediCom is requesting additional funding to provide enduring material support initiatives resulting from the content developed for the live meeting in order to maximize the reach to nurses throughout the United States. The activities described in this proposal include:

1. Live Symposia
2. Internet based activity hosted by Medscape
3. CD-ROM based on live footage accredited as a supplement in ASPMN Journal

The total grant request to fund these activities is \$366,210; please refer to the detailed budget section of this proposal for complete grant funding details of the individual educational initiatives.

These scientific events will comply with all OIG, PhRAM, FDA, and ANCC regulations for industry-supported professional continuing education.

Thank you in advance, for your consideration of this request.

Respectfully,

A handwritten signature in cursive script, appearing to read "Joan Meyer".

Joan Meyer  
Executive Director, Continuing Education

MediCom Worldwide, Inc.  
101 Washington Street • Morrisville, PA 19067 • 215-337-9991

Confidential

Page 2

## MediCom Worldwide, Inc.

### Needs Assessment



#### Needs Assessment:

Pain management encompasses various types of pain experiences throughout an individual's life cycle from birth to the end of life. Pain experiences may include acute and chronic pain, pain from a chronic deteriorating condition, or pain as one of many symptoms of the patient receiving palliative care. The goal of pain management throughout the life cycle is the same; to address the dimensions of pain and to provide maximum relief with minimal side effects.

Every day, nurses in all clinical settings work closely with patients who are experiencing various types and intensities of pain. Advances in pain management have given present patients and their families a variety of options that allow them a renewed dimension to the quality of their lives. Because of this it is important that nurses keep up to date on basic principles of assessment, pain management/treatment options and current pharmacologic and nonpharmacologic approaches.

To better understand the potential educational needs, MediCom Worldwide, Inc has utilized the following sources of information:

- 2005-2006 MediCom Needs Assessment Survey
- Consultation with Nursing Advisors in the Field of Pain Management
- Environmental Scan
  - Literature Review
  - Pain Management Core Competency Guide for Nurses
  - Therapeutic Research Review
  - Consensus Panel Recommendations on the Assessment and Management of BTP
  - Position Papers on Chronic Pain
  - APS survey publications

#### Literature Review:

Pain management encompasses various types of pain experiences throughout an individual's life cycle from birth to the end of life. Pain experiences may include acute and chronic pain, pain from a chronic deteriorating condition, or pain as one of many symptoms of the patient receiving palliative care. The goal of pain management throughout the life cycle is the same; to address the dimensions of pain and to provide maximum relief with minimal side effects <sup>(1)</sup>.

Classical pain categories are chronic and acute, nociceptive and neuropathic, within nociceptive classification, somatic and visceral. The experience of pain is complex. Pain is modulated at several different central nervous system levels. <sup>(6,17,18)</sup> Pain is known to be influenced by past experience and cognitive function. Throughout the literature there is a general tendency to separate malignant from non-malignant pain however studies have demonstrated that there is no difference anatomically, physiologically, by



biochemical substrate or through mechanisms of nociception which justifies separating the two.

Almost 50% of all Americans seek medical care each year for pain, making pain the single most frequent reason for a physician consultation in the U.S. Pain is inadequately controlled in many of these patients.<sup>(1,2,3)</sup> In some patients the pain that was established at the baseline examination persists, affecting quality of life and functioning, often even with drug therapy. Up to 86% of Americans suffering from chronic pain experience BTP, even when the persistent pain is well managed, yet it is often misunderstood aspect of chronic pain that requires a tailored strategy for care.<sup>(4)</sup>

Pain management begins with the use of appropriate assessment tools and includes planning, implementing, and evaluating a comprehensive treatment plan that addresses persistent and BTP. Persistent pain is present to some degree throughout the day and primarily is controlled with around the clock medication. However, it often is accompanied by episodes of short, intermittent pain, also known as BTP. Breakthrough pain is characterized as a transitory exacerbation of pain that occurs on a background of otherwise stable pain in a patient receiving chronic opioid therapy. Breakthrough pain typically is moderate to severe in intensity and can be triggered by various activities, be entirely unpredictable, or occur toward the end of around-the-clock medication.<sup>(5, 17, 18)</sup>

Breakthrough pain or transient worsening of pain in patients with an ongoing steady pain is a common feature in most chronic pain conditions with involvement of nerves, muscles, bones or viscera.<sup>(16)</sup> Although the mechanisms of spontaneous ongoing pain and intermittent flares of pain (BTP) may be difficult to separate, a recent study published in the European Journal of Pain suggest that peripheral and/or central sensitization (hyperexcitability) may play a major role in many causes of BTP.<sup>(6)</sup>

Despite the considerable variability in how BTP is defined, it is clear that BTP is associated with significant patient morbidity, including decreased functioning and increased levels of depression and anxiety.<sup>(7, 8)</sup> Breakthrough pain may also predict a poor medical outcome. Breakthrough pain is a major component of the public health problem related to the under treatment of pain, which has become a national quality of care issue and is a priority concern of the Agency for Healthcare Research and Quality.

A wide variety of factors including inaccurate information, myths, rumors, fear and cultural issues contribute to inadequate pain management.

Barriers to recognition in the treatment of pain are numerous despite multiple advances in the field. Nurses may have incomplete or inaccurate information about the following variables which contribute to ineffective pain management:

- Definition of pain and how patients demonstrate their pain
- How pain is assessed and managed
- Use of opioids and fears associated with dosing
- Cultural norms as it relates to expression of pain

Investigating the continuing education needs of nurses and the impact they have on the interdisciplinary team review of the literature reveals that the majority of patients do not receive adequate pain management. Myths and misinformation may contribute to ineffective management strategies. Some common myths include: <sup>(15)</sup>

1. Too much pain medication too frequently constitutes substance abuse, causes addiction, will result in respiratory depression or will hasten death
2. Pain should be treated, not prevented
3. People in pain always report their pain to their healthcare provider
4. People in pain demonstrate or show that they have pain-pain can be seen in the patient's behavior
5. The level of pain is often exaggerated by the patient
6. Generally a patient cannot be relieved of all pain
7. Some pain is good so that the patient's symptoms are not masked
8. Newborn infants and children do not have pain
9. It is expected that the elderly, especially the frail elderly, always have some pain

Because of multiple barriers to adequate pain management, all patients are at risk for under treatment of pain. Since pain is identified and reported primarily through patient self-reporting, difficulty in communicating increases the patient's risk for under-treatment. Clinicians should address persistent and BTP as distinct entities to accurately assess it and develop appropriate pain management plans.

The choice of therapeutic agents for many patients with unrelieved chronic pain is opioids. As a class, opioids have proven efficacy, not only in providing meaningful pain relief to many patients, but also in improving functionality.<sup>(10,11)</sup> Opioids offer pharmacologic advantages through the availability of diverse formulations and doses that provide significant flexibility when tailoring a therapeutic regimen for the chronic pain patient.

Clinicians need to understand the pharmacokinetics, pharmacodynamics, and pharmacogenomics of opioids to appropriately include them in treatment plans, including multimodal therapy.<sup>(9,14)</sup> New formulations and new delivery systems are in various stages of development, with an aim to offer even more options to clinicians to further advance patient care. The core principle of opioid analgesia is a balanced and responsible approach that allows appropriate access and minimizes potential risks for misuse and side effects, while providing pain relief and restoring functionality.<sup>(10,11,14)</sup>

### Consultation with Clinical Experts:

April Vallerand PhD, RN, FAAN  
Associate Professor  
Wayne State University  
College of Nursing

Steve Stanos, DO  
Medical Director  
Chronic Pain Care Center  
Rehab Institute of Chicago

Candace Coggins, MS, MA, CARN, RN-C  
Metropolitan Jewish Health Systems  
Brooklyn, NY  
Immediate Past President-Elect of the  
American Society of Pain Management Nurses

Daniel M Gruener, MD  
Clinical Assistant Professor of Psychiatry  
Jefferson Medical College

Peggy Compton, RN, PhD  
Associate Professor  
School of Nursing  
UCLA

### Major issues discussed

- Practice setting for nursing; the role of the nurse based on practice setting
- Assessment tools available
- Continuing educational needs of pain management nurses
- Communication techniques; assessment intervals; recognition of BTP
- Pharmacologic management; non pharmacologic management
- Fears and misconceptions
- Preferred source of continuing education; live, web based, journals
- Interdisciplinary teams

### Conclusions:

- Pain management nursing encompasses a wide and diverse range of practice settings each with their own unique needs
- No formalized training programs to educate nursing students on multi faceted issues relating to pain management assessment and management. Training is of a fundamental nature during course of study. Nurses rely on continuing education opportunities to seek advancement in skill and knowledge
- Assessment tools available to nursing professionals are adequate; education on the use of these tools are what's needed
- Myths and misconceptions still abound relative to utilization of opioids
- Fear of over medicating; loss of functionality
- Hesitancy to utilize adequate doses of meds for fear of abuse, addiction, side effects



- Ongoing communication with patients; knowing the right questions to ask in the assessment process in order to accurately assess pain states and the impact on successful pain relief
- Maintaining and enhancing functionality very important to nursing goals for their patients

#### Needs Assessment Survey/Past Participant Evaluation Outcome:

To further define the educational needs of clinicians, MediCom conducted a review of 325 nursing professionals perceived continuing educational needs. The survey provided data regarding clinicians' top interest, preferred method of learning and other details regarding continuing education. The following results demonstrate topics that the respondents view to be the top 10 highest interests and need and ranked priority of need. <sup>(19)</sup>

Educational Assessment of Needs	High Priority	Moderate Priority	Low Priority	NA
Women's Health Issues		X		
General Pharmacology	X			
Cancer Care	X			
Pain Management	X			
Geriatric Care		X		
Opioids		X		
Psychiatry	X			
ADHD		X		
Sleep Disorders		X		
Abuse and Addiction	X			

Specific topics of interest related to pain are evaluated on an ongoing basis. The following information is a summary of completed survey reports from 2005 through 2006, year to date. Total number of evaluations completed were 1285; of those returned approximately 41% were from a healthcare professional in the field of nursing i.e.; RN, LPN, NP <sup>(19)</sup>

Topics of Interest	No Interest	Some Interest	High Interest
Acute Pain Management	10%	30%	60%
Chronic Non Malignant Pain	6%	16%	78%
Cancer Pain Management	20%	35%	45%
Pharmacological Advances in Pain Management	3%	15%	82%
Addiction, Abuse	16%	31%	53%

## Conclusion

Effective pain management by nurses requires them to have an understanding of the biological basis of the pain interventions which may be used to control pain. In addition an emphasis on a complete and ongoing pain assessment is paramount to developing a comprehensive treatment plan. Based on a review of the literature, needs assessment surveys as well as input from clinical experts there is a continued need to provide a platform for nurses to gain the most up to date information relative to the issues and challenges of managing patients with chronic pain. Nurses are an instrumental member of the interdisciplinary team and have a great need to understand the newer trends in pain management as well as novel analgesic delivery systems arriving on to the healthcare arena in order to impact pain care and promote a successful outcome of sustained pain relief.

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## MediCom Worldwide, Inc.

### Program Summary



#### Program Overview:

Pain management encompasses various types of pain experiences throughout an individual's life cycle from birth to the end of life. Pain experiences may include acute and chronic pain, pain from a chronic deteriorating condition, or pain as one of many symptoms of the patient receiving palliative care. The goal of pain management throughout the life cycle is the same; to address the dimensions of pain and to provide maximum relief with minimal side effects.

Almost 50% of all Americans seek medical care each year for pain, making pain the single most frequent reason for a physician consultation in the U.S. Pain is inadequately controlled in many of these patients. In some patients the pain that was established at the baseline examination persists, affecting quality of life and functioning, often even with drug therapy. Furthermore, such patients may also experience breakthrough pain (BTP), which affects 19% to 95% of all patients with pain, depending on the population surveyed and the definition of BTP used.<sup>(1,5,7,18)</sup>

Despite the considerable variability in how BTP is defined, it is clear that BTP is associated with significant patient morbidity, including decreased functioning and increased levels of depression and anxiety. Breakthrough pain may also predict a poor medical outcome. Breakthrough pain is a major component of the public health problem related to the undertreatment of pain, which has become a national quality of care issue and is a priority concern of the Agency for Healthcare Research and Quality.

Every day, nurses in all clinical settings work closely with patients who are experiencing various types and intensities of pain. Advances in pain management have given present patients and their families a variety of options that allow them a renewed dimension to the quality of their lives. Because of this it is important that nurses keep up to date on basic principles of assessment, pain management and current pharmacologic and nonpharmacologic approaches.

These symposia will review the major clinical issues related to persistent pain and more specifically BTP including recognition and impact; pharmacologic and nonpharmacologic therapy; expert treatment guideline recommendations will be reviewed. Cases will be presented guided by a clinical expert in pain as seen through the eyes of a pain patient. It is our goal to provide participants with practical information and data that can be applied in daily practice, to provide the tools and skills required to assess patients, and determine the appropriate treatments for each individual's own unique pain management needs. Breakthrough pain is a common problem affecting the quality of life of patients. Improved management of BTP is contingent on accurate pain assessment, optimum use of analgesics, and patient education.

**Program Title:*****Assessment, Diagnosis and Treatment of Breakthrough Pain: Breaking the Pain Cycle*****Program Objectives:**

Upon completion of this activity, participants should be able to:

1. Summarize advances in understanding and management of chronic pain
  - a. Distinguish features, types and definition pain; acute, chronic and BTP
  - b. Recognize BTP; read the signals in your patients
  - c. Identify tools, questions and communication techniques that are designed to improve patient/healthcare provider dialogue
  - d. Outline current guidelines available which impact management of BTP
2. Define and manage the pain cycle
  - a. Summarize current and emerging pharmacologic and nonpharmacologic treatment options for BTP
  - b. Evolving options in opioid therapy: Timing of pain dictates timing of treatment
  - c. Challenges and opportunities relative to opioid therapy in treating patients with chronic pain
3. Identify effective clinical strategies and treatment options which demonstrate how appropriate assessments and tools may be incorporated into the practice setting
  - a. Utilization of pain dairies to assist in identification and optimal treatment options; The Patients Story
  - b. Summarize goals of treatment
  - c. Guidelines in managing treatment

**Faculty:**

**Steve Stanos, DO**

Medical Director

Chronic Pain Care Center

Rehab Institute of Chicago

**April Vallerand PhD, RN, FAAN**

Associate Professor

Wayne State University

College of Nursing

**Candace Coggins, MS, MA, CARN, RN-C**

Metropolitan Jewish Health Systems

Brooklyn, NY

Immediate Past President-Elect of the

American Society of Pain Management Nurses



# MediCom Worldwide, Inc.

## Program Overview



### Targeted Audience:

Nursing participants attending the American Society of Pain Management Nurses Conference

Target participation: 500 attendees

### CE Provider:

The symposia will be accredited by MediCom Worldwide, Inc. in joint sponsorship with the American Academy of Pain Management Nurses

- Each activity will be approved for two contact hours.

### Format:

Live symposia held in Dallas, Texas in conjunction with the American Society of Pain Management Nurses Conference. Program will consist of live didactic presentation in addition to integrated immediate learning assessment activities captured via audience response systems. In addition, MediCom will prerecord via videotape a story of pain experienced through the eyes of a pain patient. Post live event, final content will be formatted to allow for additional enduring self study adaptation; enduring material will be developed for internet access via Medscape as well as CD-ROM adaptation to be distributed via American Society of Pain Management Nurses journal.

### Enduring Material

Format	Description	Expected Reach
Symposium adaptation: online accredited <b>streaming video program</b>	Symposium filmed and edited into accredited streaming video posted at Medscape.com	Medscape nursing eNewsletter subscribers: 270,000 nurses
Symposium adaptation: <b>accredited monograph series</b>	Symposium accredited monograph series distributed as a journal supplement to the ASPMN	ASPMN journal: 2,500 pain management nurses;

## MediCom Worldwide, Inc.

### Program Overview



#### Distribution/Invitation Process:

##### Live Event

The live symposium will be announced and promoted through the use of approximately 2,500 printed invitations via direct mail to all members of the American Society of Pain Management Nurses followed by a secondary mailing of approximately 650 to all those pre registered to attend the conference.

##### Request for Sponsor Support Live Event

As a supplement to these primary methods, MediCom Worldwide, Inc may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical/nursing community. The content of such information, however, is the responsibility of MediCom and any such distribution will solely be as a supplement to MediCom's primary methods of announcement and promotion.

##### Enduring Material

##### Medscape Distribution Plan

Activity posts online 8-12 weeks following the live event

Medscape educational activities are cross posted to all relevant specialty areas and audience types.

All formats are posted, archived and searchable on Medscape for a 12 month period.

Drivers to content include features on the following areas:

- Specialty relevant Medscape Homepages
- CE center on relevant specialty
- Email newsletters
- Medscape search engine

Online promotion reminder emails and links in relevant specialty homepages

Reach: 770,000 US nurses

##### ASPMN Journal Supplement

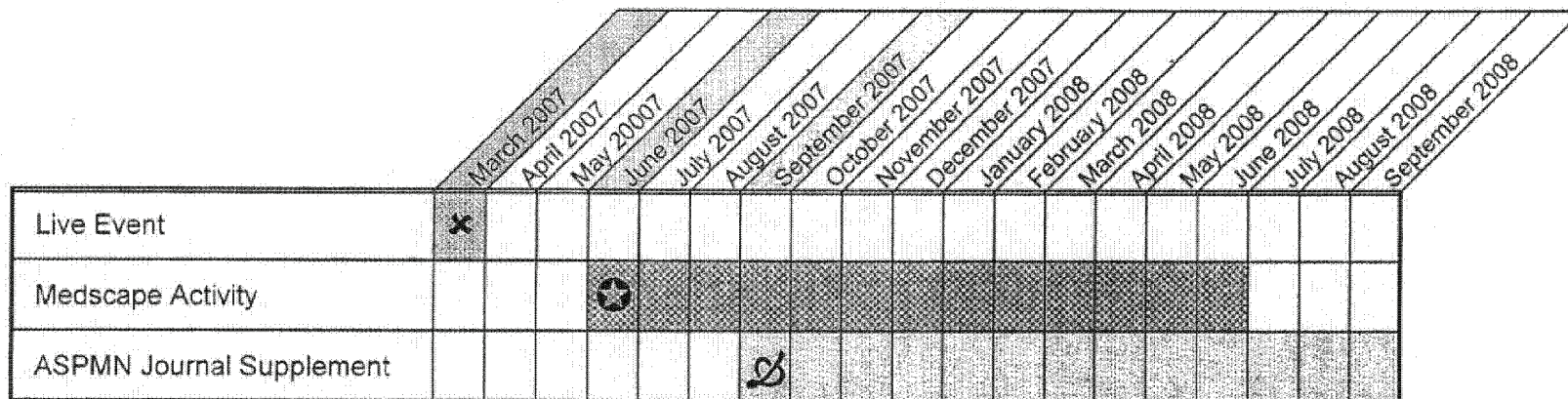
CD-ROM format is to be polybagged as a journal supplement in association with the American Society for Pain Management Nursing Journal.

Supplement to be distributed in conjunction with the September Journal via direct mail to approximately 2,500 ASPMN subscribers.



# ASPMN Activity Timeline

2007



- Lunch Symposium, March 25, 2007
- Medscape activity release date, June 25, 2007
- ASPMN Journal Supplement release date, September 20, 2007



## MediCom Worldwide, Inc.

### Program Overview



#### MediCom Worldwide, Inc. Policies:

##### Conflict of Interest Identification and Resolution

MediCom Worldwide, Inc is in full compliance with all rules and regulations put forth by the ACCME in the revised Standards for Commercial Support. MediCom has defined all those in position to control content as faculty, authors, presenters, planning committee members and all those internal staff who are in position to write, alter or impact the content of a CME activity.

All members identified in the planning process must provide signed disclosures to MediCom prior to the planning of the activity.

When individuals in a position to control content have reported Financial Relationships with one or more commercial interests, MediCom works with them to resolve such conflicts to ensure that the content presented is free of commercial bias. The following mechanisms have been identified in which to resolve conflicts as identified:

- Peer review of content by external reviewer
- Content validation by external topic expert and internal MediCom clinical editorial staff

##### MediCom Worldwide, Inc. Disclosure Policy

(Attachment A)

##### MediCom Worldwide, Inc. Content Development Policy

(Attachment B)

##### MediCom Worldwide, Inc. Faculty Selection Policy

(Attachment C)



**MediCom Worldwide, Inc.****Program Overview****Post-Activity Reporting:**

Course evaluation forms will be required for all participants who seek to receive continuing education credit. MediCom will summarize the information collected in a formal report to evaluate program effectiveness and participant learning.

Participants will evaluate the following components:

1. Overall content
2. Faculty teaching effectiveness
3. Format
4. Usefulness of information
5. Relevance to practice setting
6. Fair balance
7. Impact to the care of the patient experiencing pain

In addition to rating scales participants will be asked to participate in pre/post testing scenarios as a measurement of learning. Learning will be analyzed based on self-reported changes in knowledge or perceptions by the participants as a result of this activity and how well he or she will be able to apply learning to a specific practice setting.

# MediCom Worldwide, Inc.

## Budget Summary and Options



### Budget Summary Overview

#### ASPMN Accredited Satellite Symposium Plus Enduring Material Options Proposal Overview

Tactic	Description	Expected Outcome	Proposed Budget	
Satellite symposium at 2007 ASPMN, interview	Three-speaker accredited live symposium	500 ASPMN members	Direct Costs	\$94,110
			Indirect Costs	\$ 73,200
			<b>Total</b>	<b>\$167,310</b>
Symposium adaptation: accredited journal supplements in ASPMN Association journal	Symposium filmed and edited into accredited video-based CD-ROM distributed as a polybagged journal supplement to the ASPMN journal	ASPMN journal: 2,500 pain management nurses;	Direct Costs	\$ 43,500
			Indirect Costs	\$ 26,250
			<b>Total</b>	<b>\$ 69,750</b>
Symposium adaptation: online accredited streaming video program	Symposium filmed and edited into accredited streaming video posted at Medscape.com	Medscape nursing eNewsletter subscribers: 270,000 nurses	Direct Costs	\$ 3,400
			Medscape Hosting Fees	\$100,000
			Indirect Costs	\$ 25,750
			<b>Total</b>	<b>\$129,150</b>



MediCom Worldwide, Inc.  
101 Washington Street  
Morrisville, Pennsylvania 19067

### 2007 American Society of Pain Management Nursing

Program Parameters		
	Accreditation Hours	2
	Faculty	3
	Symposium Attendees	525
	Direct mail invitations to health care professionals	4,000
Cost Summary		
	Approximate Total, Direct Expenses	\$ 84,110
	Total, Indirect Expenses	\$ 73,200
	Cost of 2007 American Society of Nursing Management	\$ 167,310

Approval Signature \_\_\_\_\_

Date \_\_\_\_\_

Note: no work may begin until MediCom receives, via email or fax, this approval with signature and date

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Morrisville, Pennsylvania 19067

### 2007 American Society of Pain Management Nursing

<i>Direct Expenses, Approximate</i>	
ASPMN Fee (Lunch symposia)	\$ 35,000
Direct mail invitations	
Direct mail invitations, mailed to registered meeting attendees; includes printing; development of database email homepage for registration	\$ 4,000
Direct mail list purchase	No charge
Mail Services, postage, phone, fax, email registration	\$ 1,500
Includes assembly, mail services and postage. Follow up recruitment per phone, fax, email	
Invitation door-drop/advertisement fee	\$ 5,000
Participant handouts	\$ 11,500
Includes printing of participant workbook; will include accreditation information, speaker biographical and disclosure information, agenda, and symposium graphics; total quantity 525 color copy	
Posters advertisement materials	\$ 2,400
Faculty expenses	
Honoraria:	
Nursing Experts (2)	\$ 3,000
MD Expert (1)	\$ 2,500
Travel (3 faculty members)	\$ 1,800
Accommodations (assumed one night stay)	\$ 1,500
Meal expense faculty	\$ 300
Ground transportation	\$ 525
Room Rental	No charge
Catering provided by ASPMN up to 500 attendees; assumed coverage amount of 50 attendees	\$ 3,500
Audience Response System	\$ 5,750
Onsite equipment rental	\$ 4,500
Audio/visual services: Basic AV provided by ASPMN; upcharge related to additional AV requirements	\$ 2,000
MediCom expenses	
Air travel	\$ 1,200
Accommodations	\$ 1,600
Meals	\$ 300
Ground transportation	\$ 350
OOP	\$ 75
Travel/expense film crew; production	\$ 5,000
Shipping/Fed Ex	\$ 750
<b>Approximate Total Meeting Management Direct Expenses</b>	
	<b>\$ 94,110</b>



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### 2007 American Society of Pain Management Nursing

<i>Indirect Expenses</i>	
MediCom pre-meeting coordination and Development of Video Case Study	\$ 25,000
Includes faculty recruitment, agenda coordination, coordination with association; coordination with venue; participant recruitment; coordination of filming of patient video case study	
equipment rental; actor; studio rental; filming; editing; production of video case presentation	\$ 15,000
Onsite filming of entire live event; includes interview segments with presenters	\$ 10,000
Development Editorial	\$ 5,000
Includes presentation slides x3 faculty approx 125 slides; editorial content review; reference and fact checking; design and format	
MediCom on-site symposium coordination; 2 MediCom staff	\$ 3,200
Graphic design	\$ 2,500
Accreditation of program for CNE coordinated in conjunction with ASPMN	\$ 2,500
Project management	\$ 10,000
<i>Total Indirect Expenses</i>	<i>\$ 73,200</i>





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## Multi-Media Online Adaptation from Live Symposium Hosted as Internet Activity on Medscape

### Program Description

This proposal is for a multi-media online streaming video adapted from a live symposium and accredited for self-study for nurses. The self-study program will include: (1) live footage of speaker presentations; (2) all graphic images used in the presentations, including animations of graphs and charts; (3) content to be posted on line via Medscape.

<i>Cost Summary</i>	
Approximate Total, Direct Expenses	\$ 103,400
Total, Indirect Expenses	\$ 25,750
<b>Cost of One Self-Study Multi-Media Online Program Adapted from Live Symposium</b>	<b>\$ 129,150</b>

Approval Signature \_\_\_\_\_

Date \_\_\_\_\_

Note: no work may begin until MediCom receives, via email or fax, this approval with signature and date

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 Morrisville, PA 19067

### Multi-Media Online Adaptation from Live Symposium Hosted as Internet Activity on Medscape

#### Detailed Budget Itemization

<i>Direct Expenses, Approximate</i>	
Transcription	\$ 400
Speaker honoraria: post-symposium interviews	\$ 3,000
Medscape Hosting Fee	\$ 100,000
<i>Approximate Total, Direct Expenses</i>	<i>\$ 103,400</i>

<i>Indirect Expenses</i>	
Program Development	\$ 10,000
Includes creation of graphic user interface; coordination with speakers for interview segments; coordination with speaker for final review	
Programming	\$ 5,000
Accreditation of program for CNE	\$ 5,000
Data management	\$ 750
Includes management of participant database, data analysis, quarterly reports, final summary report	
Project management	\$ 5,000
<i>Total, Indirect Expenses</i>	<i>\$ 25,750</i>

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### **Multi-Media CD-ROM Adaptation from Live Symposium Journal Supplement in ASPMN Journal**

#### **Program Description**

This proposal is for a multi-media CD-ROM adapted from a live symposium and accredited for self-study for nurses. The CD-ROM will include: (1) live footage of speaker presentations; (2) all graphic images used in the presentations, including animations of graphs and charts; (3) text and/or PDF files of all program support and CE-related information. Clinicians will request CE certificates using the enclosed self-assessment/program evaluation form. Distribution method via polybagged supplement in the ASPMN Journal following live activity in 2007. Budget allows for an additional duplication of 500 CD's which could be distributed based on request.

<i>Cost Summary</i>	
Approximate Total, Direct Expenses	\$ 43,500
Total, Indirect Expenses	\$ 26,250
<b>Cost of One Self-Study Multi-Media CD-ROM Adapted from Live Symposium Distributed via Supplement in ASPMN Journal</b>	<b>\$ 69,750</b>

Approval Signature \_\_\_\_\_

Date \_\_\_\_\_

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Morrisville, Pennsylvania 19067

### Multi-Media CD-ROM Adaptation from Live Symposium Journal Supplement in ASPMN Journal

#### Detailed Budget Itemization

<i>Direct Expenses, Approximate</i>	
CD duplication; quantity: 3,000 Includes printing of program insert containing self-assessment questions, accreditation information and program evaluation form; printing and assembly of full-color, varnished DiscPak style mailer with four-color cover for CD plus insert; silk-screen of CD labels; duplication of CDs; assembly; shrink wrapping for polybag	\$ 6,500
Speaker honoraria: post-symposium interviews	\$ 3,000
Printing of BRCs; quantity: 2500	\$ 2,000
Return postage for BRCs returned to MediCom (estimated return of 500 BRCs)	\$ 1,500
Postage for mailing CDs out in response to BRCs; quantity: 500	\$ 500
Distribution in ASPMN Journal Supplement	\$ 30,000
<i>Approximate Total, Direct Expenses</i>	<i>\$ 43,500</i>

<i>Indirect Expenses</i>	
Program Development Includes creation of graphic animated CD user interface; coordination with faculty and journal staff; design, typesetting and layout; proofing	\$ 5,000
CD-ROM production Includes programming, production of duplication master	\$ 7,500
Accreditation of program for CNE	\$ 5,000
Data management	\$ 750
Project management	\$ 8,000
<i>Total, Indirect Expenses</i>	<i>\$ 25,250</i>

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# MediCom Worldwide, Inc.

## Budget Summary and Options



### Budget:

Live Activity:	\$167,310
Medscape Activity:	\$129,150
ASPMN Journal Supplement:	\$69,750
Total Budget:	\$366,210

### Budget Reporting and Reconciliation:

#### Appropriate Use of Commercial Support:

- Funds should be in the form of an educational grant made payable to MediCom Worldwide, Inc.
- No other funds from Cephalon, Inc. will be paid to the program director, faculty, or others involved with the CE activity (additional honoraria, extra social events, etc.).
- MediCom Worldwide, Inc. will furnish the commercial interest with documentation detailing the receipt and expenditure of the commercial support within 90 days of activity completion.

### Payment Structure:

1/3 due upon signing of agreement:	\$122,070
1/3 due 1 <sup>st</sup> quarter 2007 (March 1, 2007):	\$122,070
Final 1/3 due 2 <sup>nd</sup> quarter 2007 (June 1, 2007):	\$122,070





### Standard Operating Procedures

<b>Manual</b>	Department of Continuing Education Policy and Procedure	<b>Policy Number</b>	<b>II-203</b>
<b>Subject</b>	Disclosure	<b>Date of Origin</b>	March 2003
<b>Approved By</b>	Joan Meyer	<b>Revision Date</b>	March 2005
<b>Signature</b>		<b>Approval Date</b>	May 2005

### Purpose

The policy on disclosure exists to provide guidance for staff, faculty and joint/co-sponsors of the requirement to disclose specific information to participants in order to comply with the following standards for all activities sponsored by MediCom Worldwide, Inc.: ACCME's 2004 Updated Standards for Commercial Support; ACPE's Criteria for Quality and Interpretive Guidelines; California Board of Registered Nursing Standards and Guidelines. This includes (a) sponsor financial relationships, (b) faculty and family/significant others financial relationships, (c) discussion of unlabeled or unapproved uses of drugs and devices. As an approved provider, MediCom Worldwide, Inc. is required to collect information from individuals who have an opportunity to affect the CE content about products or services of a commercial interest with which he/she has a financial relationship to allow a determination to be made as to whether that relationship may constitute a conflict of interest that must be resolved.

### Policy

1. Disclosure documents must be completed by anyone involved in planning or presenting educational content at CE programs approved for CME/CPE/CNE inclusive of MediCom advisory committee members, clinical content reviewers and identified faculty members.
2. MediCom Worldwide, Inc. requires all those in a position to control content to provide specific information to CE participants.
3. MediCom requires faculty to provide specific information to CE participants. Disclosure is required in two areas:
  - Financial Relationships - Faculty must disclose any significant relationship between themselves/significant others and (a) the commercial supporter(s) of the program, and (b) the manufacturer of any product discussed in the CE program or related to the topic of the event. Information reported shall include financial relationships in place over the preceding twelve-month period. If the faculty has nothing to report, that information must be indicated.
  - Discussion of Unlabeled Use - Faculty must disclose in writing and communicate in writing through course materials, that a product is not labeled for the use under discussion or that the product is still investigational and not approved for use in the United States.
4. Faculty are required to complete the MediCom Worldwide, Inc. Faculty Disclosure Forms, and Attestation Forms prior to the program development process.
  - (Required forms attached)
5. Disclosure Forms must be completed and returned to MediCom prior to content development. Faculty refusing to disclose may not participate as a speaker for program in which disclosure was not obtained.
6. Potential conflicts of interest disclosed will be reviewed by MediCom and must be resolved prior to the educational activity.
7. Once a conflict is identified, a content validation process is initiated to ensure that the content or format of the CE activity and related materials will promote improvements or quality in health care and not promote a specific proprietary business interest of a commercial interest.
8. MediCom conducts an unbiased review of all planned content for activities certified for credit to resolve any actual or perceived conflict of interest that exists.
9. Faculty must disclose to participants prior to the start of the educational activity the existence of significant situations where a direct commercial support relationship exists with the educational activity.



