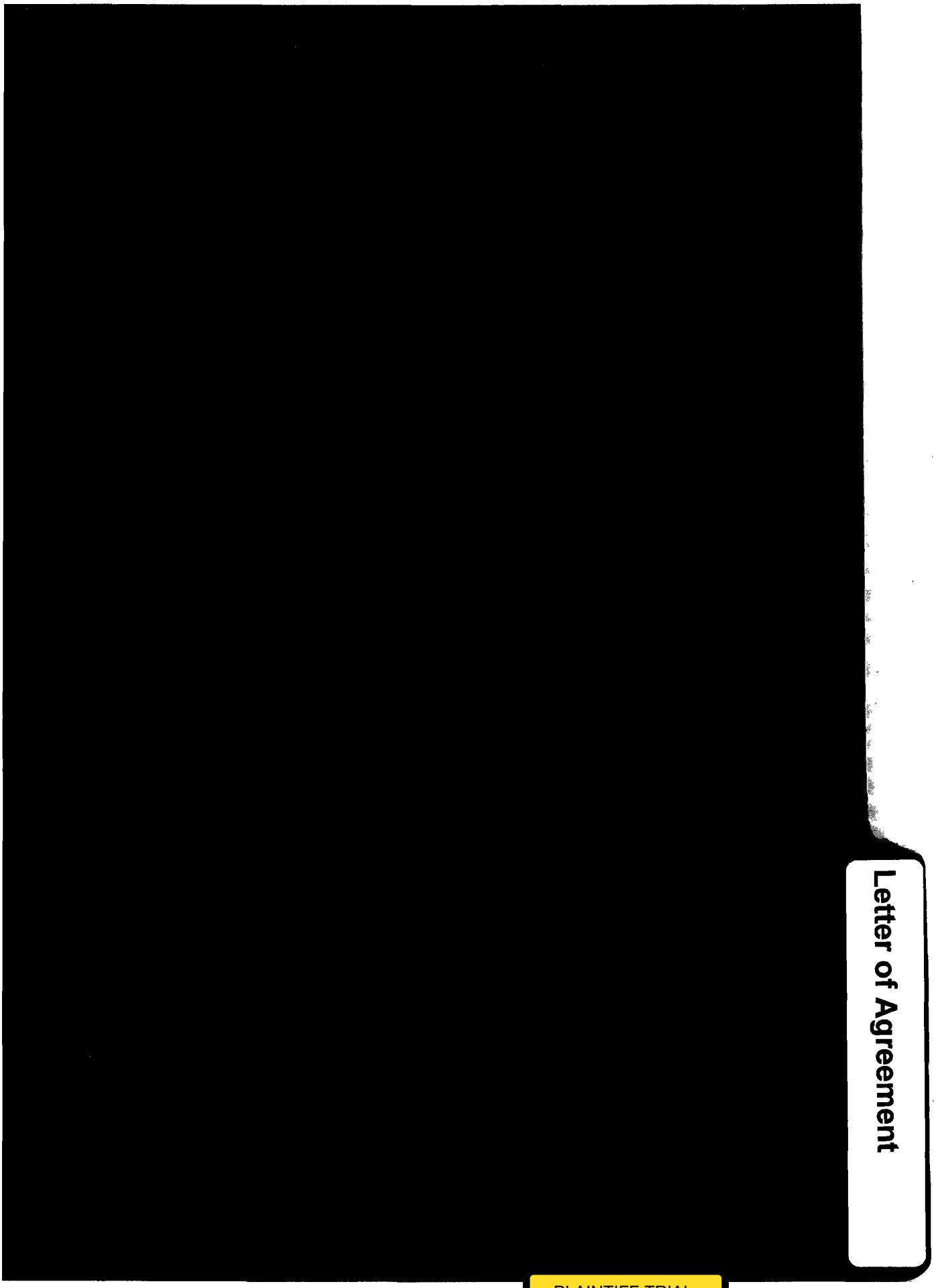

Cephalon
deliver more

Cephalon, Inc
41 Moores Road
Frazer, PA 19355
tel 610 344 0200
fax 610 344 0065
www.cephalon.com

Pre-Approved Template Archiving Cover Memo

To:	Legal Department – Archives
From:	Kimber Titus x86766
Date:	January 15, 2009
Re:	Fully-Executed Agreement(s) for Archiving in Central Files

I have attached hereto a fully-executed

☐ **Confidential Disclosure Agreement**
☐ **Mutual Confidential Disclosure Agreement**
☐ **Clinical Trial Agreement**
☐ **Master Clinical Trial Agreement**
☒ **IEP Grant Agreements**

I have completed the checklist below in preparation for archiving in Central Files:

☒ I prepared and finalized this agreement in accordance with the most currently approved template located on the Legal Department Intranet Page.

☒ If any changes to the template agreement were made, I forwarded the agreement to the Legal Department for review and approval.

☒ An authorized Cephalon officer has signed the agreement (at the level of Vice President or above, or for CDAs, a Director or Senior Director who has a valid Delegation of Authority to sign CDAs on file in the Legal Department).

☒ The agreement(s) is fully executed by both parties and both original signatures are attached.

Thank you!

Cephalon
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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 16th day of December, 2008, by and between Cephalon ("Cephalon"), located at 41 Moores Road, Post Office Box 4011, Frazer, PA 19355, and Montefiore Medical Center ("Provider") located at CCME, 3301 Bainbridge Avenue, Bronx, NY 10467 and Asante Communications, LLC ("Educational Partner") located at 800 Third Avenue, 9th Floor, New York, NY 10022.

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 "Persistent and BTP: Multidimensional Assessment and Multimodal Opioid-Based Treatment Strategies," 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. The name of the Educational Partner is Asante Communications, LLC.

5. Educational Components. The expected components of the Program (e.g., number of live meetings, CD ROM, web-based, etc.) are as follows:

   (a) Thirteen Live National Meetings;
   (b) Two Additional Live Meetings;
   (c) Five Web Tactics;
   (d) One Print Piece;

(e) Three Print Supplements;

6. 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.

7. Grant Amount Funding Arrangements.

(a) Cephalon will provide support for the Program by means of an educational grant in the total amount of $1,316,295, 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.

8. 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.

9. 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.

10. 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

11. 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.

12. Question and Answer Session. To the extent the Program is a presentation, Provider will ensure meaningful opportunities for questioning by the audience.

13. 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.

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.

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 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.

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.

(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.

MONTEFIORE MEDICAL CENTER

By: Steven Jay Feld

Name: STEVEN JAY FELD

Title: ASSOCIATE DIRECTOR, CCME

The above signatory is a duly authorized corporate officer of the IEP Provider.

Date: 12/23/08

Tax ID #: 13 1740114

CEPHALON, INC.

By:

Name: Robert Kaper, MD

Title: Vice President, Medical Affairs

Date: 12/16/08

APPROVED AS TO LEGAL FORM CEPHALON LEGAL DEPT.

PROVED DAP FINANCE

ASANTE COMMUNICATIONS LLC

By:

Name: PETER HURWITZ

Title: PRESIDENT, MANAGING DIRECTOR

The above signatory is a duly authorized corporate officer of the Educational Partner.

Date: 12/24/08

Tax ID #: 80-0251570

Exhibit A

Copy of Grant Request

Albert Einstein
College of Medicine
of Yeshiva University

Center for Continuing Medical Education

Bridging the Gap Between Education and Practice

The University Hospital and
Academic Medical Center for the
Albert Einstein College of Medicine

Steven Jay Feld
Associate Director

December 8, 2008

Ms. Karen Roy
Director of Medical Education
Cephalon
41 Moores Road
Frazer, PA 19355

Dear Ms. Roy:

Per your request for additional information, please find below a more detailed overview of the Level and Type of data to be collected via the patient questionnaire.

Under the guidance of the Albany Medical Center's Institutional Review Board (IRB), and approved by Albert Einstein College of Medicine, CME, the Stage III Durable Outcomes measurement will be used to gather non-biased, independent and measurable information for the proposed Outcome Study.

As mentioned in the grant, the Stage III patient questionnaire will assess improvements in the management of persistent and breakthrough pain with patients whose physicians participated in the preceptorship program, when compared to patients who were under the care of control group physicians who did not participate in the preceptorship. The questionnaire will consist of 5-multiple choice questions, each inquiring into their perceptions of the clinician's attentiveness to the pain complaint. Sample questions that may be included, pending further discussion and approval by the Albany IRB, Albert Einstein College of Medicine and based on the approach utilized by Dr. Michael Brennan are as follows:

When compared to the beginning of the year has your clinician devoted more time to discuss the "ups-and-downs" in the severity of your chronic pain?

Parameters to be Measured

2 Significantly improved
1 Improved
0 No change

When compared to the beginning of the year has your clinician devoted more time to discuss changes in your pain severity caused by increased activity?

Parameters to be Measured

2 Significantly improved
1 Improved
0 No change

3361 Bainbridge Avenue Bronx, NY 10467 Phone 718 920 6671 Fax 718 798 2336 mecme.org sfeld@montefiore.org

When compared to the beginning of the year has your clinician devoted more time to discuss how to treat episodes when your pain is at its worst?

Parameters to be Measured

2	Significantly improved
1	Improved
0	No change

Lastly as a point of clarification, the sole data source from patients will be the patient questionnaire. **There aren't any needs for the Durable Outcomes Evaluation to review or collect data from patient charts. Patients will participate in this program on a strictly voluntary basis, can decide not to participate at any time, and will be assured of the confidentiality of their responses.** Dr. Charles Argoff and the Albany Medical Center IRB will supervise the administration and data analysis of Stage III, in collaboration with Dr. Hatcher (Associate Dean of CME at Einstein and Director of Research and CME at Montefiore) and Asante Communications.

We hope this clarifies the Stage III section of the proposed grant. As always, should you have any further questions, please do not hesitate to contact me with any questions.

Sincerely,

Steven Jay Feld

cc: Peter Hurwitz

3301 Bainbridge Avenue Bronx, NY 10467 Phone 718 920 5671 Fax 718 798 2436 mcecme.org sfeld@montefiore.org

Albert Einstein
College of Medicine
of Yeshiva University

Center for Continuing Medical Education

Bridging the Gap Between Education and Practice™

The University Hospital and
Academic Medical Center for the
Albert Einstein College of Medicine

November 20, 2008

Educational Grant Review Committee
Cephalon

Dear Sir and/or Madam:

On behalf of the Albert Einstein College of Medicine & Montefiore Medical Center, Center of Continuing Medical Education (CCME) and our Educational Collaborator and Joint Sponsor, Asante Communications LLC, please find the requested clarification information for Grant #2569.

Albert Einstein would like to reaffirm its commitment to providing high quality education. Of particular importance to us is adapting and refining each successive activity as the year unfolds. Applying our learnings from one program to the next invariably improves the substance of the program, and provides up-to-date insights from the faculty and participants alike.

Upon further discussion with our education collaborator, Asante Communications, in lieu of providing a specific book for the participants, originally suggested to be distributed to after the Full-day Regional Meeting and the Preceptorship program, it would be more prudent to provide a Reference Guide to these participants, in addition to quarterly online updates.

In addition, we see considerable benefits in combining the enduring material of the Teleconferences and the Cases and Commentary into a single enduring material, rather than producing two separate activities. This will limit any overlap that may occur from the content of these two activities. We would like to present this as an attractive option.

Enduring materials posted online will be targeted to pain specialists. Websites that are selected will have an audience which consists of pain specialists, including anesthesiologists, oncologists, neurologists, and physiatrists, among others.

In addition to being an accredited activity, the Position Paper that will be developed from the International Experts Forum will be submitted to a peer-reviewed journal for publication. We will request permission from the journal prior to submission of the article to be published as a CME activity in their journal and elsewhere. This will enhance the current BTP literature.

3341 Bainbridge Avenue Bronx, N.Y. 10467 Phone 718.920.6671 Fax 718.798.2336 ccme@aecom.yu.edu cme@montefiore.org

We would also like to comment further on two select items. First, as noted in the grant, nurses, nurse practitioners and physician assistants represent an important target audience and as such we will be making a concerted effort to recruit these pain clinicians for each educational activity. In addition, we would like to propose that a *Cases and Commentary* workshop be held at the Oncology Nurses Society (ONS) in 2009. An enduring activity will be developed from this Workshop and will extend the reach of this very valuable educational activity. This activity will be accredited for continuing education (CE) credit for nurses by an approved academic institution or noted medical center, such as Montefiore Medical Center. Further, as noted in the accompanying materials, one of the workshops will be held at the American Pain Society, a multidisciplinary organization that requires triple accreditation for all programs.

The other items uploaded for clarification purposes include:

- Timeline on all proposed activities
- Schematic of Chronic Pain Management Preceptorship (CPMP)
- Full-Day Regional Budget (clarification on Reference Guide)
- Preceptorship Budget (clarification on Reference Guide)

If you need any further information, or have any questions that relate to this grant request, please contact me at 718 920-6674, ext. 232.

On behalf of Albert Einstein College of Medicine & Montefiore Medical Center, I would like to thank Cephalon for the continued consideration of this request.