10. MediCom discloses the following information to learners: 1) the name of the individual, 2) the name of the commercial interest(s), and 3) the nature of the relationship the individual has with the commercial interest. MediCom also discloses to learners the name(s) of commercial interests supporting each CE activity. Faculty disclosures will be documented and available to all participants via written participant handout information i.e.; syllabi, introductory slides, workbooks.
  - Disclosure will be made available to audience at the start of each activity.
11. Faculty must also disclose prior to the start of the educational activity if no significant financial relationships exist.
12. If faculty members present at multiple independent educational activities, a separate disclosure form is required for each activity.
13. Implementation:
 

All internal content review staff and outside external expert reviewers and faculty will complete a Financial Disclosure Form that contains the following information:

  - The form shall note the title and date of the activity, as well as the name(s) of the commercial supporter(s) associated with the activity.
  - The form shall solicit information about the financial relationship(s) of the reviewer, faculty member, his/her immediate family member or significant other has with any commercial supporter, as well as manufacturers of products associated with the activity or related to the topic of the activity.
  - If no relationship exists, there shall be a box to check to that effect.
  - The form shall solicit information from the faculty member as to plan to address off-label discussion or investigational use of a drug in his/her presentation.
14. Timeline for disclosure of financial relationships:
  - Internal reviewer will complete the disclosure form upon employment.
  - External experts will complete the disclosure form at the time a relationship with MediCom has been identified.
  - Presenting faculty will be asked to sign a disclosure form at the time of invitation to participate in a planned program.





### Standard Operating Procedures

<b>Manual</b>	Department of Continuing Education Policy and Procedure	<b>Policy Number</b>	<b>II-205</b>
<b>Subject</b>	Content Without Commercial Bias	<b>Date of Origin</b>	March 2004
<b>Approved By</b>	Joan Meyer	<b>Review/Revision Date</b>	July 2005
<b>Signature</b>		<b>Approval Date</b>	October 2005

#### Purpose

To establish criteria, policy and process of implementation of content standards of CE activities in accordance with the ACCME Standard for Commercial Support; Content and Format without Commercial Bias, and the content requirements of the ACPE and California Board of Registered Nursing.

#### Policy

- MediCom must review the planned content of a CE activity to be certified by MediCom and demonstrate in documentation that the content or format of a CE activity adheres to the following criteria:
  - Presentations and/or its related materials must promote improvements or quality in health care and not a specific proprietary business interest of a commercial interest.
  - Presentations and/or its related materials must give a balanced view of therapeutic options.
  - Use of generic names within the body of the presentation or its related materials is required.
    - Related presentation materials may contain trade names for all generic products contained within the presentation that are from several companies, as available.
- All content from CE activities will undergo content validation process.
  - Content must conform to the generally accepted standards of experimental design, data collection and analysis.
  - Faculty must attest to MediCom that the presentation content or content of its related materials promote improvement or quality in health care and not a specific proprietary business interest of a commercial interest.
  - Faculty must attest to MediCom that the presentation gives a balanced view of therapeutic options.
  - MediCom's internal and external reviewers must evaluate and attest that faculty presentation and its related materials promote improvements or quality in health care and not a specific proprietary business interest of a commercial interest.
  - Internal and external content reviewers must evaluate and attest that the presentation gives a balanced view of therapeutic options.
- Activities are not eligible for certification if the content and/or format promote recommendations, treatments or manners of practicing medicine that are not within the definition of CME or are known to have risks or dangers that outweigh the benefits or are known to be ineffective in the treatment of patients. Activities that offer recommendation, treatments or practice manners outside of the definition of continuing pharmacy or nursing education, or that have risks or dangers that outweigh the benefits or are known to be ineffective are not eligible for certification.
- CE activities must be developed and presented utilizing the principles of adult learning, which includes thorough assessment of learners' needs and focus on participant involvement in the learning process.
- Faculty selected to participate must be demonstrated thought leaders in the topic of the CE activity and must have demonstrated skill in providing education to adult learners. Faculty should hold advanced degrees in their area of specialty, and should be active in research or patient care within an academic or clinical setting. Faculty may not be employees of the commercial supporter of an educational activity, regardless of qualification. Faculty will be asked to provide their qualifications and educational background to activity planners for review. Faculty will be advised of content requirements in their faculty letters.



6. MediCom may solicit the review by an expert reviewer; members of the MediCom Worldwide, Inc. advisory committee provide oversight of MediCom's program planning and design. A member of the advisory committee may be asked to provide content review for selected MediCom activities. Whenever possible, advisory committee members are asked to review activities that fall within their area of clinical expertise.
7. The clinical pharmacy consultant provides oversight and review of program planning, design and in-depth content review of each activity, and verifies that the proposed amounts of pharmacology hours and content are appropriate for pharmacy credit.
8. The executive director will give final approval for the activity content and appropriate credit/contact hour designation, indicating that the content is deemed valid and within the criteria as stated in this policy. This form will be signed by the executive director. This is contained in the CE planning document.
9. Evidence of valid content will be placed in the activity file under planning.





### Standard Operating Procedures

<b>Manual</b>	Department of Continuing Education Policy and Procedure	<b>Policy Number</b>	II-208
<b>Subject</b>	Faculty/Speaker Selection	<b>Date of Origin</b>	January 2000
<b>Approved By</b>	Joan Meyer	<b>Revision Date</b>	August 2004
<b>Signature</b>		<b>Approval Date</b>	August 2005

#### Purpose

To establish guidelines for the determination of qualitative and quantitative considerations in the faculty selection process.

#### Policy

##### I. Qualitative Considerations

Faculty selected to participate must be demonstrated thought leaders in the topic of the CE activity and must have demonstrated skill in providing education to adult learners. Faculty should hold advanced degrees in their area of specialty, and should be active in research or patient care within an academic or clinical setting. Faculty may not be employees of the commercial supporter of an educational activity, regardless of qualifications. Faculty will be asked to provide their qualifications and educational background to MediCom for review. Faculty will be advised of content requirements in their faculty letters sent by MediCom.

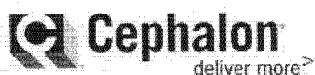
1. Faculty must attest to MediCom that the presentation content or content of its related materials promote improvement or quality in healthcare and not a specific proprietary business interest of a commercial interest.
  - Faculty must attest to MediCom that the presentation gives a balanced view of therapeutic options.
  - MediCom's internal and external reviewers must evaluate and attest that faculty presentation and its related materials promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.
  - CE activities must be developed and presented utilizing the principles of adult learning, which includes thorough assessment of learners' needs and focus on participant involvement in the learning process.
2. Upon selection and approval of the faculty, a letter of guidance is written to the faculty outlining the expectations.
3. Each faculty member must submit a CV for review.
4. Each faculty member must complete and sign a disclosure form and attestation form.
5. Those faculty members who do not complete required disclosure information will not be permitted to participate in the activity as planned.
6. The executive director or designee will communicate directly with faculty, providing each faculty member with written information related to objectives of the program.
7. The executive director or designee will provide technical assistance necessary to prepare materials for presentation.

**II. Determination of Number of Faculty Required Per Planned Activity**

1. An appropriate number of qualified faculty members shall be utilized for each continuing education program
2. The executive director will be responsible for determination of number of faculty required for each program. Determination will be based on number of topics, depth of subject matter and anticipated duration of the program.
3. MediCom will strive to maintain a ratio of at least one faculty member per every one hour of formal didactic lecture.

**III. Program Evaluation**

1. A program evaluation form is developed for each activity, which is intended to solicit participant's assessment of faculty effectiveness.
2. Evaluation forms are distributed to participants at the end of each activity. Each participant is required to complete the form as designed, as well as provide any written feedback or comments regarding program.
3. A formal summary report is completed following each program or program series. This report compiles the results of the evaluation form as well as narrative comments from participants.
4. A designated member of the CE staff will directly monitor each educational activity.



## Exhibit B

## ACTIQ Risk Management Program

Provider is aware that ACTIQ® (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- ACTIQ is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- ACTIQ is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.
- ACTIQ is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.



## FENTORA Risk Management Program

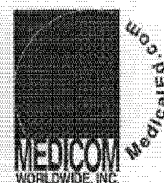
Provider is aware that FENTORA™ (fentanyl buccal tablet) [C-II] was approved subject to a Risk Minimization Action Plan (RiskMAP). The RiskMAP includes key safety messages that are essential to the safe use of this product. They are:

- FENTORA is indicated for the management of breakthrough pain in patients with cancer who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- FENTORA is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- No misuse of FENTORA should occur.
- Unintended (accidental) exposure to FENTORA should not occur.
- Patients considered opioid tolerant are those who are taking at least 60 mg oral morphine/day, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that FENTORA can be fatal to a child. Keep all units away from children and discard properly.
- FENTORA is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.



MediCom Worldwide, Inc.

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October 10, 2006

Bhaval Shah-Bell, PhD  
Cephalon, Inc.  
41 Moores Road  
Frazer, PA 19355

Dear Dr. Shah-Bell:

As an accredited provider of continuing education for nurses, MediCom Worldwide, Inc. has recently completed a comprehensive needs assessment to identify the educational needs of professional nurses who provide care to patients for ongoing pain management. This needs assessment was compiled from the following sources:

- Expert Opinion
- Needs Assessment Survey
- Past Participant Feedback
- Environment Scan including literature search

Based on the identified educational need, MediCom is requesting an educational grant from Cephalon, Inc to support the development of a live symposium in conjunction with the American Society of Pain Management Nurses scheduled to be held in March of 2007 in Dallas, Texas. In addition to the live program MediCom is requesting additional funding to provide enduring material support initiatives resulting from the content developed for the live meeting in order to maximize the reach to nurses throughout the United States. The activities described in this proposal include:

1. Live Symposia
2. Internet based activity hosted by Medscape
3. CD-ROM based on live footage accredited as a supplement in ASPMN Journal

The total grant request to fund these activities is \$366,210; please refer to the detailed budget section of this proposal for complete grant funding details of the individual educational initiatives.

These scientific events will comply with all OIG, PhRAM, FDA, and ANCC regulations for industry-supported professional continuing education.

Thank you in advance, for your consideration of this request.

Respectfully,

A handwritten signature in cursive script, appearing to read "Joan Meyer".

Joan Meyer  
Executive Director, Continuing Education

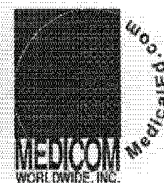
MediCom Worldwide, Inc.  
101 Washington Street • Morrisville, PA 19067 • 215-337-9991

Confidential

Page 2

## MediCom Worldwide, Inc.

### Needs Assessment



#### Needs Assessment:

Pain management encompasses various types of pain experiences throughout an individual's life cycle from birth to the end of life. Pain experiences may include acute and chronic pain, pain from a chronic deteriorating condition, or pain as one of many symptoms of the patient receiving palliative care. The goal of pain management throughout the life cycle is the same; to address the dimensions of pain and to provide maximum relief with minimal side effects.

Every day, nurses in all clinical settings work closely with patients who are experiencing various types and intensities of pain. Advances in pain management have given present patients and their families a variety of options that allow them a renewed dimension to the quality of their lives. Because of this it is important that nurses keep up to date on basic principles of assessment, pain management/treatment options and current pharmacologic and nonpharmacologic approaches.

To better understand the potential educational needs, MediCom Worldwide, Inc has utilized the following sources of information:

- 2005-2006 MediCom Needs Assessment Survey
- Consultation with Nursing Advisors in the Field of Pain Management
- Environmental Scan
  - Literature Review
  - Pain Management Core Competency Guide for Nurses
  - Therapeutic Research Review
  - Consensus Panel Recommendations on the Assessment and Management of BTP
  - Position Papers on Chronic Pain
  - APS survey publications

#### Literature Review:

Pain management encompasses various types of pain experiences throughout an individual's life cycle from birth to the end of life. Pain experiences may include acute and chronic pain, pain from a chronic deteriorating condition, or pain as one of many symptoms of the patient receiving palliative care. The goal of pain management throughout the life cycle is the same; to address the dimensions of pain and to provide maximum relief with minimal side effects<sup>(1)</sup>.

Classical pain categories are chronic and acute, nociceptive and neuropathic, within nociceptive classification, somatic and visceral. The experience of pain is complex. Pain is modulated at several different central nervous system levels.<sup>(6,17,18)</sup> Pain is known to be influenced by past experience and cognitive function. Throughout the literature there is a general tendency to separate malignant from non-malignant pain however studies have demonstrated that there is no difference anatomically, physiologically, by



biochemical substrate or through mechanisms of nociception which justifies separating the two.

Almost 50% of all Americans seek medical care each year for pain, making pain the single most frequent reason for a physician consultation in the U.S. Pain is inadequately controlled in many of these patients.<sup>(1,2,3)</sup> In some patients the pain that was established at the baseline examination persists, affecting quality of life and functioning, often even with drug therapy. Up to 86% of Americans suffering from chronic pain experience BTP, even when the persistent pain is well managed, yet it is often misunderstood aspect of chronic pain that requires a tailored strategy for care.<sup>(4)</sup>

Pain management begins with the use of appropriate assessment tools and includes planning, implementing, and evaluating a comprehensive treatment plan that addresses persistent and BTP. Persistent pain is present to some degree throughout the day and primarily is controlled with around the clock medication. However, it often is accompanied by episodes of short, intermittent pain, also known as BTP. Breakthrough pain is characterized as a transitory exacerbation of pain that occurs on a background of otherwise stable pain in a patient receiving chronic opioid therapy. Breakthrough pain typically is moderate to severe in intensity and can be triggered by various activities, be entirely unpredictable, or occur toward the end of around-the-clock medication.<sup>(5, 17, 18)</sup>

Breakthrough pain or transient worsening of pain in patients with an ongoing steady pain is a common feature in most chronic pain conditions with involvement of nerves, muscles, bones or viscera.<sup>(16)</sup> Although the mechanisms of spontaneous ongoing pain and intermittent flares of pain (BTP) may be difficult to separate, a recent study published in the European Journal of Pain suggest that peripheral and/or central sensitization (hyperexcitability) may play a major role in many causes of BTP.<sup>(6)</sup>

Despite the considerable variability in how BTP is defined, it is clear that BTP is associated with significant patient morbidity, including decreased functioning and increased levels of depression and anxiety.<sup>(7, 8)</sup> Breakthrough pain may also predict a poor medical outcome. Breakthrough pain is a major component of the public health problem related to the under treatment of pain, which has become a national quality of care issue and is a priority concern of the Agency for Healthcare Research and Quality.

A wide variety of factors including inaccurate information, myths, rumors, fear and cultural issues contribute to inadequate pain management.

Barriers to recognition in the treatment of pain are numerous despite multiple advances in the field. Nurses may have incomplete or inaccurate information about the following variables which contribute to ineffective pain management:

- Definition of pain and how patients demonstrate their pain
- How pain is assessed and managed
- Use of opioids and fears associated with dosing
- Cultural norms as it relates to expression of pain

Investigating the continuing education needs of nurses and the impact they have on the interdisciplinary team review of the literature reveals that the majority of patients do not receive adequate pain management. Myths and misinformation may contribute to ineffective management strategies. Some common myths include: <sup>(15)</sup>

1. Too much pain medication too frequently constitutes substance abuse, causes addiction, will result in respiratory depression or will hasten death
2. Pain should be treated, not prevented
3. People in pain always report their pain to their healthcare provider
4. People in pain demonstrate or show that they have pain-pain can be seen in the patient's behavior
5. The level of pain is often exaggerated by the patient
6. Generally a patient cannot be relieved of all pain
7. Some pain is good so that the patient's symptoms are not masked
8. Newborn infants and children do not have pain
9. It is expected that the elderly, especially the frail elderly, always have some pain

Because of multiple barriers to adequate pain management, all patients are at risk for under treatment of pain. Since pain is identified and reported primarily through patient self-reporting, difficulty in communicating increases the patient's risk for under-treatment. Clinicians should address persistent and BTP as distinct entities to accurately assess it and develop appropriate pain management plans.

The choice of therapeutic agents for many patients with unrelieved chronic pain is opioids. As a class, opioids have proven efficacy, not only in providing meaningful pain relief to many patients, but also in improving functionality. <sup>(10,11)</sup> Opioids offer pharmacologic advantages through the availability of diverse formulations and doses that provide significant flexibility when tailoring a therapeutic regimen for the chronic pain patient.

Clinicians need to understand the pharmacokinetics, pharmacodynamics, and pharmacogenomics of opioids to appropriately include them in treatment plans, including multimodal therapy. <sup>(9,14)</sup> New formulations and new delivery systems are in various stages of development, with an aim to offer even more options to clinicians to further advance patient care. The core principle of opioid analgesia is a balanced and responsible approach that allows appropriate access and minimizes potential risks for misuse and side effects, while providing pain relief and restoring functionality. <sup>(10,11,14)</sup>

### Consultation with Clinical Experts:

April Vallerand PhD, RN, FAAN  
Associate Professor  
Wayne State University  
College of Nursing

Steve Stanos, DO  
Medical Director  
Chronic Pain Care Center  
Rehab Institute of Chicago

Candace Coggins, MS, MA, CARN, RN-C  
Metropolitan Jewish Health Systems  
Brooklyn, NY  
Immediate Past President-Elect of the  
American Society of Pain Management Nurses

Daniel M Gruener, MD  
Clinical Assistant Professor of Psychiatry  
Jefferson Medical College

Peggy Compton, RN, PhD  
Associate Professor  
School of Nursing  
UCLA

### Major issues discussed

- Practice setting for nursing; the role of the nurse based on practice setting
- Assessment tools available
- Continuing educational needs of pain management nurses
- Communication techniques; assessment intervals; recognition of BTP
- Pharmacologic management; non pharmacologic management
- Fears and misconceptions
- Preferred source of continuing education; live, web based, journals
- Interdisciplinary teams

### Conclusions:

- Pain management nursing encompasses a wide and diverse range of practice settings each with their own unique needs
- No formalized training programs to educate nursing students on multi faceted issues relating to pain management assessment and management. Training is of a fundamental nature during course of study. Nurses rely on continuing education opportunities to seek advancement in skill and knowledge
- Assessment tools available to nursing professionals are adequate; education on the use of these tools are what's needed
- Myths and misconceptions still abound relative to utilization of opioids
- Fear of over medicating; loss of functionality
- Hesitancy to utilize adequate doses of meds for fear of abuse, addiction, side effects



- Ongoing communication with patients; knowing the right questions to ask in the assessment process in order to accurately assess pain states and the impact on successful pain relief
- Maintaining and enhancing functionality very important to nursing goals for their patients

#### Needs Assessment Survey/Past Participant Evaluation Outcome:

To further define the educational needs of clinicians, MediCom conducted a review of 325 nursing professionals perceived continuing educational needs. The survey provided data regarding clinicians' top interest, preferred method of learning and other details regarding continuing education. The following results demonstrate topics that the respondents view to be the top 10 highest interests and need and ranked priority of need. <sup>(19)</sup>

Educational Assessment of Needs	High Priority	Moderate Priority	Low Priority	NA
Women's Health Issues		X		
General Pharmacology	X			
Cancer Care	X			
Pain Management	X			
Geriatric Care		X		
Opioids		X		
Psychiatry	X			
ADHD		X		
Sleep Disorders		X		
Abuse and Addiction	X			

Specific topics of interest related to pain are evaluated on an ongoing basis. The following information is a summary of completed survey reports from 2005 through 2006, year to date. Total number of evaluations completed were 1285; of those returned approximately 41% were from a healthcare professional in the field of nursing i.e.; RN, LPN, NP <sup>(19)</sup>

Topics of Interest	No Interest	Some Interest	High Interest
Acute Pain Management	10%	30%	60%
Chronic Non Malignant Pain	6%	16%	78%
Cancer Pain Management	20%	35%	45%
Pharmacological Advances in Pain Management	3%	15%	82%
Addiction, Abuse	16%	31%	53%

## Conclusion

Effective pain management by nurses requires them to have an understanding of the biological basis of the pain interventions which may be used to control pain. In addition an emphasis on a complete and ongoing pain assessment is paramount to developing a comprehensive treatment plan. Based on a review of the literature, needs assessment surveys as well as input from clinical experts there is a continued need to provide a platform for nurses to gain the most up to date information relative to the issues and challenges of managing patients with chronic pain. Nurses are an instrumental member of the interdisciplinary team and have a great need to understand the newer trends in pain management as well as novel analgesic delivery systems arriving on to the healthcare arena in order to impact pain care and promote a successful outcome of sustained pain relief.

## References:

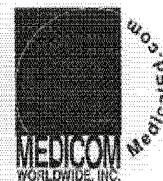
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## MediCom Worldwide, Inc.

### Program Summary



#### Program Overview:

Pain management encompasses various types of pain experiences throughout an individual's life cycle from birth to the end of life. Pain experiences may include acute and chronic pain, pain from a chronic deteriorating condition, or pain as one of many symptoms of the patient receiving palliative care. The goal of pain management throughout the life cycle is the same; to address the dimensions of pain and to provide maximum relief with minimal side effects.

Almost 50% of all Americans seek medical care each year for pain, making pain the single most frequent reason for a physician consultation in the U.S. Pain is inadequately controlled in many of these patients. In some patients the pain that was established at the baseline examination persists, affecting quality of life and functioning, often even with drug therapy. Furthermore, such patients may also experience breakthrough pain (BTP), which affects 19% to 95% of all patients with pain, depending on the population surveyed and the definition of BTP used.<sup>(1,5,7,18)</sup>

Despite the considerable variability in how BTP is defined, it is clear that BTP is associated with significant patient morbidity, including decreased functioning and increased levels of depression and anxiety. Breakthrough pain may also predict a poor medical outcome. Breakthrough pain is a major component of the public health problem related to the undertreatment of pain, which has become a national quality of care issue and is a priority concern of the Agency for Healthcare Research and Quality.

Every day, nurses in all clinical settings work closely with patients who are experiencing various types and intensities of pain. Advances in pain management have given present patients and their families a variety of options that allow them a renewed dimension to the quality of their lives. Because of this it is important that nurses keep up to date on basic principles of assessment, pain management and current pharmacologic and nonpharmacologic approaches.

These symposia will review the major clinical issues related to persistent pain and more specifically BTP including recognition and impact; pharmacologic and nonpharmacologic therapy; expert treatment guideline recommendations will be reviewed. Cases will be presented guided by a clinical expert in pain as seen through the eyes of a pain patient. It is our goal to provide participants with practical information and data that can be applied in daily practice, to provide the tools and skills required to assess patients, and determine the appropriate treatments for each individual's own unique pain management needs. Breakthrough pain is a common problem affecting the quality of life of patients. Improved management of BTP is contingent on accurate pain assessment, optimum use of analgesics, and patient education.



**Program Title:*****Assessment, Diagnosis and Treatment of Breakthrough Pain: Breaking the Pain Cycle*****Program Objectives:**

Upon completion of this activity, participants should be able to:

1. Summarize advances in understanding and management of chronic pain
  - a. Distinguish features, types and definition pain; acute, chronic and BTP
  - b. Recognize BTP; read the signals in your patients
  - c. Identify tools, questions and communication techniques that are designed to improve patient/healthcare provider dialogue
  - d. Outline current guidelines available which impact management of BTP
2. Define and manage the pain cycle
  - a. Summarize current and emerging pharmacologic and nonpharmacologic treatment options for BTP
  - b. Evolving options in opioid therapy: Timing of pain dictates timing of treatment
  - c. Challenges and opportunities relative to opioid therapy in treating patients with chronic pain
3. Identify effective clinical strategies and treatment options which demonstrate how appropriate assessments and tools may be incorporated into the practice setting
  - a. Utilization of pain dairies to assist in identification and optimal treatment options; The Patients Story
  - b. Summarize goals of treatment
  - c. Guidelines in managing treatment

**Faculty:**

**Steve Stanos, DO**

Medical Director

Chronic Pain Care Center

Rehab Institute of Chicago

**April Vallerand PhD, RN, FAAN**

Associate Professor

Wayne State University

College of Nursing

**Candace Coggins, MS, MA, CARN, RN-C**

Metropolitan Jewish Health Systems

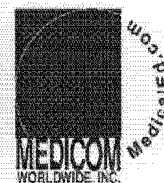
Brooklyn, NY

Immediate Past President-Elect of the

American Society of Pain Management Nurses

## MediCom Worldwide, Inc.

## Program Overview

**Targeted Audience:**

Nursing participants attending the American Society of Pain Management Nurses Conference

Target participation: 500 attendees

**CE Provider:**

The symposia will be accredited by MediCom Worldwide, Inc. in joint sponsorship with the American Academy of Pain Management Nurses

- Each activity will be approved for two contact hours.

**Format:**

Live symposia held in Dallas, Texas in conjunction with the American Society of Pain Management Nurses Conference. Program will consist of live didactic presentation in addition to integrated immediate learning assessment activities captured via audience response systems. In addition, MediCom will prerecord via videotape a story of pain experienced through the eyes of a pain patient. Post live event, final content will be formatted to allow for additional enduring self study adaptation; enduring material will be developed for internet access via Medscape as well as CD-ROM adaptation to be distributed via American Society of Pain Management Nurses journal.

**Enduring Material**

Format	Description	Expected Reach
Symposium adaptation: online accredited <b>streaming video program</b>	Symposium filmed and edited into accredited streaming video posted at Medscape.com	Medscape nursing eNewsletter subscribers: 270,000 nurses
Symposium adaptation: <b>accredited monograph series</b>	Symposium accredited monograph series distributed as a journal supplement to the ASPMN	ASPMN journal: 2,500 pain management nurses;

## MediCom Worldwide, Inc.

### Program Overview



#### Distribution/Invitation Process:

##### Live Event

The live symposium will be announced and promoted through the use of approximately 2,500 printed invitations via direct mail to all members of the American Society of Pain Management Nurses followed by a secondary mailing of approximately 650 to all those pre registered to attend the conference.

##### Request for Sponsor Support Live Event

As a supplement to these primary methods, MediCom Worldwide, Inc may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical/nursing community. The content of such information, however, is the responsibility of MediCom and any such distribution will solely be as a supplement to MediCom's primary methods of announcement and promotion.

##### Enduring Material

##### Medscape Distribution Plan

Activity posts online 8-12 weeks following the live event

Medscape educational activities are cross posted to all relevant specialty areas and audience types.

All formats are posted, archived and searchable on Medscape for a 12 month period.

Drivers to content include features on the following areas:

- Specialty relevant Medscape Homepages

- CE center on relevant specialty

- Email newsletters

- Medscape search engine

Online promotion reminder emails and links in relevant specialty homepages

Reach: 770,000 US nurses

##### ASPMN Journal Supplement

CD-ROM format is to be polybagged as a journal supplement in association with the American Society for Pain Management Nursing Journal.

Supplement to be distributed in conjunction with the September Journal via direct mail to approximately 2,500 ASPMN subscribers.





# ASPMN Activity Timeline

2007

	March 2007	April 2007	May 2007	June 2007	July 2007	August 2007	September 2007	October 2007	November 2007	December 2007	January 2008	February 2008	March 2008	April 2008	May 2008	June 2008	July 2008	August 2008	September 2008
Live Event	x																		
Medscape Activity			☆																
ASPMN Journal Supplement						℘													



Lunch Symposium, March 25, 2007



Medscape activity release date, June 25, 2007



ASPMN Journal Supplement release date, September 20, 2007

**MediCom Worldwide, Inc.****Program Overview****MediCom Worldwide, Inc. Policies:****Conflict of Interest Identification and Resolution**

MediCom Worldwide, Inc is in full compliance with all rules and regulations put forth by the ACCME in the revised Standards for Commercial Support. MediCom has defined all those in position to control content as faculty, authors, presenters, planning committee members and all those internal staff who are in position to write, alter or impact the content of a CME activity.

All members identified in the planning process must provide signed disclosures to MediCom prior to the planning of the activity.

When individuals in a position to control content have reported Financial Relationships with one or more commercial interests, MediCom works with them to resolve such conflicts to ensure that the content presented is free of commercial bias. The following mechanisms have been identified in which to resolve conflicts as identified:

- Peer review of content by external reviewer
- Content validation by external topic expert and internal MediCom clinical editorial staff

**MediCom Worldwide, Inc. Disclosure Policy**

(Attachment A)

**MediCom Worldwide, Inc. Content Development Policy**

(Attachment B)

**MediCom Worldwide, Inc. Faculty Selection Policy**

(Attachment C)

## MediCom Worldwide, Inc.

## Program Overview

**Post-Activity Reporting:**

Course evaluation forms will be required for all participants who seek to receive continuing education credit. MediCom will summarize the information collected in a formal report to evaluate program effectiveness and participant learning.

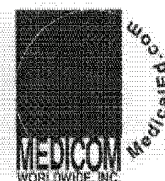
Participants will evaluate the following components:

1. Overall content
2. Faculty teaching effectiveness
3. Format
4. Usefulness of information
5. Relevance to practice setting
6. Fair balance
7. Impact to the care of the patient experiencing pain

In addition to rating scales participants will be asked to participate in pre/post testing scenarios as a measurement of learning. Learning will be analyzed based on self-reported changes in knowledge or perceptions by the participants as a result of this activity and how well he or she will be able to apply learning to a specific practice setting.

# MediCom Worldwide, Inc.

## Budget Summary and Options



### Budget Summary Overview

#### ASPMN Accredited Satellite Symposium Plus Enduring Material Options Proposal Overview

Tactic	Description	Expected Outcome	Proposed Budget	
Satellite symposium at 2007 ASPMN, interview	Three-speaker accredited live symposium	500 ASPMN members	Direct Costs	\$94,110
			Indirect Costs	\$ 73,200
			<b>Total</b>	<b>\$167,310</b>
Symposium adaptation: accredited journal supplements in ASPMN Association journal	Symposium filmed and edited into accredited video-based CD-ROM distributed as a polybagged journal supplement to the ASPMN journal	ASPMN journal: 2,500 pain management nurses;	Direct Costs	\$ 43,500
			Indirect Costs	\$ 26,250
			<b>Total</b>	<b>\$ 69,750</b>
Symposium adaptation: online accredited streaming video program	Symposium filmed and edited into accredited streaming video posted at Medscape.com	Medscape nursing eNewsletter subscribers: 270,000 nurses	Direct Costs	\$ 3,400
			Medscape Hosting Fees	\$100,000
			Indirect Costs	\$ 25,750
			<b>Total</b>	<b>\$129,150</b>





MediCom Worldwide, Inc.  
101 Washington Street  
Morrisville, Pennsylvania 19067

### 2007 American Society of Pain Management Nursing

<i>Program Parameters</i>	
Accreditation Hours	2
Faculty	3
Symposium Attendees	525
Direct mail invitations to health care professionals	4,000

<i>Cost Summary</i>	
Approximate Total, Direct Expenses	\$ 94,110
Total, Indirect Expenses	\$ 73,200
<b>Cost of 2007 American Society of Nursing Management</b>	<b>\$ 167,310</b>

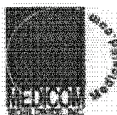
Approval Signature \_\_\_\_\_

Date \_\_\_\_\_

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### 2007 American Society of Pain Management Nursing

<i>Direct Expenses; Approximate</i>	
ASPMN Fee (Lunch symposia)	\$ 35,000
Direct mail invitations	
Direct mail invitations, mailed to registered meeting attendees; includes printing; development of database email homepage for registration	\$ 4,000
Direct mail list purchase	No charge
Mail Services, postage, phone, fax, email registration	\$ 1,560
Includes assembly, mail services and postage. Follow up recruitment per phone, fax, email	
Invitation door-drop/advertisement fee	\$ 5,000
Participant handouts	\$ 11,500
Includes printing of participant workbook; will include accreditation information, speaker biographical and disclosure information, agenda, and symposium graphics; total quantity 525 color copy	
Posters advertisement materials	\$ 2,400
Faculty expenses	
Honoraria:	
Nursing Experts (2)	\$ 3,000
MD Expert (1)	\$ 2,500
Travel (3 faculty members)	\$ 1,800
Accommodations (assumed one night stay)	\$ 1,500
Meal expense faculty	\$ 300
Ground transportation	\$ 525
Room Rental	No charge
Catering provided by ASPMN up to 500 attendees; assumed average amount of 50 attendees	\$ 3,500
Audience Response System	\$ 5,750
Onsite equipment rental	\$ 4,500
Audio/visual services: Basic AV provided by ASPMN; upcharge related to additional AV requirements	\$ 2,000
MediCom expenses	
Air travel	\$ 1,200
Accommodations	\$ 1,600
Meals	\$ 300
Ground transportation	\$ 350
OOP	\$ 75
Travel/expense film crew; production	\$ 5,000
Shipping/Fed Ex	\$ 750
<b>Approximate Total, Meeting Management Direct Expenses</b>	<b>\$ 94,110</b>

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### 2007 American Society of Pain Management Nursing

<i>Indirect Expenses</i>	
MediCom pre-meeting coordination and Development of Video Case Study Includes faculty recruitment, agenda coordination, coordination with association; coordination with venue; participant recruitment; coordination of filming of patient video case study equipment rental; actor; studio rental; filming; editing; production of video case presentation	\$ 25,000
Onsite filming of entire live event; Includes interview segments with presenters	\$ 15,000
Development Editorial Includes presentation slides x3 faculty approx 125 slides; editorial content review; reference and fact checking; design and format	\$ 10,000
MediCom on-site symposium coordination; 2 MediCom staff	\$ 5,000
Graphic design	\$ 3,200
Accreditation of program for CNE coordinated in conjunction with ASPMN	\$ 2,500
Project management	\$ 10,000
<b>Total, Indirect Expenses</b>	<b>\$ 73,200</b>

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Morrisville, PA 19067

## Multi-Media Online Adaptation from Live Symposium Hosted as Internet Activity on Medscape

### Program Description

This proposal is for a multi-media online streaming video adapted from a live symposium and accredited for self-study for nurses. The self-study program will include: (1) live footage of speaker presentations; (2) all graphic images used in the presentations, including animations of graphs and charts; (3) content to be posted on line via Medscape

<i>Cost Summary</i>	
Approximate Total, Direct Expenses	\$ 103,400
Total, Indirect Expenses	\$ 25,750
<b>Cost of One Self-Study Multi-Media Online Program Adapted from Live Symposium</b>	<b>\$ 129,150</b>

Approval Signature \_\_\_\_\_

Date \_\_\_\_\_

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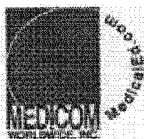
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101 Washington Street  
Morrisville, PA 19067

### Multi-Media Online Adaptation from Live Symposium Hosted as Internet Activity on Medscape

#### Detailed Budget Itemization

<i>Direct Expenses, Approximate</i>	
Transcription	\$ 400
Speaker honoraria: post-symposium interviews	\$ 3,000
Medscape Hosting Fee	\$ 100,000
<i>Approximate Total, Direct Expenses</i>	<i>\$ 103,400</i>

<i>Indirect Expenses</i>	
Program Development	\$ 10,000
Includes creation of graphic user interface; coordination with speakers for interview segments; coordination with speaker for final review	
Programming	\$ 5,000
Accreditation of program for CNE	\$ 5,000
Data management	\$ 750
Includes management of participant database, data analysis, quarterly reports, final summary report	
Project management	\$ 5,000
<i>Total, Indirect Expenses</i>	<i>\$ 25,750</i>



MediCom Worldwide, Inc.  
101 Washington Street  
Morrisville, Pennsylvania 19067

### Multi-Media CD-ROM Adaptation from Live Symposium *Journal Supplement in ASPMN Journal*

#### Program Description

This proposal is for a multi-media CD-ROM adapted from a live symposium and accredited for self-study for nurses. The CD-ROM will include: (1) live footage of speaker presentations; (2) all graphic images used in the presentations, including animations of graphs and charts; (3) text and/or PDF files of all program support and CE-related information. Clinicians will request CE certificates using the enclosed self-assessment/program evaluation form. Distribution method via polybagged supplement in the ASPMN Journal following live activity in 2007. Budget allows for an additional duplication of 500 CD's which could be distributed based on request.