Sincerely,

Steven Jay Feld

3301 Bainbridge Avenue Bronx, N Y 10467 Phone 718 920 6674 Fax 718 798 2336 mec me org crie@montefiore.org

DESCRIPTION / CATEGORY	ASSUMPTIONS			COST	TOTAL COST
	Rate	Persons			
Protocol Director Honorarium	$2,000	1		$2,000	
Faculty Honoraria (Data Review/Interpretation	$2,000	4		$8,000	
				TOTAL	$10,000.00
Protocol Review and Approval					$5,000.00
Technical Programming/Quarterly Webinars					$6,000.00
Online Hosting and Monthly Maintenance					$2,500.00
Email Recruitment Stage II(Control and Participant Groups)					$2,500.00
Data Analysis/Statistician					$5,000.00
Patient Enrollment for Stage III					$1,000.00
Miscellaneous expenses					$1,500.00
TOTAL OOPs					$33,500.00
Management Fee					$15,000.00
Includes:					
* Manage design and production of all materials					
* Grant/Needs development					
*Administer outcomes tools (pre-test, post-test, and follow up questions)					
*Analyze results from pre-test, post-test and follow-up questions					
*Liaise with IRB and faculty					
*Manage all aspects of Patient enrollment under IRB supervision					
* Final reconciliation					
* Internal IRB compliance					
Content Development/Editorial/Creative Fee					$25,000.00
Content Development Includes:					
* Development of pre-test, post-test and follow-up questions					
* Liaise with faculty					
*Development of Case Vignettes					
*Development of Patient Survey					
*Development of outcomes report					
*Development of ideas for future educational tactics					
* Editorial/copy editorial review and formatting					
Creative Fee Includes:					
* Design of evaluation survey					
* All costs associated with project design and development					
TOTAL FEES					$40,000.00

GRAND TOTAL	$73,500.00

Variance +/- 10%

SPECIAL NOTE:

Any change in scope will require an approved revised budget. Cancellation of program will be subject to costs-to-date for all expenses and staff hours.

DESCRIPTION / CATEGORY	ASSUMPTIONS			COST		TOTAL COST
	Rate	Persons				
Course Director	$3,500	1				$3,500.00
Faculty Honoraria	$2,000	5				$10,000.00
Albert Einstein Accreditation and Certificate Fee				2.5 hrs.		$12,500.00
List Purchase						$1,500.00
Survey Distribution						$500.00
Development of Participant Database with tracking software						$3,250.00
Food and Beverage	Cost/Tax/ Gratuity	Persons/ Quantity	Number of Functions			
To Include Breakfast(s)	$40	20	1	$800		
				TOTAL		$800.00
Production/Printing 150 Binders						$1,500.00
Reference Guide	$ 30	200				$6,000.00
Purchase artwork						$750.00
Transcription Services						$3,000.00
Participant Communications (Teleconference/E-Communications)						$2,000.00
Creative Design for Program Template						$2,500.00
Express Mail Shipping (faculty mailings, materials shipping)						$1,000.00
Postage for participant materials		150				$1,000.00
Assembly of participant material		150				$500.00
Miscellaneous expenses other than group						$500.00
OOP TOTAL						$50,800.00
Management Fee						$32,000.00
Includes:						
* Timeline development & maintenance						
*Manage internal team and project flow						
* Coordinate faculty invitational process including invitations, confirmations, and enrollment process						
* Coordination of participants involvement and gathering of necessary information (Bios, etc)						
* Coordinate all initial faculty, faculty/participant, and quarterly teleconference calls						
*Manage the development of database of program and apprpropriate clinician tracking						
* Manage design and production of all meeting materials/reference binders including bios						
* Traffic meeting materials for review and production						
* Arrange for honoraria						
* Grant/Needs development						
*Reconciliation management						
* Certification collaboration (joint sponsorship, compliance review, Albert Einstein liaison)						
* Internal CME compliance						
Content Development/Editorial/Creative Fee						$35,250.00
Includes:						
* Develop learning objectives						
* Collaboration with faculty on agenda and discussion guide development						
* Collaborate with faculty on discussion guide for teleconference calls						
* Liaise with presenters (chair, faculty)						
* Editorial/copy editorial review and formatting						
* Development of program logo						
* All costs associated with meeting content design and development						
FEE TOTAL						$67,250.00
GRAND TOTAL						$118,050.00

Variance +/- 10%

SPECIAL NOTE:

Any change in scope will require an approved revised budget.
Cancellation of program will be subject to costs-to-date for all expenses and staff hours.

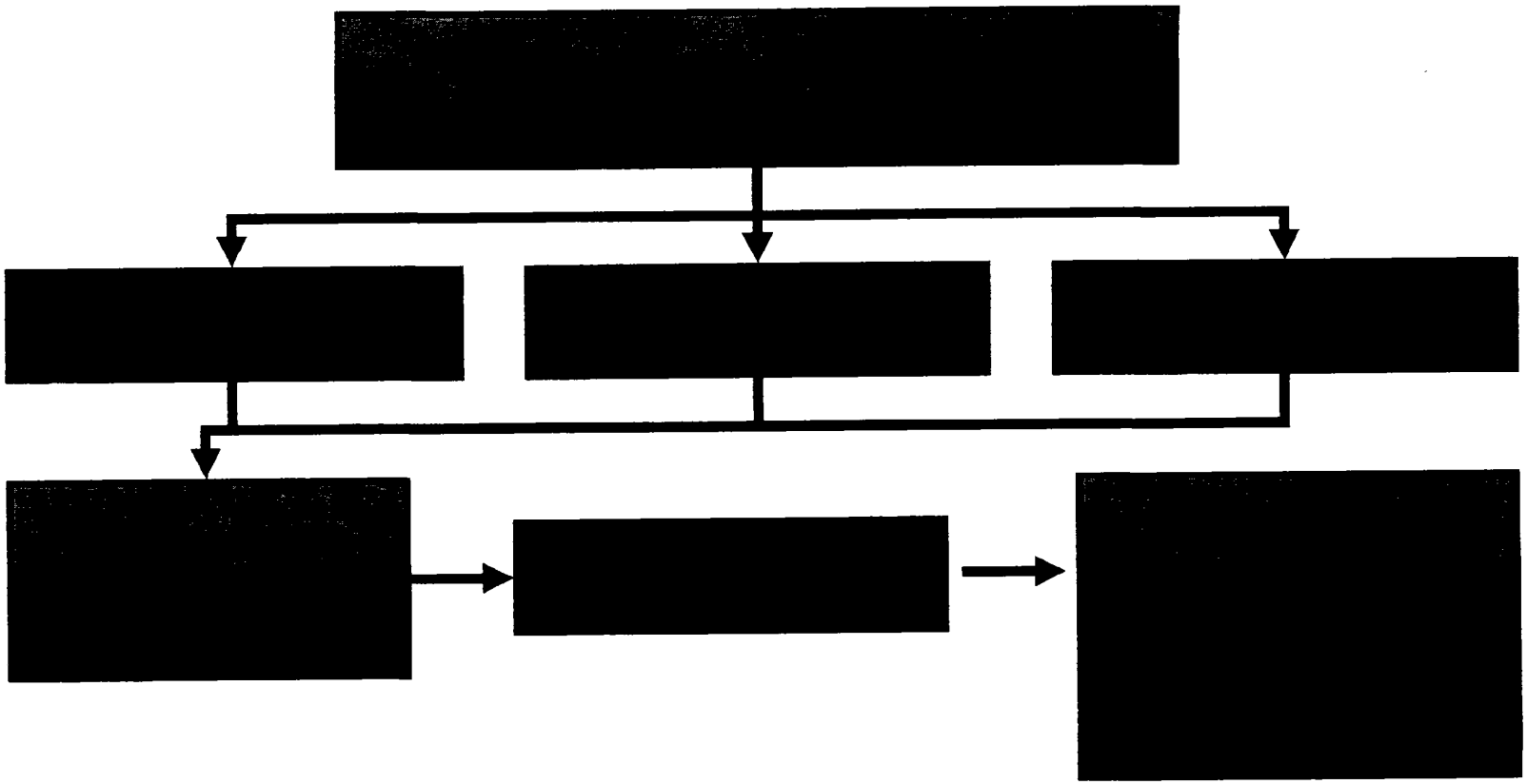
DESCRIPTION / CATEGORY	ASSUMPTIONS			COST		TOTAL COST
GENERAL COSTS						
	Rate	Persons				
Course Director Honorarium	$3,500	1		$3,500		
Chair Honorarium	$2,500	1		$2,500		
Faculty Honoraria	$2,000	4		$8,000		
				TOTAL		$14,000.00
Albert Einstein Accreditation and Certificate Fee						$9,500.00
Albert Einstein Outcomes Measurement Fee						$3,500.00
LOGISTICS						
Hotel Accommodations						
	Room & Tax	Persons	Nights			
To Include: Faculty	$275	6	1	$1,650		
Accreditor	$275	1	1	$275		
Asante	$275	3	1	$825		
Additional Suppliers	$275	2	1	$550		
				TOTAL		$3,300.00
Airfare	Fare & Tax	Persons	Service			
To Include: Faculty	$600	6	Coach	$3,600		
Accreditor	$600	1	Coach	$600		
Asante	$600	0	Coach	$0		
Additional Suppliers	$600	2	Coach	$1,200		
				TOTAL		$5,400.00
Ground Transportation	Fare & Tax	Persons	Service			
To Include Faculty	$300	6	Sedan	$1,800		
Accreditor	$100	1	Taxi	$100		
Asante	$100	3	Taxi	$300		
Additional Suppliers	$100	2	Taxi	$200		
				TOTAL		$2,400.00
Expenses	Rate	Persons				
To Include: Faculty	$100	6		$600		
Accreditor	$100	1		$100		
Asante	$100	3		$300		
Additional Suppliers	$100	2		$200		
				TOTAL		$1,200.00
Food and Beverage	Cost/Tax/ Gratuity	Persons/ Quantity	Number of Functions			
To Include: Continental Breakfast	$40	100	1	$4,000		
Lunch	$55	100	1	$5,500		
Break	$30	100	1	$3,000		
Faculty Dinner	$100	10	1	$1,000		
On-site Slide Review	$250	1	1	$250		
				TOTAL		$13,750.00
Meeting Room(s) Rental	$750	------	1			$750.00
Business Center	$50	------	------			$50.00
Gratuities (Hotel Staff)	$100	------	------			$100.00
On-Site Telephone/Fax	$750	------	------			$0.00
On-Site Internet Connection	$750	------				$0.00

Production/Printing							
Reference Guide		$ 30	100				**$3,000.00**
		Quantity	**Design**				
Services Include:	Printing of syllabus (includes printing & assembly charges for. Agenda, Participant List, Faculty List, color slices, evaluations, etc)	125	4-Color	**$5,250**			
	Printing of self-mailer, wafer-sealed invitation	8,500	4-Color	**$2,750**			
				TOTAL			**$8,000.00**
Signage, Name Badges, Tent Cards							**$1,375.00**
Pens, Pads							**$250.00**
Postage for Invites							**$2,500.00**
Postage for meeting materials							**$250.00**
EDITORIAL/PUBLICATIONS - OOP							
Editorial Research (articles/permissions)							**$750.00**
AUDIOVISUAL - OOP							
Audiovisual - All equipment for Slide Review and General Session							**$5,000.00**
Technical Supervisor/Support - Labor/PowerPoint Tech							**$1,500.00**
MISCELLANEOUS - OOP							
Express Mail Shipping (faculty mailings, materials shipping)							**$250.00**
Additional recruitment tactics/purchase lists							**$5,000.00**
Meeting Planner							**$7,000.00**
Creative, Design, and Layout							**$7,000.00**
Transcription							**$1,500.00**
Miscellaneous expenses							**$250.00**
OOP TOTAL							**$97,575.00**
FEES:							
Management Fee							**$25,000.00**
Includes: ** Timeline development & maintenance* **Manage internal team and project flow* ** Coordinate faculty invitational process including invitations, confirmations, final and welcome packets* ** Manage attendee recruitment process including invitations, confirmations, final logistical information* ** Oversee coordination of venue selection, negotiation and contracting* ** Oversee all travel, hotel, ground transportation, food functions and AV both pre-meeting and onsite* ** Manage all on-site operations of the program including registration area* ** Manage design and production of all meeting materials including participant handouts, badges, tent cards, etc.* ** Traffic meeting materials for review and production* ** Arrange for honoraria* ** Grant/Needs development* **Reconciliation management* ** Certification collaboration (joint sponsorship, compliance review, Albert Einstein I.* ** Internal CME compliance*							
Content Development/Editorial Fee							**$28,000.00**
Includes: ** Collaborate with faculty on learning objectives, agenda and discussion guide development* ** Collaborate with faculty on presentations* ** Liaise with faculty and incorporate faculty comments* ** Liaise with accreditor and incorporate accreditor comments* ** Editorial/copy editorial review and formatting* ** All costs associated with meeting content development*							
FEE TOTAL							**$53,000.00**
GRAND TOTAL							**$150,575.00**

DESCRIPTION / CATEGORY	ASSUMPTIONS			COST		TOTAL COST
FACULTY COSTS						
		Rate	Persons			
Course Director Honorarium		$2,500	1	$2,500		
Chair Honorarium		$2,500	1	$2,500		
				TOTAL		$5,000.00
Albert Einstein Accreditation and Certificate Fee						$9,500.00
Albert Einstein Outcomes Measurement Fee						$3,500.00
OUTSIDE VENDORS						
Production/Printing						
			Quantity	Design		
	Printing of self-mailer, wafer-sealed invitation, Recruitment and Awareness Campaign To Medscape and Pain Clinician		10,000	4-Color	$3,500	
Webification (Medscape or Similar Pain Related Website eg. Pain.edu)						$60,000.00
Additional awareness and recruitment tactics						$5,000.00
Creative, Design, and Layout						$7,000.00
Transcription						$2,000.00
Postage						$1,500.00
OOP TOTAL						$93,500.00
FEES						
Management Fee						$20,000.00
Includes:						
* Timeline development & maintenance						
*Manage internal team and project flow						
* Manage attendee recruitment process including invitations, confirmations, and awareness campaign						
* Manage design and production of all awareness campaign and Medscape Liaison						
* Traffic meeting materials for review and production						
* Arrange for honoraria						
* Grant/Needs development						
*Reconciliation management						
* Certification collaboration (joint sponsorship, compliance review, Albert Einstein liaison)						
* Internal CME compliance						
Content Development/Editorial Fee						$20,000.00
Includes:						
* Collaborate with faculty on learning objectives, agenda and discussion guide development						
* Collaborate with faculty on presentations						
* Liaise with faculty and incorporate faculty comments						
* Liaise with accreditor and incorporate accreditor comments						
* Editorial/copy editorial review and formatting						
* All costs associated with meeting content development						
FEE TOTAL						$40,000.00
GRAND TOTAL						$133,500.00

Reference Guide

Chronic Pain Management Preceptorship (CPMP)



*DOE= Durable Outcomes Evaluation

**Control Group for Stage II includes 150 participants from other educational initiatives that do not participate in CPMP

Persistent and Breakthrough Supported Medical Education Initiatives

2009

International Experts Forum	**Live Event**	**30**	
Cases and Commentary	**Live Event**	**225**	
Full-Day Regional Meeting	**Live Event**	**75-100**	
Teleconference Series	**Live Event**	**200-400**	
Cases and Commentary Print Monograph/Online	***PMN News*** **PainClinician** **Pain.edu**	**45-60,000**	
Full-Day Regional Satellite Webcast	**International Forum for Pain Experts** **Pain.edu**	**20-25,000**	
Teleconference Print Monogrpaph/Online	***PMN News*** **PainClinician** **Pain.edu**	**45-60,000**	
Pain/Risk Management Compendium	***PMN News*** **PainClinician** **Pain.edu**	**45-60,000**	
International Experts Forum Position Paper/Online	***PMN News*** **PainClinician** **Pain.edu**	**45-60,000**	
Preceptorship Program		**300**	

In order to review your grant request #2569, Cephalon requires the following additional information:

1. **Please explain how HCPs for the outcomes study will be recruited for the Stage I.**

   The participants for the Stage I outcomes study will be recruited through the live educational initiatives proposed in the grant—namely, the *Cases and Commentary* Workshops, Teleconference Series, Full-day Regional Meeting and potentially the International Expert Forum. The latter will be a closed, invitation only meeting that will be held at the 2009 American Pain Society meeting in San Diego, pending availability of select thought leaders.

2. **Will the WebPanel series be accredited?**

   Yes. The quarterly WebPanel series is a component of the Chronic Pain Management Preceptorship (n=~200, pending approval of proposed activities) and will be accredited through Albert Einstein College of Medicine. Of note, participants will complete a Durable Outcomes Evaluation (DOE)* Stage II structured questionnaire upon completion of the WebPanel series. The questionnaire will measure the evolution of thought and practice since completion of the DOE Stage I questionnaire, as measured against control clinicians who limited their education to an enduring material and/or live event and who did not participate in the Preceptorship (Stage II) WebPanel. Notably, clinicians who chose not to participate in the preceptorship, and who have otherwise successfully completed at least one post-test from any of the educational initiatives (Live, Print, and/or Online), may participate in the WebPanel series. Their educational outcomes will not, however, contribute to the DOE Stage II outcomes, which is restricted to preceptorship clinicians only.

3. **How will participants be incentivized to participate in the outcomes study?**

   Incentivization is largely based on the opportunity to participate in a novel educational outcomes study, the results from which will likely be published in a peer-reviewed journal. Requirements will be minimally time consuming. Clinicians attending the live educational initiatives will necessarily complete a structured questionnaire before and after the event, and will therefore provide DOE Stage I study data. After completing the pre-post questionnaire, participants will confirm their interest in joining the Chronic Pain Management Preceptorship, comprising a quarterly WebPanel series facilitated by expert pain clinicians. Preceptorship clinicians (DOE Stage II participants) will have an opportunity to collaborate with their peers and thought leaders during the WebPanel series. In addition, preceptorship clinicians will be invited to a closed, invitation-only International Expert Forum (See Question 1). Qualified clinicians may also serve as adjunct faculty for activities that may be held in 2010, pending evaluation by program faculty

4. **Is the preceptorship a separate activity to the outcomes study? How will participants be recruited for this activity?**

   Preceptorship participants will be required to complete a Stage II structured questionnaire, providing data on the durability of high level outcomes when integrated within an ongoing educational series. Preceptorship participants will be recruited during the registration period through e-mail

correspondence, and during one of the live events—teleconference call, *Cases and Commentary* workshop and/or full-day regional meeting— that they are required to complete.

5. **The RFP stated that the proposal could cover educational events at national meetings, however none is proposed. Please clarify.**

   Pending availability of the expert pain clinicians, the International Pain Expert Forum may take place at a selected National Congress, currently planned to be held at the American Pain Society (APS; May 2009, San Diego). Preceptorship participants who attend the American Pain Society at their own cost and discretion will be invited to this closed, invitation-only satellite (off-agenda) live event.

   In addition, as a point of clarification, we are planning to hold at least one of the *Cases and Commentary* programs will be held immediately before or after the APS in May 2009 and/or a Regional Chronic Pain meeting (e.g.; **Emerging Practices in Opioid Prescribing for Chronic Pain,** March 2009).

6. **Please clarify the types of HCPS that may take part in the cases workshops.**

   HCPs that will be recruited to take part in the *Cases and Commentary* workshops are pain clinicians, including, among others, neurologists, psychiatrists, anesthesiologists, oncologists, rheumatologists, psychologists, and other general practitioners with an interest in pain management.

7. **Please clarify PainClinician (TM). Is this a quarterly newsletter?**

   PainClinician™ is a proprietary component of a larger educational initiative, *The International Chronic Pain Forum*™, to be formally launched in Q1 2009. The PainClinician quarterly newsletter will drive program recruitment, advertisements, and distribution of accredited pain enduring materials. Our *PainClinician*™ internal database currently includes thousands of practicing pain clinicians who have participated in previous accredited programs, CSNA surveys, or have otherwise expressed an interest in pain education.

8. **Please clarify how you will recruit for the teleconferences and satellite webcasts.**

   Recruitment efforts for the Teleconference and Webcasts will be multifaceted. Reliable tactics include extending invitations to clinicians in our proprietary *PainClinician*™ database, to clinicians identified by the Albert Einstein College of Medicine and to the membership of American Academy of Pain Medicine (AAPM), APS and other medical congresses; announcing the programs in relevant print journals, (e.g., *Pain Medicine News, the Journal of Pain, PainClinician),* and on selected pain-related websites (e.g., WebMD, pain.edu, International Chronic Pain Forum, etc.).

9. **Is the literature surveillance included in the grant costs?**

   The Literature Surveillance program, including monthly written summaries, as detailed in the grant is not included in the total grant costs. However, the Albert Einstein College of Medicine working collaboratively with Asante routinely forwards to the grant supporters select articles from peer-reviewed journals and related reference materials, all of which are relevant to the educational objectives of the proposed grant initiatives.

3301 Bainbridge Avenue, Bronx, N.Y. 10467 Phone 718.920.6674 Fax 718.798.2430 mccme.org cme@mccme.org

10. **Please include a timeline of when activities will be disseminated.**

Please see attached.

11. **Additional Information:**

Proposed Payment Schedule: If Albert Einstein College of Medicine is fortunate enough to have its grant approved, the proposed payment schedule is 1/3 of program costs upon LOA acceptance, 1/3 of program costs at a time point identified as approximately 50% through the completion of the grant, and the remaining 1/3 payment during the last 1/3 of the scheduled program completion.

3301 Bainbridge Avenue, Bronx, NY 10467 PHONE 718.920.6674 FAX 718.798.2336 mccrne.org cpc@montefiore.org

Albert Einstein and Asahi Communications
International Expert Forum with Accredited Position Paper

DESCRIPTION / CATEGORY	ASSUMPTIONS			COST		TOTAL COST
	Rate	Persons				
Course Director	$2,500	1				$2,500.00
Faculty Honoraria	$1,500	4				$6,000.00
Albert Einstein Accreditation and Certificate Fee						$9,500.00
Albert Einstein Outcomes Measurement Fee						$3,500.00
Food and Beverage	Cost/Tax/ Gratuity	Persons/ Quantity	Number of Functions			
To include: Breakfast(s)	$40	10	1	$400		
				TOTAL		$400.00
MATERIALS OOP						
	Quantity	Design				
Production & Printing of *Position Paper*	35,000	4-Color		$10,800		
Pain Clinician Postage Cost	35,000	n/a		$11,000		
Purchase Mailing Lists AAPM/APS				$4,000		
					Total	$25,800.00
ONLINE CONTENT OOP						
Webification of enduring materials						$5,000.00
Purchase artwork						$750.00
SUPPORTING DOCUMENTATION OOP						
References/Permissions						$750.00
MISC OOP						
Intercall Teleconference Charges						$1,000.00
Transcription Services						$1,500.00
SHIPPING OOP						
Express Mail Shipping (faculty mailings, materials shipping)						$250.00
OOP TOTAL						**$56,950.00**
Management Fee						$18,000.00

Includes:

* *Timeline development & maintenance*
* *Manage internal team and project flow*
* *Coordinate faculty invitational process including teleconference coordination, confirmations*
* *Coordination of venue selection, negotiation and contracting*

* Manage all aspects of program including position paper logistics and trafficking	
* Manage all on-site needs for meetings with faculty	
* Manage design and production of all materials relating to position paper	
* Manage design and production of all materials relating to webification of position paper	
* Arrange for honoraria	
* Grant/Needs development	
*Reconciliation management	
* Certification collaboration (joint sponsorship, compliance review, Albert Einstein liaison)	
* Internal CME compliance	
Content Development/Editorial/Creative Fee	**$23,500.00**
Includes:	
* Develop learning objectives	
* Collaboration with faculty on teleconference agenda and discussion guide development	
*Manage all research associated with identification of prospective Journals for Distribution	
* Collaborate with faculty on position paper	
* Liaise with presenters (chair, faculty)	
* Editorial/copy editorial review and formatting	
FEE TOTAL	**$41,500.00**
GRAND TOTAL	**$98,450.00**
Variance +/- 10%	
SPECIAL NOTE:	
Any change in scope will require an approved revised budget.	
Cancellation of program will be subject to costs-to-date for all expenses and staff hours.	

Albert Einstein and Asante Communications
Pain Clinical Update Reference Compendium

DESCRIPTION / CATEGORY	ASSUMPTIONS			COST		TOTAL COST
GENERAL COSTS						
		Rate	Persons			
Course Director Honorarium		$1,500	1			
Faculty Honoraria		$1,500	2			$4,500.00
Albert Einstein Accreditation and Certificate Fee						$9,500.00
Albert Einstein Outcome Measurement Fee						$3,500.00
MATERIALS COSTS						
Production/Printing						
		Quantity	Design	Total		
Services Include	Printing of Reference Tool for Pain Specialists and Other Clinicians	35000	4-Color	$20,000		
	Printing of Envelope	35000	4-Color	$4,800		
					TOTAL	$24,800.00
ONLINE COSTS						
Webification of Enduring Material						$10,000.00
SHIPPING/POSTAGE COSTS						
Distribution Costs to AAPM and APS Membership						$8,000.00
Pain Clinical Update Costs for Distribtution						$4,000.00
Mail house Handling Fee						$1,750.00
CREATIVE COSTS						
Creative, Design, and Layout						$7,000.00
Purchase Artwork						$250.00
SCIENTIFIC COMMUNICATIONS COST						
Permissions/Copyrights						$750.00
MISCELLANEOUS						
Misc Expenses						$250.00
TOTAL OOPs						**$74,300.00**
FEES						
Management Fee						$22,500.00
Includes:						
* Timeline development & maintenance						
*Internal team and project management						
* Arrange for faculty review and honoraria						
* Traffic Reference Tool for review and production						
* Manage design and production of reference tool						
* Liaise with course director & faculty						
*Review and manage content translation into online format						
*Develop grant and needs assessment						
* Certification collaboration (compliance review,Albert Einstein liaison)						
*Reconciliation management						
*Ensure internal CME compliance						
Content Development/Editorial						$30,000.00
Includes:						
* Collaborate with faculty on the development of the content outline, and learning objectives						
* Collaborate with faculty on the development of the reference tool manuscript						
*Liaise with faculty & incorporate faculty comments						
*Liaise with accreditor & incorporate comments						
* Editorial/copy editoral review and formatting of reference tool						
* All costs associated with reference tool content development						
TOTAL FEES						**$52,500.00**
GRAND TOTAL						**$126,800.00**