<i>Cost Summary</i>	
Approximate Total, Direct Expenses	\$ 43,500
Total, Indirect Expenses	\$ 26,250
<b>Cost of One Self-Study Multi-Media CD-ROM Adapted from Live Symposium Distributed via Supplement in ASPMN Journal</b>	<b>\$ 69,750</b>

Approval Signature

Date

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Morrisville, Pennsylvania 19067

### Multi-Media CD-ROM Adaptation from Live Symposium Journal Supplement in ASPMN Journal

#### Detailed Budget Itemization

<i>Direct Expenses, Approximate</i>	
CD duplication; quantity: 3,000	\$ 6,500
Includes printing of program insert containing self-assessment questions, accreditation information and program evaluation form; printing and assembly of full-color, varnished DiscPak style mailer with four-color cover for CD plus insert; silk-screen of CD labels; duplication of CDs; assembly; shrink wrapping for pollybag	
Speaker honoraria: post-symposium interviews	\$ 3,000
Printing of BRCs; quantity: 2500	\$ 2,000
Return postage for BRCs returned to MediCom (estimated return of 500 BRCs)	\$ 1,500
Postage for mailing CDs out in response to BRCs; quantity: 500	\$ 500
Distribution in ASPMN Journal Supplement	\$ 30,000
<i>Approximate Total, Direct Expenses</i>	\$ 43,500

<i>Indirect Expenses</i>	
Program Development	\$ 5,000
Includes creation of graphic animated CD user interface; coordination with faculty and journal staff; design, typesetting and layout; proofing	
CD-ROM production	\$ 7,500
Includes programming, production of duplication master	
Accreditation of program for CNE	\$ 5,000
Data management	\$ 750
Project management	\$ 8,000
<i>Total, Indirect Expenses</i>	\$ 26,250



# MediCom Worldwide, Inc. Budget Summary and Options



## **Budget:**

Live Activity:	\$167,310
Medscape Activity:	\$129,150
ASPMN Journal Supplement:	\$69,750
Total Budget:	\$366,210

## **Budget Reporting and Reconciliation:**

### **Appropriate Use of Commercial Support:**

- a. Funds should be in the form of an educational grant made payable to MediCom Worldwide, Inc.
- b. No other funds from Cephalon, Inc. will be paid to the program director, faculty, or others involved with the CE activity (additional honoraria, extra social events, etc.).
- c. MediCom Worldwide, Inc. will furnish the commercial interest with documentation detailing the receipt and expenditure of the commercial support within 90 days of activity completion.

## **Payment Structure:**

1/3 due upon signing of agreement:	\$122,070
1/3 due 1 <sup>st</sup> quarter 2007 (March 1, 2007):	\$122,070
Final 1/3 due 2 <sup>nd</sup> quarter 2007 (June 1, 2007):	\$122,070



### Standard Operating Procedures

<b>Manual</b>	Department of Continuing Education Policy and Procedure	<b>Policy Number</b>	<b>II-203</b>
<b>Subject</b>	Disclosure	<b>Date of Origin</b>	March 2003
<b>Approved By</b>	Joan Meyer	<b>Revision Date</b>	March 2005
<b>Signature</b>		<b>Approval Date</b>	May 2005

### Purpose

The policy on disclosure exists to provide guidance for staff, faculty and joint/co-sponsors of the requirement to disclose specific information to participants in order to comply with the following standards for all activities sponsored by MediCom Worldwide, Inc.: ACCME's 2004 Updated Standards for Commercial Support; ACPE's Criteria for Quality and Interpretive Guidelines; California Board of Registered Nursing Standards and Guidelines. This includes (a) sponsor financial relationships, (b) faculty and family/significant others financial relationships, (c) discussion of unlabeled or unapproved uses of drugs and devices. As an approved provider, MediCom Worldwide, Inc. is required to collect information from individuals who have an opportunity to affect the CE content about products or services of a commercial interest with which he/she has a financial relationship to allow a determination to be made as to whether that relationship may constitute a conflict of interest that must be resolved.

### Policy

1. Disclosure documents must be completed by anyone involved in planning or presenting educational content at CE programs approved for CME/CPE/CNE inclusive of MediCom advisory committee members, clinical content reviewers and identified faculty members.
2. MediCom Worldwide, Inc. requires all those in a position to control content to provide specific information to CE participants.
3. MediCom requires faculty to provide specific information to CE participants. Disclosure is required in two areas:
  - Financial Relationships - Faculty must disclose any significant relationship between themselves/significant others and (a) the commercial supporter(s) of the program, and (b) the manufacturer of any product discussed in the CE program or related to the topic of the event. Information reported shall include financial relationships in place over the preceding twelve-month period. If the faculty has nothing to report, that information must be indicated.
  - Discussion of Unlabeled Use - Faculty must disclose in writing and communicate in writing through course materials, that a product is not labeled for the use under discussion or that the product is still investigational and not approved for use in the United States.
4. Faculty are required to complete the MediCom Worldwide, Inc. Faculty Disclosure Forms, and Attestation Forms prior to the program development process.
  - (Required forms attached)
5. Disclosure Forms must be completed and returned to MediCom prior to content development. Faculty refusing to disclose may not participate as a speaker for program in which disclosure was not obtained.
6. Potential conflicts of interest disclosed will be reviewed by MediCom and must be resolved prior to the educational activity.
7. Once a conflict is identified, a content validation process is initiated to ensure that the content or format of the CE activity and related materials will promote improvements or quality in health care and not promote a specific proprietary business interest of a commercial interest.
8. MediCom conducts an unbiased review of all planned content for activities certified for credit to resolve any actual or perceived conflict of interest that exists.
9. Faculty must disclose to participants prior to the start of the educational activity the existence of significant situations where a direct commercial support relationship exists with the educational activity.





10. MediCom discloses the following information to learners: 1) the name of the individual, 2) the name of the commercial interest(s), and 3) the nature of the relationship the individual has with the commercial interest. MediCom also discloses to learners the name(s) of commercial interests supporting each CE activity. Faculty disclosures will be documented and available to all participants via written participant handout information i.e.; syllabi, introductory slides, workbooks.
  - Disclosure will be made available to audience at the start of each activity.
11. Faculty must also disclose prior to the start of the educational activity if no significant financial relationships exist.
12. If faculty members present at multiple independent educational activities, a separate disclosure form is required for each activity.
13. Implementation:
 

All internal content review staff and outside external expert reviewers and faculty will complete a Financial Disclosure Form that contains the following information:

  - The form shall note the title and date of the activity, as well as the name(s) of the commercial supporter(s) associated with the activity.
  - The form shall solicit information about the financial relationship(s) of the reviewer, faculty member, his/her immediate family member or significant other has with any commercial supporter, as well as manufacturers of products associated with the activity or related to the topic of the activity.
  - If no relationship exists, there shall be a box to check to that effect.
  - The form shall solicit information from the faculty member as to plan to address off-label discussion or investigational use of a drug in his/her presentation.
14. Timeline for disclosure of financial relationships:
  - Internal reviewer will complete the disclosure form upon employment.
  - External experts will complete the disclosure form at the time a relationship with MediCom has been identified.
  - Presenting faculty will be asked to sign a disclosure form at the time of invitation to participate in a planned program.



### Standard Operating Procedures

<b>Manual</b>	Department of Continuing Education Policy and Procedure	<b>Policy Number</b>	<b>II-205</b>
<b>Subject</b>	Content Without Commercial Bias	<b>Date of Origin</b>	March 2004
<b>Approved By</b>	Joan Meyer	<b>Review/Revision Date</b>	July 2005
<b>Signature</b>		<b>Approval Date</b>	October 2005

#### Purpose

To establish criteria, policy and process of implementation of content standards of CE activities in accordance with the ACCME Standard for Commercial Support; Content and Format without Commercial Bias, and the content requirements of the ACPE and California Board of Registered Nursing.

#### Policy

1. MediCom must review the planned content of a CE activity to be certified by MediCom and demonstrate in documentation that the content or format of a CE activity adheres to the following criteria:
  - a. Presentations and/or its related materials must promote improvements or quality in health care and not a specific proprietary business interest of a commercial interest.
  - b. Presentations and/or its related materials must give a balanced view of therapeutic options.
  - c. Use of generic names within the body of the presentation or its related materials is required.
    - Related presentation materials may contain trade names for all generic products contained within the presentation that are from several companies, as available.
2. All content from CE activities will undergo content validation process.
  - Content must conform to the generally accepted standards of experimental design, data collection and analysis.
  - Faculty must attest to MediCom that the presentation content or content of its related materials promote improvement or quality in health care and not a specific proprietary business interest of a commercial interest.
  - Faculty must attest to MediCom that the presentation gives a balanced view of therapeutic options.
  - MediCom's internal and external reviewers must evaluate and attest that faculty presentation and its related materials promote improvements or quality in health care and not a specific proprietary business interest of a commercial interest.
  - Internal and external content reviewers must evaluate and attest that the presentation gives a balanced view of therapeutic options.
3. Activities are not eligible for certification if the content and/or format promote recommendations, treatments or manners of practicing medicine that are not within the definition of CME or are known to have risks or dangers that outweigh the benefits or are known to be ineffective in the treatment of patients. Activities that offer recommendation, treatments or practice manners outside of the definition of continuing pharmacy or nursing education, or that have risks or dangers that outweigh the benefits or are known to be ineffective are not eligible for certification.
4. CE activities must be developed and presented utilizing the principles of adult learning, which includes thorough assessment of learners' needs and focus on participant involvement in the learning process.
5. Faculty selected to participate must be demonstrated thought leaders in the topic of the CE activity and must have demonstrated skill in providing education to adult learners. Faculty should hold advanced degrees in their area of specialty, and should be active in research or patient care within an academic or clinical setting. Faculty may not be employees of the commercial supporter of an educational activity, regardless of qualification. Faculty will be asked to provide their qualifications and educational background to activity planners for review. Faculty will be advised of content requirements in their faculty letters.



6. MediCom may solicit the review by an expert reviewer; members of the MediCom Worldwide, Inc. advisory committee provide oversight of MediCom's program planning and design. A member of the advisory committee may be asked to provide content review for selected MediCom activities. Whenever possible, advisory committee members are asked to review activities that fall within their area of clinical expertise.
7. The clinical pharmacy consultant provides oversight and review of program planning, design and in-depth content review of each activity, and verifies that the proposed amounts of pharmacology hours and content are appropriate for pharmacy credit.
8. The executive director will give final approval for the activity content and appropriate credit/contact hour designation, indicating that the content is deemed valid and within the criteria as stated in this policy. This form will be signed by the executive director. This is contained in the CE planning document.
9. Evidence of valid content will be placed in the activity file under planning.





## Standard Operating Procedures

<b>Manual</b>	Department of Continuing Education Policy and Procedure	<b>Policy Number</b>	<b>II-208</b>
<b>Subject</b>	Faculty/Speaker Selection	<b>Date of Origin</b>	January 2000
<b>Approved By</b>	Joan Meyer	<b>Revision Date</b>	August 2004
<b>Signature</b>		<b>Approval Date</b>	August 2005

### Purpose

To establish guidelines for the determination of qualitative and quantitative considerations in the faculty selection process.

### Policy

#### I. Qualitative Considerations

Faculty selected to participate must be demonstrated thought leaders in the topic of the CE activity and must have demonstrated skill in providing education to adult learners. Faculty should hold advanced degrees in their area of specialty, and should be active in research or patient care within an academic or clinical setting. Faculty may not be employees of the commercial supporter of an educational activity, regardless of qualifications. Faculty will be asked to provide their qualifications and educational background to MediCom for review. Faculty will be advised of content requirements in their faculty letters sent by MediCom.

1. Faculty must attest to MediCom that the presentation content or content of its related materials promote improvement or quality in healthcare and not a specific proprietary business interest of a commercial interest.
  - Faculty must attest to MediCom that the presentation gives a balanced view of therapeutic options.
  - MediCom's internal and external reviewers must evaluate and attest that faculty presentation and its related materials promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.
  - CE activities must be developed and presented utilizing the principles of adult learning, which includes thorough assessment of learners' needs and focus on participant involvement in the learning process.
2. Upon selection and approval of the faculty, a letter of guidance is written to the faculty outlining the expectations.
3. Each faculty member must submit a CV for review.
4. Each faculty member must complete and sign a disclosure form and attestation form.
5. Those faculty members who do not complete required disclosure information will not be permitted to participate in the activity as planned.
6. The executive director or designee will communicate directly with faculty, providing each faculty member with written information related to objectives of the program.
7. The executive director or designee will provide technical assistance necessary to prepare materials for presentation.

**II. Determination of Number of Faculty Required Per Planned Activity**

1. An appropriate number of qualified faculty members shall be utilized for each continuing education program.
2. The executive director will be responsible for determination of number of faculty required for each program. Determination will be based on number of topics, depth of subject matter and anticipated duration of the program.
3. MediCom will strive to maintain a ratio of at least one faculty member per every one hour of formal didactic lecture.

**III. Program Evaluation**

1. A program evaluation form is developed for each activity, which is intended to solicit participant's assessment of faculty effectiveness.
2. Evaluation forms are distributed to participants at the end of each activity. Each participant is required to complete the form as designed, as well as provide any written feedback or comments regarding program.
3. A formal summary report is completed following each program or program series. This report compiles the results of the evaluation form as well as narrative comments from participants.
4. A designated member of the CE staff will directly monitor each educational activity.



**EDUCATIONAL GRANT DRAFT REQUEST**

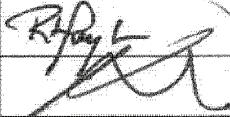


The attached material has been reviewed and is approved:

Payee: Medicom Worldwide, Inc.

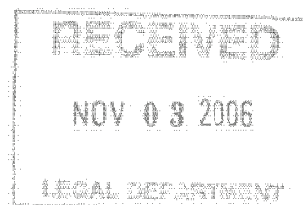
Amount: \$246,110

Type of Program: International Association of Pain and Chemical  
Dependency Satellite Symposium: Opioid Therapy in  
Chronic Pain with Breakthrough Episodes: Therapeutic  
Advances and Their Impact on Risk

Submitted for Review: 11/2/06

DEPARTMENT	NAME	SIGNATURE	DATE
Scientific Communications	Rod Hughes		11.3.06
Medical Affairs	Kiumars Vadie		11/3/06
Legal & Government	Eric Siegel		11-8-2006

Please Return to: Suz Steczak, x86537 – Scientific Communications



**EDUCATIONAL GRANT DRAFT REQUEST**  
(Scientific Communications)

Submission to Committee Date: 11/2/06 Grant Tracking # \_\_\_\_\_ Amount: \$ 246,110

NOTE: •Submission must be 30 days prior to program date

•Grant Tracking # if applicable

•Grant request must be submitted on provider letterhead

Educational Provider Name: Medicom Worldwide, Inc.

Accredited (CME/CE) ☒ Yes

Street Address: 101 Washington Street

City: Morrisville

State: PA

Zip: 19067

Program title: IAPCD Satellite Symposium: Opioid Therapy in Chronic Pain with Breakthrough Episodes: Therapeutic Advances and Their Impact on Risk

Start Date: June 21-24, 2007

Location: New York City

Is Cephalon the only sponsor of program: ☒ Yes ☐ No ☐ Unknown

Type of Program (choose all that apply): ☒ Nat'l Symposia ☐ Teleconference ☐ Print

☐ Grand Rounds ☐ Website ☐ DVD/CD-ROM

☐ Regional or Local Meeting ☒ Other: E-Procures delivery  
RP

Will Grant Support Enduring Materials: ☒ Yes ☐ No

Was Cephalon Involved in the Grant Request to Date? ☐ Yes ☒ No If Yes, describe \_\_\_\_\_

Will Cephalon have future Involvement? ☐ Yes ☒ No If Yes, describe \_\_\_\_\_

Manager Signature: Bhaval Shah

Print Name: Bhaval Shah Bell, PhD, Senior Manager, Medical Education

Medical Education Director/Sr. Director Signature: Jacqui Brooks

Print Name: Jacqui Brooks, Senior Director, Medical Education

GRANT COMMITTEE APPROVAL ☐ Yes ☐ No Date: \_\_\_\_\_

If no, state reason: \_\_\_\_\_

For Budgetary Purposes Only - Product: (Check One)

☐ Actiq ☐ Gabitril ☐ Provigil ☐ Trisenox ☐ Vivitrol ☐ Other: \_\_\_\_\_



Cephalon, Inc.  
41 Moores Road  
Frazer, PA 19355  
tel 610.344.0200  
fax 610.344.0065  
www.cephalon.com

# Memo

---

To: Legal Department – Archives  
From: Kimber Titus x86766  
Date: December 7, 2006  
Re: Fully-Executed Agreement(s) for Archiving in Central Files

I have attached hereto a fully executed agreement for archiving in Central Files.

I have completed the checklist below in preparation for archiving in Central Files:

- ☒ An authorized Cephalon officer has signed the agreement(s) (at the level of Vice President or above. If this is a CDA, a Director or Senior Director may be authorized to sign if a valid Delegation of Authority to sign CDAs is on file in the Legal Department).
- ☒ The agreement(s) is fully executed by both parties and both original signatures are attached.
- ☒ The signature page contains the Legal Department approval stamp, which signifies that the agreement(s) was routed to Legal for review and approval prior to signature.

Thank you!



www.cephalon.com

Cephalon, Inc.  
41 Moores Road  
P.O. Box 4011  
Frazer, PA 19355  
Phone 610-344-0000  
Fax 610-344-0080

## INDEPENDENT EDUCATIONAL PROGRAM ("IEP") GRANT AGREEMENT

This Agreement is entered into as of this 20th day of November, 2006 by and between Cephalon ("Cephalon"), located at 41 Moores Road, Post Office Box 4011, Frazer, PA 19355, and MediCom Worldwide, Inc. ("IEP Provider") located at 101 Washington Street, Morrisville, PA 19067.

WHEREAS, Cephalon has reviewed IEP Provider's grant request to support a medical education program ("Program"); and

WHEREAS, Cephalon has determined that the Program has the potential to significantly further medical knowledge and improve patient care; and

WHEREAS, it is the intent of the parties to ensure that the Program will be independent, objective, balanced and scientifically rigorous, so that it will not be viewed by the United States Food and Drug Administration ("FDA") as promotional and that Cephalon will not be viewed as responsible for its content; and

WHEREAS, Cephalon agrees to provide funding for the Program under the conditions set forth below.

NOW THEREFORE, IEP Provider and Cephalon agree to the following terms under this Agreement:

1. Title of Program. The IEP is entitled, IAPCD Satellite Symposium: Opioid Therapy in Chronic Pain with Breakthrough Episodes: Therapeutic Advances and Their Impact on Risk and a copy of the grant request for the Program is attached hereto as Exhibit A.
2. Type of Program. The Program is:
  - ☒ accredited (e.g., continuing medical education or "CME"); or
  - ☐ an independent program where CE credits will not be offered.
3. IEP Provider. The IEP Provider is the following type of entity:
  - ☒ Accredited continuing medical education provider
  - ☐ University/Hospital
  - ☐ Professional Organization
  - ☐ Medical Education Company
4. Educational Partner. The IEP Provider ☐ shall ☒ shall not use a third party that will provide assistance in support of the Program ("Educational Partner").





5. Educational Components. The expected components of the Program (e.g., number of live meetings, CD ROM, web-based, etc.) are as follows:

- (a) Live Symposia;
- (b) MobileCME educational modules hosted via Epocrates software and delivery system;

6. Program Purpose. The Program is for scientific and educational purposes only and is not intended to promote a Cephalon product directly or indirectly. The Program is not a repeat performance of a prior program.

7. Grant Amount Funding Arrangements.

- (a) Cephalon will provide support for the Program by means of an educational grant in the total amount of \$246,110. If the Program is canceled or terminated prior to completion, IEP Provider shall return the grant, or any unused portion thereof, to Cephalon within thirty (30) days of such termination or cancellation. IEP Provider shall have full responsibility for all funding arrangements of the Program, including any funding to be provided to IEP Provider's Educational Partner. Payment of the grant shall be made in accordance with a schedule agreed to by the parties. All payments due hereunder shall be made by Cephalon within forty-five (45) days of its receipt of an invoice for same, provided IEP Provider is in compliance with the terms of this Agreement.
- (b) Within thirty (30) days of completion of the Program, IEP Provider shall provide Cephalon with a detailed reconciliation of actual out-of-pocket expenses incurred, and to the extent Cephalon has overpaid IEP Provider for same, IEP Provider shall provide a refund to Cephalon within thirty (30) days thereafter. Such detailed reconciliation shall be forwarded to Cephalon at the address above to the attention of Rod J Hughes, Ph.D., Vice President, Scientific Communications.
- (c) IEP Provider may not use funds provided by Cephalon to pay travel, lodging, honoraria or personal expenses for non-faculty attendees. Grant funds may be used to reduce the overall registration fees for attendees. Grant funds may not be used to purchase capital equipment or to provide general operational support for an institution. Funds for hospitality shall not be provided except that funds may be used for modest meals or receptions that are held as part of the Program, but such events shall not compete with nor take precedence over educational events. The appropriateness of any reception shall be at the sole discretion of the IEP Provider, and IEP Provider shall have final decision making authority in connection with any such activities.
- (d) Funds may be used by the IEP Provider to permit medical students, residents, fellows or other health care professionals in training to travel to and attend the Program; provided, however, that the selection of such



students, residents or fellows who receive funds is made by either the academic or training institution or, if by the IEP Provider, such selection shall be made with the full concurrence of the academic or training institution.

- (e) In accordance with the Accreditation Council for Continuing Medical Education ("ACCME") Standards and to assist Cephalon in complying with its internal auditing procedures, IEP Provider agrees to verify the manner in which the grant is used. Accordingly, within thirty (30) days following a request from Cephalon, IEP Provider shall provide to Cephalon:

- i. A written statement verifying that the Program occurred, and
- ii. An itemized list of expenditures supported by the grant.

- 8. Objectivity and Balance. IEP Provider shall retain full responsibility for control of the content of the Program and shall ensure that the following requirements are met:

- (a) The Program material/information will be objective, balanced and free from commercial bias. All topics shall be treated in an impartial, unbiased manner. All discussions shall include a range of views about each class of drug and disease treatment options. Information shall not unfairly represent a spectrum of views favoring a product or class of products marketed by Cephalon or any other company. The title of the Program will fairly and accurately represent the scope of the presentation.
- (b) IEP Provider agrees that neither Cephalon nor its agents shall control the content of the Program. IEP Provider agrees that there will be no scripting, targeting of points for emphasis, or other activities by Cephalon or its agents that are designed to influence the content of the Program. If requested in writing by the IEP Provider, medical/scientific representatives from Cephalon may attend content development meetings or other planning meetings, for the purpose of addressing any scientific inaccuracies they observe. Personnel from Cephalon must not discuss or in any way attempt to control (either during the meeting or at breaks or meals), the content of the program. An appropriate medical/scientific representative from Cephalon may provide a presentation at a content development meeting at the request of the provider, or may respond to specific questions at such meeting regarding the results of a Cephalon-sponsored research study, provided the information presented conforms to the generally accepted standards of experimental design, data collection and analysis, and provided any presentation is accompanied by a detailed outline of the presentation, which can be used by the IEP Provider/Educational Partner to confirm the scientific objectivity of the presentation.
- (c) If the IEP Provider, in its sole discretion, requests a Cephalon medical representative to review the Program for medical accuracy and





completeness, Cephalon will comply with such request. The parties acknowledge there is no obligation or any condition requiring IEP Provider to make such a request. Any such request must be made after the Program materials are fully developed and such request must be made by the IEP Provider only to a Cephalon medical representative that has responsibility for the therapeutic area that will be covered by the Program. IEP Provider will not ask any marketing or sales representatives at Cephalon to comment on the material. All final decisions regarding whether to modify the material based on any comments provided by the Cephalon medical representative shall be in the sole discretion of IEP Provider.

- (d) If a product marketed by Cephalon is the subject of discussion, the data will be objectively selected and presented, with an accurate reflection of favorable and unfavorable information about the product and shall also include a balanced discussion of prevailing information on alternative products and /or therapies.
  - (e) Any suggestions of superiority of one product or treatment over another will be supported by the body of available data, and will not result from selective presentation or emphasis on data favorable to particular treatment.
  - (f) IEP Provider represents that neither it nor the Educational Partner (if any) has either an open complaint or decision from the ACCME or the Food and Drug Administration that a program provided by the IEP Provider or the Educational Partner failed to meet standards of independence, balance, objectivity, or scientific rigor.
9. Risk Minimization Action Plan. Cephalon provides the following Risk Minimization Action Plan ("RiskMAP") information to all IEP Providers. Neither Cephalon nor its agents shall influence or control whether a product marketed by Cephalon is the subject of discussion. A RiskMAP is a strategic safety program designed to meet specific goals and objectives in minimizing known risks of a product while preserving its benefits. Any product marketed by Cephalon that is approved with a RiskMAP, and the key safety-related health outcomes outlined in that RiskMAP, are listed in Exhibit B. IEP Provider agrees that it is aware of the RiskMAP(s) and the key safety messages.
10. Faculty Selection. IEP Provider shall retain full responsibility for the selection of the presenters, authors, moderators, and/or other faculty (hereinafter referred to collectively as "Faculty"). Cephalon, through its Scientific Communications Department, may respond only to IEP Provider-initiated, written requests (or requests from the Educational Partner) for suggestions of Faculty or sources of possible Faculty. In response to such requests at least three (3) names will be suggested (if possible) for each open position and this information will be provided in writing. IEP Provider will record the role of Cephalon in suggesting Faculty; will seek suggestions from other sources; and will make its selection of Faculty based on objective criteria. IEP Provider shall not be obligated to





request or accept such assistance from Cephalon or its agents as a condition of receiving the educational grant hereunder.

11. Disclosures. IEP Provider will ensure meaningful disclosure of limitations of data (e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion). IEP Provider will require that Faculty disclose when a product is not approved in the United States for the use under discussion.
12. Question and Answer Session. To the extent the Program is a presentation, IEP Provider will ensure meaningful opportunities for questioning by the audience.
13. Financial Relationships. IEP Provider will ensure meaningful disclosure to the audience of Cephalon funding and any significant relationship between individual Faculty and Cephalon. All meaningful disclosure(s) shall also be made in any written materials, including but not limited to announcements, brochures, syllabi and enduring material. Disclosures shall not mention product trade names.
14. Metrics/Copies of Program Material.
  - (a) IEP Provider and/or Educational Partner shall provide certain outcome measurements and metrics to Cephalon as requested by the Scientific Communications Department. Such metrics shall be provided either after the conclusion of a single live event or monthly for a year-long accredited program and may at Cephalon's request include the number of program participants, number of certifications, assessment of the program and faculty, and demonstration of learning by program participants.
  - (b) After the Program has occurred, IEP Provider shall provide Cephalon with 5 copies of all Program materials in CD ROM or electronic format and 20 copies in print format.
15. Representations and Warranties. IEP Provider represents that:
  - (a) Neither it nor the Educational Partner, if any, provides marketing, advertising, public relations, market research, medical education services or other consulting services (e.g., support for advisory boards) to any other department within Cephalon ("Marketing Activities");
  - (b) If IEP Provider or the Educational Partner has an affiliated company that provides Marketing Activities to Cephalon, IEP Provider has instituted appropriate controls and safeguards to ensure the Program (i) remains independent, objective, balanced and scientifically rigorous, (ii) is not intended to promote a Cephalon product directly or indirectly, and (iii) is not in any way biased due to the affiliated company's relationship with Cephalon;
  - (c) IEP has determined that it is appropriate to use the Educational Partner in light of the requirements under this Agreement; and



- (d) If IEP Provider or its Educational Partner employs a former Cephalon employee who worked at Cephalon anytime during the most recent year and who had marketing responsibility in the therapeutic area that will be covered by the Program, then that former employee will not have any role in the planning, development or delivery of the Program.
16. Invitations/Enduring Materials. The Program audience will be selected by the IEP Provider. The IEP Provider shall be responsible for distributing materials about the Program, including invitations, reminder notices, and business reply cards that can be used by third parties to obtain any enduring Program material from the IEP Provider.
17. Ancillary Promotional Activities. To the extent the Program is a live presentation, no promotional activities or product advertisements will be permitted in the same room as or in an obligate path to the Program. If the Program is a teleconference or webcast, no product advertisements or promotional activities will be permitted immediately prior to, during, or immediately after the delivery of the Program. If the Program is in print format, no product advertisements or promotional materials will be interleaved within the pages of the Program. If the Program is made available electronically, no product advertisements or promotional materials will appear within the Program material or interleaved between computer windows or screens of the Program.
18. Compliance with Guidelines. IEP Provider represents that the Program, including development of the Program and Program materials, shall conform to the American Medical Association ("AMA") Guidelines on Gifts to Physicians, the AMA Ethical Opinion on Continuing Medical Education, the ACCME Standards for Commercial Support, the FDA December 3, 1997 Final Guidance for Industry-Supported Scientific and Educational Activities, and the Pharmaceutical Research and Manufacturers Association ("PhRMA") Code on Interactions with Healthcare Professionals.
19. Logistical Status Reports. IEP Provider and/or Educational Partner shall provide periodic reports to Cephalon regarding the management and logistics of program components.
20. Miscellaneous.
- (a) No party shall use the other party's or its affiliates' name or trademarks for publicity or advertising purposes, except with the prior written consent of the other party.
  - (b) IEP Provider agrees to obtain all consents, authorizations, approvals and releases that may be necessary for the production of the Program and of any written materials prepared in connection therewith. IEP Provider agrees to indemnify Cephalon with respect to any claims, actions or demands, including reasonable attorneys' fees that may arise in any manner out of IEP Provider's failure to secure such consents, authorizations, approvals or releases.



- (c) No term, condition or other provision of any attachment or addendum to this Agreement shall supersede any term, condition or other provision of this Agreement and with respect to any inconsistency or ambiguity, the Agreement shall control.

IN WITNESS WHEREOF, the parties, by their duly authorized representatives, agree to comply with all the terms and conditions of this Agreement.

**MEDICOM WORLDWIDE, INC.**

By: Joan Meyer  
Name: JOAN MEYER  
Title: Executive Director  
Continuing Education  
The above signatory is a duly authorized corporate officer of the IEP Provider.

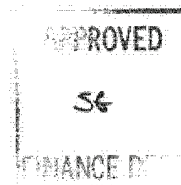
Date: 12/6/2006

Tax ID #: 23-3063738

**CEPHALON, INC.**

By: RJ Hughes  
Name: Rod J. Hughes, Ph.D.  
Title: Vice President, Scientific Communications

Date:





MediCom Worldwide, Inc.

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October 31, 2006

Bhaval Shah-Bell, PhD  
Cephalon, Inc.  
41 Moores Road  
Frazer, PA 19355

Dear Dr. Shah-Bell:

As an accredited provider of continuing medical education, MediCom Worldwide, Inc. has recently completed a comprehensive needs assessment to identify the educational needs of health care professionals in the field of pain management.

Based on the identified educational need, MediCom is requesting an educational grant from Cephalon, Inc. to support the development of a live symposium in conjunction with the International Association of Pain and Chemical Dependency Conference to be held June 21-24, 2007 in New York City. In addition to the live program, MediCom is requesting additional funding to provide enduring material support initiatives resulting from the content developed for the live meeting in order to maximize the reach to physicians throughout the United States. The activities described in this proposal include:

1. Live symposia
2. MobileCME educational modules hosted via Epocrates software and delivery system

The total grant request to fund these activities is \$246,110; please refer to the detailed budget section of this proposal for complete grant funding details of the individual educational initiatives.

These scientific events will comply with all OIG, PhRMA, FDA, and ANCC regulations for industry-supported professional continuing education.

Thank you in advance for your consideration of this request.

Respectfully,

A handwritten signature in cursive script, appearing to read 'Joan Meyer'.

Joan Meyer  
Executive Director, Continuing Education

MediCom Worldwide, Inc.  
101 Washington Street • Morrisville, PA 19067 • 215-337-9991

Confidential

Page 2

## MediCom Worldwide, Inc.

## Needs Assessment

*Overview*

The National Pain Foundation suggests that more than 75 million Americans experience chronic pain with an associated annual cost of approximately \$100 billion in medical expenses, lost wages and lost productivity.<sup>1</sup> The high prevalence of chronic pain, combined with its enormous cost, make unrelieved pain a huge public health problem.

The 1999 JCAHO guidelines for management of pain were one of the first steps toward the United States congressional mandate for a decade of pain control and research (2000-2010) meant to increase awareness of chronic pain and treatment requirements for health care providers.<sup>2,3</sup> Although health care providers are becoming better educated about the *science* of pain management, an educational void still exists on how to *care* for the chronic pain patient population.<sup>4,5</sup> In light of this void, continued federal congressional support for pain research initiatives, conducted by the National Institutes of Health, is expected to be approved by the Senate prior to January 1, 2007.<sup>1</sup>

Chronic pain is persistent, multifactorial, often intractable, and affects multiple health domains. Patients' responses to chronic pain and therapies are highly individualized. The most common types of chronic pain are backaches, headaches, and arthritis; although many other types of chronic pain exist, such as neuropathic pain and fibromyalgia. Chronic pain impacts and compromises the patient's normal ability to function physiologically, psychologically and socially, negatively affecting overall quality of life.<sup>6</sup>

Either a multi- or interdisciplinary care model is considered one of the preferred methodologies to assess and treat chronic pain comprehensively. Accurate assessment and monitoring of pain and comorbidities using validated diagnostic tools help to stratify patients and determine individualized therapeutic plans.<sup>7</sup>

Frequently, patients with persistent pain types experience relatively short episodes of worsening pain which is referred to as breakthrough pain. Breakthrough pain is abrupt, short-lived and intense. It presents as a painful episode or episodes in patients with otherwise stable, persistent baseline pain. Assessment is critical to determine the existence of breakthrough pain, as inadequate persistent pain therapy may confuse the diagnosis. Chronic baseline pain must be assessed as stable before a diagnosis of breakthrough pain can be confirmed. The characteristics of breakthrough pain require a therapeutic approach that is different from the ones usually prescribed to patients with persistent pain.<sup>8</sup>



Chronic pain is considered undertreated or inappropriately treated. Inadequate treatment may be attributed, in part, to the clinician's lack of recognition of breakthrough pain. Breakthrough pain may be incidental (predictable, unpredictable), idiopathic, or related to end-of-dose. Breakthrough pain (BTP) adds significantly to the existing burden of chronic pain in terms of both health domains and economic impact. Proper assessment and diagnosis of both chronic and breakthrough pain is essential for adequate and appropriate treatment.<sup>8</sup>

Barriers to treatment, whether as a result of the patient, physician or health care/insurance system, are necessary to understand in order to circumvent successfully. Understanding therapeutics, both pharmacologic and nonpharmacologic, and their applications also help to restore functionality for the chronic pain patient across all health domains, restoring or improving quality of life.<sup>8</sup>

#### *An Educational Need*

As the therapeutic specialty of pain management rapidly evolves, it is critical for practitioners who treat patients in pain to fully understand the latest research and improvements in assessment and management of chronic pain and breakthrough pain.

It is evident through reviews of survey results, expert opinion, guidelines, research and publications, that pain management practitioners require medical education to better understand the complexities and subtle nuances of the physiology of pain, types of pain, therapeutic options, patient assessment and therapeutic management. The potential benefits of continued education are improved patient care and outcomes.

#### *Surveys*

In June 2005, it was reported that 60% of 303 participants in an American Pain Foundation (APF) *Voices of Chronic Pain* survey claimed to experience BTP one or more times daily, severely impacting the quality of their life and overall well-being.<sup>9</sup> Will Rowe, executive director of the APF in Baltimore, was reported as stating, "Although medical solutions exist to relieve or ease pain, the reality is that most pain goes untreated, undertreated or improperly treated, with millions of patients suffering in silence."<sup>9</sup> The *Voices of Chronic Pain Survey* also found more than three-quarters (77%) of patients surveyed said they are looking for new options to treat their pain. Only 14% of those surveyed reported that they were satisfied with their current medications and less than half (48%) of respondents felt they were currently getting enough information on the most effective ways to manage chronic pain. It is estimated that only one in four patients received adequate treatment for their pain.<sup>10</sup>

Results from a 2005 survey of chronic pain patients in Ohio demonstrated that 20% of the respondents reported to the emergency department within the previous six months for BTP, suggesting that their pain was not being managed appropriately.<sup>11</sup> The increased utilization of emergency departments as a substitute for outpatient pain management, resulting in increased and prolonged hospital admissions, is not a cost-



effective solution and indicates that education may be necessary in order to achieve practice improvement.

Table 1 from the Ohio survey demonstrates the support or information desired by the survey respondents with chronic pain. Almost 40% did not know what they needed. Ten percent requested better access to and more effective pharmacotherapy.<sup>11</sup>

Table 1<sup>a</sup>

Support or information desired (n=100)	% of respondents
Pain medications (better access, more effective drugs)	10%
Information about disease, new research and techniques	8%
Surgery	7%
Nothing will help / have learned to live with it	7%
Better access to physicians / access to better physicians	6%
More opportunities for physical therapy, exercise	5%
More support or understanding (from family and/or doctors)	5%
Find a cure	5%
Financial assistance (to seek therapy or purchase insurance)	4%
Make more (alternative) treatments available	3%
Assistance with transportation difficulties	2%
Ability to quit working	1%
Other	3%
NA – no obstacles, no pain	8%
Don't know	36%

Note: Because multiple responses were allowed, percentages may not sum to 100.

Nearly one-half of the respondents in a 2004 APF survey entitled *Americans Living with Pain* reported that their pain is not under control. These reports were especially true in patients with ever-present pain, in men, and in patients of middle age.<sup>12</sup>

A recent survey, conducted at Beth Israel, New York City, reported recruitment of 228 patients with diverse types of chronic noncancer pain from nine (9) pain programs who were administered a telephone questionnaire with a breakthrough pain assessment algorithm originally designed for cancer patients. All patients had controlled baseline pain, and 168 (74%) experienced severe to excruciating BTP with a total of 189 different types reported. The median number of episodes per day was 2 (range <1 to 12) and median time to maximum intensity was 10 minutes (range 0 to 180 minutes). Median duration of the breakthrough pain was 60 minutes (range 1 to 720 minutes). Patients identified a precipitant for 69% of pains, and 92% of these were activity related. Onset could never be predicted for 45% of pains and only sometimes predicted for 31% of pains. The authors concluded that BTP is highly prevalent and varied in this population.<sup>13</sup>

Survey results suggest that BTP is not managed appropriately; is costly, challenging, and debilitating to the patient.

*Expert Opinion*

*Raymond Sinatra, MD, PhD - Director Inpatient Pain Management Services, Yale University School of Medicine.*

"Clearly pain is undertreated in many hospitals. As a baseline, physicians are taught very little about the assessment or management of pain in their medical training. In 2001, the Joint Commission on Healthcare Accreditation (JCAHO) enacted a series of guidelines aimed at improving pain management in hospitals, nursing homes, rehabilitation centers and ambulatory medical facilities. JCAHO mandated that health care practitioners be educated about pain scales, analgesic medications and nonpharmacological techniques for pain control."<sup>11</sup>

*Daniel Bennett, MD - Assistant Clinical Professor of Anesthesiology and Pain Medicine at the University of Colorado.*

"Some physicians rely on laboratory data/objective physical findings and such, I believe you miss the mark in pain treatment by focusing only on these traditional (ie, allopathic) approaches. This is not to say that we should not use these in the definition of structural pathology (one would be remiss to not do this). We cannot directly measure pain, and thus what we observe is the summation of how the particular pain signal (ie, stimulus) affects the individual person (ie, pain behavior). Obviously, what is presented to us is the summation of the layering of the supratentorial processes that make us individual as human beings."

"Therefore, my philosophy in treating people who live with pain is to recognize their individuality, and incorporate what I understand of pathophysiology with the effects to them as a person. This allows the individual direction of care to optimize the functional outcome, which I believe is the most important determinate in successful treatment."<sup>12</sup>

*Donald R. Taylor, MD – a board certified anesthesiologist and pain medicine physician in private practice in Marietta, Georgia.*

"The shift from the PRN pain management model to a model based upon around-the-clock dosing with breakthrough pain (rescue) medications represents a shift from an old to a new pain treatment paradigm."<sup>13</sup>

*Lynn Webster, MD, FACPM, FASAM – Medical Director, Lifetree Pain Clinic; Medical Director and CEO, Lifetree Clinical Research, Salt Lake City, Utah.*

"According to the 2003 National Survey on Drug Use and Health, new nonmedical users of pain relievers more than quadrupled during the 10-year period of the 1990s. Many of these first-time users are young people. Substance abuse is a leading cause of preventable illness and death in the United States, and opioid analgesics are among the most frequently abused prescriptions. To

keep opioids available to treat pain, as we must, doctors who treat pain are called on to help prevent abuse and addiction, too."<sup>14</sup>

*Joyce Lowinson, MD – Professor Emeritus of Psychiatry, Albert Einstein College of Medicine, Bronx, New York, Adjunct Faculty, The Rockefeller University, NY, NY*

"Undertreatment of pain is a global public health problem. Pain is the complaint that brings the highest percentage of patients to their doctor's offices. There have been great strides in understanding in recent decades in the treatment of pain, yet the problem remains."<sup>15</sup>

The experts acknowledge that pain assessment and management models are changing, while misuse of opioid is on the rise. Practitioners need continuing education in pain assessment and management, including risk minimization through patient assessment and monitoring.

#### *Research and Publications*

The Cochrane Collaboration recently published their "Evidence-based Pain Management and Palliative Care" in Issue One for 2006 of the Cochrane Library. This edition of the Library contains 83 new reviews of which the three have potential relevance for practitioners in pain and palliative medicine.<sup>19</sup>

A study authored by Stillman, Cleveland Clinic, addresses new advances in the treatment of neuropathic pain.<sup>20</sup>

Spacek authored a recent article about inadequate and/or inconsequential pain therapy and the importance of selecting appropriate therapies.<sup>21</sup>

Several studies published in 2006 underscore the growing problem of opioid abuse in America.<sup>22-24</sup> Educational programs designed to address the growing risk, to demonstrate tools that can help assess and monitor patients for risk of misuse, and yet emphasize the need to treat chronic pain patients adequately will help clinicians minimize the individual and public risk associated with prescription opioids.

#### *Educational Recommendations*

There appears to be continuing need for education surrounding chronic pain, including episodic BTP. The accompanying social responsibilities required to limit opioid misuse must also be addressed. A recent publication by Bennett et al supports that breakthrough pain is identified as an important clinical problem commonly experienced by patients with chronic pain. Teaching clinicians how to balance adequate treatment with risk minimization and patient monitoring practices will help alleviate fears associated with prescribing opioids. Key objectives for practitioners to be aware of in treating patients with chronic pain are aimed at individualizing treatment, maximizing outcomes by improving functionality for the patient, and minimizing potential risk.



*Key Points*

- Chronic pain is a public health challenge; recognized as such by the federal government
- Chronic pain is inadequately or undertreated; an estimated 19%-95% of all patients with pain experience breakthrough pain depending on the population surveyed and the definition of breakthrough pain used
- Breakthrough pain is unpredictable and often different for each individual
- Treatment barriers need to be identified and overcome
- Holistic therapy includes both pharmacologic and nonpharmacologic options
- Risk management is a critical feature of controlled-substance prescribing

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MediCom Worldwide, Inc.

Program Summary



**Program Title:**

***Opioid Therapy in Chronic Pain with Breakthrough Episodes:  
Therapeutic Advances and Their Impact on Risk***

**Program Objectives:**

*Upon completion of this activity, participants should be able to:*

1. Summarize advances in understanding and management of chronic pain
  - a. Distinguish features, types and definition of pain; chronic and BTP
  - b. Recognize BTP in your patients
  - c. Identify tools, questions and communication techniques that are designed to improve patient/health care provider dialogue
  - d. Outline current guidelines available which impact management of chronic pain
2. Identify options in therapeutic selection both pharmacologic and non pharmacologic which may be prescribed after stratifying patients for different types of pain and risk levels
3. Outline effective clinical strategies and monitoring protocols for preventing abuse and diversion while effectively managing patients in pain



**MediCom Worldwide, Inc.****Program Summary****Faculty:****Russell K. Portenoy, MD**

Chairman, Department of Pain Medicine and Palliative Care  
Beth Israel Medical Center  
New York, New York

**Lynn Webster, MD**

Medical Director, Lifetree Pain Clinic  
Medical Director and CEO, Lifetree Clinical Research  
Salt Lake City, Utah

**Targeted Audience:**

Health care professionals specializing in the treatment of pain and addiction medicine in attendance at the 7th Annual Conference on Pain and Chemical Dependency.

Target participation: 250 attendees

**CE Provider:**

The educational activity will be accredited by MediCom Worldwide, Inc. MediCom Worldwide, Inc. is a fully accredited provider of:

- CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each activity within the series will be accredited for a maximum of 1.5 AMA PRA Category 1 Credits™.
- CPE credit for pharmacists by the Accreditation Council for Pharmacy Education (ACPE). Each activity will be approved for 1.5 contact hours of Continuing Pharmacy Education.
- CNE credit for nurses by the California State Board of Registered Nursing. Each activity will be approved for 1.5 contact hours.

## MediCom Worldwide, Inc.

### Program Overview



#### Targeted Audience:

Health care professionals specializing in the treatment of pain and addiction medicine in attendance at the 7th Annual Conference on Pain and Chemical Dependency.

Target participation: 250 attendees

#### Format:

Live symposia held in NYC in conjunction with the IAPCD Conference. The live event will consist of live didactic presentations delivered by two clinical experts in the field of pain management. Topics to be addressed will be focused on assessment, diagnosis and treatment of chronic pain, as well as identification of risk assessment tools and treatment strategies to employ in the practice setting.

Post-live event final content will be edited to allow for additional enduring self-study adaptation. The live activity will be subdivided into two distinct 30 minute educational modules and will be adapted for distance learning activities via personal PDA systems utilizing software developed and distributed by Epocrates MobileCME platforms.

#### Distribution/Invitation Process:

##### Live Event

The live symposium will be announced and promoted through the use of approximately 10,000 printed invitations via direct mail to identified target audience related to the IAPCD conference. A second mailing of approximately 650 to all those pre-registered to attend the conference.

##### Request for Sponsor Support Live Event

As a supplement to these primary methods, MediCom Worldwide, Inc. may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of MediCom and any such distribution will solely be as a supplement to MediCom's primary methods of announcement and promotion.

##### Enduring Material

###### *Epocrates Distribution Plan*

Epocrates will distribute educational content through Epocrates proprietary MobileCME system to Epocrates subscribers. Hosting period of the activity will continue 12 months post-launch of the activity.

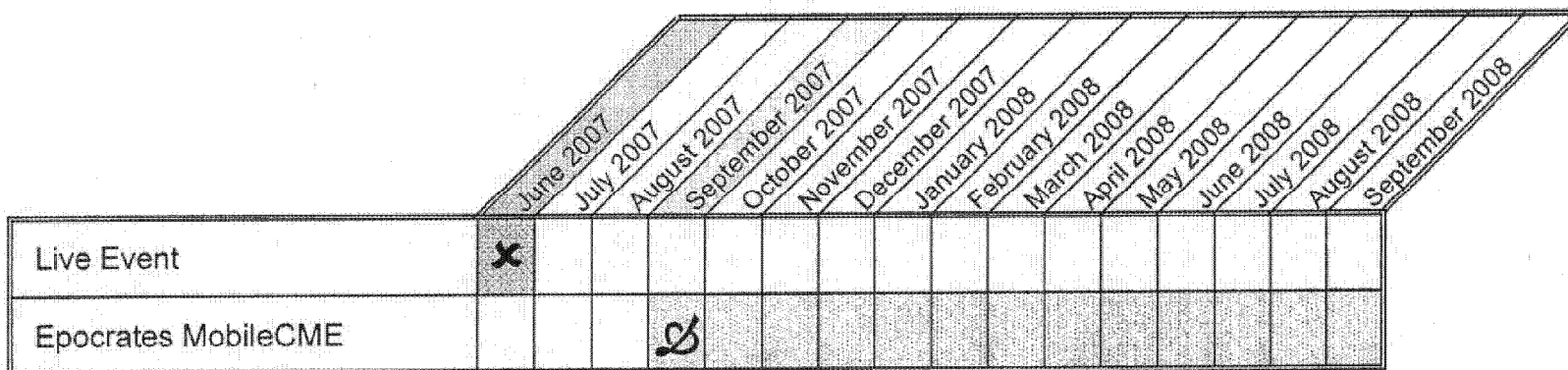
##### Target date of launch

Activity will launch via MobileCME no less than 60 days post-live event and will maintain accreditation throughout the 12-month hosting period.



# IAPCD Satellite Symposium Activity Timeline

2007



Live Satellite Symposium during ICPCD, June 21 to 24, 2007



Epocrates MobileCME release date, September 15, 2007



**MediCom Worldwide, Inc.****Program Overview****MediCom Worldwide, Inc. Policies:****Conflict of Interest Identification and Resolution**

MediCom Worldwide, Inc. is in full compliance with all rules and regulations put forth by the ACCME in the revised Standards for Commercial Support. MediCom has defined all those in position to control content as faculty, authors, presenters, planning committee members and all those internal staff who are in position to write, alter or impact the content of a CME activity.

All members identified in the planning process must provide signed disclosures to MediCom prior to the planning of the activity.

When individuals in a position to control content have reported Financial Relationships with one or more commercial interests, MediCom works with them to resolve such conflicts to ensure that the content presented is free of commercial bias. The following mechanisms have been identified in which to resolve conflicts as identified:

- Peer review of content by external reviewer
- Content validation by external topic expert and internal MediCom clinical editorial staff

**MediCom Worldwide, Inc. Disclosure Policy:**

(Attachment A)

**MediCom Worldwide, Inc. Content Development Policy:**

(Attachment B)

**MediCom Worldwide, Inc. Faculty Selection Policy:**

(Attachment C)

## MediCom Worldwide, Inc.

## Program Overview

**Post-Activity Reporting:**

Course evaluation forms will be required for all participants who seek to receive continuing education credit. MediCom will summarize the information collected in a formal report to evaluate program effectiveness and participant learning.

Participants will evaluate the following components:

1. Overall content
2. Faculty teaching effectiveness
3. Format
4. Usefulness of information
5. Relevance to practice setting
6. Fair balance
7. Impact to the care of the patient experiencing pain

In addition to rating scales, participants will be asked to participate in pre-/post-testing scenarios as a measurement of learning. Learning will be analyzed based on self-reported changes in knowledge or perceptions by the participants as a result of this activity, and how well he or she will be able to apply learning to a specific practice setting.

MediCom Worldwide, Inc.  
Budget Summary and Options



**Budget Summary Overview**

**IAPCD Accredited Satellite Symposium Plus Enduring Material Option  
Proposal Overview**

Tactic	Description	Expected Outcome	Proposed Budget	
Satellite symposium at 2007 IAPCD conference	Two-speaker accredited live symposium	250 conference attendees	Direct Costs	\$75,935
			Indirect Costs	\$ 44,625
			<b>Total</b>	<b>\$120,560</b>
Symposium adaptation: two independently accredited modules based on content from live activity	1.5 hour symposia edited to allow for two 30 minute educational modules based on content provided at live event	2 MobileCME broadcasted events based on content from live event  Minimum guarantee of 600 CME completions per activity	Direct Costs	\$ 112,800
			Indirect Costs	\$ 12,750
			<b>Total</b>	<b>\$ 125,550</b>



MediCom Worldwide, Inc.  
 101 Washington Street  
 Morrisville, Pennsylvania 19067

**Satellite Symposium in conjunction with the 7th International Pain and Chemical Dependency Conference**

<i>Program Parameters</i>	
Accreditation Hours	1.5
Faculty	2
Symposium Attendees	250
Direct mail invitations to health care professionals	4,000

<i>Cost Summary</i>	
Approximate Total, Direct Expenses	\$ 75,935
Total, Indirect Expenses	\$ 44,625
Chronic Pain Today: Addressing the Challenges; Defining the Treatment	\$ 120,560

Approval Signature

Date

Note: no work may begin until MediCom receives, via email or fax, this approval with signature and date

Confidential

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MediCom Worldwide, Inc.  
101 Washington Street  
Morrisville, Pennsylvania 19067

**Satellite Symposium in conjunction with the 7th International Pain and Chemical  
Dependency Conference**

<i>Direct Expenses, Approximate</i>	
IPCD Admin Fee	\$ 25,000
Direct mail invitations Direct mail invitations, mailed to registered meeting attendees; includes printing, development of database email homepage for registration	\$ 5,750
Direct mail list purchase	No charge
Mail Services, postage, phone, fax, email registration	\$ 1,560
Includes assembly, mail services and postage. Follow up recruitment per phone, fax, email	
Invitation door-drop/advertisement fee	\$ 5,000
Participant handouts Includes printing of participant workbook; will include accreditation information, speaker biographical and disclosure information, agenda, and symposium graphics; total quantity 225 color copy	\$ 5,250
Posters advertisement materials	\$ 2,400
Faculty expenses	
Honoraria:	
MD Expert (2)	\$ 4,500
Meal expense faculty	\$ -
Ground transportation	\$ 75
Room Rental	No charge
Catering 250 X \$85 pp	\$ 21,250
Audio/visual services: Including digital audio record	\$ 4,000
MediCom expenses	
Accommodations	\$ 800
Meals	\$ 150
Ground transportation	\$ 125
Shipping/Fed Ex	\$ 75
<b>Approximate Total, Meeting Management Direct Expenses</b>	<b>\$ 75,935</b>

<i>Indirect Expenses</i>	
MediCom pre-meeting coordination and development Includes faculty recruitment, agenda coordination, coordination with association; coordination with venue; participant recruitment; coordination of filming of patient video case study equipment rental:	\$ 25,000
Development Editorial	\$ 2,500
Includes presentation slides x2 faculty approx 90 slides; editorial content review; reference and fact checking; design and format	
MediCom on-site symposium coordination; 2 MediCom staff	\$ 1,800
Graphic design	\$ 1,250
Accreditation of program for CME; includes distribution of ce certificates	\$ 10,000
Database development; record tracking	\$ 775
Project management	\$ 3,500
<b>Total, Indirect Expenses</b>	<b>\$ 44,025</b>



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 101 Washington Street  
 Morrisville, Pennsylvania 19067

### Online Adaptation from Live Symposium Hosted as MobileCME via Epocrates

#### Program Description

This proposal is for adaptation of a live symposium accredited for self study via MobileCME through Epocrates mobile medical software. The 90 minute live program will be formatted into two separate thirty minute educational modules to be posted for credit post live activity. Each faculty presentation and topic will be tailored to meet the specifications for mobile posting

<i>Cost Summary</i>	
Approximate Total, Direct Expenses	\$ 112,800
Total, Indirect Expenses	\$ 12,750
<b>Cost of One Self-Study Multi-Media Online Program Adapted from Live Symposium</b>	<b>\$ 125,550</b>

Approval Signature

Date

Note: no work may begin until MediCom receives, via email or fax, this approval with signature and date

Confidential

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MediCom Worldwide, Inc.  
 101 Washington Street  
 Morrisville, Pennsylvania 19067

### Online Adaptation from Live Symposium Hosted as MobileCME via Epocrates

#### Detailed Budget Itemization

<i>Direct Expenses, Approximate</i>	
Transcription	\$ 800
Speaker honoraria: post-symposium interviews	\$ 2,000
Epocrates Hosting Fee (includes fees for two 30 minute programs)	\$ 110,000
<i>Approximate Total, Direct Expenses</i>	<i>\$ 112,800</i>

<i>Indirect Expenses</i>	
Program Development	\$ 5,000
Includes creation of graphic user interface; coordination with activity specifications from Epocrates technical team; coordination with speaker for final review; Medical review and editing of live activity. 90 minute activity will be subdivided into two 30 minute educational modules	
Accreditation of program for CME; includes both 30 minute modules; Fees include a guarantee from Epocrates for a minimum of 600 CME certificates per accredited activity	\$ 5,000
Data management	\$ 750
Includes management of participant database, data analysis, quarterly reports, final summary report	
Project management	\$ 2,000
<i>Total, Indirect Expenses</i>	<i>\$ 12,750</i>

# MediCom Worldwide, Inc.

## Budget Summary and Options



<b>Budget:</b>	
<b>Live Activity:</b>	<b>\$120,560</b>
<b>Epocrates Activity:</b>	<b>\$125,550</b>
<b>(Inclusive of two independent 30 minute activities)</b>	
<b>Total Budget:</b>	<b>\$246,110</b>

### **Budget Reporting and Reconciliation:** ***Appropriate Use of Commercial Support:***

- a. Funds should be in the form of an educational grant made payable to MediCom Worldwide, Inc.
- b. No other funds from Cephalon, Inc. will be paid to the program director, faculty, or others involved with the CE activity (additional honoraria, extra social events, etc).
- c. MediCom Worldwide, Inc. will furnish the commercial interest with documentation detailing the receipt and expenditure of the commercial support within 90 days of activity completion.

### **Payment Structure:**

<b>50% due upon signing of agreement:</b>	<b>\$123,055</b>
<b>Final 50% due June 1, 2007:</b>	<b>\$123,055</b>





### Standard Operating Procedures

<b>Manual</b>	Department of Continuing Education Policy and Procedure	<b>Policy Number</b>	<b>II-203</b>
<b>Subject</b>	Disclosure	<b>Date of Origin</b>	March 2003
<b>Approved By</b>	Joan Meyer	<b>Revision Date</b>	March 2005
<b>Signature</b>		<b>Approval Date</b>	May 2005

### Purpose

The policy on disclosure exists to provide guidance for staff, faculty and joint/co-sponsors of the requirement to disclose specific information to participants in order to comply with the following standards for all activities sponsored by MediCom Worldwide, Inc.: ACCME's 2004 Updated Standards for Commercial Support; ACPE's Criteria for Quality and Interpretive Guidelines; California Board of Registered Nursing Standards and Guidelines. This includes (a) sponsor financial relationships, (b) faculty and family/significant others financial relationships, (c) discussion of unlabeled or unapproved uses of drugs and devices. As an approved provider, MediCom Worldwide, Inc. is required to collect information from individuals who have an opportunity to affect the CE content about products or services of a commercial interest with which he/she has a financial relationship to allow a determination to be made as to whether that relationship may constitute a conflict of interest that must be resolved.

### Policy

1. Disclosure documents must be completed by anyone involved in planning or presenting educational content at CE programs approved for CME/CPE/CNE inclusive of MediCom advisory committee members, clinical content reviewers and identified faculty members.
2. MediCom Worldwide, Inc. requires all those in a position to control content to provide specific information to CE participants.
3. MediCom requires faculty to provide specific information to CE participants. Disclosure is required in two areas:
  - Financial Relationships - Faculty must disclose any significant relationship between themselves/significant others and (a) the commercial supporter(s) of the program, and (b) the manufacturer of any product discussed in the CE program or related to the topic of the event. Information reported shall include financial relationships in place over the preceding twelve-month period. If the faculty has nothing to report, that information must be indicated.
  - Discussion of Unlabeled Use - Faculty must disclose in writing and communicate in writing through course materials, that a product is not labeled for the use under discussion or that the product is still investigational and not approved for use in the United States.
4. Faculty are required to complete the MediCom Worldwide, Inc. Faculty Disclosure Forms, and Attestation Forms prior to the program development process.
  - (Required forms attached)
5. Disclosure Forms must be completed and returned to MediCom prior to content development. Faculty refusing to disclose may not participate as a speaker for program in which disclosure was not obtained.
6. Potential conflicts of interest disclosed will be reviewed by MediCom and must be resolved prior to the educational activity.
7. Once a conflict is identified, a content validation process is initiated to ensure that the content or format of the CE activity and related materials will promote improvements or quality in health care and not promote a specific proprietary business interest of a commercial interest.
8. MediCom conducts an unbiased review of all planned content for activities certified for credit to resolve any actual or perceived conflict of interest that exists.
9. Faculty must disclose to participants prior to the start of the educational activity the existence of significant situations where a direct commercial support relationship exists with the educational activity.



10. MediCom discloses the following information to learners: 1) the name of the individual, 2) the name of the commercial interest(s), and 3) the nature of the relationship the individual has with the commercial interest. MediCom also discloses to learners the name(s) of commercial interests supporting each CE activity. Faculty disclosures will be documented and available to all participants via written participant handout information i.e.; syllabi, introductory slides, workbooks.
  - Disclosure will be made available to audience at the start of each activity.
11. Faculty must also disclose prior to the start of the educational activity if no significant financial relationships exist.
12. If faculty members present at multiple independent educational activities, a separate disclosure form is required for each activity.
13. Implementation:
 

All internal content review staff and outside external expert reviewers and faculty will complete a Financial Disclosure Form that contains the following information:

  - The form shall note the title and date of the activity, as well as the name(s) of the commercial supporter(s) associated with the activity.
  - The form shall solicit information about the financial relationship(s) of the reviewer, faculty member, his/her immediate family member or significant other has with any commercial supporter, as well as manufacturers of products associated with the activity or related to the topic of the activity.
  - If no relationship exists, there shall be a box to check to that effect.
  - The form shall solicit information from the faculty member as to plan to address off-label discussion or investigational use of a drug in his/her presentation.
14. Timeline for disclosure of financial relationships:
  - Internal reviewer will complete the disclosure form upon employment.
  - External experts will complete the disclosure form at the time a relationship with MediCom has been identified.
  - Presenting faculty will be asked to sign a disclosure form at the time of invitation to participate in a planned program.





### Standard Operating Procedures

<b>Manual</b>	Department of Continuing Education Policy and Procedure	<b>Policy Number</b>	<b>II-205</b>
<b>Subject</b>	Content Without Commercial Bias	<b>Date of Origin</b>	March 2004
<b>Approved By</b>	Joan Meyer	<b>Review/Revision Date</b>	July 2005
<b>Signature</b>		<b>Approval Date</b>	October 2005

#### Purpose

To establish criteria, policy and process of implementation of content standards of CE activities in accordance with the ACCME Standard for Commercial Support; Content and Format without Commercial Bias, and the content requirements of the ACPE and California Board of Registered Nursing.

#### Policy

- MediCom must review the planned content of a CE activity to be certified by MediCom and demonstrate in documentation that the content or format of a CE activity adheres to the following criteria:
  - Presentations and/or its related materials must promote improvements or quality in health care and not a specific proprietary business interest of a commercial interest.
  - Presentations and/or its related materials must give a balanced view of therapeutic options.
  - Use of generic names within the body of the presentation or its related materials is required.
    - Related presentation materials may contain trade names for all generic products contained within the presentation that are from several companies, as available.
- All content from CE activities will undergo content validation process.
  - Content must conform to the generally accepted standards of experimental design, data collection and analysis.
  - Faculty must attest to MediCom that the presentation content or content of its related materials promote improvement or quality in health care and not a specific proprietary business interest of a commercial interest.
  - Faculty must attest to MediCom that the presentation gives a balanced view of therapeutic options.
  - MediCom's internal and external reviewers must evaluate and attest that faculty presentation and its related materials promote improvements or quality in health care and not a specific proprietary business interest of a commercial interest.
  - Internal and external content reviewers must evaluate and attest that the presentation gives a balanced view of therapeutic options.
- Activities are not eligible for certification if the content and/or format promote recommendations, treatments or manners of practicing medicine that are not within the definition of CME or are known to have risks or dangers that outweigh the benefits or are known to be ineffective in the treatment of patients. Activities that offer recommendation, treatments or practice manners outside of the definition of continuing pharmacy or nursing education, or that have risks or dangers that outweigh the benefits or are known to be ineffective are not eligible for certification.
- CE activities must be developed and presented utilizing the principles of adult learning, which includes thorough assessment of learners' needs and focus on participant involvement in the learning process.
- Faculty selected to participate must be demonstrated thought leaders in the topic of the CE activity and must have demonstrated skill in providing education to adult learners. Faculty should hold advanced degrees in their area of specialty, and should be active in research or patient care within an academic or clinical setting. Faculty may not be employees of the commercial supporter of an educational activity, regardless of qualification. Faculty will be asked to provide their qualifications and educational background to activity planners for review. Faculty will be advised of content requirements in their faculty letters.