DESCRIPTION / CATEGORY	ASSUMPTIONS			Cost	TOTAL COST
	Rate	Persons			
Course Director Honorarium	$2,500	1		$2,500.00	
Faculty Honorarium (per call)	$1,000	1	8	$8,000.00	
				TOTAL	$10,500.00
Albert Einstein Accreditation and Certificate Fee					$15,000.00
Albert Einstein Outcomes Measurement Fee					$3,500.00
	Quantity	Design			
	syllabus (includes printing & assembly charges for Agenda, Participant List, Faculty List, color slides,	400	4-Color	$15,000.00	
	Printing of self-mailer, wafer-sealed invitation	45,000	4-Color	$10,000.00	
				TOTAL	$25,000.00
Invitation Distribution Costs					$14,000.00
Priority mail shipping of syllabus & confirmation letters to participants and faculty					$3,250.00
Teleconference Charges (Total for 8)					$7,500.00
Transcription Services (Total for 8)					$1,500.00
Purchase of Articles and Reprints					$1,500.00
Additional recruitment tactics/Purchase lists					$5,000.00
Creative, Design, and Layout					$6,500.00
OOP TOTAL					$93,250.00
Management Fee (Total for 8 teleconferences)					$22,500.00
Includes:					
* Timeline development & maintenance					
*Manage internal team and project flow					
*Arrange for faculty honoraria					
*Coordinate invitational process including confirmations					
*Develop call schedule					
*Coordinate with call center to insure appropriate project flow					
*Develop meeting materials (invites, announcement cards, syllabus, agenda, participant list, faculty bio list, evaluation survey)					
*Manage design and production of meeting syllabus					
*Ship meeting materials to participants & faculty					
*Lead and moderate 8 teleconference sessions					
*Develop, process and review evaluations & summary report					
*Liaise with internal teams, faculty, and accreditor					
* Certification collaboration (joint sponsorship, compliance review, Albert Einstein liaison)					
*Develop Grants & Needs Assessment					
*Complete final reconciliation					
*Ensure internal CME compliance					
Content Development/Editorial (Total for 8 teleconferences)					$25,000.00

Includes:	
* Collaborate with faculty on learning objectives, agenda and discussion guide development	
* Collaborate with faculty on presentations	
*Liaise with faculty & incorporate faculty comments	
*Liaise with accreditor & incorporate comments	
*Edit, copyedit, review and format all materials	
*Participate in teleconferences	
*Pre- and post-teleconference liaise with faculty	
FEE TOTAL	**$47,500.00**
GRAND TOTAL (8 Teleconferences)	**$140,750.00**

DESCRIPTION / CATEGORY	ASSUMPTIONS			COST	TOTAL COST
	Rate	Persons			
Course Director Honorarium	$2,500	1		$2,500	
Faculty Honorarium	$1,500	2		$3,000	
				TOTAL	$5,500.00
Albert Einstein Accreditation and Certificate Fee					$9,500.00
Albert Einstein Outcomes Measurement Fee					$3,500.00
Production/Printing					
		Quantity	Design	Cost	
Services Include	Monograph Printing	45,000	4-Color	$20,000	
				TOTAL	$20,000.00
SHIPPING/MAILING COST-OOP					
Distribution Fee Pain Medicine News/Clinical Updates/Congresses					$14,000.00
Express Mail Shipping (faculty mailings, materials shipping)					$200.00
ONLINE-OOP					
Webification of Monograph					$10,000.00
Creative, Design and Layout					$6,500.00
Purchase Artwork					$250.00
TOTAL OOPs					$69,450.00
Management Fee					$17,500.00
Includes: * Timeline development & maintenance *Internal team and Project management * Coordinate faculty review invitational process * Arrange for faculty review and honoraria * Arrange for honoraria * Manage design and production of all materials * Traffic materials for review and production * Certification collaboration (joint sponsorship, compliance review, Albert Einstein liaison) * Evaluation summary development and processing * Grant/Needs development *Reconciliation management					
Content Development/Editorial					$25,000.00
Content Development includes: *Develop learning objectives *Develop outline for an 8-page monograph *Collaborate with faculty in the development of the monograph manuscript *Liaise with faculty & incorporate faculty comments *Liaise with accreditor & incorporate comments * Editorial/copy editorial review and formatting of special report monograph * All costs associated with meeting content development					
TOTAL FEES					$42,500.00
GRAND TOTAL					$111,950.00

Albert Einstein and Asante Communications
Costs and Contingency Worksheet

DESCRIPTION / CATEGORY	ASSUMPTIONS				COST	TOTAL COST
	Rate	Persons				
Course Director Honorarium	$3,500	1			$3,500	
Chair Honorarium	$2,500	1			$2,500	
Faculty Honoraria	$2,000	5			$10,000	
					TOTAL	$16,000.00
Albert Einstein Accreditation and Certificate Fee						$9,500.00
Albert Einstein Outcome Measurement Fee						$3,500.00
Hotel Accommodations						
	Room & Tax	Persons	Nights			
To Include. Faculty	$275	7	1		$1,925	
Accreditor	$275	1	1		$275	
Asante	$275	3	1		$825	
Additional Suppliers	$275	2	1		$550	
					TOTAL	$3,575.00
Hotel Miscellaneous						$0.00
Airfare	Fare & Tax	Persons	Service			
To Include. Faculty	$600	7	Coach		$4,200	
Accreditor	$600	1	Coach		$600	
Asante	$600	0	Coach		$0	
Additional Suppliers	$600	2	Coach		$1,200	
					TOTAL	$6,000.00
Ground Transportation	Fare & Tax	Persons	Service			
To Include Faculty	$300	7	Sedan		$2,100	
Accreditor	$100	1	Taxi		$100	
Asante	$100	3	Taxi		$300	
Additional Suppliers	$100	2	Taxi		$200	
					TOTAL	$2,700.00
Expenses	Rate	Persons				
To Include: Faculty	$100	7			$700	
Asante	$100	3			$300	
Accreditor	$100	1			$100	
Additional Suppliers	$100	2			$200	
					TOTAL	$1,300.00
Food and Beverage	Cost/Tax/ Gratuity	Persons/ Quantity	Number of Functions			
Continental Breakfast	$40	0	1		$0	
To Include. Lunch	$65	70	1		$4,550	
Break	$30	70	1		$2,100	
Faculty Dinner	$100	11	1		$1,100	
On-site Slide Review	$250	1	1		$250	
					TOTAL	$8,000.00
Meeting Room(s) Rental	$750	-------	1			$750.00
Gratuities (Hotel Staff)	$100	-------	-------			$100.00
On-Site Telephone/Fax	$750	-------	-------			$750.00
On-Site Internet Connection	$750	------				$750.00
Production/Printing						
		Quantity	Design			

Services Include:	Printing of syllabus (includes printing & assembly charges for. Agenda, Participant List, Faculty List, color slides, evaluations, etc)	100	4-Color	$4,500	
	Printing of self-mailer, wafer-sealed invitation	5,000	4-Color	$3,000	
				TOTAL	$7,500.00
Signage, Name Badges, Tent Cards					$1,375.00
Pens, Pads					$250.00
Postage for Invites					$3,500.00
Postage for meeting materials					$500.00
AUDIO/VISUAL TOTAL					
Audiovisual - All equipment for Slide Review and General Session					$5,000.00
Technical Supervisor/Support - Labor/PowerPoint Tech					$1,200.00
OTHER					
Express Mail Shipping (faculty mailings, materials shipping)					$250.00
Additional recruitment tactics/purchase lists					$5,000.00
Meeting Planner					$7,000.00
Creative, Design, and Layout					$7,000.00
Transcription (each table)					$4,000.00
Miscellaneous expenses					$250.00
OOP TOTAL					$95,750.00
FEES					
Management Fee					$26,000.00
Includes:					
** Timeline development & maintenance*					
**Manage internal team and project flow*					
** Coordinate faculty invitational process including invitations, confirmations, final and welcome packets*					
** Manage attendee recruitment process including invitations, confirmations, final logistical information*					
** Oversee coordination of venue selection, negotiation and contracting*					
** Oversee all travel, hotel, ground transportation, food functions and AV both pre-meeting and onsite*					
** Manage all on-site operations of the program including registration area*					
** Manage design and production of all meeting materials including participant handouts, badges, tent cards, etc.*					
** Traffic meeting materials for review and production*					
** Arrange for honoraria*					
** Grant/Needs development*					
**Reconciliation management*					
** Certification Collaboration (joint sponsorship, compliance review, Albert Einstein liaison)*					
** Internal CME compliance*					
Content Development/Editorial Fee					$31,500.00
Includes:					
** Collaborate with faculty on learning objectives, agenda and discussion guide development*					
** Collaborate with faculty on presentations*					
** Liaise with faculty and incorporate faculty comments*					
** Liaise with accreditor and incorporate accreditor comments*					
** Editorial/copy editorial review and formatting*					
** All costs associated with meeting content development*					
FEE TOTAL					$57,500.00

GRAND TOTAL	**$153,250.00**

Albert Einstein and Asante Communications

DESCRIPTION / CATEGORY	ASSUMPTIONS			COST	TOTAL COST
	Rate	Persons			
Course Director Honorarium	$0	1		$0	
Chair Honorarium	$2,500	1		$2,500	
Faculty Honoraria	$2,000	5		$10,000	
				TOTAL	$12,500.00
Albert Einstein Accreditation and Certificate Fee					$1,000.00
Albert Einstein Outcome Measurement Fee					$0.00
LOGISTICS					
Hotel Accommodations					
	Room & Tax	Persons	Nights		
To Include: Faculty	$275	7	1	$1,925	
Accreditor	$275	1	1	$275	
Asante	$275	3	1	$825	
Additional Suppliers	$275	2	1	$550	
				TOTAL	$3,575.00
Hotel Miscellaneous					$0.00
Airfare	Fare & Tax	Persons	Service		
To Include. Faculty	$600	7	Coach	$4,200	
Accreditor	$600	1	Coach	$600	
Asante	$600	3	Coach	$1,800	
Additional Suppliers	$600	2	Coach	$1,200	
				TOTAL	$7,800.00
Ground Transportation (arrival/departure)	Fare & Tax	Persons	Service		
To Include. Faculty	$300	7	Sedan	$2,100	
Accreditor	$100	1	Taxi	$100	
Asante	$100	3	Taxi	$300	
Additional Suppliers	$100	2	Taxi	$200	
				TOTAL	$2,700.00
Expenses	Rate	Persons			
To Include: Faculty	$100	7		$700	
Asante	$100	3		$300	
Accreditor	$100	1		$100	
Additional Suppliers	$100	2		$200	
				TOTAL	$1,300.00
Food and Beverage	Cost/Tax/ Gratuity	Persons/ Quantity	Number of Functions		
To Include Continental Breakfast	$40	0	1	$0	
Lunch	$65	70	1	$4,550	
Break	$30	70	1	$2,100	
Faculty Dinner	$100	11	1	$1,100	
On-site Slide Review	$250	1	1	$250	
				TOTAL	$8,000.00
Meeting Room(s) Rental	$750	-------	1		$750.00
Gratuities (Hotel Staff)	$100	-------	-------		$100.00
On-Site Telephone/Fax	$750	-------	-------		$750.00
On-Site Internet Connection	$750	------			$750.00

MATERIALS - COP						
Production/Printing						
			Quantity	Design		
Services include	(includes printing &		100	4-Color	$4,500	
	wafer-sealed invitation		5,000	4-Color	$3,000	
					TOTAL	$7,500.00
Signage, Name Badges, Tent Cards						$1,375.00
Pens, Pads						$250.00
Postage for Invites						$3,500.00
Postage for meeting materials						$500.00
AUDIOVISUAL - COP						
Audiovisual - All equipment for Slide Review and General Session						$5,000.00
Technical Supervisor/Support - Labor/PowerPoint Tech						$1,200.00
MISCELLANEOUS - COP						
Express Mail Shipping (faculty mailings, materials shipping)						$250.00
Additional recruitment tactics/purchase lists						$5,000.00
Meeting Planner						$7,000.00
Creative, Design, and Layout						$5,000.00
Transcription (each table)						$4,000.00
Miscellaneous expenses						$250.00
OOP TOTAL						$80,050.00
FEE						
Management Fee						$26,000.00
Includes:						
** Timeline development & maintenance*						
**Manage internal team and project flow*						
** Coordinate faculty invitational process including invitations, confirmations, final and welcome packets*						
** Manage attendee recruitment process including invitations, confirmations, final logistical information*						
** Oversee coordination of venue selection, negotiation and contracting*						
** Oversee all travel, hotel, ground transportation, food functions and AV both pre-meeting and onsite*						
** Manage all on-site operations of the program including registration area participant handouts, badges, tent cards, etc.*						
** Traffic meeting materials for review and production*						
** Arrange for honoraria*						
** Grant/Needs development*						
**Reconciliation management*						
** Certification Collaboration (joint sponsorship, compliance review, Albert Einstein liaison)*						
** Internal CME compliance*						
Content Development/Editorial Fee						$15,750.00
Includes:						
** Collaborate with faculty on learning objectives, agenda and discussion guide development*						
** Collaborate with faculty on presentations*						
** Liaise with faculty and incorporate faculty comments*						
** Liaise with accreditor and incorporate accreditor comments*						
** Editorial/copy editorial review and formatting*						
** All costs associated with meeting content development*						
FEE TOTAL						$41,750.00
GRAND TOTAL						$121,800.00

DESCRIPTION / CATEGORY	ASSUMPTIONS				COST	TOTAL COST
	Rate	Persons				
Course Director Honorarium	$0	1			$0	
Chair Honorarium	$2,500	1			$2,500	
Faculty Honoraria	$2,000	5			$10,000	
					TOTAL	$12,500.00
Albert Einstein Accreditation and Certificate Fee						$1,000.00
Albert Einstein Outcome Measurement Fee						$0.00
Hotel Accommodations						
	Room & Tax	Persons	Nights			
To Include: Faculty	$275	7	1		$1,925	
Accreditor	$275	1	1		$275	
Asante	$275	3	1		$825	
Additional Suppliers	$275	2	1		$550	
					TOTAL	$3,575.00
Hotel Miscellaneous						$0.00
Airfare	Fare & Tax	Persons	Service			
To Include: Faculty	$600	7	Coach		$4,200	
Accreditor	$600	1	Coach		$600	
Asante	$600	3	Coach		$1,800	
Additional Suppliers	$600	2	Coach		$1,200	
					TOTAL	$7,800.00
Ground Transportation (arrival/departure)	Fare & Tax	Persons	Service			
To Include: Faculty	$300	7	Sedan		$2,100	
Accreditor	$100	1	Taxi		$100	
Asante	$100	3	Taxi		$300	
Additional Suppliers	$100	2	Taxi		$200	
					TOTAL	$2,700.00
Expenses	Rate	Persons				
To Include: Faculty	$100	7			$700	
Asante	$100	3			$300	
Accreditor	$100	1			$100	
Additional Suppliers	$100	2			$200	
					TOTAL	$1,300.00
Food and Beverage	Cost/Tax/ Gratuity	Persons/ Quantity	Number of Functions			
To Include: Continental Breakfast	$40	0	1		$0	
Lunch	$65	70	1		$4,550	
Break	$30	70	1		$2,100	
Faculty Dinner	$100	11	1		$1,100	
On-site Slide Review	$250	1	1		$250	
					TOTAL	$8,000.00
Meeting Room(s) Rental	$750	-------	1			$750.00
Gratuities (Hotel Staff)	$100	-------	-------			$100.00
On-Site Telephone/Fax	$750	-------	-------			$750.00
On-Site Internet Connection	$750	------				$750.00

MATERIALS OOP						
Production/Printing						
			Quantity	Design		
Services Include	(includes printing &		100	4-Color	$4,500	
	wafer-sealed invitation		5,000	4-Color	$3,000	
					TOTAL	$7,500.00
Signage, Name Badges, Tent Cards						$1,375.00
Pens, Pads						$250.00
Postage for Invites						$3,500.00
Postage for meeting materials						$500.00
AUDIOVISUAL OOP						
Audiovisual - All equipment for Slide Review and General Session						$5,000.00
Technical Supervisor/Support - Labor/PowerPoint Tech						$1,200.00
MISCELLANEOUS OOP						
Express Mail Shipping (faculty mailings, materials shipping)						$250.00
Additional recruitment tactics/purchase lists						$5,000.00
Meeting Planner						$7,000.00
Creative, Design, and Layout						$5,000.00
Transcription (each table)						$4,000.00
Miscellaneous expenses						$250.00
OOP TOTAL						$80,050.00
FEE						
Management Fee						$26,000.00
Includes:						
* *Timeline development & maintenance*						
**Manage internal team and project flow*						
* *Coordinate faculty invitational process including invitations, confirmations, final and welcome packets*						
* *Manage attendee recruitment process including invitations, confirmations, final logistical information*						
* *Oversee coordination of venue selection, negotiation and contracting*						
* *Oversee all travel, hotel, ground transportation, food functions and AV both pre-meeting and onsite*						
* *Manage all on-site operations of the program including registration area*						
participant handouts, badges, tent cards, etc						
* *Traffic meeting materials for review and production*						
* *Arrange for honoraria*						
* *Grant/Needs development*						
**Reconciliation management*						
* *Certification Collaboration (joint sponsorship, compliance review, Albert Einstein liaison)*						
* *Internal CME compliance*						
Content Development/Editorial Fee						$15,750.00
Includes:						
* *Collaborate with faculty on learning objectives, agenda and discussion guide development*						
* *Collaborate with faculty on presentations*						
* *Liaise with faculty and incorporate faculty comments*						
* *Liaise with accreditor and incorporate accreditor comments*						
* *Editorial/copy editorial review and formatting*						
* *All costs associated with meeting content development*						
FEE TOTAL						$41,750.00

GRAND TOTAL	**$121,800.00**

DESCRIPTION / CATEGORY	ASSUMPTIONS				COST	TOTAL COST
SPEAKER OOP						
		Rate	Persons			
Course Director Honorarium		$2,500	1		$2,500	
Faculty Honorarium		$1,500	2		$3,000	
					TOTAL	$5,500.00
Albert Einstein Accreditation and Certificate Fee						$9,500.00
Albert Einstein Outcome Measurement Fee						$3,500.00
MATERIALS						
Production/Printing						
			Quantity	Design	Cost	
Services Include:	Monograph - Printing		45,000	4-Color	$20,000	
					TOTAL	$20,000.00
SHIPPING/MAILING COST OOP						
Distribution Pain Clinician, Pain Medicine News, and Congresses						$14,000.00
Express Mail Shipping (faculty mailings, materials shipping)						$200.00
ONLINE OOP						
Webification of Monograph						$10,000.00
CERTIFICATE OOP						
CREATIVE DESIGN OOP						
Creative, Design and Layout						$6,500.00
Purchase Artwork						$250.00
TOTAL OOPs						$69,450.00
FEES						
Management Fee						$17,500.00
Includes:						
* Timeline development & maintenance						
*Internal team and Project management						
* Coordinate faculty review invitational process						
* Arrange for faculty review and honoraria						
* Arrange for honoraria						
* Manage design and production of all materials						
* Traffic materials for review and production						
* Certification collaboration (joint sponsorship, compliance review, Albert Einstein liaison)						
* Evaluation summary development and processing						
* Grant/Needs development						
*Reconciliation management						
Content Development/Editorial						$25,000.00
Content Development includes:						
*Develop learning objectives						
*Develop outline for an 8-page monograph						
*Collaborate with faculty in the development of the monograph manuscript						
*Liaise with faculty & incorporate faculty comments						
*Liaise with accreditor & incorporate comments						
* Editorial/copy editorial review and formatting of special report monograph						
* All costs associated with meeting content development						
TOTAL FEES						$42,500.00
GRAND TOTAL						$111,950.00

PERSISTENT AND BREAKTHROUGH PAIN

MULTIDIMENSIONAL ASSESSMENT AND MULTIMODAL OPIOID-BASED TREATMENT STRATEGIES

An Educational Platform Initiative

Medical Education Grant Request

Presented to | Cephalon, Inc.

Submitted by | Albert Einstein College of Medicine

Submitted on | 11/06/2008

Outline of Request

I. Overview

Albert Einstein College of Medicine (Einstein) in association with its educational collaborator, Asante Communications LLC (Asante), respectfully request a grant for the development, certification, production, and distribution of an educational initiative tentatively entitled "Persistent and Breakthrough Pain: Multidimensional Assessment and Multimodal Opioid-Based Treatment Strategies." This educational platform is intended to provide continuing medical education (CME) credit to healthcare professionals who treat patients with chronic pain.

The sponsors seek support through an educational grant from Cephalon, Inc. A support statement identifying Cephalon, Inc. as the Grantor will be included in the preamble of each activity, as well as in all announcements regarding the platform and individual activities.

Einstein will certify the initiative for CME credit for physicians.

II. Platform Sponsorship, Management, and Outcomes Measurement

Albert Einstein College of Medicine

For more than 5 decades, Einstein has exemplified excellence in medical research, teaching, and patient care. Established in 1955, and guided by the vision of Professor Albert Einstein, the College was one of the first medical schools to integrate bedside experience with classroom study. Einstein also led the way in the development of bioethics as an accepted academic discipline in medical school curricula and was the first private medical school in New York City to establish an academic Department of Family Medicine as well as a residency program in internal medicine with an emphasis on women's health. Today, Einstein is one of the nation's premier institutions for medical education, basic research, and clinical investigation.

Although education is at the heart of Einstein's mission, biomedical research drives its growth. Einstein has 300 research laboratories, which allow it to consistently be on the forefront of medical breakthroughs via development of cutting-edge techniques and clinical trials. A national leader in biomedical research support from the federal government, Einstein received more than $150 million in funding from the National Institutes of Health (NIH) in 2006. Einstein ranks sixth in the nation in terms of NIH awards to basic-science departments, and 7 of its programs are designated as NIH "Centers of Excellence."

Einstein and Montefiore Medical Center (the University Hospital and Academic Medical Center for the Albert Einstein College of Medicine) Center for Continuing Medical Education (CCME) was founded in 1976. It is accredited by the Accreditation Council

for Continuing Medical Education (ACCME) to provide CME for physicians. CCME is committed to the utilization of resources for the advancement of CME throughout the physician's professional career. CCME's mission is to enhance patient care by bringing diagnostic and therapeutic innovations to the clinical environment through professional medical education for physicians that maintains, develops, and increases their knowledge, skills, and competence.

Independence

CCME does not maintain financial relationships with commercial supporters or educational partners outside of the receipt of normal fee for services. Commercial interests are not involved in the development of content, program planning, or budget-determination. Responsibility for assuring that the CME activities meet the highest requirements and standards of Einstein and the ACCME rests solely with the CCME and is not transferable.

Disclosure and Conflict of Interest

CCME requires written, signed disclosure of the existence of relevant financial interests or relationships with commercial interests from any individual contributing to or in a position to influence the content of a CME activity sponsored by Einstein. Individuals not disclosing relevant financial relationships will be disqualified from an association with the CME activity in question.

CCME has established policies that will identify and resolve all conflicts of interest prior to activity certification by applying the disclosed information and activity subject to ACCME's policies.

Content Validation

All scientific research referred to, reported on, or used in a CME activity certified by Einstein in support or justification of a patient care recommendation will conform to the generally accepted standards of experimental design, data collection, and analysis.

Compliance

Asante has retained Hogan & Hartson LLP, an international law firm, to provide Asante with consultancy and expert insights into current federal and state regulations, ACCME codes of conduct, Pharmaceutical Research and Manufacturers of America (PhRMA) code, and their potential impact on the quality and delivery of our medical education programs.

Experts in all relevant accreditation issues, Hogan & Hartson will ensure that the continuing medical education programs Asante proposes and executes—including such full spectrum communications vehicles as regional meetings, teleconferences, web-based and print activities—will be conducted in an irreproachably compliant fashion. By ensuring that the educational programs faithfully adhere to all relevant law and regulations, Hogan & Hartson will help us meet the educational needs of critical therapeutic areas, develop clinicians' skill sets and improve patient care.

As the 2009 educational year unfolds, Hogan & Hartson will continually monitor our policies and programs and may instruct our team accordingly, facilitating any necessary adjustments. Additionally, the global law firm will help Asante develop employee and faculty educational programs.

Asante Communications, LLC

Asante is a full-service medical education company specializing in physician and patient education for the biopharmaceutical industry. Utilizing proprietary research methodologies, the Asante team of scientists, writers, and strategists delivers high quality CME, tailored to the objectives of our accreditors and grantors, grounded in the science of current and investigational treatment options, and shaped by an expert understanding of adult learning principles. In particular, the company integrates the latest insights into disease management with comprehensive preclinical and clinical data, creating coherent and credible educational platforms. Asante provides strategically sharp content across print, live, video, and Web-based outlets and distribution channels,

and leverages its diverse network of pain clinicians to develop, validate and critically review needs assessments and all relevant scientific content. Further, the full spectrum of educational materials proposed in this grant is based on a fundamental tenet that clinicians have idiosyncratic learning preferences and often prefer to self-direct their learning across multiple vehicles. Such a multifaceted, interactive and needs-based approach is critical to instructing clinicians in chronic pain management. Based in New York City, the company is managed by seasoned veterans of the healthcare communications industry.

Platform Management

Asante will be responsible for the development, production, and distribution of the activities within the educational platform under the direction of Einstein. Asante will operate as an extension of the sponsor, working within Einstein's guidelines as well as those of the accrediting organizations and governmental agencies regulating medical education.

Einstein will provide oversight for the development, production, and distribution of the activities within the educational platform as well as the certification for CME credit.

Outcome Levels

Asante reaches Level 4 of Outcomes Measurement as defined by the North American Association of Medical Education and Communication Companies, Inc (NAAMECC) with our standard evaluation process:

Level 1: Participation (via the participant report)

Level 2: Satisfaction (via the activity evaluation)

Level 3: Learning (via the self-assessment exam)

Level 4: Performance (via the commitment-to-change questions on the activity evaluation)

Durable Outcomes Measurement and Evaluation

Einstein and Asante are committed to providing high quality education associated with durable outcomes that promote best practices in pain management and improve patient care. In addition to traditional outcomes measurements reported and evaluated by Einsten for Level 4 Outcomes as noted above, a randomized controlled study approved by Victor Hatcher, PhD, David Kaufman, MD, of Einstein and the Institutional Review Board (IRB) of Albany Medical Center will be conducted to measure the effectiveness of the educational interventions.

Stage I

In this study, clinicians (N=~300~350) will demonstrate their baseline level of attitudes, awareness, knowledge and current practices by completing a structured questionnaire (20-questions; 10 multiple choice and 10 case-based short answer questions). The questionnaire—a self-developed instrument in early stages of psychometric evaluation—will be based on educational deficits initially identified in the Clinical Survey and Needs Assessment (CSNA). After completing the diagnostic, clinicians will participate in a teleconference program and/or live regional meeting, immediately after which they will again complete a similarly structured questionnaire. Pre and post differences in attitudes, awareness and knowledge will be determined, reflecting the extent to which the participants have achieved the learning objectives. To gain additional context, face-to-face focus group discussions will be conducted immediately after the regional meeting as well. Here, participants will have an opportunity to elaborate on self-reported performance indicators that go beyond the structured questionnaire.