6. MediCom may solicit the review by an expert reviewer; members of the MediCom Worldwide, Inc. advisory committee provide oversight of MediCom's program planning and design. A member of the advisory committee may be asked to provide content review for selected MediCom activities. Whenever possible, advisory committee members are asked to review activities that fall within their area of clinical expertise.
7. The clinical pharmacy consultant provides oversight and review of program planning, design and in-depth content review of each activity, and verifies that the proposed amounts of pharmacology hours and content are appropriate for pharmacy credit.
8. The executive director will give final approval for the activity content and appropriate credit/contact hour designation, indicating that the content is deemed valid and within the criteria as stated in this policy. This form will be signed by the executive director. This is contained in the CE planning document.
9. Evidence of valid content will be placed in the activity file under planning.



### Standard Operating Procedures

<b>Manual</b>	Department of Continuing Education Policy and Procedure	<b>Policy Number</b>	<b>II-208</b>
<b>Subject</b>	Faculty/Speaker Selection	<b>Date of Origin</b>	January 2000
<b>Approved By</b>	Joan Meyer	<b>Revision Date</b>	August 2004
<b>Signature</b>		<b>Approval Date</b>	August 2005

#### Purpose

To establish guidelines for the determination of qualitative and quantitative considerations in the faculty selection process.

#### Policy

##### I. Qualitative Considerations

Faculty selected to participate must be demonstrated thought leaders in the topic of the CE activity and must have demonstrated skill in providing education to adult learners. Faculty should hold advanced degrees in their area of specialty, and should be active in research or patient care within an academic or clinical setting. Faculty may not be employees of the commercial supporter of an educational activity, regardless of qualifications. Faculty will be asked to provide their qualifications and educational background to MediCom for review. Faculty will be advised of content requirements in their faculty letters sent by MediCom.

1. Faculty must attest to MediCom that the presentation content or content of its related materials promote improvement or quality in healthcare and not a specific proprietary business interest of a commercial interest.
  - Faculty must attest to MediCom that the presentation gives a balanced view of therapeutic options.
  - MediCom's internal and external reviewers must evaluate and attest that faculty presentation and its related materials promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.
  - CE activities must be developed and presented utilizing the principles of adult learning, which includes thorough assessment of learners' needs and focus on participant involvement in the learning process.
2. Upon selection and approval of the faculty, a letter of guidance is written to the faculty outlining the expectations.
3. Each faculty member must submit a CV for review.
4. Each faculty member must complete and sign a disclosure form and attestation form.
5. Those faculty members who do not complete required disclosure information will not be permitted to participate in the activity as planned.
6. The executive director or designee will communicate directly with faculty, providing each faculty member with written information related to objectives of the program.
7. The executive director or designee will provide technical assistance necessary to prepare materials for presentation.

**II. Determination of Number of Faculty Required Per Planned Activity**

1. An appropriate number of qualified faculty members shall be utilized for each continuing education program.
2. The executive director will be responsible for determination of number of faculty required for each program. Determination will be based on number of topics, depth of subject matter and anticipated duration of the program.
3. MediCom will strive to maintain a ratio of at least one faculty member per every one hour of formal didactic lecture.

**III. Program Evaluation**

1. A program evaluation form is developed for each activity, which is intended to solicit participant's assessment of faculty effectiveness.
2. Evaluation forms are distributed to participants at the end of each activity. Each participant is required to complete the form as designed, as well as provide any written feedback or comments regarding program.
3. A formal summary report is completed following each program or program series. This report compiles the results of the evaluation form as well as narrative comments from participants.
4. A designated member of the CE staff will directly monitor each educational activity.



## Exhibit B

## ACTIQ Risk Management Program

Provider is aware that ACTIQ® (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- ACTIQ is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- ACTIQ is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.
- ACTIQ is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.





## FENTORA Risk Management Program

Provider is aware that FENTORA™ (fentanyl buccal tablet) [C-II] was approved subject to a Risk Minimization Action Plan (RiskMAP). The RiskMAP includes key safety messages that are essential to the safe use of this product. They are:

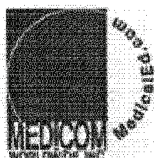
- FENTORA is indicated for the management of breakthrough pain in patients with cancer who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- FENTORA is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- No misuse of FENTORA should occur.
- Unintended (accidental) exposure to FENTORA should not occur.
- Patients considered opioid tolerant are those who are taking at least 60 mg oral morphine/day, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that FENTORA can be fatal to a child. Keep all units away from children and discard properly.
- FENTORA is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

## MediCom Worldwide, Inc.

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October 31, 2006

Bhaval Shah-Bell, PhD  
Cephalon, Inc.  
41 Moores Road  
Frazer, PA 19355

Dear Dr. Shah-Bell:

As an accredited provider of continuing medical education, MediCom Worldwide, Inc. has recently completed a comprehensive needs assessment to identify the educational needs of health care professionals in the field of pain management.

Based on the identified educational need, MediCom is requesting an educational grant from Cephalon, Inc. to support the development of a live symposium in conjunction with the International Association of Pain and Chemical Dependency Conference to be held June 21-24, 2007 in New York City. In addition to the live program, MediCom is requesting additional funding to provide enduring material support initiatives resulting from the content developed for the live meeting in order to maximize the reach to physicians throughout the United States. The activities described in this proposal include:

1. Live symposia
2. MobileCME educational modules hosted via Epocrates software and delivery system

The total grant request to fund these activities is \$246,110; please refer to the detailed budget section of this proposal for complete grant funding details of the individual educational initiatives.

These scientific events will comply with all OIG, PhRMA, FDA, and ANCC regulations for industry-supported professional continuing education.

Thank you in advance for your consideration of this request.

Respectfully,

A handwritten signature in cursive script, appearing to read 'Joan Meyer'.

Joan Meyer  
Executive Director, Continuing Education

MediCom Worldwide, Inc.  
101 Washington Street • Morrisville, PA 19067 • 215-337-9991

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Page 2



## MediCom Worldwide, Inc.

## Needs Assessment



## Overview

The National Pain Foundation suggests that more than 75 million Americans experience chronic pain with an associated annual cost of approximately \$100 billion in medical expenses, lost wages and lost productivity.<sup>1</sup> The high prevalence of chronic pain, combined with its enormous cost, make unrelieved pain a huge public health problem.

The 1999 JCAHO guidelines for management of pain were one of the first steps toward the United States congressional mandate for a decade of pain control and research (2000-2010) meant to increase awareness of chronic pain and treatment requirements for health care providers.<sup>2,3</sup> Although health care providers are becoming better educated about the *science* of pain management, an educational void still exists on how to *care* for the chronic pain patient population.<sup>4,5</sup> In light of this void, continued federal congressional support for pain research initiatives, conducted by the National Institutes of Health, is expected to be approved by the Senate prior to January 1, 2007.<sup>1</sup>

Chronic pain is persistent, multifactorial, often intractable, and affects multiple health domains. Patients' responses to chronic pain and therapies are highly individualized. The most common types of chronic pain are backaches, headaches, and arthritis; although many other types of chronic pain exist, such as neuropathic pain and fibromyalgia. Chronic pain impacts and compromises the patient's normal ability to function physiologically, psychologically and socially, negatively affecting overall quality of life.<sup>6</sup>

Either a multi- or interdisciplinary care model is considered one of the preferred methodologies to assess and treat chronic pain comprehensively. Accurate assessment and monitoring of pain and comorbidities using validated diagnostic tools help to stratify patients and determine individualized therapeutic plans.<sup>7</sup>

Frequently, patients with persistent pain types experience relatively short episodes of worsening pain which is referred to as breakthrough pain. Breakthrough pain is abrupt, short-lived and intense. It presents as a painful episode or episodes in patients with otherwise stable, persistent baseline pain. Assessment is critical to determine the existence of breakthrough pain, as inadequate persistent pain therapy may confuse the diagnosis. Chronic baseline pain must be assessed as stable before a diagnosis of breakthrough pain can be confirmed. The characteristics of breakthrough pain require a therapeutic approach that is different from the ones usually prescribed to patients with persistent pain.<sup>8</sup>

Chronic pain is considered undertreated or inappropriately treated. Inadequate treatment may be attributed, in part, to the clinician's lack of recognition of breakthrough pain. Breakthrough pain may be incidental (predictable, unpredictable), idiopathic, or related to end-of-dose. Breakthrough pain (BTP) adds significantly to the existing burden of chronic pain in terms of both health domains and economic impact. Proper assessment and diagnosis of both chronic and breakthrough pain is essential for adequate and appropriate treatment.<sup>8</sup>

Barriers to treatment, whether as a result of the patient, physician or health care/insurance system, are necessary to understand in order to circumvent successfully. Understanding therapeutics, both pharmacologic and nonpharmacologic, and their applications also help to restore functionality for the chronic pain patient across all health domains, restoring or improving quality of life.<sup>8</sup>

#### *An Educational Need*

As the therapeutic specialty of pain management rapidly evolves, it is critical for practitioners who treat patients in pain to fully understand the latest research and improvements in assessment and management of chronic pain and breakthrough pain.

It is evident through reviews of survey results, expert opinion, guidelines, research and publications, that pain management practitioners require medical education to better understand the complexities and subtle nuances of the physiology of pain, types of pain, therapeutic options, patient assessment and therapeutic management. The potential benefits of continued education are improved patient care and outcomes.

#### *Surveys*

In June 2005, it was reported that 60% of 303 participants in an American Pain Foundation (APF) *Voices of Chronic Pain* survey claimed to experience BTP one or more times daily, severely impacting the quality of their life and overall well-being.<sup>9</sup> Will Rowe, executive director of the APF in Baltimore, was reported as stating, "Although medical solutions exist to relieve or ease pain, the reality is that most pain goes untreated, undertreated or improperly treated, with millions of patients suffering in silence."<sup>9</sup> The *Voices of Chronic Pain Survey* also found more than three-quarters (77%) of patients surveyed said they are looking for new options to treat their pain. Only 14% of those surveyed reported that they were satisfied with their current medications and less than half (48%) of respondents felt they were currently getting enough information on the most effective ways to manage chronic pain. It is estimated that only one in four patients received adequate treatment for their pain.<sup>10</sup>

Results from a 2005 survey of chronic pain patients in Ohio demonstrated that 20% of the respondents reported to the emergency department within the previous six months for BTP, suggesting that their pain was not being managed appropriately.<sup>11</sup> The increased utilization of emergency departments as a substitute for outpatient pain management, resulting in increased and prolonged hospital admissions, is not a cost-



effective solution and indicates that education may be necessary in order to achieve practice improvement.

Table 1 from the Ohio survey demonstrates the support or information desired by the survey respondents with chronic pain. Almost 40% did not know what they needed. Ten percent requested better access to and more effective pharmacotherapy.<sup>11</sup>

**Table 1<sup>8</sup>**

Support or information desired (n=100)	% of respondents
Pain medications (better access, more effective drugs)	10%
Information about disease, new research and techniques	8%
Surgery	7%
Nothing will help / have learned to live with it	7%
Better access to physicians / access to better physicians	6%
More opportunities for physical therapy, exercise	5%
More support or understanding (from family and/or doctors)	5%
Find a cure	5%
Financial assistance (to seek therapy or purchase insurance)	4%
Make more (alternative) treatments available	3%
Assistance with transportation difficulties	2%
Ability to quit working	1%
Other	3%
NA – no obstacles, no pain	8%
Don't know	36%

Note: Because multiple responses were allowed, percentages may not sum to 100.

Nearly one-half of the respondents in a 2004 APF survey entitled *Americans Living with Pain* reported that their pain is not under control. These reports were especially true in patients with ever-present pain, in men, and in patients of middle age.<sup>12</sup>

A recent survey, conducted at Beth Israel, New York City, reported recruitment of 228 patients with diverse types of chronic noncancer pain from nine (9) pain programs who were administered a telephone questionnaire with a breakthrough pain assessment algorithm originally designed for cancer patients. All patients had controlled baseline pain, and 168 (74%) experienced severe to excruciating BTP with a total of 189 different types reported. The median number of episodes per day was 2 (range <1 to 12) and median time to maximum intensity was 10 minutes (range 0 to 180 minutes). Median duration of the breakthrough pain was 60 minutes (range 1 to 720 minutes). Patients identified a precipitant for 69% of pains, and 92% of these were activity related. Onset could never be predicted for 45% of pains and only sometimes predicted for 31% of pains. The authors concluded that BTP is highly prevalent and varied in this population.<sup>13</sup>

Survey results suggest that BTP is not managed appropriately; is costly, challenging, and debilitating to the patient.

*Expert Opinion*

*Raymond Sinatra, MD, PhD - Director Inpatient Pain Management Services, Yale University School of Medicine.*

"Clearly pain is undertreated in many hospitals. As a baseline, physicians are taught very little about the assessment or management of pain in their medical training. In 2001, the Joint Commission on Healthcare Accreditation (JCAHO) enacted a series of guidelines aimed at improving pain management in hospitals, nursing homes, rehabilitation centers and ambulatory medical facilities. JCAHO mandated that health care practitioners be educated about pain scales, analgesic medications and nonpharmacological techniques for pain control."<sup>11</sup>

*Daniel Bennett, MD - Assistant Clinical Professor of Anesthesiology and Pain Medicine at the University of Colorado.*

"Some physicians rely on laboratory data/objective physical findings and such, I believe you miss the mark in pain treatment by focusing only on these traditional (ie, allopathic) approaches. This is not to say that we should not use these in the definition of structural pathology (one would be remiss to not do this). We cannot directly measure pain, and thus what we observe is the summation of how the particular pain signal (ie, stimulus) affects the individual person (ie, pain behavior). Obviously, what is presented to us is the summation of the layering of the supratentorial processes that make us individual as human beings."

"Therefore, my philosophy in treating people who live with pain is to recognize their individuality, and incorporate what I understand of pathophysiology with the effects to them as a person. This allows the individual direction of care to optimize the functional outcome, which I believe is the most important determinate in successful treatment."<sup>12</sup>

*Donald R. Taylor, MD – a board certified anesthesiologist and pain medicine physician in private practice in Marietta, Georgia.*

"The shift from the PRN pain management model to a model based upon around-the-clock dosing with breakthrough pain (rescue) medications represents a shift from an old to a new pain treatment paradigm."<sup>13</sup>

*Lynn Webster, MD, FACPM, FASAM – Medical Director, Lifetree Pain Clinic; Medical Director and CEO, Lifetree Clinical Research, Salt Lake City, Utah.*

"According to the 2003 National Survey on Drug Use and Health, new nonmedical users of pain relievers more than quadrupled during the 10-year period of the 1990s. Many of these first-time users are young people. Substance abuse is a leading cause of preventable illness and death in the United States, and opioid analgesics are among the most frequently abused prescriptions. To

keep opioids available to treat pain, as we must, doctors who treat pain are called on to help prevent abuse and addiction, too."<sup>14</sup>

*Joyce Lowinson, MD – Professor Emeritus of Psychiatry, Albert Einstein College of Medicine, Bronx, New York, Adjunct Faculty, The Rockefeller University, NY, NY*

"Undertreatment of pain is a global public health problem. Pain is the complaint that brings the highest percentage of patients to their doctor's offices. There have been great strides in understanding in recent decades in the treatment of pain, yet the problem remains."<sup>18</sup>

The experts acknowledge that pain assessment and management models are changing, while misuse of opioid is on the rise. Practitioners need continuing education in pain assessment and management, including risk minimization through patient assessment and monitoring.

#### *Research and Publications*

The Cochrane Collaboration recently published their "Evidence-based Pain Management and Palliative Care" in Issue One for 2006 of the Cochrane Library. This edition of the Library contains 83 new reviews of which the three have potential relevance for practitioners in pain and palliative medicine.<sup>19</sup>

A study authored by Stillman, Cleveland Clinic, addresses new advances in the treatment of neuropathic pain.<sup>20</sup>

Spacek authored a recent article about inadequate and/or inconsequent pain therapy and the importance of selecting appropriate therapies.<sup>21</sup>

Several studies published in 2006 underscore the growing problem of opioid abuse in America.<sup>22-24</sup> Educational programs designed to address the growing risk, to demonstrate tools that can help assess and monitor patients for risk of misuse, and yet emphasize the need to treat chronic pain patients adequately will help clinicians minimize the individual and public risk associated with prescription opioids.

#### *Educational Recommendations*

There appears to be continuing need for education surrounding chronic pain, including episodic BTP. The accompanying social responsibilities required to limit opioid misuse must also be addressed. A recent publication by Bennett et al supports that breakthrough pain is identified as an important clinical problem commonly experienced by patients with chronic pain. Teaching clinicians how to balance adequate treatment with risk minimization and patient monitoring practices will help alleviate fears associated with prescribing opioids. Key objectives for practitioners to be aware of in treating patients with chronic pain are aimed at individualizing treatment, maximizing outcomes by improving functionality for the patient, and minimizing potential risk.



*Key Points*

- Chronic pain is a public health challenge; recognized as such by the federal government
- Chronic pain is inadequately or undertreated; an estimated 19%-95% of all patients with pain experience breakthrough pain depending on the population surveyed and the definition of breakthrough pain used
- Breakthrough pain is unpredictable and often different for each individual
- Treatment barriers need to be identified and overcome
- Holistic therapy includes both pharmacologic and nonpharmacologic options
- Risk management is a critical feature of controlled-substance prescribing

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MediCom Worldwide, Inc.

Program Summary



**Program Title:**

***Opioid Therapy in Chronic Pain with Breakthrough Episodes:  
Therapeutic Advances and Their Impact on Risk***

**Program Objectives:**

*Upon completion of this activity, participants should be able to:*

1. Summarize advances in understanding and management of chronic pain
  - a. Distinguish features, types and definition of pain; chronic and BTP
  - b. Recognize BTP in your patients
  - c. Identify tools, questions and communication techniques that are designed to improve patient/health care provider dialogue
  - d. Outline current guidelines available which impact management of chronic pain
2. Identify options in therapeutic selection both pharmacologic and non pharmacologic which may be prescribed after stratifying patients for different types of pain and risk levels
3. Outline effective clinical strategies and monitoring protocols for preventing abuse and diversion while effectively managing patients in pain

## MediCom Worldwide, Inc.

## Program Summary

**Faculty:****Russell K. Portenoy, MD**

Chairman, Department of Pain Medicine and Palliative Care  
Beth Israel Medical Center  
New York, New York

**Lynn Webster, MD**

Medical Director, Lifetree Pain Clinic  
Medical Director and CEO, Lifetree Clinical Research  
Salt Lake City, Utah

**Targeted Audience:**

Health care professionals specializing in the treatment of pain and addiction medicine in attendance at the 7th Annual Conference on Pain and Chemical Dependency.

Target participation: 250 attendees

**CE Provider:**

The educational activity will be accredited by MediCom Worldwide, Inc. MediCom Worldwide, Inc. is a fully accredited provider of:

- CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each activity within the series will be accredited for a maximum of 1.5 AMA PRA Category 1 Credits™.
- CPE credit for pharmacists by the Accreditation Council for Pharmacy Education (ACPE). Each activity will be approved for 1.5 contact hours of Continuing Pharmacy Education.
- CNE credit for nurses by the California State Board of Registered Nursing. Each activity will be approved for 1.5 contact hours.



## MediCom Worldwide, Inc.

### Program Overview



#### Targeted Audience:

Health care professionals specializing in the treatment of pain and addiction medicine in attendance at the 7th Annual Conference on Pain and Chemical Dependency.

Target participation: 250 attendees

#### Format:

Live symposia held in NYC in conjunction with the IAPCD Conference. The live event will consist of live didactic presentations delivered by two clinical experts in the field of pain management. Topics to be addressed will be focused on assessment, diagnosis and treatment of chronic pain, as well as identification of risk assessment tools and treatment strategies to employ in the practice setting.

Post-live event final content will be edited to allow for additional enduring self-study adaptation. The live activity will be subdivided into two distinct 30 minute educational modules and will be adapted for distance learning activities via personal PDA systems utilizing software developed and distributed by Epocrates MobileCME platforms.

#### Distribution/Invitation Process:

##### Live Event

The live symposium will be announced and promoted through the use of approximately 10,000 printed invitations via direct mail to identified target audience related to the IAPCD conference. A second mailing of approximately 650 to all those pre-registered to attend the conference.

##### Request for Sponsor Support Live Event

As a supplement to these primary methods, MediCom Worldwide, Inc. may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of MediCom and any such distribution will solely be as a supplement to MediCom's primary methods of announcement and promotion.

##### Enduring Material

###### *Epocrates Distribution Plan*

Epocrates will distribute educational content through Epocrates proprietary MobileCME system to Epocrates subscribers. Hosting period of the activity will continue 12 months post-launch of the activity.

##### Target date of launch

Activity will launch via MobileCME no less than 60 days post-live event and will maintain accreditation throughout the 12-month hosting period.



# IAPCD Satellite Symposium Activity Timeline

2007

	June 2007	July 2007	August 2007	September 2007	October 2007	November 2007	December 2007	January 2008	February 2008	March 2008	April 2008	May 2008	June 2008	July 2008	August 2008	September 2008
Live Event	x															
Epocrates MobileCME				∞												



Live Satellite Symposium during ICPD, June 21 to 24, 2007



Epocrates MobileCME release date, September 15, 2007

**MediCom Worldwide, Inc.****Program Overview****MediCom Worldwide, Inc. Policies:****Conflict of Interest Identification and Resolution**

MediCom Worldwide, Inc. is in full compliance with all rules and regulations put forth by the ACCME in the revised Standards for Commercial Support. MediCom has defined all those in position to control content as faculty, authors, presenters, planning committee members and all those internal staff who are in position to write, alter or impact the content of a CME activity.

All members identified in the planning process must provide signed disclosures to MediCom prior to the planning of the activity.

When individuals in a position to control content have reported Financial Relationships with one or more commercial interests, MediCom works with them to resolve such conflicts to ensure that the content presented is free of commercial bias. The following mechanisms have been identified in which to resolve conflicts as identified:

- Peer review of content by external reviewer
- Content validation by external topic expert and internal MediCom clinical editorial staff

**MediCom Worldwide, Inc. Disclosure Policy:**

(Attachment A)

**MediCom Worldwide, Inc. Content Development Policy:**

(Attachment B)

**MediCom Worldwide, Inc. Faculty Selection Policy:**

(Attachment C)



## MediCom Worldwide, Inc.

## Program Overview

**Post-Activity Reporting:**

Course evaluation forms will be required for all participants who seek to receive continuing education credit. MediCom will summarize the information collected in a formal report to evaluate program effectiveness and participant learning.

Participants will evaluate the following components:

1. Overall content
2. Faculty teaching effectiveness
3. Format
4. Usefulness of information
5. Relevance to practice setting
6. Fair balance
7. Impact to the care of the patient experiencing pain

In addition to rating scales, participants will be asked to participate in pre-/post-testing scenarios as a measurement of learning. Learning will be analyzed based on self-reported changes in knowledge or perceptions by the participants as a result of this activity, and how well he or she will be able to apply learning to a specific practice setting.

MediCom Worldwide, Inc.  
Budget Summary and Options



**Budget Summary Overview**

**IAPCD Accredited Satellite Symposium Plus Enduring Material Option  
Proposal Overview**

Tactic	Description	Expected Outcome	Proposed Budget	
Satellite symposium at 2007 IAPCD conference	Two-speaker accredited live symposium	250 conference attendees	Direct Costs	\$75,935
			Indirect Costs	\$ 44,625
			<b>Total</b>	<b>\$120,560</b>
Symposium adaptation: two independently accredited modules based on content from live activity	1.5 hour symposia edited to allow for two 30 minute educational modules based on content provided at live event	2 MobileCME broadcasted events based on content from live event  Minimum guarantee of 600 CME completions per activity	Direct Costs	\$ 112,800
			Indirect Costs	\$ 12,750
			<b>Total</b>	<b>\$ 125,550</b>



MediCom Worldwide, Inc.  
101 Washington Street  
Morrisville, Pennsylvania 19067

**Satellite Symposium in conjunction with the 7th International Pain and Chemical Dependency Conference**

<i>Program Parameters</i>	
Accreditation Hours	1.5
Faculty	2
Symposium Attendees	250
Direct mail invitations to health care professionals	4,000

<i>Cost Summary</i>	
Approximate Total, Direct Expenses	\$ 75,935
Total, Indirect Expenses	\$ 44,625
<b>Chronic Pain Today: Addressing the Challenges; Defining the Treatment</b>	<b>\$ 120,560</b>

Approval Signature

Date

Note: no work may begin until MediCom receives, via email or fax, this approval with signature and date

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MediCom Worldwide, Inc.  
101 Washington Street  
Morrisville, Pennsylvania 19067

**Satellite Symposium in conjunction with the 7th International Pain and Chemical Dependency Conference**

<b>Direct Expenses: Approximate</b>	
IPCD Admin Fee	\$ 25,000
Direct mail invitations	
Direct mail invitations, mailed to registered meeting attendees; includes printing; development of database email homepage for registration	\$ 5,750
Direct mail list purchase	No charge
Mail Services, postage, phone, fax, email registration	\$ 1,560
Includes assembly, mail services and postage. Follow up recruitment per phone, fax, email	
Invitation door-drop/advertisement fee	\$ 5,000
Participant handouts	\$ 5,250
Includes printing of participant workbook; will include accreditation information, speaker biographical and disclosure information, agenda, and symposium graphics; total quantity 225 color copy	
Posters advertisement materials	\$ 2,400
Faculty expenses	
Honoraria:	
MD Expert (2)	\$ 4,500
Meal expense faculty	\$ -
Ground transportation	\$ 75
Room Rental	No charge
Catering 250 X \$85 pp	\$ 21,250
Audio/visual services: Including digital audio record	\$ 4,000
MediCom expenses	
Accommodations	\$ 800
Meals	\$ 150
Ground transportation	\$ 125
Shipping/Fed Ex	\$ 75
<b>Approximate Total, Meeting Management Direct Expenses</b>	
	\$ 75,935

<b>Indirect Expenses</b>	
MediCom pre-meeting coordination and development	\$ 25,000
Includes faculty recruitment, agenda coordination, coordination with association; coordination with venue; participant recruitment; coordination of filming of patient video case study equipment rental;	
Development Editorial	\$ 2,500
Includes presentation slides x2 faculty approx 90 slides; editorial content review; reference and fact checking; design and format	
MediCom on-site symposium coordination; 2 MediCom staff	\$ 1,600
Graphic design	\$ 1,250
Accreditation of program for CME; Includes distribution of ce certificates	\$ 10,000
Database development; record tracking	\$ 775
Project management	\$ 3,500
<b>Total, Indirect Expenses</b>	
	\$ 44,625



MediCom Worldwide, Inc.  
101 Washington Street  
Morrisville, Pennsylvania 19067

### Online Adaptation from Live Symposium Hosted as MobileCME via Epocrates

#### Program Description

This proposal is for adaptation of a live symposium accredited for self study via MobileCME through Epocrates mobile medical software. The 90 minute live program will be formatted into two separate thirty minute educational modules to be posted for credit post live activity. Each faculty presentation and topic will be tailored to meet the specifications for mobile posting

<i>Cost Summary</i>	
Approximate Total, Direct Expenses	\$ 112,800
Total, Indirect Expenses	\$ 12,750
<b>Cost of One Self-Study Multi-Media Online Program Adapted from Live Symposium</b>	<b>\$ 125,550</b>

Approval Signature \_\_\_\_\_

Date \_\_\_\_\_

**Note: no work may begin until MediCom receives, via email or fax, this approval with signature and date**

Confidential

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MediCom Worldwide, Inc.  
 101 Washington Street  
 Morrisville, Pennsylvania 19067

### Online Adaptation from Live Symposium Hosted as MobileCME via Epocrates

#### Detailed Budget Itemization

<i>Direct Expenses, Approximate</i>	
Transcription	\$ 800
Speaker honoraria: post-symposium interviews	\$ 2,000
Epocrates Hosting Fee (includes fees for two 30 minute programs)	\$ 110,000
<b>Approximate Total, Direct Expenses</b>	<b>\$ 112,800</b>

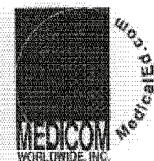
<i>Indirect Expenses</i>	
<b>Program Development</b>	\$ 5,000
Includes creation of graphic user interface; coordination with activity specifications from Epocrates technical team; coordination with speaker for final review; Medical review and editing of live activity. 90 minute activity will be subdivided into two 30 minute educational modules	
<b>Accreditation of program for CME; includes both 30 minute modules; Fees include a guarantee from Epocrates for a minimum of 600 CME certificates per accredited activity</b>	\$ 5,000
<b>Data management</b>	\$ 750
Includes management of participant database, data analysis, quarterly reports, final summary report	
<b>Project management</b>	\$ 2,000
<b>Total, Indirect Expenses</b>	<b>\$ 12,750</b>

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**MediCom Worldwide, Inc.**  
**Budget Summary and Options**



<b>Budget:</b>	
<b>Live Activity:</b>	<b>\$120,560</b>
<b>Epocrates Activity:</b>	<b>\$125,550</b>
<b>(Inclusive of two independent 30 minute activities)</b>	

<b>Total Budget:</b>	<b>\$246,110</b>
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**Budget Reporting and Reconciliation:**  
***Appropriate Use of Commercial Support:***

- a. Funds should be in the form of an educational grant made payable to MediCom Worldwide, Inc.
- b. No other funds from Cephalon, Inc. will be paid to the program director, faculty, or others involved with the CE activity (additional honoraria, extra social events, etc).
- c. MediCom Worldwide, Inc. will furnish the commercial interest with documentation detailing the receipt and expenditure of the commercial support within 90 days of activity completion.

**Payment Structure:**

<b>50% due upon signing of agreement:</b>	<b>\$123,055</b>
<b>Final 50% due June 1, 2007:</b>	<b>\$123,055</b>



### Standard Operating Procedures

<b>Manual</b>	Department of Continuing Education Policy and Procedure	<b>Policy Number</b>	<b>II-203</b>
<b>Subject</b>	Disclosure	<b>Date of Origin</b>	March 2003
<b>Approved By</b>	Joan Meyer	<b>Revision Date</b>	March 2005
<b>Signature</b>		<b>Approval Date</b>	May 2005

### Purpose

The policy on disclosure exists to provide guidance for staff, faculty and joint/co-sponsors of the requirement to disclose specific information to participants in order to comply with the following standards for all activities sponsored by MediCom Worldwide, Inc.: ACCME's 2004 Updated Standards for Commercial Support; ACPE's Criteria for Quality and Interpretive Guidelines; California Board of Registered Nursing Standards and Guidelines. This includes (a) sponsor financial relationships, (b) faculty and family/significant others financial relationships, (c) discussion of unlabeled or unapproved uses of drugs and devices. As an approved provider, MediCom Worldwide, Inc. is required to collect information from individuals who have an opportunity to affect the CE content about products or services of a commercial interest with which he/she has a financial relationship to allow a determination to be made as to whether that relationship may constitute a conflict of interest that must be resolved.

### Policy

1. Disclosure documents must be completed by anyone involved in planning or presenting educational content at CE programs approved for CME/CPE/CNE inclusive of MediCom advisory committee members, clinical content reviewers and identified faculty members.
2. MediCom Worldwide, Inc. requires all those in a position to control content to provide specific information to CE participants.
3. MediCom requires faculty to provide specific information to CE participants. Disclosure is required in two areas:
  - Financial Relationships - Faculty must disclose any significant relationship between themselves/significant others and (a) the commercial supporter(s) of the program, and (b) the manufacturer of any product discussed in the CE program or related to the topic of the event. Information reported shall include financial relationships in place over the preceding twelve-month period. If the faculty has nothing to report, that information must be indicated.
  - Discussion of Unlabeled Use - Faculty must disclose in writing and communicate in writing through course materials, that a product is not labeled for the use under discussion or that the product is still investigational and not approved for use in the United States.
4. Faculty are required to complete the MediCom Worldwide, Inc. Faculty Disclosure Forms, and Attestation Forms prior to the program development process.
  - (Required forms attached)
5. Disclosure Forms must be completed and returned to MediCom prior to content development. Faculty refusing to disclose may not participate as a speaker for program in which disclosure was not obtained.
6. Potential conflicts of interest disclosed will be reviewed by MediCom and must be resolved prior to the educational activity.
7. Once a conflict is identified, a content validation process is initiated to ensure that the content or format of the CE activity and related materials will promote improvements or quality in health care and not promote a specific proprietary business interest of a commercial interest.
8. MediCom conducts an unbiased review of all planned content for activities certified for credit to resolve any actual or perceived conflict of interest that exists.
9. Faculty must disclose to participants prior to the start of the educational activity the existence of significant situations where a direct commercial support relationship exists with the educational activity.



10. MediCom discloses the following information to learners: 1) the name of the individual, 2) the name of the commercial interest(s), and 3) the nature of the relationship the individual has with the commercial interest. MediCom also discloses to learners the name(s) of commercial interests supporting each CE activity. Faculty disclosures will be documented and available to all participants via written participant handout information i.e., syllabi, introductory slides, workbooks.
  - Disclosure will be made available to audience at the start of each activity.
11. Faculty must also disclose prior to the start of the educational activity if no significant financial relationships exist.
12. If faculty members present at multiple independent educational activities, a separate disclosure form is required for each activity.
13. Implementation:
 

All internal content review staff and outside external expert reviewers and faculty will complete a Financial Disclosure Form that contains the following information:

  - The form shall note the title and date of the activity, as well as the name(s) of the commercial supporter(s) associated with the activity.
  - The form shall solicit information about the financial relationship(s) of the reviewer, faculty member, his/her immediate family member or significant other has with any commercial supporter, as well as manufacturers of products associated with the activity or related to the topic of the activity.
  - If no relationship exists, there shall be a box to check to that effect.
  - The form shall solicit information from the faculty member as to plan to address off-label discussion or investigational use of a drug in his/her presentation.
14. Timeline for disclosure of financial relationships:
  - Internal reviewer will complete the disclosure form upon employment.
  - External experts will complete the disclosure form at the time a relationship with MediCom has been identified.
  - Presenting faculty will be asked to sign a disclosure form at the time of invitation to participate in a planned program.





### Standard Operating Procedures

<b>Manual</b>	Department of Continuing Education Policy and Procedure	<b>Policy Number</b>	<b>II-205</b>
<b>Subject</b>	Content Without Commercial Bias	<b>Date of Origin</b>	March 2004
<b>Approved By</b>	Joan Meyer	<b>Review/Revision Date</b>	July 2005
<b>Signature</b>		<b>Approval Date</b>	October 2005

### Purpose

To establish criteria, policy and process of implementation of content standards of CE activities in accordance with the ACCME Standard for Commercial Support; Content and Format without Commercial Bias, and the content requirements of the ACPE and California Board of Registered Nursing.

### Policy

- MediCom must review the planned content of a CE activity to be certified by MediCom and demonstrate in documentation that the content or format of a CE activity adheres to the following criteria:
  - Presentations and/or its related materials must promote improvements or quality in health care and not a specific proprietary business interest of a commercial interest.
  - Presentations and/or its related materials must give a balanced view of therapeutic options.
  - Use of generic names within the body of the presentation or its related materials is required.
    - Related presentation materials may contain trade names for all generic products contained within the presentation that are from several companies, as available.
- All content from CE activities will undergo content validation process.
  - Content must conform to the generally accepted standards of experimental design, data collection and analysis.
  - Faculty must attest to MediCom that the presentation content or content of its related materials promote improvement or quality in health care and not a specific proprietary business interest of a commercial interest.
  - Faculty must attest to MediCom that the presentation gives a balanced view of therapeutic options.
  - MediCom's internal and external reviewers must evaluate and attest that faculty presentation and its related materials promote improvements or quality in health care and not a specific proprietary business interest of a commercial interest.
  - Internal and external content reviewers must evaluate and attest that the presentation gives a balanced view of therapeutic options.
- Activities are not eligible for certification if the content and/or format promote recommendations, treatments or manners of practicing medicine that are not within the definition of CME or are known to have risks or dangers that outweigh the benefits or are known to be ineffective in the treatment of patients. Activities that offer recommendation, treatments or practice manners outside of the definition of continuing pharmacy or nursing education, or that have risks or dangers that outweigh the benefits or are known to be ineffective are not eligible for certification.
- CE activities must be developed and presented utilizing the principles of adult learning, which includes thorough assessment of learners' needs and focus on participant involvement in the learning process.
- Faculty selected to participate must be demonstrated thought leaders in the topic of the CE activity and must have demonstrated skill in providing education to adult learners. Faculty should hold advanced degrees in their area of specialty, and should be active in research or patient care within an academic or clinical setting. Faculty may not be employees of the commercial supporter of an educational activity, regardless of qualification. Faculty will be asked to provide their qualifications and educational background to activity planners for review. Faculty will be advised of content requirements in their faculty letters.



6. MediCom may solicit the review by an expert reviewer; members of the MediCom Worldwide, Inc. advisory committee provide oversight of MediCom's program planning and design. A member of the advisory committee may be asked to provide content review for selected MediCom activities. Whenever possible, advisory committee members are asked to review activities that fall within their area of clinical expertise.
7. The clinical pharmacy consultant provides oversight and review of program planning, design and in-depth content review of each activity, and verifies that the proposed amounts of pharmacology hours and content are appropriate for pharmacy credit.
8. The executive director will give final approval for the activity content and appropriate credit/contact hour designation, indicating that the content is deemed valid and within the criteria as stated in this policy. This form will be signed by the executive director. This is contained in the CE planning document.
9. Evidence of valid content will be placed in the activity file under planning.



## Standard Operating Procedures

<b>Manual</b>	Department of Continuing Education Policy and Procedure	<b>Policy Number</b>	<b>II-208</b>
<b>Subject</b>	Faculty/Speaker Selection	<b>Date of Origin</b>	January 2000
<b>Approved By</b>	Joan Meyer	<b>Revision Date</b>	August 2004
<b>Signature</b>		<b>Approval Date</b>	August 2005

### Purpose

To establish guidelines for the determination of qualitative and quantitative considerations in the faculty selection process.

### Policy

#### I. Qualitative Considerations

Faculty selected to participate must be demonstrated thought leaders in the topic of the CE activity and must have demonstrated skill in providing education to adult learners. Faculty should hold advanced degrees in their area of specialty, and should be active in research or patient care within an academic or clinical setting. Faculty may not be employees of the commercial supporter of an educational activity, regardless of qualifications. Faculty will be asked to provide their qualifications and educational background to MediCom for review. Faculty will be advised of content requirements in their faculty letters sent by MediCom.

1. Faculty must attest to MediCom that the presentation content or content of its related materials promote improvement or quality in healthcare and not a specific proprietary business interest of a commercial interest.
  - Faculty must attest to MediCom that the presentation gives a balanced view of therapeutic options.
  - MediCom's internal and external reviewers must evaluate and attest that faculty presentation and its related materials promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.
  - CE activities must be developed and presented utilizing the principles of adult learning, which includes thorough assessment of learners' needs and focus on participant involvement in the learning process.
2. Upon selection and approval of the faculty, a letter of guidance is written to the faculty outlining the expectations.
3. Each faculty member must submit a CV for review.
4. Each faculty member must complete and sign a disclosure form and attestation form.
5. Those faculty members who do not complete required disclosure information will not be permitted to participate in the activity as planned.
6. The executive director or designee will communicate directly with faculty, providing each faculty member with written information related to objectives of the program.
7. The executive director or designee will provide technical assistance necessary to prepare materials for presentation.



**II. Determination of Number of Faculty Required Per Planned Activity**

1. An appropriate number of qualified faculty members shall be utilized for each continuing education program.
2. The executive director will be responsible for determination of number of faculty required for each program. Determination will be based on number of topics, depth of subject matter and anticipated duration of the program.
3. MediCom will strive to maintain a ratio of at least one faculty member per every one hour of formal didactic lecture.

**III. Program Evaluation**

1. A program evaluation form is developed for each activity, which is intended to solicit participant's assessment of faculty effectiveness.
2. Evaluation forms are distributed to participants at the end of each activity. Each participant is required to complete the form as designed, as well as provide any written feedback or comments regarding program.
3. A formal summary report is completed following each program or program series. This report compiles the results of the evaluation form as well as narrative comments from participants.
4. A designated member of the CE staff will directly monitor each educational activity.



www.cephalon.com

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 Cephalon, Inc.  
 41 Moores Road  
 P.O. Box 4011  
 Frazer, PA 19355  
 Phone 610-344-0200  
 Fax 610-344-0065

## INDEPENDENT EDUCATIONAL PROGRAM ("IEP") GRANT AGREEMENT

This Agreement is entered into as of this 19th day of December, 2006 by and between Cephalon ("Cephalon"), located at 41 Moores Road, Post Office Box 4011, Frazer, PA 19355, and MediCom Worldwide, Inc. ("IEP Provider") located at 101 Washington Street, Morrisville, PA 19067 and American Pain Society ("Sponsor of the 26<sup>th</sup> Annual Scientific Meeting") located at 4700 West Lake Avenue, Glenview, IL 60025.

WHEREAS, Cephalon has reviewed IEP Provider's grant request to support a medical education program ("Program"); and

WHEREAS, Cephalon has determined that the Program has the potential to significantly further medical knowledge and improve patient care; and

WHEREAS, it is the intent of the parties to ensure that the Program will be independent, objective, balanced and scientifically rigorous, so that it will not be viewed by the United States Food and Drug Administration ("FDA") as promotional and that Cephalon will not be viewed as responsible for its content; and

WHEREAS, Cephalon agrees to provide funding for the Program under the conditions set forth below.

NOW THEREFORE, IEP Provider and Cephalon agree to the following terms under this Agreement:

1. Title of Program. The IEP is entitled "Signal Transduction of Pain: Implications for Opioid Therapy," which will be presented at the 26<sup>th</sup> Annual Scientific Meeting of the American Pain Society on May 3, 2007 in Washington, DC, and a copy of the grant request for the Program is attached hereto as Exhibit A.
2. Type of Program. The Program is:
  - ☒ accredited (e.g., continuing medical education or "CME"); or
  - ☐ an independent program where CE credits will not be offered.
3. IEP Provider. The IEP Provider is the following type of entity:
  - ☒ Accredited continuing medical education provider
  - ☐ University/Hospital
  - ☐ Professional Organization
  - ☐ Medical Education Company



4. Educational Partner. The IEP Provider \_\_\_ shall X shall not use a third party that will provide assistance in support of the Program ("Educational Partner").
5. Educational Components. The expected components of the Program (e.g., number of live meetings, CD ROM, web-based, etc.) are as follows:
  - (a) live symposia; and
  - (b) slide-audio adaptation hosted and distributed via Medscape.
6. Program Purpose. The Program is for scientific and educational purposes only and is not intended to promote a Cephalon product directly or indirectly. The Program is not a repeat performance of a prior program.
7. Grant Amount Funding Arrangements.
  - (a) Cephalon will provide support for the Program by means of an educational grant in the total amount of \$320,760. If the Program is canceled or terminated prior to completion, IEP Provider shall return the grant, or any unused portion thereof, to Cephalon within thirty (30) days of such termination or cancellation. IEP Provider shall have full responsibility for all funding arrangements of the Program, including any funding to be provided to IEP Provider's Educational Partner. Payment of the grant shall be made in accordance with a schedule agreed to by the parties. All payments due hereunder shall be made by Cephalon within forty-five (45) days of its receipt of an invoice for same, provided IEP Provider is in compliance with the terms of this Agreement.
  - (b) Within thirty (30) days of completion of the Program, IEP Provider shall provide Cephalon with a detailed reconciliation of actual out-of-pocket expenses incurred, and to the extent Cephalon has overpaid IEP Provider for same, IEP Provider shall provide a refund to Cephalon within thirty (30) days thereafter. Such detailed reconciliation shall be forwarded to Cephalon at the address above to the attention of Rod J Hughes, Ph.D., Vice President, Scientific Communications.
  - (c) IEP Provider may not use funds provided by Cephalon to pay travel, lodging, honoraria or personal expenses for non-faculty attendees. Grant funds may be used to reduce the overall registration fees for attendees. Grant funds may not be used to purchase capital equipment or to provide general operational support for an institution. Funds for hospitality shall not be provided except that funds may be used for modest meals or receptions that are held as part of the Program, but such events shall not compete with nor take precedence over educational events. The appropriateness of any reception shall be at the sole discretion of the IEP Provider, and IEP Provider shall have final decision making authority in connection with any such activities.
  - (d) Funds may be used by the IEP Provider to permit medical students, residents, fellows or other health care professionals in training to travel to



and attend the Program; provided, however, that the selection of such students, residents or fellows who receive funds is made by either the academic or training institution or, if by the IEP Provider, such selection shall be made with the full concurrence of the academic or training institution.

(e) In accordance with the Accreditation Council for Continuing Medical Education ("ACCME") Standards and to assist Cephalon in complying with its internal auditing procedures, IEP Provider agrees to verify the manner in which the grant is used. Accordingly, within thirty (30) days following a request from Cephalon, IEP Provider shall provide to Cephalon:

- i. A written statement verifying that the Program occurred, and
- ii. An itemized list of expenditures supported by the grant.

8. Objectivity and Balance. IEP Provider shall retain full responsibility for control of the content of the Program and shall ensure that the following requirements are met:

(a) The Program material/information will be objective, balanced and free from commercial bias. All topics shall be treated in an impartial, unbiased manner. All discussions shall include a range of views about each class of drug and disease treatment options. Information shall not unfairly represent a spectrum of views favoring a product or class of products marketed by Cephalon or any other company. The title of the Program will fairly and accurately represent the scope of the presentation.

(b) IEP Provider agrees that neither Cephalon nor its agents shall control the content of the Program. IEP Provider agrees that there will be no scripting, targeting of points for emphasis, or other activities by Cephalon or its agents that are designed to influence the content of the Program. If requested in writing by the IEP Provider, medical/scientific representatives from Cephalon may attend content development meetings or other planning meetings, for the purpose of addressing any scientific inaccuracies they observe. Personnel from Cephalon must not discuss or in any way attempt to control (either during the meeting or at breaks or meals), the content of the program. An appropriate medical/scientific representative from Cephalon may provide a presentation at a content development meeting at the request of the provider, or may respond to specific questions at such meeting regarding the results of a Cephalon-sponsored research study, provided the information presented conforms to the generally accepted standards of experimental design, data collection and analysis, and provided any presentation is accompanied by a detailed outline of the presentation, which can be used by the IEP Provider/Educational Partner to confirm the scientific objectivity of the presentation.



- (c) If the IEP Provider, in its sole discretion, requests a Cephalon medical representative to review the Program for medical accuracy and completeness, Cephalon will comply with such request. The parties acknowledge there is no obligation or any condition requiring IEP Provider to make such a request. Any such request must be made after the Program materials are fully developed and such request must be made by the IEP Provider only to a Cephalon medical representative that has responsibility for the therapeutic area that will be covered by the Program. IEP Provider will not ask any marketing or sales representatives at Cephalon to comment on the material. All final decisions regarding whether to modify the material based on any comments provided by the Cephalon medical representative shall be in the sole discretion of IEP Provider.
  - (d) If a product marketed by Cephalon is the subject of discussion, the data will be objectively selected and presented, with an accurate reflection of favorable and unfavorable information about the product and shall also include a balanced discussion of prevailing information on alternative products and /or therapies.
  - (e) Any suggestions of superiority of one product or treatment over another will be supported by the body of available data, and will not result from selective presentation or emphasis on data favorable to particular treatment.
  - (f) IEP Provider represents that neither it nor the Educational Partner (if any) has either an open complaint or decision from the ACCME or the Food and Drug Administration that a program provided by the IEP Provider or the Educational Partner failed to meet standards of independence, balance, objectivity, or scientific rigor.
9. Risk Minimization Action Plan. Cephalon provides the following Risk Minimization Action Plan ("RiskMAP") information to all IEP Providers. Neither Cephalon nor its agents shall influence or control whether a product marketed by Cephalon is the subject of discussion. A RiskMAP is a strategic safety program designed to meet specific goals and objectives in minimizing known risks of a product while preserving its benefits. Any product marketed by Cephalon that is approved with a RiskMAP, and the key safety-related health outcomes outlined in that RiskMAP, are listed in Exhibit B. IEP Provider agrees that it is aware of the RiskMAP(s) and the key safety messages.
10. Faculty Selection. IEP Provider shall retain full responsibility for the selection of the presenters, authors, moderators, and/or other faculty (hereinafter referred to collectively as "Faculty"). Cephalon, through its Scientific Communications Department, may respond only to IEP Provider-initiated, written requests (or requests from the Educational Partner) for suggestions of Faculty or sources of possible Faculty. In response to such requests at least three (3) names will be suggested (if possible) for each open position and this information will be provided in writing. IEP Provider will record the role of Cephalon in suggesting



Faculty; will seek suggestions from other sources; and will make its selection of Faculty based on objective criteria. IEP Provider shall not be obligated to request or accept such assistance from Cephalon or its agents as a condition of receiving the educational grant hereunder.

11. Disclosures. IEP Provider will ensure meaningful disclosure of limitations of data (e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion). IEP Provider will require that Faculty disclose when a product is not approved in the United States for the use under discussion.
12. Question and Answer Session. To the extent the Program is a presentation, IEP Provider will ensure meaningful opportunities for questioning by the audience.
13. Financial Relationships. IEP Provider will ensure meaningful disclosure to the audience of Cephalon funding and any significant relationship between individual Faculty and Cephalon. All meaningful disclosure(s) shall also be made in any written materials, including but not limited to announcements, brochures, syllabi and enduring material. Disclosures shall not mention product trade names.
14. Metrics/Copies of Program Material.
  - (a) IEP Provider and/or Educational Partner shall provide certain outcome measurements and metrics to Cephalon as requested by the Scientific Communications Department. Such metrics shall be provided either after the conclusion of a single live event or monthly for a year-long accredited program and may at Cephalon's request include the number of program participants, number of certifications, assessment of the program and faculty, and demonstration of learning by program participants.
  - (b) After the Program has occurred, IEP Provider shall provide Cephalon with 5 copies of all Program materials in CD ROM or electronic format and 20 copies in print format.
15. Representations and Warranties. IEP Provider represents that:
  - (a) Neither it nor the Educational Partner, if any, provides marketing, advertising, public relations, market research, medical education services or other consulting services (e.g., support for advisory boards) to any other department within Cephalon ("Marketing Activities");
  - (b) If IEP Provider or the Educational Partner has an affiliated company that provides Marketing Activities to Cephalon, IEP Provider has instituted appropriate controls and safeguards to ensure the Program (i) remains independent, objective, balanced and scientifically rigorous, (ii) is not intended to promote a Cephalon product directly or indirectly, and (iii) is not in any way biased due to the affiliated company's relationship with Cephalon;





- (c) IEP has determined that it is appropriate to use the Educational Partner in light of the requirements under this Agreement; and
  - (d) If IEP Provider or its Educational Partner employs a former Cephalon employee who worked at Cephalon anytime during the most recent year and who had marketing responsibility in the therapeutic area that will be covered by the Program, then that former employee will not have any role in the planning, development or delivery of the Program.
- 16. Invitations/Enduring Materials. The Program audience will be selected by the IEP Provider. The IEP Provider shall be responsible for distributing materials about the Program, including invitations, reminder notices, and business reply cards that can be used by third parties to obtain any enduring Program material from the IEP Provider.
- 17. Ancillary Promotional Activities. To the extent the Program is a live presentation, no promotional activities or product advertisements will be permitted in the same room as or in an obligate path to the Program. If the Program is a teleconference or webcast, no product advertisements or promotional activities will be permitted immediately prior to, during, or immediately after the delivery of the Program. If the Program is in print format, no product advertisements or promotional materials will be interleaved within the pages of the Program. If the Program is made available electronically, no product advertisements or promotional materials will appear within the Program material or interleaved between computer windows or screens of the Program
- 18. Compliance with Guidelines. IEP Provider represents that the Program, including development of the Program and Program materials, shall conform to the American Medical Association ("AMA") Guidelines on Gifts to Physicians, the AMA Ethical Opinion on Continuing Medical Education, the ACCME Standards for Commercial Support, the FDA December 3, 1997 Final Guidance for Industry-Supported Scientific and Educational Activities, and the Pharmaceutical Research and Manufacturers Association ("PhRMA") Code on Interactions with Healthcare Professionals.
- 19. Logistical Status Reports. IEP Provider and/or Educational Partner shall provide periodic reports to Cephalon regarding the management and logistics of program components.
- 20. Miscellaneous.
  - (a) No party shall use the other party's or its affiliates' name or trademarks for publicity or advertising purposes, except with the prior written consent of the other party.
  - (b) IEP Provider agrees to obtain all consents, authorizations, approvals and releases that may be necessary for the production of the Program and of any written materials prepared in connection therewith. IEP Provider agrees to indemnify Cephalon with respect to any claims, actions or



demands, including reasonable attorneys' fees that may arise in any manner out of IEP Provider's failure to secure such consents, authorizations, approvals or releases.

- (c) No term, condition or other provision of any attachment or addendum to this Agreement shall supersede any term, condition or other provision of this Agreement and with respect to any inconsistency or ambiguity, the Agreement shall control.

IN WITNESS WHEREOF, the parties, by their duly authorized representatives, agree to comply with all the terms and conditions of this Agreement.

**MEDICOM WORLDWIDE, INC.**

By: *Joan Meyer*  
 Name: JOAN MEYER  
 Title: President

The above signatory is a duly authorized corporate officer of the IEP Provider.

Date: 1-4-07

Tax ID #: 23-3063738

**CEPHALON, INC.**

By: *Rod J. Hughes*  
 Name: Rod J. Hughes, Ph.D.  
 Title: Vice President, Scientific Communications

Date: 12-20-06

**AMERICAN PAIN SOCIETY**

By: *Guth Tiersman*  
 Name: GUTH TIERSMAN  
 Title: DIRECTOR OF EDUCATION

The above signatory is a duly authorized corporate officer of the Sponsor of the 26<sup>th</sup> Annual Scientific Meeting.

Date: 1-8-07

Tax ID #: 52-1180177

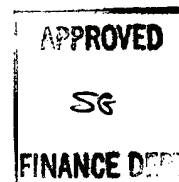




Exhibit A  
Copy of Grant Request



December 18, 2006

Bhaval Shah-Bell, PhD  
Cephalon, Inc.  
41 Moores Road  
Frazer, PA 19355

Dear Dr. Shah-Bell:

As an accredited provider of continuing medical education, MediCom Worldwide, Inc. has recently completed a comprehensive needs assessment to identify the educational needs of health care professionals in the field of pain management.

Based on the identified educational need, MediCom is requesting an educational grant from Cephalon, Inc. to support the development of a live symposium in conjunction with the American Pain Society Conference to be held May 3, 2007 in Washington, DC. In addition to the live program, MediCom is requesting additional funding to provide an enduring material support initiative resulting from the content developed for the live meeting in order to maximize the reach to physicians throughout the United States. The activities described in this proposal include:

1. Live symposia
2. Slide-Audio adaptation hosted and distributed via Medscape

The total grant request to fund these activities is \$ 320,760; please refer to the detailed budget section of this proposal for complete grant funding details of the individual educational initiatives.

These scientific events will comply with all OIG, PhRMA, FDA, and ANCC regulations for industry-supported professional continuing education.

Thank you in advance for your consideration of this request.

Respectfully,

A handwritten signature in cursive script, appearing to read 'Joan Meyer'.

Joan Meyer  
Executive Director, Continuing Education

MediCom Worldwide, Inc.  
101 Washington Street • Morrisville, PA 19067 • 215-337-9991

FAX 800-679-0959

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MediCom Worldwide, Inc.

## Needs Assessment



The 1998 National Academy of Sciences Colloquium of Neurobiology of Pain was organized by Drs. Liebeskind, Dubner and Gold to bring together scientists and researchers who had made significant advances in the field of pain through integrative sciences of neural cellular and molecular biology. The colloquium was organized into six sessions that included the following: channels, receptors, imaging systems neuroscience, growth factors and cytokines, development and plasticity, and molecular genetics. [1] This extraordinary meeting of the very best minds in neurobiology turned out to be the quintessential kick-off for a new millennium and decade of technological advancements that in 1998 could only have been imagined. Dr. Liebeskind, the primary organizer of this colloquium, succumbed to cancer and was never able to attend the meeting that was the realization of his personal and professional vision. If Dr. Liebeskind were alive today, he would certainly be amazed at how his vision catapulted neurobiology of pain research initiatives to the fast-track, resulting in a constant stream of insights that continually debunk traditional beliefs, creating a new fundamental understanding of pain.

In previous decades and in the current Decade of Pain Control and Research (2001–2010), pain research has undergone recent and major changes, from a system level to cellular, subcellular and molecular levels. [2] With the advent of improved and more affordable functional imaging systems, like positron emission tomography (PET), functional magnetic resonance imaging (fMRI), and biophotonic imaging, it is now possible to "map" pain stimuli to pain response mechanisms through out the nervous systems of animal and human subjects. The ongoing Human Genome Project, with first-phase completed in 2003, used the analytical power arising from the reference DNA sequences of entire genomes and other genomics resources to jump-start what some call the "biology century." [3] These two major technological advancements have provided a firm foundation for today's researchers to expand study objectives and release reliable, reproducible, and believable study results. Exciting developments in the knowledge of afferent pain neurons such as altered spinal connections, changes in transmitter and receptor complement, growth-factor contributions to inflammation, and the cloning of genes for opioid receptors and sodium channels are being published. [2]

At least two major hurdles remain in the treatment of chronic pain. The first is that no objective test for pain currently exists. A blood test, genetic marker or psychophysical measure would greatly improve diagnosis of chronic pain. The second is the lack of an "antibiotic equivalent" (i.e., drugs with high sensitivity and specificity) for the treatment of chronic pain subtypes (e.g., neuropathic pain). Controlled trials of drug efficacy indicate that, on average, the most effective drugs of different classes have similar efficacy (around 30% greater than placebo) across neuropathic conditions. [4-8]

Functional imaging has already redefined chronic pain as a degenerative disease, and has shed some light on complex diseases such as fibromyalgia. [8] Since brain responses are the final common pathway in behavioral responses to pain (unconscious and conscious), the application of functional imaging will allow categorization of pain conditions in an objective manner to better understand the underlying circuitry. [9, 10]

The final phase of the Human Genome Project is currently underway and includes supporting research on novel technologies that can lead to significant improvements in sequencing technology. The explosive progress in neurobiology of pain, including neural plasticity, cognitive response to pain, receptor regulation, and transcriptional regulation of genes, also sets the stage for significant advances in developing a new generation of novel analgesics. Pain research at the cellular, subcellular, and molecular levels has also provided insights that help guide the current treatment and management of intractable pain conditions including neuropathic pain, cancer pain and other chronic pain conditions. [2, 3]

The educational challenge now is how to translate and disseminate the molecular findings into the clinical environment to achieve improved therapeutic management of patients in pain.

Physicians involved in the medical management of patients with chronic pain often find themselves undertaking complex pharmacologic therapies aimed at modulating both the endogenous pain-sensing and pain-relieving systems, which translates to influencing a broad variety of mu and other opioid analgesic receptors, substance P, dopamine, neuronal sodium channels and glutamate receptors. They embark upon these therapeutic maneuvers amidst a population of patients with a genetic variety that gives rise to a broad diversity of both disease expression and response to treatment. In addition to this, people undergo profound individual changes due to chronic pain, not only cognitively and psychologically but also neurologically through the processes of excitatory neurotransmission: nerve growth, nerve death and neural re-connection that we collectively term "neuronal plasticity", involving both spine and supraspinal structures.[11-12]

Understanding the pattern of temporal variations in a patient's pain is important in developing an opioid-based treatment plan. Tailored opioid treatment plans can be developed that manage pain, improve patient function and minimize side effects. Recent findings have pointed out the efficacy, as well as challenges about the use of opioids in the treatment of chronic pain. [23] Although some have questioned the long-term benefits of opioids in the management of chronic pain, current practices suggest that such concerns now represent the minority view. [23]

Many substances have been shown to block or reverse antinociceptive tolerance. A non-inclusive list of examples of substances reported to block or reverse opioid antinociceptive tolerance include: substance P receptor (NK-1) antagonists, calcitonin gene-related peptide (CGRP) receptor antagonists, nitric oxide (NO) synthase inhibitors, calcium channel blockers, cyclooxygenase (COX) inhibitors,



protein kinase C inhibitors, competitive and non-competitive antagonists of the NMDA (N-methyl-D-aspartate) receptor, AMPA (alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid) antagonists, anti-dynorphin antiserum, and cholecystokinin (CCK) receptor antagonists. These substances are also antagonists of pain-enhancing agents. Prolonged opiate administration indeed induces upregulation of substance P (SP) and calcitonin gene-related peptide (CGRP) within sensory fibers in vivo, and this is accompanied by an enhanced release of excitatory neurotransmitters and neuropeptides from primary afferent fibers upon stimulation.

N-methyl-D-aspartate receptors (NMDARs) activate ion channels and permit electrolyte flow. These receptors are thought to play a critical role in synaptic plasticity, a cellular mechanism required for learning and memory. In this regard, they contribute to chronic pain by assisting the mind in remembering the initial pain, creating "pain memory". NMDARs are also implicated in central sensitization, leading to: allodynia, hyperalgesia, spontaneous pain and pain in the absence of stimulation. [14]

Opioids are among the oldest and most effective drugs known, with references to their use extending back for more than 40 centuries. [24] Although commonly employed, appropriate opioid use is not as straightforward as it had once seemed. Variations in clinical response are now recognized to result in dose-limiting adverse effects and differential responses with different opioids. An increased awareness of these variations and information concerning their underlying mechanisms has led to refined strategies for optimizing opioid analgesia. [24] In recent years, there have been considerable advances in our knowledge of the pharmacokinetics of these drugs and of the possible influence of pharmacogenomics on opioid metabolism and consequent alteration in pharmacodynamic effects. Understanding the pathophysiologic framework for acute and chronic pain and its treatment will allow physicians to develop a rational strategy for the selection of the most effective opioid medication. Realization that the mode of drug delivery (e.g. oral, transdermal, transbuccal, intrathecal) may be an equally important determinant of the success of a pharmacologic treatment for pain as the molecular identity of the drug itself is also an essential component of management. Long-acting, short-acting drugs and neural targets all play a role in successful analgesia. [15-18]

The ultimate goal is for practitioners to find the best balance between the pharmacologic and behavioral therapies to restore comfort and function to each of their patient's unique lives.

### **Expert Opinion**

*Dr. Katja Wiech; Wellcome Trust Centre for Neuroimaging at UCL, London [19]*

"Patients with persistent pain report that often it is not the pain itself that makes their situation unbearable, but the fact that there is nothing they can do against it which makes them feel helpless," explains Dr. Wiech. "Unfortunately, this feeling of uncontrollability in turn tends to worsen the pain. On the other hand, teaching persistent pain patients psychological coping strategies to handle their pain usually does help reduce its effects."

*Richard Ambron; Columbia University Medical Center, NY, NY [20]*

"Pain does not receive anywhere near the recognition it should, chronic pain is debilitating and greatly diminishes the quality of life, but it has yet to generate the funding that is needed to understand its biological and molecular basis."

*Jon-Kar Zunbieta, MD; University of Michigan [21]*

"Practicing pain management clinicians need to know how that the new knowledge in pain pathways and tracts relates to therapeutic decision-making. Current clinical guidelines do not reflect the latest information."

*The National Institutes of Health Testimony, 2005 [22]*

"The NIH Roadmap is a series of far-reaching initiatives designed to transform the nation's medical research capabilities and speed the movement of research discoveries from bench to bedside."

### **Research and Publications**

There are an extraordinary number of publications regarding molecular/cellular pain. The National Institutes of Health are funding numerous studies (\$223 million in 2004) to honor their commitment to address the inadequacies of pain treatment in the United States (NIH Pain Consortium; NIH Roadmap and Blueprint for Neurosciences). The NIH is also funding research dedicated to finding novel analgesics targeted to specific types of pain, in specific populations, supporting personalized medicine. [22]

The Molecular Pain.com journal has an impressive list of recently published literature (<http://www.molecularpain.com/articles/browse.asp>) and they also offer a literature feed, with an equally impressive list of newly published findings in molecular pain (<http://www.molecularpain.com/rss/>), as does PubMed (<http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?CMD=search&DB=pubmed>)

As the therapeutic specialty of pain management rapidly evolves, it is critical for practitioners who treat patients in pain to fully understand the latest research and improvements in the management of chronic pain.

In light of the plethora of new data published monthly, clinicians are evidently challenged to keep up with the latest developments and may require expert guidance in translating research discoveries to practical applications in management of patient care.

It is evident through reviews of expert opinion, guidelines, research and publications, that pain management practitioners require medical education to better understand the complexities and subtle nuances of the physiology of pain, types of pain, therapeutic options, and therapeutic management. The potential benefits of continued education are improved patient care and outcomes.

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MediCom Worldwide, Inc.

Program Summary



**Program Overview**

Medical training has traditionally focused upon the "treatment of normal people with normal diseases". Unfortunately, for patients suffering with chronic pain these conditions seldom apply. Physicians involved in the medical management of patients with chronic pain often find themselves undertaking complex pharmacologic therapies aimed at modulating both the endogenous pain-sensing and pain-relieving systems, which translates to influencing a broad variety of mu receptors, neuronal sodium channels and glutamate receptors. They embark upon these therapeutic maneuvers amidst a population of patients with a genetic variety that gives rise to a broad diversity of both disease expression and response to treatment. In addition to this, people undergo profound individual changes due to chronic pain, not only psychologically but also neurologically, as manifest by the processes of nerve growth, nerve death and neural re-connection that we collectively term "neuronal plasticity". This often leaves pain physicians promoting treatments they can't explain for patients they can't understand.

This symposium will review the basics of pain transmission and responses to pharmacologic treatment informed by new developments in our understanding of receptor diversity and pharmacogenetics. The role of neural reorganization in response to chronic pain and how this determines the individual's response to treatment will then be explored, with a special emphasis on how the treatment of pain with opioid medications can influence this process. Understanding the pathophysiologic framework for acute and chronic pain and its treatment should allow us to develop a rational strategy for the selection of the most effective opioid medication and for finding the best balance between the pharmacologic and behavioral therapies that will restore comfort and function to our patients.

In summary, this activity is designed to provide a comprehensive review of the physiology of pain transduction, emphasizing receptor physiology. The impact of exogenous opioids on the plasticity of synaptic receptors and channels will be discussed. Novel opioid delivery systems will be described and justified based on what is known about receptor and synaptic physiology and the etiology of the pain.

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**Program Title:**

Signal Transduction of Pain: Implications for Opioid Therapy

**Program Objectives:**

*Upon completion of this activity, participants should be able to:*

1. Recognize the molecular mechanisms involved with analgesic opioid use in chronic pain therapy
2. Identify emerging data in the development and understanding of the role and function of NMDA receptors in chronic pain
3. Recognize that there are a variety of receptors involved in pain perception and analgesia and understand their importance in therapeutic decision making
4. Recognition of effective treatment strategies in chronic pain assessing the rationale for the prescribed use of different types of opioids, methods of administration, and durations of action to maximize improved therapeutic outcomes.