Stage II

Upon completion of Stage I, a subset of interested clinicians will be randomized to either an intervention group (~n=150), within which clinicians will participate in a monthly WebPanel series with thought leaders for 6 months, or randomized to a control group of clinicians (~n=150), who will receive no further instruction and provide a benchmark against which the effectiveness of continual intervention may be measured. Adult learning principles suggest that such reinforcement helps translate knowledge into practices with enduring value. Clinicians may benefit from the collegial relationship and outcomes-driven mentoring provided by the WebPanel. Outcome variables for Stage II will include the clinicians' confidence in pain management skills and intent-to-change by: (1) employing functional goals to guide patient care (2) implementing structured pain and risk assessment methodologies (3) monitoring breakthrough and persistent pain longitudinally and (4) documenting level of risk.

Stage III

A more precise measure of effectiveness may be obtained in a third and final stage of this study. A subset of clinicians from the Stage II intervention (n=~5 clinicians) and control groups (~n=5 clinicians) will invite as many as 10 patients each to participate in this stage (~N=100 patients; ~n=50 experimental group; ~n=50 control group). Appropriate disclaimers and IRB approval will be secured for each patient upon initiation of Stage II. Once Stage II is completed, patients in each group will complete a brief questionnaire (5 multiple choice questions). Outcome variables for Stage III will be patients' overall satisfaction with the consultations and satisfaction with the clinician's assessment of the quality, severity and temporal components of chronic pain. Differences in patient outcomes will be compared between the Stage II intervention group and control group. The working hypothesis is that those patients treated by clinicians who received ongoing interventions will have sharper assessment skills, translating into discernable and self-reported differences in patient care.

Importantly, this study design and methodology will provide qualitative and quantitative data longitudinally, throughout each stage of the study. Reported outcomes in physician performance and patient care—particularly those demonstrating sustainability—may constitute publishable data for the *Journal of Continuing Education in the Health Professions*, a peer-reviewed journal specializing in CME.

III. Educational Platform, Learning Objectives, and Needs Assessment

Educational Platform

Guided by an expert panel and comprehensive needs assessment, the educational initiatives within this platform are intended to disseminate chronic pain and risk management strategies to a multidisciplinary audience of clinicians who treat patients with chronic pain, including pain specialists, neurologists, rheumatologists, physical medicine and rehabilitation specialists, family practitioners, oncologists, and internal medicine and general practitioners. In a grant proposal to be submitted subsequently, physician assistants, nurse practitioners, and registered nurses will be addressed as an important secondary audience.

Each activity will provide a venue for healthcare professionals to increase their clinical knowledge and awareness of pain and risk-mitigation strategies in the opioid-based treatment of chronic pain. Upon successful completion of the CME activities, healthcare professionals may use the CME credit(s) earned toward their licensure and/or certification requirements.

Einstein and Asante have completed a thorough analysis of the current state of chronic pain education, researching publications and clinical trials, soliciting in-depth thought-leader feedback, and conducting a survey of potential participants regarding current practice patterns, existing educational opportunities, and the need for focused and targeted activities.

Asante has developed a proprietary approach to identifying unmet educational needs among clinicians, to tailoring educational programs accordingly, and to developing sensitive outcomes-based approaches to evaluating changes in awareness, knowledge and practice. Briefly, working with Einstein, Asante has employed its CSNA data which helps distinguish among clinicians with various levels of expertise. While the psychometric properties have yet to be fully determined, the questions reveal different approaches to the assessment and treatment of specific disorders. After identifying gaps in understanding among responders, specific replies are shared with thought leaders, who are asked to share their insights into a specific educational deficit and how it may be treated through targeted interventions. Finally, teleconference calls are then conducted to confirm identified gaps among target audiences.

Based on this research and feedback, Einstein and Asante have identified specific educational needs within the therapeutic area and recommend addressing those needs via a series of educational approaches to chronic pain and risk management linking evidence-based medicine with expert perspective.

Intended Audience

These activities are developed for pain specialists, neurologists, rheumatologists, physical medicine and rehabilitation specialists, family practitioners, oncologists, and internal medicine and general practitioners

Activity Goals

It is the goal of these activities to increase their competence and abilities to treat and appropriately manage pain and learn important methods to incorporate risk management strategies into pain management plans.

Learning Objectives

At the conclusion of this program, participants will be better prepared to:

1. Define, recognize, and independently assess breakthrough and persistent pain in patients with chronic pain syndromes
2. Implement a multidimensional, continual, and vigilant assessment of persistent and breakthrough pain based, in part, on the phenomenology and inferred pathophysiology of the pain syndrome, patient function, goals, and level of risk
3. Select appropriate patients for opioid-based management of persistent and breakthrough pain
4. Employ multimodal opioid-based therapies tailored to the multidimensional pain assessment of patients with persistent and breakthrough pain
5. Explain the respective roles of long-acting, short acting and rapid onset opioids in the management of persistent and breakthrough pain
6. Distinguish clinical constructs of physical dependence, tolerance, pseudotolerance, addiction, pseudoaddiction and their impact on medical management of patients with chronic pain syndromes

Clinical Survey and Needs Assessment (CSNA)

Two thousand one hundred and thirty five surveys were e-mailed to U.S. based pain clinicians. One hundred and fifty-seven electronic surveys were completed (7% response rate). Respondents provided answers to several yes/no questions and to open-ended questions about breakthrough and persistent pain management. Select questions from the survey are included below.

- Most (82%) of the sample employed multimodal and multidrug approaches

- Nearly 40% of respondents cited the need for more education on multimodal treatment strategies (eg, behavioral, relaxation strategies, cognitive behavioral therapy)
- Approximately 74% of respondents cited a need to learn more about principles of opioid-based therapy, including when to prescribe, how to maintain, and when to discontinue opioids. ("How do I manage a patient with a legitimate pain syndrome who has broken the contract?")
- Nearly half (47%) of the respondents agreed that opioid based therapy is time consuming, poorly reimbursed and increasingly difficult in this environment. Respondents agreed that guidance on formulating a treatment plan within the current 15-minute visit paradigm is needed.
- An estimated 34% of respondents do not risk stratify their patients for problematic opioid use.
- Few subjects (<10%) disagreed with the notion that chronic pain comprises two distinct components (Sample responses below). Rather, the educational need appears to center on definitional issues, and how best to assess and treat the constructs. Operationalizing breakthrough and persistent pain, in other words, appears to be the threshold educational need.
- Most respondents (65%) used the Numeric Rating Scale to evaluate baseline pain, highlighting the need for education on thorough assessment strategies.
- Only 55% of respondents provided an adequate definition of breakthrough pain.

Question: **How do you determine whether baseline persistent pain is controlled? Please elaborate as needed.**

"Actually, very complex assessment: I begin with comparing both the peak and average pain scores since last encounter, the frequency and duration, comparing these to values from the previous visit; the total daily long-acting and average short-acting (excluding transmucosal fentanyl) opioid dosages are calculated as oral oxycodone equivalents, and the percentage of short-acting medication of the total of the two components is estimated, and compared with last visit. In the interview, adjustments are made in interpretation of these "hard" data points based on any acute injuries or exacerbations which may have disturbed the balance that month, desirable increases in activity vs. overextension, and the end-effect on mood, sleep, energy, motivation, appetite, and perceived areas of improvement or deterioration are assessed. "

Question: **How would define breakthrough pain?**

Adequate definitions included:

"Sudden onset or rapidly (a relatively soft subjective definition) escalating pain beyond usual tolerable levels (not just above baseline). I do not accept the additional qualification that it is of short duration or even necessarily spontaneously subsides; patients with CRPS I or II, TGN, PHN, or painful MS may experience flares that sustain for hours or even a full day."

"Episodic occurrences, commonly related to changes in activity not well controlled by baseline pain medication use that works the majority of the time."

Inadequate breakthrough pain definitions included:

- *Disturbing pain despite taking long acting opioid*
- *I would just say it is an increase over baseline; the pain is getting worse or it still isn't well controlled in the first place*
- *When a person still has pain on and off, while taking maintenance pain medications*
- *Pain that occurs at the end of dose drop off of the long acting med regimen before the next dose is due*
- *BTP is pain occurring in mid-dose regimen with chronic pain controlled by long acting narcotic*
- *If the baseline pain is not managed then there will be more breakthrough pain. Baseline pain management requires maximizing dosages or other interventions*
- *Pain that unexpectedly breaks through the baseline pain regimen, as distinct from activity related pain and end-of-dose pain*

Critical Assessment of Unmet Educational Needs in Chronic Pain Management

Chronic pain is prevalent, underdiagnosed, often misdiagnosed, and undertreated. (Walid, 2008; Gore, 2006) Previously regarded as a symptom of underlying disorders, the neuroplastic changes that characterize chronic pain constitute a disease state unto itself, a state of peripheral and central sensitization and hyperexcitability that requires comprehensive, continual assessment and treatment. (Woolf, 2007) Chronic pain is a significant burden to the patient, impairing multiple dimensions of function—affective, cognitive, physical, and work-related—which, in turn, adversely affect public health. (McCarberg, 2008) Numerous epidemiologic studies have estimated an annual cost of 80 billion dollars in the United States alone, reflecting the more than 50 million people who have chronic pain syndromes. (APS, 2008) The incidence and prevalence of chronic pain syndromes is projected to increase as the population ages, particularly with such age-related syndromes as osteoporosis, low back pain, osteoarthritis, and multifocal joint pains. (Robinson, 2007) Many patients with chronic pain will be cancer survivors, a group recently estimated to include more than 10.8 million people. (Ries, 2008) The prevalence and cost of chronic pain, and its debilitating signs and symptoms, have driven pain practitioners, academicians and several medical societies to collaboratively develop screening methodologies, validated assessment tools, and multimodal treatment strategies that provide pain relief and improve patient function. All of these approaches require an ongoing commitment to medical education. (Stanos, 2008; Webster, 2005; Passik, 2008) (CSNA; **Learning Objectives 2, 3, 4**)

Chronic pain comprises heterogeneous and frequently complex disorders that often require opioid analgesics, a medication class with an equally complex pharmacology and epidemiology. (Pasternak, 2005) Opioids have long been regarded as a cornerstone in the treatment of cancer pain; numerous randomized controlled studies have documented their safety, tolerability and efficacy across a wide variety of cancer-related syndromes. (Pergolizzi, 2008; Ballantyne, 2005; Miaskowski, 2005; Carr, 2004) Over the past 20 years, opioids have gained increasing, though not unqualified, acceptance for noncancer pain as well. (Ballantyne, 2008; Noble, 2008; Riley, 2008; Portenoy, 2007; Furlan, 2006; Coluzzi, 2005; Nicholson, 2003) Concerns about opioids in the management of moderate to severe pain of noncancerous origin, extensively reviewed elsewhere, help explain, at least in part, an unjustifiable undertreatment of pain, especially in the elderly. (Lin, 20007; Robinson, 2007; APS, 2005; Ballantyne and Mao, 2003) Educational programs are urgently needed to help clinicians select appropriate patients with cancer and noncancer pain syndromes for opioid-based pharmacotherapy, and to develop an individualized therapeutic regimen based

on the pain syndrome, level of risk, and goals of each patient. (Portenoy, 2008; Keeney, 2008; Comley, 2000) (CSNA; **Learning Objectives 3, 4**)

Assessment as a Process

Multidimensional comprehensive assessment strategies improve patient care and outcomes. (Barbuto, 2008; Breivik H, 2008; Davidson, 2008; Locker, 2007; Yennurajalingam, 2004) Identifying objective findings through a patient work up—including, for example, laboratory electrodiagnostic and imaging studies—remains critical; however, clinicians must operationalize the International Association for the Study of Pain (IASP) definition of pain, which does not require actual tissue damage for pain to be experienced. (Merskey, 1994) Pain is an untestable hypothesis (Fishman, 2008); absent any objective data supporting the pain complaint, clinicians need to rely on patient function and quality of life as goals and benchmarks for success. Listening to the patient is indispensable. By characterizing the quality of the pain, its radiation pattern, and temporal profile—when is the pain minimal, and when is it excruciating?—the patient may help the clinician translate the phenomenology of the pain complaint into a pathophysiology that informs mechanism-based treatment. (Davies, 2008; Maag, 2006; Baron, 2006; Woolf, 2004)

"We need to listen to monitor what's going on with these patients over time, to evaluate the results of therapy, and to control as best we can adherence to the plan of care through a very well thought out monitoring program, and then over time tailor and adjust therapies according to what happens. Because I think if there's one thing we've learned, it is that we really do not have great predictors of either efficacy or safety, except in a very obvious group of high-risk patients."

Perry G. Fine, MD

In time-constrained clinical practice, reducing irreducibly complex chronic pain syndromes is manifestly challenging; their broad phenomenology must therefore be assessed methodically, through a semi-structured approach over time. (Breiveik, 2008; Guarino, 2007; Passik, 2005) There is an urgent need for educational programs addressing practical solutions for ongoing patient assessment, several of which are briefly discussed below. (CSNA; **Learning Objective 2**)

Assessment is a process that takes time, takes multiple encounters with the patient. And when I discuss with nurses the assessment of pain, I often say for all of us, we have to get the patient's pain story, and in our truncated world of a 15-minute patient visit, that's often a hard thing to achieve, trying to get the patient back with the appropriate frequency so we can detect the subtleties that need to be managed with these types of pain problems."

Christine Miaskowski, PhD, RN

Mechanism-Based Therapy

First, pain must be correctly classified to drive appropriate treatment selection. (Baron, 2008) Underlying etiologies of chronic pain vary considerably. Cancer pain syndromes may involve soft tissue, bones, or joints, and could be related to a polyneuropathy, plexopathy, or another form of nerve injury. (Berger, 2006) Similarly, noncancer pain syndromes may involve chronic tissue injury, inflammatory disorders, or nerve injury. These disease classifications, although helpful, require additional insights into disease mechanisms. Gradually, clinicians are classifying less by disease than by inferred pathophysiology. (Woolf,

2004) Simply, chronic pain syndromes may have a nociceptive (somatic or visceral) component marked by constitutive activation of an otherwise intact nervous system. Inflammatory bowel disease, interstitial cystitis, osteoarthritis, and discogenic back pain are classified as nociceptive. Pain with a predominantly neuropathic component is characterized by reorganization of normal neural circuits, and includes cancer-related neuropathy, complex regional pain syndrome (CRPS), post-laminectomy syndrome, HIV-related neuropathy, central post-stroke pain, post-herpetic neuralgia, diabetic neuropathy, and phantom limb pain, among others. (Argoff, 2006; McMahon & Koltzenburg, 2005) Matching treatment to disease is gradually being eclipsed by matching treatment to mechanism. (Woolf, 2008; de Leon-Casasola, 2008; Baron, 2008) Clinicians require concerted educational efforts to understand this paradigm shift. (CSNA; **Learning Objective 2**)

Temporal Dimensions of Chronic Pain

Second, temporal characteristics of chronic pain must be captured during each visit. Chronic pain is dynamic, ebbing and flowing as a function of movement, stress, and other idiosyncratic factors. (Davies, 2008; Bennett, 2005) The persistent, baseline component of pain, even when controlled, fluctuates; often, the pain breaks through an otherwise effective analgesic regimen. (Bennett, 2007) Breakthrough pain, the second temporal component of chronic pain, is an often overlooked clinical construct. (William, 2008; Swanwick, 2001) Recently discussed by an expert panel, breakthrough pain is a transitory pain more severe than the persistent baseline pain that adversely affects function or quality of life in patients who are receiving analgesic therapy on most days. (Expert Panel on Breakthrough Pain, 2006) The requirement for an adverse functional impact is essential for the management of BTP, and mirrors the increasing focus on function in the Federation of State Medical Boards (FSMB) model policy. (Fishman, 2008) Clinicians require expert guidance on how best to employ patient function as a standard by which to measure treatment success. (CSNA; **Learning Objectives 2, 5**)

> *"An important question in pain management: Does an observed reduction in pain intensity translate into clinically relevant functional improvement? That is to say, because a patient says, "Yes, in fact I am experiencing an analgesic effect," does that lead to demonstrable, meaningful accomplishment of certain goals that we may say, other than pain relief, are very important from a clinical or therapeutic standpoint?"* **Perry G. Fine, MD**

Epidemiologic studies have demonstrated that the majority of patients experience breakthrough pain; the prevalence in cancer patients is estimated at 64%, and that in noncancer pain patients is closer to 74%. (Portenoy 1990; Portenoy, 2006) Patients with breakthrough pain have decreased satisfaction with their analgesic regimen, increased healthcare utilization and associated costs, increased hospital visits and hospitalization, increased mood disturbances, and impaired function. (Abernethy, 2008; Taylor, 2007; Fortner, 2003, Fortner, 2002) Independent assessment and treatment of this clinical entity is therefore critical to patient care. (Taylor, 2007) Clinicians face formidable challenges, however. Breakthrough pain is a highly variable clinical construct—its duration, frequency, severity, and predictability vary among and within patients. (Portenoy, 2006; Mercadante, 2002; Portenoy, 1990; Portenoy, 1989) Continual assessment helps characterize these temporal features and distinguish breakthrough pain from uncontrolled baseline pain. Clinicians require educational programs that help clarify breakthrough pain as a measurable and treatable clinical construct. (CSNA; **Learning Objectives 1, 4**)

Risk Mitigation

Third, a careful consideration of the risk-benefit relationship of opioids in the context of other pharmacologic and nonpharmacologic treatment options is critical to individualized patient care. (Fine and Portenoy, 2007) Russell K. Portenoy, MD and colleagues have developed a conceptual framework within which clinicians can decide to initiate, maintain, or discontinue opioid-based therapy. Specifically, the "Portenoy principles" require identifying the conventional therapeutic approach for the pain syndrome; evaluating the risk-benefit ratios of all feasible treatment options; assessing the risk of opioid-related adverse

pharmacologic outcomes (eg, gastrointestinal distress, sedation, endocrine dysfunction); and stratifying the risk of nonmedical opioid use. This approach helps structure opioid-based therapy consistent with risk, an increasingly critical driver of chronic pain management. (Portenoy, 2004) Clinicians can benefit from an educational program that helps them incorporate the principles suggested by Dr Portenoy into their clinical practice. (CSNA; **Learning Objective 1, 4**)

> *"Conventional management may not be evidence based and may not be appropriate for the individual person. But we all exist in a network of relationships with other physicians, other health care providers, a regulatory network, a legal network, a managed care network. And you need to have that understanding of conventional practices, within the network, in order to make an informed judgment. If you decide not to do what is conventional, from my perspective, that's totally okay. We do that every day as clinicians. We decide to do something that's not conventional. But, if it's not conventional, you need three things. You need a good reason. You need informed consent. And you need documentation."* **Russell K. Portenoy, MD**

Understanding the social milieu in which the patient lives and works, and obtaining the personal and/or family history of medical and psychiatric comorbidities, especially substance use disorders, creates a three-dimensional, biopsychosocial representation of the patient. (Wasan, 2007; Adams, 2006; Wool, 2005) Validated screening tools—including the Opioid Risk Tool and the Screener and Opioid Assessment for Patients With Pain—are available to help stratify the risk of inappropriate opioid use. (Belgrade, 2006; Akbig, 2006; Webster, 2005) Such problematic opioid use includes failure to use the opioid as prescribed (misuse), the deliberate use of a drug for nonmedical reasons, in particular for psychotropic effects (abuse), and the willful or accidental transfer of the medication to others (diversion). (Katz, 2008; Katz, 2007) Amid the escalating epidemic of prescription opioid abuse, clinicians need expert insights into balancing the benefits of opioid medications with the risk of abuse, misuse, and diversion. (CASA, 2008; CASA 2005; SAMHSA, 2004) There is an unmet medical and educational need for thorough and careful assessment of biological, psychological, and social dimensions of patients with chronic pain. (Denisco, 2008; Martelli, 2004; Marcus, 2000) (CSNA; **Learning Objective 2**)

Patients with chronic pain who are assessed as high risk may require a highly structured plan. (Gourlay, 2005) Pill counts, urine drug screening, weekly visits for prescription refills, pharmacy monitoring plans and treatment agreements are all available options. Risk mitigation is an inherently imprecise methodology, as familiar as it is essential. Patients with diabetes, hypertension, or schizophrenia all require careful stratification of risk. The universal applicability of risk stratification to all disciplines of medicine underscores its central importance and the need for ongoing education. (CSNA; **Learning Objectives 2, 3**)

> *"In every sector of medicine, we always have to balance the risk or burdens of treatment against the benefits. The benefits in analgesic treatment are going to be pain relief, improved functionality, and decreased or at least more appropriate healthcare utilization. The risks include the side effects of the medication, diminution of quality of life as a result, and abuse behaviors, which can be problematic not only to the patient, but for our society."* **Neal E. Slatkin, MD**

Multimodal, Opioid-Based Management of Persistent and Breakthrough Pain

Multidisciplinary, collaborative pain management is often required, particularly for complex chronic pain syndromes with demonstrable biopsychosocial elements. (Stanos, 2007; Wiedemer, 2007) Clinical data and experience support the use of opioids, often in combination with behavioral, psychosocial, rehabilitative, and interventional treatments, customized to the individual patient's pain complaint, risk status, and goals. (Pergolizzi, 2008; de Leon-Casasola, 2008; Soares, 2007; Jensen, 2006) Further, patient care is often improved by combining opioids with nonopioid analgesics—$\alpha_2\delta$, tricyclic antidepressants, serotonin norepinephrine reuptake inhibitors, or nonsteroidal anti-inflammatory drugs. (Gilron, 2008) By targeting therapies at distinct neuraxial sites that transduce, transmit, modulate, and perceive pain signals, patients may receive opioid-sparing and additive analgesic effects. (Baron, 2008)

The rationale for multidrug therapy has considerable face validity, although few randomized controlled studies have been performed to date. (Dworkin, 2007; Backonja, 2006; Kalso, 2005) As discussed, classifying pain as neuropathic or nociceptive significantly influences these combination treatment approaches. (Horowitz, 2007; Argoff, 2006) Recently, Gilron and coworkers reported the benefits of a morphine sulfate-gabapentin combination for neuropathic pain. (Gilron, 2005) Many questions remain. Is there differential benefit to sequential or concurrent combination strategies? Should the maximal tolerated dose for monotherapy be achieved before combining a second agent? How should breakthrough pain be treated within this multidrug treatment paradigm? (Raja, 2005) These and other issues require educational fora to foster peer-to-peer learning and to capture the clinical experience with opioid-based multimodal approaches for persistent and breakthrough pain management. (CSNA; **Learning Objectives 4, 5**)

Orchestrating an Opioid Trial

In his recently published text, *Responsible Opioid Prescribing: A Physician's Guide*, Scott Fishman, MD, describes the model policy of the Federation of State Medical Boards (FSMB) for safe, rational, and transparent prescribing of opioids. (Fishman, 2008) Briefly, the FSMB reinforces the need for thorough assessment and ongoing evaluation of the patient on the formulation and continual refinement of a therapeutic plan. Further, FSMB policy highlights the central importance of tailoring opioid-based therapy commensurate with the degree of risk, and based on a transparent, beneficent, and vigilant relationship with the patient. The paradigm for an opioid trial has been extensively documented, though rarely evaluated in randomized controlled studies. (APS Annual Meeting, 2008) Presently, experts recommend that physicians initiate a trial with predefined functional goals: to achieve control of the baseline pain and to assess and treat fluctuations that break through the multimodal analgesic regimen. (Dy, 2008; Pergolizzi, 2008; Davies, 2008; Portenoy, 2004) There is an urgent need for physicians to integrate this approach into their daily care of patients with chronic pain syndromes. (CSNA; **Learning Objectives 1, 4, 5**)

"Clinicians should make sure that their records are generally complete, but the key is not to just document everything that's going on, but to be transparent about risk management, to recognize that every patient has risk, whether or not they are taking opioids, whether they are being treated for pain or treated for infections with antibiotics. There is risk in doing nothing, and there is risk in doing the treatment. Recognize the risk and have a plan for follow-up. If there is a problem, then there is a risk management plan." **Scott M. Fishman, MD**

Numerous guidelines and consensus statements recommend the use of regularly scheduled opioid agonists for cancer-related persistent pain. (Pergolizzi, 2008; Moulin, 2007; Trescot, 2006) In addition, "rescue" doses of short-acting and rapid-onset opioids are recommended for the intense fluctuations that often occur despite adequate control of baseline pain—namely, breakthrough pain. (Fishbain, 2008; Aronoff, 2005) For the past 20 years, evidence-based guidelines and empirical decision making in cancer pain management have become the basis by which to evaluate the roles and risks of opioid medications in chronic noncancer pain. (Ballantyne, 2007) Data continue to emerge demonstrating the utility of opioids for common noncancer pain syndromes. (Furlan, 2007; Eisenberg, 2005) Still, more rigorously controlled studies are needed; meanwhile, clinicians must balance evidence-based medicine with practice-based evidence when initiating and maintaining opioid-based therapies. (Davis, 2004; Carr, 2004)

Maintenance of the long-acting opioid (LAO)–based regimen requires continual monitoring and occasional baseline medication adjustments to achieve a measure of dose stability. (Portenoy, 2004) Robust trial data have demonstrated that pharmacologic outcomes—a favorable balance between analgesia and side effects—improve when, during this maintenance phase, breakthrough pain episodes are recognized, assessed, and treated. (Hagen, 2008; Portenoy, 2007; Simpson, 2007; Portenoy, 2006; Zeppetella, 2006; Coluzzi, 2001; Portenoy, 1999; Christie, 1998) Challenges persist, however, and educational programs are required to provide guidance for clinicians to identify well-controlled baseline pain through continual assessment, allowing the independent and tight therapeutic management of breakthrough pain. (CSNA; **Learning Objectives 1, 2, 5**)

"When clinicians see people who have inadequate pain relief back in their offices, and they're on a long-acting opioid, what it really boils down to during that visit is: Do you decide to raise the background opioid or do you add on another drug, and what drives your decision making at that critical point? And it will depend on how you view the pain phenomenology, the patient, and other factors. And I don't think it's a straightforward question in a disease state in which the best therapies only reduce the background pain by 57 percent." **Steven D. Passik, PhD**

Breakthrough pain is not a unitary phenomenon; rather, several subtypes have been evaluated clinically and shown to have telltale characteristics that aid assessment and treatment. (Webster, 2008; Caraceni, 2004; Gutgsell, 2003) First, incident breakthrough pain may be precipitated by volitional (eg, gardening) or nonvolitional (eg, spasm) activity. (Svendsen, 2005) Second, breakthrough pain attributed to end-of-dose failure emerges with a periodicity that coincides roughly with the pharmacokinetic troughs of the baseline medication, typically an LAO. (McCarberg, 2001) Baseline dose adjustments may reduce the frequency and severity of these episodes, although the LAO may reach dose-limiting toxicities, causing some clinicians to switch opioid baseline medications or to prescribe a short-acting opioid to compensate for the drop in LAO serum levels. (Dy, 2008; De Leon-Casasola, 2008) Finally, idiopathic breakthrough pain is associated with paroxysmal spikes that may reach peak intensity in as little as 3-5 minutes. (Portenoy, 2006; Simon, 2006; Bennett, 2005; Portenoy, 1990)