**Agenda****Overview**

Learning to Read the Map: The Road to Improved therapeutic Selection  
Dr. Pasternak

**Pain perception and transmission: the impact of opioids on activation and plasticity of mu receptors:**

**Challenges in predicting which patients will respond to which therapy**  
Dr. Pasternak

**Current Research and Trends as it Relates to Opioid Receptors and Activity**

Dr. Inturrisi: Recent findings in NMDA receptor research and its impact on the treatment of chronic pain

Dr. Porreca: Recent findings in neuronal mechanisms affecting peripheral and central mechanisms of pain generation

**Integrating Ongoing Research and Knowledge into the Clinical Management of Chronic Pain**

Dr. Rowbotham

**Faculty:****Moderator**

Gavril Pasternak, MD, PhD  
 Department of Neurology  
 Sloan-Kettering Cancer Center  
 1275 York Avenue  
 New York, NY 10021  
**Phone Number:** 212-639-7046  
**Fax Number:** 212-794-4332  
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**Presenter**

Charles Inturrisi, PhD  
 Professor  
 Pharmacology  
 Weill Med College of Cornell  
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**Presenter**

Frank Porreca, PhD  
 Pharmacology  
 University of Arizona  
 1501 N. Campbell Ave.  
 Tucson, AZ 85724  
**Phone Number:** (520) 626-7421  
**Email:** frankp@u.arizona.edu

**Presenter**

Michael C. Rowbotham, MD  
 Professor of Neurology and Anesthesia  
 UCSF Department of Neurology  
 Pain Clinical Research Center  
 1701 Divisadero Street, Suite 480  
 San Francisco, CA 94115  
**Phone Number:** 415-885-7899  
**Fax Number:** 415-885-7855  
**Email:** Michael.Rowbotham@ucsf.edu

**Targeted Audience:**

Health care professionals specializing in the treatment of pain in attendance at the American Pain Society Conference

**CE Provider:**

The educational activity will be accredited by MediCom Worldwide, Inc. MediCom Worldwide, Inc. is a fully accredited provider of:

- CME credit for physicians by the Accreditation Council for Continuing Medical Education. Each activity within the series will be accredited for a maximum of 1.5 AMA PRA Category 1 Credits™.
- CNE credit for nurses by the California State Board of Registered Nursing. Each activity will be approved for 1.5 contact hours.

## MediCom Worldwide, Inc.

### Program Overview



#### **Format:**

Live symposia held in Washington, DC in conjunction with the American Pain Society Conference. The live event will consist of live didactic presentations delivered by four clinical experts in the field of pain management research and practice. Post-live event final content will be edited to allow for additional enduring self-study adaptation. The live activity will be adapted and reformatted via slide audio and hosted via Medscape

#### **Distribution/Invitation Process:**

##### **Live Event**

The live symposium will be announced and promoted through the use of approximately 5,000 printed invitations via direct mail to identified target audience related to the scientific conference.

##### **Request for Sponsor Support Live Event**

As a supplement to these primary methods, MediCom Worldwide, Inc. may request the assistance of Cephalon, Inc. in the dissemination of information regarding this program to the medical community. The content of such information, however, is the responsibility of MediCom and any such distribution will solely be as a supplement to MediCom's primary methods of announcement and promotion.

##### **Enduring Material**

###### *Medscape activity*

Hosting period of the activity will continue 12 months post-launch of the activity.

##### **Target date of launch:**

Activity will launch via Medscape no less than 90 days post-live event and will maintain accreditation throughout the 12-month hosting period.

# MediCom Worldwide, Inc.

## Program Overview



### **MediCom Worldwide, Inc. Policies:**

#### **Conflict of Interest Identification and Resolution**

MediCom Worldwide, Inc. is in full compliance with all rules and regulations put forth by the ACCME in the revised Standards for Commercial Support. MediCom has defined all those in position to control content as faculty, authors, presenters, planning committee members and all those internal staff who are in position to write, alter or impact the content of a CME activity.

All members identified in the planning process must provide signed disclosures to MediCom prior to the planning of the activity.

When individuals in a position to control content have reported Financial Relationships with one or more commercial interests, MediCom works with them to resolve such conflicts to ensure that the content presented is free of commercial bias. The following mechanisms have been identified in which to resolve conflicts as identified:

- Peer review of content by external reviewer
- Content validation by external topic expert and internal MediCom clinical editorial staff

### **MediCom Worldwide, Inc. Disclosure Policy:**

(Attachment A)

### **MediCom Worldwide, Inc. Content Development Policy:**

(Attachment B)

### **MediCom Worldwide, Inc. Faculty Selection Policy:**

(Attachment C)

## MediCom Worldwide, Inc.

### Program Overview



#### **Post-Activity Reporting:**

Course evaluation forms will be required for all participants who seek to receive continuing education credit. MediCom will summarize the information collected in a formal report to evaluate program effectiveness and participant learning.

Participants will evaluate the following components:

1. Overall content
2. Faculty teaching effectiveness
3. Format
4. Usefulness of information
5. Relevance to practice setting
6. Fair balance
7. Impact to the care of the patient experiencing pain

In addition to rating scales, participants will be asked to participate in pre-/post-testing scenarios as a measurement of learning. Learning will be analyzed based on self-reported changes in knowledge or perceptions by the participants as a result of this activity, and how well he or she will be able to apply learning to a specific practice setting.



**MediCom Worldwide, Inc.**  
**Budget Summary and Options**



**Budget Summary Overview**

**APS Accredited Satellite Symposium Plus Enduring Material Option  
 Proposal Overview**

Tactic	Description	Expected Outcome	Proposed Budget	
Satellite symposium at 2007 APS Conference	Four-speaker accredited live symposium	250 conference attendees	Direct Costs	\$145,060
			Indirect Costs	\$58,050
			<b>Total</b>	<b>\$203,110</b>
Symposium adaptation: slide-audio format based on content from live activity	1.5 hour symposia edited to allow distribution via internet access	Minimum guarantee of 600 CME completions per activity	Direct Costs	\$93,400
			Indirect Costs	\$24,250
			<b>Total</b>	<b>\$117,650</b>

**MediCom Worldwide, Inc.**  
**Budget Summary and Options**



<b>Budget:</b>	
<b>Live Activity:</b>	<b>\$203,110</b>
<b>Medscape Activity:</b>	<b>\$117,650</b>
<b>(Inclusive of two independent 30 minute activities)</b>	
<b>Total Budget:</b>	<b>\$320,760</b>

**Budget Reporting and Reconciliation:**  
***Appropriate Use of Commercial Support:***

- a. Funds should be in the form of an educational grant made payable to MediCom Worldwide, Inc.
- b. No other funds from Cephalon, Inc. will be paid to the program director, faculty, or others involved with the CE activity (additional honoraria, extra social events, etc).
- c. MediCom Worldwide, Inc. will furnish the commercial interest with documentation detailing the receipt and expenditure of the commercial support within 90 days of activity completion.

**Payment Structure:**

<b>50% due upon signing of agreement:</b>	<b>\$160,380</b>
<b>Final 50% due May 15, 2007:</b>	<b>\$160,380</b>



MediCom Worldwide, Inc.  
 101 Washington Street  
 Morrisville, Pennsylvania 19067

**Satellite Symposium in conjunction with the American Pain Society Conference**

<b>Program Parameters</b>	
Accreditation Hours	1.5
Faculty	4
Symposium Attendees	250
Direct mail invitations to health care professionals	5,000

<b>Cost Summary</b>	
Approximate Total, Direct Expenses	\$ 145,060
Total, Indirect Expenses	\$ 58,050
<b>Signal Transduction of Pain: Implications for Opioid Therapy</b>	<b>\$ 203,110</b>

Approval Signature

Date

**Note: no work may begin until MediCom receives, via email or fax, this approval with signature and date**

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Highly Confidential

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MediCom Worldwide, Inc.  
101 Washington Street  
Morrisville, Pennsylvania 19067

### Satellite Symposium in conjunction with the American Pain Society Conference

<b>Direct Expenses; Approximate</b>	
<b>APS Admin Fee</b>	\$ 50,000
<b>Direct mail invitations</b>	
Direct mail invitations, mailed to registered meeting attendees; includes printing; development of database email homepage for registration	\$ 6,500
<b>Application Completion Fee</b>	\$ 8,900
<b>Mail Services, postage, phone, fax, email registration</b>	\$ 1,560
Includes assembly, mail services and postage. Follow up recruitment per phone, fax, email	
<b>Invitation door-drop/advertisement fee</b>	\$ 15,000
<b>Participant handouts</b>	\$ 11,500
Includes printing of participant workbook; will include accreditation information, speaker biographical and disclosure information, agenda, and symposium graphics; total quantity 275 color copy	
<b>Posters advertisement materials</b>	\$ 2,500
<b>Faculty expenses</b>	
Honoraria	
MD Chairman	\$ 2,500
Faculty presenter (3)	\$ 6,000
Travel Expense	\$ 1,500
Hotel accommodations	\$ 1,600
Meal expense faculty	\$ 400
Ground transportation	\$ 500
Room Rental	No charge
<b>Catering 250 X \$100 pp</b>	\$ 25,000
<b>Audio/visual services: Including digital audio record</b>	\$ 7,500
<b>MediCom expenses</b>	
Accommodations (two representatives )	\$ 1,600
Meals	\$ 250
Travel Expense	\$ 750
<b>Shipping/Fed Ex</b>	\$ 1,500
<b>Approximate Total; Meeting Management Direct Expenses</b>	<b>\$ 145,060</b>

<b>Indirect Expenses</b>	
<b>MediCom pre-meeting coordination and development</b>	\$ 25,000
Includes faculty recruitment, agenda coordination, coordination with association; coordination with venue; participant recruitment; Agenda and learning objective development	
Clinical advisory coordination and development	
<b>Development Editorial</b>	\$ 3,500
Includes presentation slides x4faculty approx 110 slides; editorial content review; reference and fact checking; design and format	
<b>MediCom on-site symposium coordination; 2 MediCom staff</b>	\$ 1,800
<b>Graphic design and Production</b>	\$ 3,000
<b>Accreditation of program for CME; includes distribution of ce certificates</b>	\$ 13,750
<b>Database development; record tracking</b>	\$ 1,000
<b>Project management</b>	\$ 10,000
preparation and coordination of timeline/internal teams; coordination with medscape; development of faculty advisory conferences	
<b>Total, Indirect Expenses</b>	<b>\$ 58,050</b>



## Exhibit B

### ACTIQ Risk Management Program

Provider is aware that ACTIQ® (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- ACTIQ is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- ACTIQ is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.
- ACTIQ is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.



## FENTORA Risk Management Program

Provider is aware that FENTORA™ (fentanyl buccal tablet) [C-II] was approved subject to a Risk Minimization Action Plan (RiskMAP). The RiskMAP includes key safety messages that are essential to the safe use of this product. They are:

- FENTORA is indicated for the management of breakthrough pain in patients with cancer who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain*.
- FENTORA is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- No misuse of FENTORA should occur.
- Unintended (accidental) exposure to FENTORA should not occur.
- Patients considered opioid tolerant are those who are taking at least 60 mg oral morphine/day, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that FENTORA can be fatal to a child. Keep all units away from children and discard properly.
- FENTORA is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.



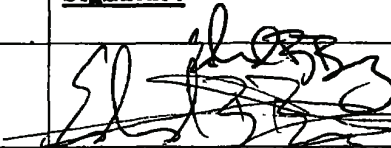
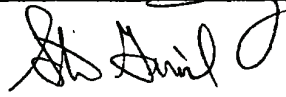

G7557

**Cephalon Review of Education Grant**

The attached Grant amount has been reviewed by members of the MEP team.

**Program Name:** Unrestricted Educational Grant:

**Medicom Worldwide, Inc.**  
**National CME Lectures and Symposia**

<u>Department</u>	<u>Name</u>	<u>Signature</u>	<u>Date</u>
Legal	Ed Berg		2/25/04
Accounting	Steve Girard		2/27/04
Marketing	Paula Castagno Andy Pyfer		2/25/04



December 12, 2003

P. Andrew Pyfer  
Product Director  
Cephalon, Inc.  
145 Brandywine Parkway  
West Chester, PA 19380

Dear Mr. Pyfer:

MediCom Worldwide is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians and by the Accreditation Council for Pharmacy Education to sponsor continuing education for pharmacists, as well as an approved provider of nursing continuing education through the California State Board of Registered Nursing.

A comprehensive needs assessment has identified interests of health care providers who manage patients suffering from pain. Based on this educational need, we are requesting an educational grant from Cephalon, Inc. to support the development and implementation of several continuing education activities on the subjects of effective pain management techniques and the changing guidelines to improve pain management. The budget to fund these activities is approximately \$4,368,980.

Proposed Educational Activities for Pain Management

A series of approximately 350 one-hour CME lectures across the United States  
A series of 30 half-day (4 CME credit hrs.) symposia strategically held across the US  
Continuation of the CEP speaker lecture bureau for invited clinical experts in pain management  
Development, production, and certification of CME slide content for four identified topics  
Continuation of access to MediCom's proprietary CEP web-based CME slide library for faculty

These scientific activities, will be developed independently and will comply with all ACCME, FDA, AMA, and ACPE regulations for industry-supported professional continuing education. The target audiences for these activities are pain management specialists, oncologists and anesthesiologists, nurses, pharmacists and those other healthcare professionals interested in pain management education.

As a supplement to our direct mail and web site announcement of these educational activities, we request Cephalon representatives to disseminate information regarding these programs to the medical community.

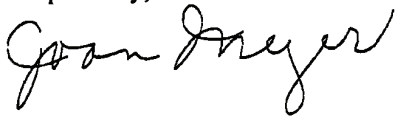
However, the content of such information is the responsibility of the accredited provider and any such distribution will be solely as a supplement to provider's primary method of announcement and promotion.

101 Washington St.  
Morrisville, PA 19067  
215-337-9991

1

Thank you, in advance, for your consideration of this request. Should you agree to provide funding for this project, Letters of Agreement will be forwarded to you as soon as possible.

Respectfully,

A handwritten signature in cursive script, appearing to read "Joan Meyer".

Joan Meyer RN, MA  
Executive Director, Continuing Education

101 Washington St.  
Morrisville, PA 19067  
215-337-9991

2



## **2004 MEDICAL EDUCATION AGREEMENT V CME LECTURE SERIES**

As a condition of Cephalon, Inc.'s contribution of funds to support a series of independent medical education programs (with CME, CPE, and CNE credits), the Scientific and Educational Activity provider agrees to the following terms and conditions:

This Agreement ("Agreement") is entered into as of December 12, 2003 by and between Cephalon, Inc. ("Cephalon") and MediCom Worldwide, Inc. ("Provider") regarding a series of 350 educational lectures and 30 symposia supported by Cephalon to be held during 2004. The parties' mutual objectives are to provide balanced, independent, scientifically rigorous lectures to promote the education of attendees. The amount of the educational grant requested is \$4,368,980.

1. Statement of Purpose. This program is for scientific and educational purposes only and not to promote any commercial drug products.
2. Control of Content and Selection of Presenters and Moderators. The provider is ultimately responsible for the control of content and selection of presenters and moderators. Cephalon or its agents may respond to requests initiated by the provider for suggestions of presenters or sources of possible presenters. Cephalon will suggest more than one name (if possible); will provide speaker qualifications; will disclose financial or other relationships between Cephalon and speaker; and will provide this information in writing. Provider will seek suggestions from other sources, and will, in its sole discretion, select presenters and moderators.
3. Disclosure of Financial Relationships. Provider will direct speakers and moderators to disclose to the audience commercial support or funding or other significant financial relationships between the speakers and moderators and Cephalon and/or any other commercial company whose products are pertinent to the content of the presentation. Provider will disclose Cephalon's support at this program.
4. Involvement in Content. There will be no "scripting," emphasis, or influence on content by Cephalon or its agents. However, Cephalon may provide technical support to speakers, e.g., furnishing slides or data, upon their request.

5. Ancillary Promotional Activities. No promotional activities will be permitted in the same room as, or in the obligatory path to, the educational activity. No product advertisements will be permitted within the program or handouts.

6. Objectivity and Balance. Provider will advise presenters that data regarding Cephalon products (or competing products) are to be objectively selected and presented. Provider will provide the opportunity for speakers and the audience to discuss information, both favorable and unfavorable, about the product(s) and/or alternative treatments.

7. Limitations of Data. Provider will request the speakers, to the extent possible, to disclose limits on the data, e.g., that it involves ongoing research, interim analyses, preliminary data, or unsupported opinion.

8. Discussion of Unapproved Uses. Provider will request that presenters disclose when a product is not approved in the United States for the use under discussion.

9. Actiq® Risk Management Program. Provider is aware that Actiq (oral transmucosal fentanyl citrate) [C-II] was approved subject to a Risk Management Program (RMP). The RMP includes key safety messages that are essential to the safe use of this product. They are:

- Actiq is indicated only for the management of breakthrough cancer pain in patients with malignancies who are *already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.*
- Actiq is contraindicated in the management of acute or postoperative pain, because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- This product must not be used in opioid nontolerant patients.
- Patients considered opioid tolerant are those who are taking at least 60 mg Morphine/day, 50 mcg transdermal fentanyl/hour, or an equianalgesic dose of another opioid for a week or longer.
- Instruct patients/caregivers that ACTIQ can be fatal to a child. Keep all units from children and discard properly.

10. Opportunity for Debate. Provider will ensure opportunities for questioning by attendees and scientific debate with and between presenters.

11. Independence of Provider in the Use of Contributed Funds.

(a) funds should be in the form of an educational grant made payable to the provider organization.

(b) Provider must be advised of all other support by Cephalon of the CME activity (e.g., distributing brochures, preparing slides). If Provider disapproves of this activity, it shall promptly notify Cephalon.

(c) no other funds from Cephalon will be paid to the program director, faculty, or others involved with this CME activity, e.g., additional honoraria.

12. General.

(a) Cephalon agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education, and acknowledges receipt of a copy of those standards.

(b) Provider agrees to: (1) abide by the ACCME Standards for Commercial Support of Continuing Medical Education; (2) acknowledge educational support from Cephalon in program brochures, syllabi, and other program materials; and (3) upon request, furnish Cephalon with a report concerning the expenditure of the funds provided by Cephalon.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

MEDICOM WORLDWIDE, INC.

CEPHALON, INC.

By: *Joan Meyer*  
Name: Joan Meyer  
Title: Executive Director, Cont. Ed  
Date: December 12, 2003

By: *[Signature]*  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

SIGN I





07028.1  
(07300MM.1)

From: Origin ID: NMZA (610) 738-6537  
 Suzanne Staczak  
 Cephalon, Inc.  
 41 Moores Road  
 Frazer, PA 19355



Ship Date: 03JAN11  
 ActWgt: 1.0 LB  
 CAD: 101300352/INET3090

Delivery Address Bar Code



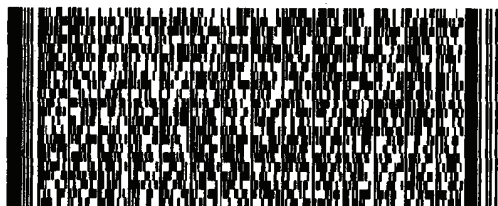
Ref # 10000440  
 Invoice #  
 PO #  
 Dept #

SHIP TO: (215) 337-9991

BILL SENDER

Joan Meyer  
 Medicom Worldwide Inc.  
 101 WASHINGTON ST

MORRISVILLE, PA 19067



TRK# 7942 7990 4528  
 0201

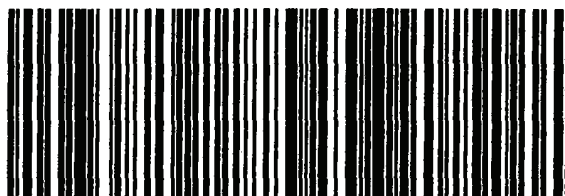
TUE - 04 JAN A2  
 STANDARD OVERNIGHT

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**After printing this label:**

1. Use the 'Print' button on this page to print your label to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

**Warning:** Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and could result in additional billing charges, along with the cancellation of your FedEx account number.

Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on [fedex.com](http://fedex.com). FedEx will not be responsible for any claim in excess of \$100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of \$100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is \$500, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see current FedEx Service Guide.

**Steczak, Suzanne**

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**From:** Cephalon Grant Management System [Admin@CephalonGrants.com]  
**Sent:** Wednesday, December 15, 2010 12:03 PM  
**To:** Steczak, Suzanne  
**Subject:** IME Agreement Accepted Grant Request # 006994

This message is to notify you that the LOA for the grant request listed below has been accepted by the Grant Requestor.

\*Therapeutic Area: Chronic Pain (General)  
\*Budget Type:  
\*Grant ID #: 006994  
\*Requesting Institution: MediCom Wordwide, Inc

12/15/2010

Confidential

TEVA\_MDL\_A\_01174645

P-29481 \_ 01207

## EDUCATIONAL GRANT REQUEST

Grant # 6994

**Title:** ESP Live! at the American Academy of Pain Medicine

**Payee:** MediCom Wordwide, Inc



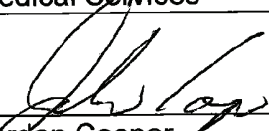
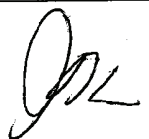


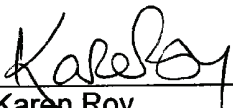

**Amount: Requested:** \$50,000

Approved: \$50,000

**Type of Program:** Web: Website

**Date GRC Review:** 12/7/10

**Program Start Date:** 03/24/2011

REVIEWER	DATE	APPROVED	REJECTED	COMMENTS/FURTHER INFORMATION
 Charles Altman MD Senior Director, Medical Services	12/7/10			
 Jordan Cooper Associate General Counsel	12/7/10			
 Karen Roy Senior Director, Medical Education	12/7			

Welcome, Joan Meyer,  
medicom101[FAQ](#) | [Help](#) | [Privacy Policy](#)| [Contact](#) | [Profile](#) | [Log out](#)[My Grants](#) | [Submit IME Agreement](#)[Submit IME Agreement](#)

This Agreement is entered into as of this 15 day of December 2010, by and between Cephalon ("Cephalon"), located at 41 Moores Road, Post Office Box 4011, Frazer, PA 19355, and MediCom Worldwide, Inc. ("Provider"), located at 101 Washington Street, Morrisville, PA 19067.

WHEREAS, Cephalon has reviewed Provider's grant request to support a medical education program ("Program"); and

WHEREAS, Cephalon has determined that the Program has the potential to address educational gaps; and

WHEREAS, it is the intent of the parties to ensure that the Program will be independent, objective, balanced, scientifically rigorous, and have reasonable expectations of meeting its educational objectives so that it will not be viewed by the United States Food and Drug Administration ("FDA") as promotional and that Cephalon will not be viewed as responsible for its content; and

WHEREAS, Cephalon agrees to provide support for the Program under the conditions set forth below.

NOW THEREFORE, Provider and Cephalon agree to the following terms under this Agreement:

1. Title of Program. The Educational Program is entitled "ESP Live! at the American Academy of Pain Medicine, 006994," and a copy of the grant request for the Program is attached hereto as Exhibit A.

2. The Program is:

- ☐ certified (CE credits are offered); or
- ☐ a non-certified independent program (where CE credits will not be offered).

3. Program Purpose. The Program is for scientific and educational purposes only, and is based on established bona fide and independently verifiable patient and/or practitioner needs or gaps in healthcare performance, and is not intended to promote a Cephalon product, directly or indirectly. The Program is

not a repeat activity or endured version of a prior program.

**4. Grant Support Arrangements.**

(a) Cephalon will provide support for the Program by means of an educational grant in the total amount of \$50,000.00. If the Program is canceled or terminated prior to completion by the Provider, Provider shall return the grant, or any unused portion thereof with full reconciliation, to Cephalon within thirty (30) days of such termination or cancellation. Provider shall have full responsibility for all funding arrangements of the Program, including any funding to be provided to its Educational Partner. Payment terms of the grant shall be made in accordance with a schedule provide be Cephalon.

Provider hereby directs Cephalon to pay \$50,000.00 to the payee at the following address: MediCom Wordwide, Inc, 101 Washington St, Morrisville, PA, 19067, 23-3063738.

(b) Upon notice from Cephalon, Provider shall provide Cephalon, within ninety (90) days, a detailed reconciliation that compares the grant proposal to the actual program (e.g., expenses, attendance levels, etc.) To the extent Cephalon has overpaid Provider, Provider shall provide a refund to Cephalon within sixty (60) days thereafter. Such detailed reconciliation information and documents shall be entered into Cephalon's web-based grants managements system at [www.cephalongrants.com](http://www.cephalongrants.com).

(c) Provider may not use funds provided by Cephalon to pay travel, lodging, honoraria or personal expenses for non faculty attendees. Grant funds may be used to reduce the overall registration fees for attendees. Grant funds may not be used to purchase capital equipment or to provide general operational support for an institution. Funds for hospitality shall not be provided, except that funds may be used for modest meals or receptions that are held as part of the Program, but such events shall not compete with, nor take precedence over, educational events. The appropriateness of any reception shall be at the sole discretion of the Provider, and Provider shall have final decision-making authority in connection with any such activities.

(d) Funds may be used by the Provider to permit medical students, residents, fellows or other health care professionals in training to travel to and attend the Program; provided, however, that this is outlined in the approved grant proposal and that the selection of such students, residents or fellows who receive funds is made by either the academic or training institution, or, if by the Provider, such selection shall be made with the full concurrence of the academic or training institution.

**5. Objectivity and Balance.** Provider shall retain full responsibility for control of the content of the Program and shall ensure that the following requirements are met:

(a) The Program material/content will be objective, balanced and free from commercial bias. All topics shall be treated in an impartial, unbiased, evidence-based manner. The title of the Program will fairly and accurately represent the scope of the presentation.

(b) Provider agrees that Cephalon shall not influence the content of the Program. Cephalon personnel will not attend content development meetings.

(c) Cephalon shall not review the Program for medical accuracy or completeness and the Provider and/or Educational Partner (if any) agree that they will not make such a request of Cephalon.

(d) If a product marketed by Cephalon is the subject of discussion, the data will be objectively selected and presented, with an accurate reflection of favorable and unfavorable information about the product and shall also include a balanced discussion of prevailing information on alternative products and /or therapies.

(e) Provider represents that neither it nor the Educational Partner (if any) has either an open complaint or decision from the Accreditation Council for Continuing Medical Education ("ACCME") or the FDA that a program provided by the Provider or the Educational Partner failed to meet standards of independence, balance, objectivity, or scientific rigor at the time of signing this agreement. If a provider is notified of any such complaint or decision during the lifetime of the supported program/activity, the Provider will inform Cephalon within 30 days of notification.

6. RiskMAPs / REMS. Certain Cephalon products have an FDA approved Risk Management Action Plan (RiskMap) or Risk Evaluation and Mitigation Strategy (REMs). Furthermore, other products in the same therapeutic class may also have RiskMAPs/ REMS. Provider acknowledges that it is aware of the key safety messages in these RiskMAPs/ REMS, shall keep up-to-date with such information, and will present such information as it deems appropriate in the Program.

7. No Faculty Selection. Provider shall retain full responsibility for the selection of the presenters, authors, moderators, and/or other faculty (hereinafter referred to collectively as "Faculty"). Provider and/or Educational Partner (if any) shall not request recommendations for Faculty from Cephalon.

8. Data. Provider will ensure meaningful disclosure of limitations of data (e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion). Provider will require that Faculty disclose when a product is not approved in the United States for the use under discussion.

9. Question and Answer Session. To the extent the Program is a presentation, Provider will ensure meaningful opportunities for questioning by the audience.

10. Financial Relationships / Disclosure. Provider will ensure meaningful disclosure to the audience of support from Cephalon and all other supporters if applicable and any significant relationship between individual Faculty and Cephalon. All meaningful disclosure(s) shall also be made where appropriate



including but not limited to, syllabi and enduring material.

11. Representations and Warranties. Provider represents that:

(a) Neither the Provider nor the Educational Partner, provides promotional or marketing services to Cephalon;

(b) If Provider or the Educational Partner has an affiliated company offering promotional or marketing services, Provider and/or Educational Partner has instituted appropriate firewall controls and safeguards to ensure the Program remains independent, objective, balanced and scientifically rigorous. Firewall documents will be supplied by the Provider and/or Educational Partner and be approved by Cephalon.

(c) Provider has determined that it is appropriate to use the Educational Partner in light of the requirements under this Agreement; and

(d) If Provider and/or Educational Partner employ a former Cephalon employee who worked at Cephalon at anytime during the most recent year, the information will be disclosed and a collective decision by the parties shall be made as to how to handle such situation to ensure that the Program is independent.

12. Invitations/Enduring Materials The Program audience will be selected by the Provider. The Provider shall be responsible for distributing materials about the Program, including invitations, reminder notices, and business reply cards that can be used by third parties to obtain any enduring Program material from the Provider. As soon as a date is finalized for a live event the Provider will notify Cephalon. For enduring material the Provider shall provide copies to Cephalon at the same time as first publication/distribution of such material.

13. Ancillary Promotional Activities. To the extent the Program is a live presentation, no promotional activities or product advertisements will be permitted in the same room as, or in an oblique path to, the Program. If the Program is a teleconference or webcast, no product advertisements or promotional activities will be permitted immediately prior to, during, or immediately after the delivery of the Program. If the Program is in print format, no product advertisements or promotional materials will be interleaved within the pages of the Program. If the Program is made available electronically, no product advertisements or promotional materials will appear within the Program material or interleaved between computer windows or screens of the Program, all as stipulated in ACCME Guidelines.

14. Compliance with Guidelines. Provider represents that the Program, regardless of whether it is certified or not, including development of the Program and Program materials, shall conform to the American Medical Association ("AMA") Guidelines on Gifts to Physicians, the AMA Ethical Opinion on Continuing Medical Education, the ACCME Standards for Commercial Support, the FDA December 3, 1997 Final Guidance for Industry-Supported Scientific and Educational Activities, and the

Pharmaceutical Research and Manufacturers Association ("PhRMA") Code on Interactions with Healthcare Professionals.

15. Logistical Status Reports. Provider and/or Educational Partner shall provide periodic reports to Cephalon regarding the management and logistics of Program components.

16. Public Disclosure of Grant Payments. Provider acknowledges that Cephalon is required to publicly disclose certain terms of this grant agreement including the identity of the recipient(s) of the grant and/or Faculty, the nature of the activities performed by grant recipient(s) and/or the Faculty, the amount of the grant as well as the amount of any honoraria paid by grant recipient(s) to the Faculty. Provider shall notify each Faculty member of these disclosure terms.

17. Miscellaneous.

(a) No party shall use the other party's or its affiliates' name or trademarks for publicity or advertising purposes, except with the prior written consent of the other party.

(b) To use the Cephalon logo, the Provider and/or Education Partner must contact the Cephalon Grants Coordinator who will supply the logo and correct use instructions.

(c) Provider agrees to obtain all consents, authorizations, approvals and releases that may be necessary for the production of the Program and of any written materials prepared in connection therewith.

[This Section is intentionally Left Blank]

(d) No term, condition or other provision of any attachment or addendum to this Agreement shall supersede any term, condition or other provision of this Agreement, and with respect to any inconsistency or ambiguity, the Agreement shall control.

IN WITNESS WHEREOF, the parties, by their duly authorized representatives, agree to comply with all the terms and conditions of this Agreement.



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Use and access of this site is subject to the terms and conditions as set out in our  
Terms and Conditions of Use Statement and Privacy Statement.

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**IP Address:** 173.15.146.158      **Username:** sgirard      **Date:** 12/9/2010 5:38:46 PM

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**IP Address:** 173.15.146.158      **Username:** rkaper      **Date:** 12/10/2010 11:33:11 AM

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**IP Address:** 173.15.146.158      **Username:** medicom101      **Date:** 12/15/2010 11:03:27 AM

**Steczak, Suzanne**

**From:** Cephalon Grant Management System [Admin@CephalonGrants.com]  
**Sent:** Wednesday, December 08, 2010 8:03 AM  
**To:** Steczak, Suzanne  
**Subject:** IME Agreement Sent Grant Coordinator - Email Grant Request #006994

This message is to notify you that the grant request listed below has been approved by the review approval group.

\*Therapeutic Area: Chronic Pain (General)  
\*Budget Type:  
\*Grant ID #: 006994  
\*Requesting Institution: MediCom Wordwide, Inc

12/8/2010

Confidential

TEVA\_MDL\_A\_01174653

P-29481 \_ 01215

**Steczak, Suzanne**

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**From:** Cephalon Grant Management System [Admin@CephalonGrants.com]  
**Sent:** Friday, December 03, 2010 3:21 PM  
**To:** Steczak, Suzanne  
**Subject:** IME Agreement Sent Grant Coordinator - Email Grant Request #006994

This message is to notify you that the grant request listed below has been approved by the review approval group.

- \*Therapeutic Area: Chronic Pain (General)
- \*Budget Type:
- \*Grant ID #: 006994
- \*Requesting Institution: MediCom Wordwide, Inc

12/3/2010

Confidential

TEVA\_MDL\_A\_01174654

P-29481 \_ 01216

**Grant Request #006994****Grant  
Comments**

Search Results: displaying 1 - 2 of 2 Grant comments		
Date	User	Comment text
11/15/2010 8:48:17 AM	ssteczak	Note: Provider is ACCME accredited, and their accreditation certificate is attached. There is no Educational Partner. Firewall policy not applicable. There is one reconciliation missing from an ONC grant #5078 from 11/24/09.
11/15/2010 8:49:26 AM	ssteczak	RAI: The Payee Information section indicates the Tax ID # is 23-3063738. The uploaded W-9 form indicates the Tax ID # is 23-3062372. Please correct.
		<Previous Next>

Is this Grant Request in response to an RFP?:No

**Organization**

Legal Name of Organization : MediCom Wordwide, Inc

Contact Name : Joan Meyer

Contact Email Address : joan@medicaled.com

Name of person with legal authority to sign on behalf of your organization : Joan Meyer

Title of person with legal authority to sign on behalf of your organization: President

Email address of person with legal authority to sign on behalf of your organization: joan@medicaled.com

Are you the authorized signer? : Yes

Is your organization accredited : Yes

Accreditating bodies : ACCME, ACPE

Other Accreditating body : California Board of Registered Nursing

Organization Type : Medical Education and Communications Company (MECC)

Percentage registrant's funding comes from Cephalon : &lt;25%

If known, please give a description of any services provided to Cephalon by the parent or sister organization

<https://cephalongrants.com/home/Admin/AdminGrantRequestReviewView.aspx?38DB1A...> 12/7/2010



**Program Overview**

Therapeutic Area : Chronic Pain (General)  
Program Title : ESP Live! at the American Academy of Pain Medicine  
Program Start Date : 03/24/2011  
Program End Date : 03/24/2012  
Decision Date : 01/14/2011  
Requested Amount : \$50,000.00  
Total Funding needed for Program : \$65,870.00

**Program Details**

Needs Assessment Summary : Nonmalignant chronic pain is one of the most common reasons for patients to seek medical attention. Physicians and other clinicians therefore require current, on-demand and easy-to-utilize continuing medical education to assist the developing the necessary skills to evaluate and r with chronic pain.

Learning Objectives : • To improve the knowledge of the benefits of u precautionary approach to assess and manage ch improve the knowledge and competence of utili assessment tool such as the Opioid Risk Tool to stratification of risk in managing a patient with To improve knowledge about which behaviors a predictive of addiction outcomes. • To improve about differentiation of physical dependence and from a diagnosis of addiction.

Program Description : In 2011, MediCom, in collaboration with the American Academy of Pain Medicine, is proposing to utilize the power of the ESP member network to broadcast live HD video meeting highlights from the 2011 American Academy of Pain Medicine in a new format, ESP Live! at the 27th AAPM. In this initiative, ESP clinical advisors – an extensive network of thought leader clinician faculty –will assist in identifying the most relevant, innovative, and timely advancements in pain management presented at the AAPM meeting.

Agenda :

Are there other financial supporters of this program? : Yes

What is the highest level of outcomes proposed in the grant? : Level 5 (Performance - The degree to which participants do what the CME activity intended them to be able to do in their practices). Please give a brief description and sample.

Please provide a description of the highest level of outcomes proposed in the grant : • L1 - Participation (Registrant Data); • L2 - Satisfaction (Rate Level of Satisfaction); • L3A - Declarative Knowledge (Learning Objectives Met); • L4 - Competence (Plan to Make a

**Program Overview**

Therapeutic Area : Chronic Pain (General)  
 Program Title : ESP Live! at the American Academy of Pain Medicine  
 Program Start Date : 03/24/2011  
 Program End Date : 03/24/2012  
 Decision Date : 01/14/2011  
 Requested Amount : \$50,000.00  
 Total Funding needed for Program : \$65,870.00

**Program Details**

Needs Assessment Summary : Nonmalignant chronic pain is one of the most common reasons for patients to seek medical attention. Physicians and other clinicians therefore require current, on-demand and easy-to-utilize continuing medical education to assist them in developing the necessary skills to evaluate and manage patients with chronic pain.

Learning Objectives : • To improve the knowledge of the benefits of using a strategic precautionary approach to assess and manage chronic pain. • To improve the knowledge and competence of utilizing a risk assessment tool such as the Opioid Risk Tool to best stratification of risk in managing a patient with chronic pain. • To improve knowledge about which behaviors are most predictive of addiction outcomes. • To improve knowledge about differentiation of physical dependence and/or tolerance from a diagnosis of addiction.

Program Description : In 2011, MediCom, in collaboration with the American Academy of Pain Medicine, is proposing to utilize the power of the ESP member network to broadcast live HD video meeting highlights from the 2011 American Academy of Pain Medicine in a new format, ESP Live! at the 27th AAPM. In this initiative, ESP clinical advisors – an extensive network of thought leader clinician faculty –will assist in identifying the most relevant, innovative, and timely advancements in pain management presented at the AAPM meeting.

Agenda :

Are there other financial supporters of this program? : Yes

What is the highest level of outcomes proposed in the grant? : Level 5 (Performance - The degree to which participants do what the CME activity intended them to be able to do in their practices). Please give a brief description and sample.

Please provide a description of the highest level of outcomes proposed in the grant : • L1 - Participation (Registrant Data); • L2 - Satisfaction (Rate Level of Satisfaction); • L3A - Declarative Knowledge (Learning Objectives Met); • L4 - Competence (Plan to Make a

Change); • L5 - Performance (Post-Activity Survey on Change)

**Delivery Format & Audience**

Delivery Format	Web: Website	If Other is selected, please describe your Delivery Format	
Rationale for Format	Effective reach and dissemination of education		
Estimated Number of Speakers/Faculty Members	14		
Venue Name	City		
State	Zip Code		
Country			
Method of audience generation	ESP membeship via email		
Is this program certified?	Yes	No	Certification/Accreditation Type CME
Audience Group	Total CE/CME Credit Hours Offered	Estimated Number of Attendees	
Pain Specialists	1.25	1000	

**Program Implementation**

Third Party assisting with Program No Implementation?

**Educational Partner Information**

Tax ID # :

Organization Name :

Contact Name (of person with legal authority to sign on behalf of this organization) :

Address :

City :

State :

Zip Code :

Primary Phone : Ext.

Fax :

Email (of person with legal :

authority to sign on behalf of this  
organization)

Roles and Responsibilities :

### Payee Information

Checks Payable To : MediCom Wordwide, Inc  
Payment Address : 101 Washington St  
Payment Address: City : Morrisville  
Payment Address: State : PA  
Payment Address: Zip Code : 19067  
Payee Tax ID # : 23-3063738  
Payee E-mail Address : joan@medicaled.com  
Payee First Name : Joan  
Payee Last Name : Meyer  
Payee Phone Number : (215) 337-9991 Ext.

### Cephalon Budget

Total Amount Requested from Cephalon \$ 50,000.00

Total Program Budget \$ 65,870.00

### Detail

Budget Item	Cost	Comments
Management Fee	\$4,250.00	
Editorial / Content Development Fee	\$2,700.00	
Creative / Graphic Design Fee	\$1,130.00	
Accreditation Fee (if accredited)	\$10,000.00	
Faculty Fee: Honoraria	\$5,500.00	
Faculty Fee: Travel	\$625.00	
Faculty Fee: Lodging	\$975.00	
Venue / Event Fee	\$5,200.00	
Association Fee (if applicable)		
Website Hosting Fee (if applicable)	\$18,350.00	
Audience Generation Fees		
Educational Materials Production	\$13,090.00	
Shipping / Postage		
Outcomes Measurement Fees		
Other (please describe)	\$4,050.00	MediCom Travel

Total Program Budget \$ 65,870.00






Revenues \$

Total Program Budget  
minus Revenues \$ 65,870.00

Development &  
management fees \$ 21,750.00

Pass-through expenses \$ 44,120.00

**Attached Documents**

Document Title	Uploaded Document File Name	Uploaded By	Date Uploaded
 Accreditation Form	Certificate.tif	REQUESTOR	11/13/2009 9:34:25 AM
 Detailed Budget Document	ESP_Live_AAPainMed_110310.pdf	REQUESTOR	11/12/2010 8:52:22 AM
 Letter of Request on Organization's Letterhead	LOR.pdf	REQUESTOR	11/12/2010 8:52:23 AM
 W-9 Form	In response to RAI.pdf	REQUESTOR	11/15/2010 9:09:30 AM
 Needs assessment	Proposal.pdf	REQUESTOR	11/12/2010 8:53:54 AM

**Budget Allocations**

GL Account	Cost Center	Amount
764000 - All Independent Medical Education grants	100FN440 - Pain	\$50,000.00

101 Washington Street  
Morrisville, Pennsylvania 19067  
Phone 215.337.9991  
Fax 215.337.0959



November 12, 2010

Dear Educational Grant Review Committee:

MediCom Worldwide, Inc. is pleased to submit the accompanying grant request to Cephalon for an educational program for clinicians that treat nonmalignant chronic pain. As accredited providers of continuing medical education, MediCom Worldwide, Inc. recently completed a comprehensive needs assessment to identify the educational needs of clinicians who treat chronic pain.

MediCom Worldwide, Inc. is committed to delivering education that addresses gaps in health care professional knowledge with the ultimate goal of improving patient care. We are therefore requesting funding for the development of 2011 *American Academy of Pain Medicine* video meeting highlights hosted on *Emerging Solutions in Pain (ESP)* website.

*Emerging Solutions in Pain (ESP)* was launched in 2005 with a leading cadre of experts in pain management and addiction medicine to help clinicians address these challenges. ESP is a robust and multi award-winning ongoing educational initiative which provides an array of information, resources, tools, and case studies to highlight and educate clinicians on the complexities surrounding the management of chronic pain.

The total budget to fund this activity is approximately \$65,870. Please refer to the detailed budget section of this proposal for complete grant funding details. MediCom is seeking multi support for this initiative and thereby requests funding up to \$50,000 to support ESP from Cephalon.

This scientific initiative will comply with all ACCME, FDA, AMA, ACPE, and nursing regulations for industry supported professional continuing education. MediCom Worldwide is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians, approved by the Accreditation Council for Pharmacy Education (ACPE) to provide pharmacy continuing education, and approved by the California State Board of Registered Nursing to provide nursing continuing education.

Educational support will be acknowledged on the educational program in compliance with ACCME Guidelines.

Thank you, in advance, for your consideration of this request.

Respectfully,

A handwritten signature in cursive script, appearing to read "Joan Meyer", is written over a horizontal line.

Joan Meyer, RN, MHA  
Executive Director, Continuing Education





101 Washington St, Suite 110  
Morrisville, PA 19067

Proposal Number: 10-284b  
Date: October 28, 2010

07028.19

(07300MM.19)

**ESP Live! at the 2011 American Academy of Pain Medicine**  
October 28, 2010

<b>Cost Summary, Live Meeting</b>	
Approximate Total, Out-of-Pocket Expenses	\$ 44,120
Total, Time of Staff Expenses	\$ 21,750
<b>ESP Live! at the 2011 AAPainMed Meeting</b>	<b>\$ 65,870</b>

<b>Detailed Budget Itemization: Meeting Management</b>	
<i>Out-of-Pocket Expenses, Approximate</i>	Total
Broadcast station space	\$ 5,200
Faculty honoraria (5 faculty members)	\$ 2,500
Moderator honoraria (1)	\$ 3,000
Moderator expenses: 1 faculty	
Air	\$ 375
Hotel	\$ 975
Ground transportation	\$ 100
OOP	\$ 150
MediCom expenses: 2 MCWW staff	
Hotel: 1 night each for 2 staff	\$ 650
Ground transportation	\$ 100
OOP: 2 days each for 2 staff	\$ 200
Corona expenses: 3 A/V staff	
Air for 1 staff	\$ 375
Hotel: 3 staff for variable number of nights per staff; 7 nights total	\$ 2,275
Ground transportation	\$ 100
OOP: 3 staff for variable number of days per staff; 7 days total	\$ 350
Production services	
Editorial, including proofreading	\$ 1,850
Audio/visual services	
Filming and all on-site production services	\$ 7,500
Remote switching	\$ 1,500
Internet fees	\$ 500
ESP programming	\$ 6,000
Pre-meeting announcement blast	\$ 1,050
Post-meeting posting of highlights	\$ 600
Project management	\$ 1,200
Equipment rental	
Broadcast station furniture and table cloth	\$ 500
Monitor / Plasma rental	\$ 800
Broadcast station functions	
Onsite management, broadcast station staffing	\$ 3,120
Broadcast station giveaways	\$ 400
Shipping	\$ 500
Fulfillment	\$ 300



101 Washington St, Suite 110  
Morrisville, PA 19067

Proposal Number: 10-284b 07028.20  
Date: October 28, 2010 (07300MM.20)

**ESP Live! at the 2011 American Academy of Pain Medicine**  
October 28, 2010

<b>Detailed Budget Itemization: Meeting Management</b>	
<b>Out-of-Pocket Expenses, Approximate (continued)</b>	<b>Total</b>
<b>Meeting management</b>	
Venue coordination	\$ 800
Travel coordination for faculty and staff	\$ 900
<b>Miscellaneous (non-fulfillment shipping, faxes, FedEx, etc.)</b>	\$ 250
<b>Approximate Total, Out-of-Pocket Expenses</b>	<b>\$ 44,120</b>
<b>Time of Staff Expenses</b>	<b>Total</b>
<b>Project management</b>	
Strategic development, account management	\$ 2,000
Coordination with faculty	\$ 900
Coordination and supervision of internal teams	\$ 600
Coordination with third-party vendors	\$ 300
Preparation and coordination of status meetings/updates	\$ 450
<b>Medical services</b>	
Meeting highlights coordination	\$ 1,200
Development of accreditation-related front matter	\$ 900
Copy writing	\$ 150
<b>Onsite management (2 staff members)</b>	\$ 4,800
<b>Accreditation for CME, CNE, CPE</b>	\$ 10,000
Includes accreditation, review, certificate processing	
<b>Administrative and accounting fees</b>	\$ 450
<b>Total, Time of Staff Expenses</b>	<b>\$ 21,750</b>

***ESP Live! at AAPM***  
Video Highlights  
Directly from the  
**AAPM's 27th Annual Meeting**  
March 24 - 27, 2011 in Washington, DC

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## 1. Needs Assessment

Nonmalignant chronic pain is one of the most common reasons for patients to seek medical attention. Physicians and other clinicians therefore require current, on-demand and easy-to-utilize continuing medical education to assist them in developing the necessary skills to evaluate and manage patients with chronic pain.

### 1a. ESP Background

Treatment of chronic pain can be a real challenge. Clinicians are increasingly faced with the need to address the associated challenges of side effects, addiction, and legal regulations with chronic opioid therapy. Physicians are increasingly utilizing the Internet, and in particular, trusted independent websites, as an essential component of obtaining professional information, as a source of continuing medical education (CME), and as a communication lifeline at the point of care.

*Emerging Solutions in Pain* (ESP) was launched in 2005 with a leading cadre of experts in pain management and addiction medicine to help clinicians address these challenges. ESP is a robust and multi award-winning ongoing educational initiative which provides an array of information, resources, tools, and case studies to highlight and educate clinicians on the complexities surrounding the management of chronic pain. It aims to inform clinicians of methods of communication, ways in which risk of abuse may be measured, and how to integrate these strategies into an individualized treatment plan. The main objective of ESP is to maximize chronic pain patient care outcomes while minimizing the risks of the associated challenges.

The ESP website has achieved many successes including<sup>1</sup>:

- ESP membership has grown phenomenally since launch. The current membership is 22,140<sup>2</sup> (+67.6% increase over 2009)
- ESP membership demographics includes all members of the multidisciplinary team, with physicians and nurses being the most represented
- The key reasons identified by ESP members for accessing the website include obtaining CE credit (81%) and staying up-to-date on vital health care issues (13.5%)
- ESP has been awarded both HONCode and Web Medica Accredited (WMA) certification, the only two worldwide organizations certifying websites adhering to the strictest guidelines and ethical standards of presenting credible and reliable information for health care professionals
- ESP has been recognized for both content and innovative design with numerous international awards
- ESP content has been rated highly in terms of usefulness (4.1), quality (4.1), change in clinical practices (3.8) and commitment to change (4.0)<sup>3</sup>
- ESP educational activities have led to the following key changes in clinical practice: patient assessment (22.6%), patient monitoring (19.1%), documentation (12.2%), risk strategy (13.9%), pharmacological management (13.9%), and other (18.3%)<sup>4</sup>

<sup>1</sup>The following are based on ESP members self-report during registration and surveys.

<sup>2</sup> ESP members to October 31, 2010.

<sup>3</sup>The numbers in brackets represents the average overall rating by ESP members to October 2010 where 5 = highest and 1 = lowest

- A recent study was conducted by CE Outcomes, LLC to determine the effectiveness of two ESP CME activities, focusing on the safe and effective treatment of chronic pain while minimizing the risks of misuse. A post-activity assessment study was conducted 3-5 months after completion to determine the effectiveness of two CME activities on the practice patterns and knowledge of physicians who manage chronic pain patients. Effectiveness was measured using a case-based survey designed to assess whether the diagnostic and therapeutic choices of program participants were consistent with evidence-based content of the CME activities. The survey was also administered to a demographically similar control group of physicians who did not participate in the educational program in order to assess differences in practice choices. The participant group was selected from a list of physicians completing the course and also agreeing to participate in future self-study activities. The control group was selected at random from the AMA Master File. The participant and control group were matched on the following characteristics: physician specialty, degree, years in practice, whether or not direct patient care was their primary responsibility, and the number of patients seen per week with chronic pain. **The large effect size (30%) suggests that the ESP Internet-based CME programs offer effective, credible, and high-impact education.** Physicians who participated in ESP CME activities are more likely to practice evidence-based care of chronic pain patients than those who did not participate in these activities, specifically:
  - Participants were more likely to recognize that a **strategic precautionary approach** to assessing a patient with moderate risk for aberrant behavior will reduce the likelihood of becoming a high-risk patient ( $P=.086$ ).
  - Participants were more likely to start a patient with severe pain that is not controlled with acetaminophen and NSAIDs who demonstrates **moderate risk for aberrant behavior on multimodal therapy** ( $P=.059$ ).
  - Participants were more likely to recognize the need to **utilize a standard risk-assessment tool** (such as the ORT or SOAPP) as the best approach to stratifying risk in a patient in the primary care setting ( $P=.06$ ).
  - Participants were more likely to recognize that some over-the-counter medications cause a **false-positive urine test and would assess a patient's OTC medications prior to stopping the patient's opioid therapy** ( $P=.131$ ).
- Clinicians exposed to ESP web-based educational activities and resources have demonstrated a positive impact to clinical performance as evidenced by the self-report measures presented above.

In summary, ESP has had a positive impact on clinicians via exposure to the availability and access of clinical support tools and resources to utilize in the assessment and monitoring of risk in their patients who are prescribed opioids.

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<sup>4</sup>Other – includes teaching, further research, and sharing with colleagues.

**1b. Sources of Data for Identified Performance and Knowledge Gaps**

During March 2010, CE Outcomes, LLC conducted a project with MediCom Worldwide, Inc. to identify specific educational gaps in the management of patients with chronic pain. A random sample of 50 physicians including pain specialists and primary care physicians (PCPs) was collected. Case vignettes were used to determine current practice patterns. Case vignettes have been shown to be a robust and noninvasive method of determining physician practice patterns in outpatient settings.<sup>5</sup> Barriers to optimal practice were also assessed.

MediCom has also evaluated all CE pre and post-test evaluation forms, poll survey questions and Text Your Knowledge (TYK) questions to identify supporting evidence for these identified gaps.

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<sup>5</sup> Peabody JW, et al. Measuring the quality of physician practice by using clinical vignettes: a prospective validation study. *Ann Intern Med*. 2004;141(10):771-780.



### 1c. Identified Performance and Knowledge Gaps

The following gaps were identified from the above sources:

#### Gap 1: Utilization of a strategic precautionary approach

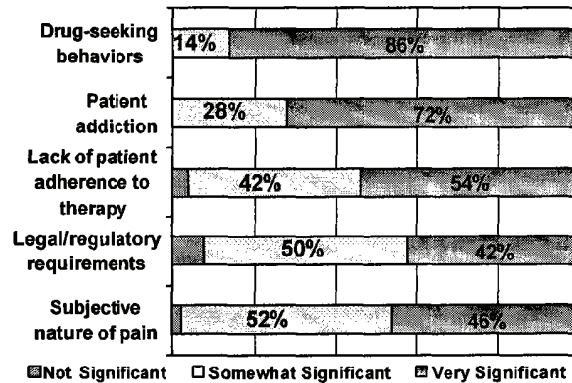
Evidence	Source
<ul style="list-style-type: none"> <li>• Half of PCPs and 1 in 3 pain specialists were unaware of the benefit of using a strategic precautionary approach to assess and manage chronic pain.</li> <li>• 2 in 5 PCPs did not recognize that utilizing a risk assessment tool such as the Opioid Risk Tool (ORT) and the Screener and Opioid Assessment for Patients with Pain (SOAPP) is the best risk stratification approach to managing a patient with chronic pain in the primary care setting.</li> <li>• Almost 2 in 5 physicians did not recognize that some over-the-counter (OTC) medications cause a false-positive urine test for methamphetamines.</li> <li>• Over two-thirds of the physician respondents failed to recognize that risk stratification assessments should not be used exclusively in deciding on a treatment plan.</li> </ul>	CE Outcomes, LLC study
<ul style="list-style-type: none"> <li>• 22.5% of responders disagreed with the following statement: "Utilizing risk assessment tools is considered the most effective in curtailing drug misuse."</li> <li>• 25% of responders got the following question correct: "Drug-seeking behavior in patients on chronic opioid therapy can be monitored with: a. BDI b. SOAPP-R c. HAM-D d. COMM"</li> <li>• 12.5% got the following correct: "A validated screener of risk of drug abuse for use in patients on long-term opioid therapy is: a. SOAPP-R b. ORT c. COMM d. CAGE-AID"</li> <li>• 14.3% selected the correct response on: "PCPs prescribing opioids limit risk by use of a(n): a. Attorney b. Hidden video cam c. Share-the-risk model d. Legal contract"</li> <li>• 33.3% got the following correct: "Which screening tool lacks questions about psychiatric disorders? a. SISAP b. ORT c. SOAPP-R d. SOAPP-24"</li> <li>• Only 24.3% and 57.7% got the following pre-test and post-test question correct respectively: "In patients on chronic opioid therapy (COT) who are at high risk or who have engaged in aberrant drug-related behaviors, clinicians should periodically obtain urine drug screens or other information to confirm adherence to the COT plan of care. This is an example of what type of recommendation: a. Strong recommendation based on high-quality evidence b. Weak recommendation based on moderate-quality evidence c. Strong recommendation based on low-quality evidence."</li> <li>• 52.5% of post-test responses were correct for the following: "Which of the following techniques is considered most effective in curtailing drug abuse, misuse, and addiction? a. Risk assessment and compliance monitoring; a highly structured therapeutic approach b. Use of prescription monitoring data and abuse-deterrent drug formulations c. Patient education d. None of the above"</li> </ul>	ESP CE evaluations, polls and TYK surveys

**Gap 2: Understanding terminology, identification and treatment of risk phenomena associated with chronic opioid therapy**

Evidence	Source
<ul style="list-style-type: none"> <li>3 in 4 physicians would not select the appropriate initial treatment for a patient with chronic pain who demonstrates moderate risk for aberrant behavior.</li> </ul>	CE Outcomes, LLC study
<ul style="list-style-type: none"> <li>Only 25.6% of responders "routinely refer to clinical guidelines when treating elderly patients for pain"</li> <li>30.8% of participants selected the correct response for: "Most state guidelines recommend the use of treatment agreements with high-risk patients only. a. True b. False"</li> <li>33.3% got the following right: "Mu-opioid receptors are the central target in opiate abuse and compulsive alcohol abuse. a. True b. False"</li> <li>26.7% got the correct answer for: "Addiction is a psychiatric disorder. a. True b. False"</li> <li>30.8% were right on the following: "Which of the following is the second most prevalent non-medically used drug in America? a. Marijuana b. Benzodiazepines c. Opioids d. Stimulants"</li> <li>40.0% selected the correct response for: "Behaviors predictive of addiction-outcomes: a. Higher dose request b. IV use of oral drug c. Abuse of illicit drugs d. Specific drug request"</li> <li>38.3% of post-test participants got the following correct "Biologic consideration of drug-taking aberrant behavioral risk does not include: a. Age b. Gender c. Presence or absence of psychiatric disease d. History of substance abuse"</li> <li>53.5% got the following correct: "Which risk group can usually be managed effectively and safely by a primary care provider? a. Only low-risk patients b. Low- and moderate-risk patients c. Only high-risk patients d. No group should be managed exclusively by a primary care provider"</li> <li>332 participants got the following incorrect: "Physical dependence and/or tolerance are appropriate criteria for a diagnosis of addiction."</li> </ul>	ESP CE evaluations, polls and TYK surveys

#### 1d. Barriers to the Optimal Management of Patients with Chronic Pain

- The CE Outcomes, LLC study identified that drug-seeking behaviors and patient addiction are the most significant barriers to physicians optimally managing patients with chronic pain



- ESP member surveys also identified legal and regulatory concerns as a significant barrier:
  - 87.7% thought that: "A common barrier to pain management among physicians is fear that they will be investigated or arrested for prescribing controlled substances."
  - 95.1% felt that: "Fears regarding opioid therapy contribute to the barriers to effective pain management."

#### 1e. Design Implications

- Given the prevalence of chronic pain and the difficulties faced in managing patient addiction and drug-seeking behaviors, education on risk assessment tools and strategies is a continuing need for clinicians.
- Educational content should focus on terminology of risk phenomena, identification of aberrant drug-taking behaviors and the best tools to utilize, and the appropriate treatment of high risk patients.
- In addition, clinicians need education that acknowledges the barriers to optimal pain management including drug-seeking behaviors, patient addiction, and legal and regulatory requirements for prescribing chronic opioid therapy.

## **2. *ESP Live!* at the 27<sup>th</sup> AAPM**

### **2a. Program Overview**

In 2011, MediCom, in collaboration with the American Academy of Pain Medicine, is proposing to utilize the power of the *ESP member* network to broadcast live HD video meeting highlights from the 2011 American Academy of Pain Medicine in a new format, ***ESP Live! at the 27<sup>th</sup> AAPM***. In this initiative, *ESP clinical advisors*—an extensive network of thought leader clinician faculty—will assist in identifying the most relevant, innovative, and timely advancements in pain management presented at the AAPM meeting. These clinician thought leaders, together with MediCom, will also select an appropriate moderator to interview the presenters of these chosen sessions. Interviews will focus on the latest data, on what the data mean to the clinical setting, and how clinicians may effectively incorporate the data to improve patient care, and ultimately, patient outcomes.

Each daily video broadcast will be advertised via multiple mechanisms to the almost 22,000 member *ESP* audience, as well as via the *ESP* broadcast station at the AAPM meeting.

### **2b. Learning Objectives**

The purpose of ***ESP Live! from the 27<sup>th</sup> AAPM*** is to educate clinicians on the effective assessment, treatment and monitoring of pain patients, and on good practice management techniques that support improved outcomes in patients with chronic pain. More specific program objectives will be developed once the AAPM schedule is released, but broadly the objectives are:

- To outline the emerging issues in pain medicine.
- To discuss in-depth topics of special interest on the latest cutting-edge pain-related information.
- To summarize key developments and research findings and translate these into practical day-to-day clinical pearls.

### **2c. Overall Program Objectives**

- To improve the knowledge of the benefits of using a strategic precautionary approach to assess and manage chronic pain.
- To improve the knowledge and competence of utilizing a risk assessment tool such as the Opioid Risk Tool to best stratification of risk in managing a patient with chronic pain.
- To improve knowledge about which behaviors are most predictive of addiction outcomes.
- To improve knowledge about differentiation of physical dependence and/or tolerance from a diagnosis of addiction.

### **2d. How will the program benefit delegates?**

*ESP* is proposing to provide dynamic and real-time updates to both the AAPM attendees and *ESP* members via ***ESP Live! at the 27<sup>th</sup> AAPM***, through an on-the-floor HD video broadcast station live from Washington, DC, which will:

- Alert meeting attendees that they may receive the meeting highlights through *ESP Live!* and *ESP Radio*
- Allow attendees to download *ESP Mobile* to their 3G network-enabled phones
- Allow attendees to view the on-air interviews with the clinician thought leaders, live and in-person, as a member of the *ESP Live!* audience

This program would therefore benefit the following:

- AAPM delegates attending the 2011 AAPM who were unable to attend all the sessions
- AAPM members unable to attend the 2011 AAPM
- ESP members unable to attend the 2011 AAPM
- Both attendees and non-attendees with discussions of interpreting the scientific data presented at the 2011 AAPM into real clinical day-to-day practice advice/suggestions
- On-demand formats would enable clinicians to listen or view discussions from anywhere and at anytime

#### **2e. Potential Faculty for *ESP Live!***

The following potential faculty has been identified to participate in the *ESP Live!* program:

- |   |                                |
|---|--------------------------------|
| • Lynn Webster, MD  | • Scott Fishman, MD            |
| • Gilbert Fanciullo, MD, MS                                     | • Rollin M. Gallagher, MD, MPH |
| • Chester C. Buckenmaier, MD, COL, MC, USA                      | • Bill McCarberg, MD           |
| • Tim J. Lamer, MD  | • Michel Y. Dubois, MD         |
| • Michael Cousins, MD DSc FANZCA FRCA<br>FACHPM(RACP) FFPMANZCA | • Sunil J. Panchal, MD         |
| • Joshua Prager, MD   | • John Markman, MD             |
| • Zahid Bajwa, MD   | • John Peppin, DO, FACP        |
| • Edward Bope, MD   | • Perry Fine, MD               |
| • Mark Sullivan, MD   | • Aaron Gilson, MS, MSSW, PhD  |
| • Chester Buckenmaier III, MD                                   | • Ben Rich, JD, PhD            |
|   | • Martin Angst, MD             |

#### **2f. Potential Topics**

The following lists potential topics to be covered during the interview sessions (two sessions will be covered each day depending on appropriateness to the *ESP* audience):

- Legal and Ethical Aspects of Pain Care
- The Importance of Producing Quality Guidelines
- Emerging Ethical Considerations in Responsible Opioid Prescribing
- Essential Tools for Treating the Patient in Pain
- Battlefield Pain Management: From Point of Injury to Home
- Using Outcome s Data to Improve Patient Care
- Patient Centered Pain Care

- The Value Proposition in Pain Care
- Evidence-Based Therapies in Cancer Pain Management
- Opioid Induced hyperalgesia
- Challenging Patients – Issues and Opportunities
- Coding Update
- REMS Update
- Optimizing Clinical Research and Publishing

Please note that **ONLY** plenary and poster sessions will be covered on *ESP Live!* (no symposia sessions will be included).

### **2g. Intended Audience**

The primary audience of *ESP Live! from the 27<sup>th</sup> AAPM* will be physicians, pharmacists, nurses, fellows, residents, and other allied health care professionals who provide care to patients with chronic pain.

These include:

- Members of the AAPM attending the 27<sup>th</sup> AAPM annual meeting
- Attendees of the 27<sup>th</sup> AAPM annual meeting who are not members of AAPM
- Members of the AAPM who are not able to attend the meeting
- Members of *Emerging Solutions in Pain*
- Subscribers to *ESP Mobile* and *The Beacon*
- Current listeners of *ESP Radio*
- Clinicians who have downloaded *ESP Mobile*

The total size of this target audience will exceed 35,000 clinicians.

### **2h. Format and Awareness**

*ESP Live! from the 27<sup>th</sup> AAPM* will be HD video broadcast sessions via the *ESP* website and *ESP Radio* which can be also be accessed via *ESP Mobile* (a Smartphone application). The interview sessions will be archived on the *ESP* website for a period of one year to enable more health care participants to access the information presented.

Each daily broadcast will be advertised via the *ESP* website and e-newsletter, *The Beacon*, the 22,000 member *ESP* audience, as well as direct mail to the AAPM membership.

Delegates will be given the option to “opt-in” to obtain CME credit for participating in this program. These delegates will receive a pre- and post-test evaluation.

## **3. Budget**

The total estimated budget to fund this activity is \$65,870.



#### 4. Compliance Information

ESP activities will be planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) as well as the Accreditation Council for Pharmacy Education (ACPE) and the California Board of Registered Nursing (CBRN).

These programs will adhere to the ACCME Standards of Commercial Support as well as all other applicable guidelines including FDA, OIG, and PhRMA.

#### 5. Funding Requirements

The total cost of funding this initiative is \$65,870. All grantors for the *ESP Live!* initiative will be acknowledged on all activity promotional materials, program syllabus, and on the *ESP* homepage.

MediCom Worldwide, Inc. understands that total funding may not be possible due to budget constraints of the grantor. Funding will be acceptable at any level. If total funding is received at a lower level than requested, then adjustments will be made in the total educational offerings.

#### 6. Payment Structure

- 100% due upon signing agreement

#### 7. Outcomes/Final Report

The final report to be sent to you 90 days after this activity has been completed will include the following metrics and outcomes:

**Metric Measures:**

- Website User Sessions
- Smartphone User Sessions
- ESP Radio Sessions

**Outcome Measures:**

- L1 - Participation (Registrant Data);
- L2 - Satisfaction (Rate Level of Satisfaction);
- L3A - Declarative Knowledge (Learning Objectives Met);
- L4 - Competence (Plan to Make a Change);
- L5 - Performance (Post-Activity Survey on Change)