Clinical studies on the differential phenomenology of breakthrough pain subtypes have been limited. The threshold frequency for breakthrough pain episodes that warrants baseline medication adjustments has not been well established. (Svendsen, 2005) Absent clear experimental evidence, clinicians need guidance on the differential diagnosis of breakthrough pain, and the respective roles of long-acting, short-acting, and rapid-onset opioids. (Davies, 2008; Hagen, 2008; Portenoy, 2008) Case-based workshops, reviews of the evidence, and other expert insights into breakthrough pain management are urgently needed. (CSNA; **Learning Objectives 1, 5**)

"Can we add some questions to the concept of a comprehensive assessment that speak more to clinical meaningfulness of breakthrough pain and treatment selection? So, for instance, the time to onset, time to severe, or time to clinically meaningful effect. And activities you avoid in an attempt to prevent episodes may help define a scope of fluctuations that should be called breakthrough pain that aren't now described as such?" **Russell K. Portenoy, MD**

Pain management perspectives continue to evolve. In particular, several concerns are often noted: lack of data supporting long-term opioid therapy; the occurrence of addictive disease in a subset of patients; inexact risk mitigation methodologies; and the potential for hyperalgesia and for endocrine and immune dysfunction with long-term opioid exposure. (Korff, 2008; Ballantyne, 2007) For some patients, opioids are associated with side effects (eg, constipation, pruritis, and sedation), poor tolerability, and serious adverse events such as respiratory depression and, as discussed, misuse, abuse, and diversion. (Harris, 2007) In addition, clinicians need to clarify the nomenclature and clinical constructs of physical dependence, tolerance, pseudotolerance, addiction, and pseudoaddiction. (Jage, 2005; Savage, 2003) (CSNA; **Learning Objective 6**) These and other safety concerns—identifying opioid-tolerant patients, for instance—rightly rank as paramount among clinicians, and demand continual and comprehensive evaluation of patient compliance and therapeutic response, informed by predefined functional goals. (Rosenblum, 2008) Educational programs should raise awareness of these issues and provide practical guidance to minimize their impact on patient care. (CSNA; **Learning Objectives 2, 4**)

"For some patients, the therapeutic window is the size of the Texas plains and you can give them medicines without much worry. But there are individuals who are extremely sensitive to medicines and instead of being the size of the Texas plains, the window is the size of a New York City street during rush hour: tight, small, and difficult to manage. When you're trying to treat these patients, you need very precise control of the medications." **Michael J. Brennan, MD**

Clearly, patient selection is the linchpin of effective opioid-based therapy. (Portenoy, 2008; Antoin, 2004) Individuals vary across multiple dimensions: in their response to nonpharmacologic and pharmacologic treatment options; in their pain phenomenology; in their affective behavior during therapy; and in their propensity for irresponsible medication use. Despite current and emerging data, no one opioid molecule—oxycodone, fentanyl, or morphine, for instance—has an *a priori* advantage over another. And data delineating the respective roles of long-acting, short-acting, and rapid-onset opioids in managing the persistent and breakthrough components of chronic pain are only beginning to emerge. (Simon, 2005) Clinicians thus need expert input on how best to structure opioid-based therapy in the context of a well orchestrated N-of-1 trial.

Multidimensional assessment governs multimodal therapeutic decision making, but the gap between evidence-based medicine and the practical, day-to-day management of patients with persistent and breakthrough pain is considerable and, for some, even prohibitive. Rational, transparent prescribing of opioids among appropriately selected patients thus presents formidable challenges that can only be met by rigorous educational efforts. (CSNA; **Learning Objectives 3, 4**)

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IV. Faculty and Programs

Potential Faculty

Under the direction of David Kaufman, MD, Professor of Neurology and Psychiatry at Albert Einstein College of Medicine, and the Albert Einstein College of Medicine, qualified faculty will be selected and may include the following:

Michael J. Brennan, MD
Chief of Rehabilitation Medicine
Bridgeport Hospital
Bridgeport, Connecticut

David A. Fishbain, MD
Professor of Psychiatry, Adjunct Professor of
Anesthesiology and Neurological Surgery
Leonard M. Miller School of Medicine
University of Miami
Miami, Florida

Scott M. Fishman, MD
Professor of Anesthesiology
Chief, Division of Pain Medicine
University of California, Davis
Sacramento, California

Gordon Irving, MD
Medical Director, Swedish Pain Center
747 Broadway
Seattle, Washington Seattle, WA 98122

Bill McCarberg, MD
Founder, Chronic Pain Management Program
Kaiser Permanente
Escondido, California

Sebastiano Mercadante, MD
La Maddalena Cancer Center
University of Palermo
Pain Relief & palliative care
Via S. Lorenzo Colli 312
90146 Palermo, ITALY.

Christine Miaskowski, RN, PhD, FAAN
Professor and Chair
Department of Physiological Nursing
UCSF School of Nursing,
San Francisco, California

Judith A. Paice, RN, PhD
Research Professor
Northwestern University Feinberg School of Medicine
Chicago, Illinois

Steven D. Passik, PhD
Clinical Psychologist
Memorial Sloan-Kettering Cancer Center
New York, New York

John Peppin, DO, FACP
Director
Iowa Pain Management Clinic
Des Moines, Iowa

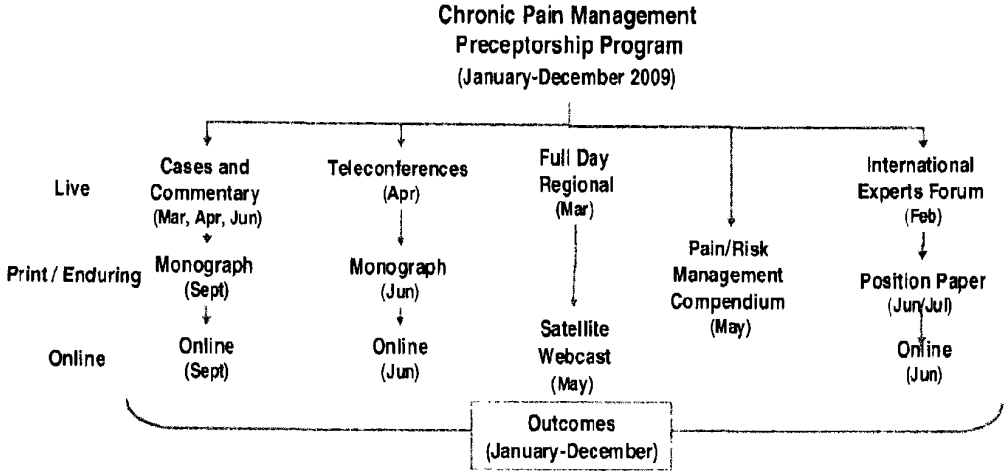
Russell K. Portenoy, MD
Chairman
Department of Pain Medicine and Palliative Care
Beth Israel Medical Center
New York, New York

Neil E. Slatkin, MD, DABPM
Director
Department of Supportive Care, Pain & Palliative Medicine
City of Hope Medical Center
Duarte, California

Lynn R. Webster, MD, FACPM, FASAM
Medical Director
Chief Executive Officer
Lifetree Clinical Research and Pain Clinic
Salt Lake City, Utah

Giovambattista Zeppetella, MD
St Clare Hospice
Hastingwood Road
Hastingwood, Essex CM17 9JX, UK

Einstein and Asante recommend developing a comprehensive, accredited, and integrated CME initiative comprising each of the proposed tactics. Further, we recommend folding the educational programs and materials under a unifying and meaningful acronym, linking them conceptually, and assuring clinicians of their quality, accuracy, and clinical relevance.



Chronic Pain Management Preceptorships

In this pilot program, approximately two-hundred (~n=200) US-based pain management clinicians will participate in a preceptorship focusing on opioid-based care of patients with chronic pain. The program will provide a forum for each clinician to interact with national thought leaders via monthly WebPanel series. The interactions will be structured around previously identified areas of educational need and interest, as determined by CSNA and as described in the learning objectives. An initial 30-minute teleconference call with the community-based pain clinicians and national thought leader will launch the pilot program, followed by 15-30 minute quarterly WebPanel calls and, potentially, a meeting at a major medical congress, half-day or full-day regional meeting. Participants will be required to participate in at least three distinct activities; and would be encouraged to participate in a live regional meeting, to be held near to a Pain Center of Excellence identified by the American Pain Society (see below). Upon completion of this program, participants will receive up to 4 hours of CME credit and a complimentary copy of *Rational Opioid Prescribing, A Physician's Guide*, by Scott Fishman, MD, and/or a copy of *Diagnosis and Treatment of Breakthrough Pain*, by Perry Fine, MD. Together, the books effectively summarize the essential elements in developing opioid-based regimens for patients with chronic pain syndromes.

Participants will be encouraged to share their newly acquired knowledge with their colleagues, potentially through a variety of outlets, including, but not limited to, in-services, lectures, and institutional publications. Upon completion of the educational series, and demonstration of improved and durable improvements in awareness, knowledge and performance (see Outcomes Measurement), select clinicians may be invited to participate as adjunct faculty for 2010 educational programs held in their respective regions. Working with national thought leaders, each adjunct faculty member will contribute to educational offerings—some in their local communities—on the assessment, differential diagnosis, and individualization of care for patients with persistent and breakthrough pain, potentially creating regional centers of excellence in pain management.

"This proposed preceptorship is superb! This is exactly what many of us have been discussing as a significant need—both for pain and for palliative care. The link to the centers of excellence is great—these are wonderful clinical centers. Some are more academic (NYU, Brigham) and others are more of a private practice model. This would allow participants a wider array of experiences. The outcomes described are perfect." **Judith A. Paice, PhD, RN**

Persistent and Breakthrough Pain Management in Cancer Survivors: Mechanism-Based Treatment for a Growing Patient Population (A Full-Day Regional Meeting)

Chronic pain in cancer survivors is an important yet under-studied problem. The prevalence of patients in long-term remission from a variety of cancer syndromes continues to grow, as does the need for guidance on how best to manage their complex pain states, particularly those with other medical and psychiatric comorbidities. Chronic pain and other long-term sequelae related to the disease and to medical, surgical, and radiation treatments significantly impair patient function and healthcare utilization, increasing the burden of illness on patients, their families, and society. This full-day workshop will consist of a morning lecture and panel session with veteran clinicians either currently or formerly associated with Memorial Sloan-Kettering Cancer Center (MSKCC). Their tenure at this premier facility will serve as a backdrop against which cancer survivorship and advances in the care of patients with cancer-related pain will be evaluated. In the afternoon session, participants will engage in a *Cases and Commentary* roundtable discussion.

Participants will receive a complimentary copy of *Rational Opioid Prescribing, A Physician's Guide,* by Scott Fishman, MD, and a copy of *Diagnosis and Treatment of Breakthrough Pain,* by Perry Fine, MD. The activity will be eligible for up to 8 hours of CME credit to physicians. Anticipated attendance is 75-100 physicians.

Satellite Web-Broadcast

Presently, the projection for attendance is 75-100 participants per full-day workshop, drawn primarily from the local and regional communities. To ensure access to other interested clinicians from across the country, a Web cast posted on Medscape or similar pain-related website (eg, www.pain.edu) is proposed. Distance learning is now turnkey, and each participant will be able to access the slide deck, related materials online, and highlights from the meeting. The activity will be eligible for up to 3 hours of CME credit to physicians. Anticipated reach is estimated to be over 20,000 physicians for the online activity.

Cases & Commentary™ Workshop

The ***Cases & Commentary***™ Workshop format is based, in part, on a small group case-based learning (SGCBL) model, allowing attendees to discuss therapeutic decision making across several case studies. Participants will benefit from the peer-to-peer design of the roundtable discussions, empowering them to listen, to probe, and to proffer solutions with their peers. The workshop provides a forum for exchange of insights into current diagnostic and therapeutic strategies. For those participants whose approach to decision making is aligned with that of their peers and thought leaders, the workshop will validate their own practice. Most participants will acquire knowledge across multiple facets of complicated disease states and patient care.

Eligible for 4 hours of CME credit each, the workshop will include no more than 50-75 participants (total n=~225), who will engage in small group discussions to evaluate best practices in persistent and breakthrough pain management. Each study group may include neurologists, physiatrists, anesthesiologists, and psychologists, and will be facilitated by a key thought leader

in pain medicine. In evaluations of previous workshops, most attendees rated the overall activity as "excellent," providing favorable comments regarding both the faculty and learning environment.

The meetings will be presented at regional locations across the country, selected from the 2007 American Pain Society Centers of Excellence. Suggested venues therefore may include the following:

- NYU Medical Center / Hospital for Joint Diseases, Bellevue Hospital Center, Comprehensive Pain Management Center, New York
- The Rosomoff Comprehensive Pain Center, Miami
- Brigham and Women's Hospital, Pain Management Center, Department of Anesthesiology, Perioperative and Pain Medicine, Boston
- UCSF Pain Management Center and UCSF PainCARE, Center for Advanced Research and Education, San Francisco
- Cincinnati Children's Hospital Medical Center, Division of Pain Management

Cases & Commentary Monograph

The case-based discussions will be audiotaped and provide substantial commentary ideally suited for a 4,500 word print monograph. The monograph will be posted on a pain-relevant website (eg www.medscape.com; www.pain.edu), distributed to pain specialists through *Pain Medicine News*, a leading trade journal with a wide readership, and/or through PainClinician™, our proprietary database and quarterly distribution vehicle. Written in a narrative style, the case-based monograph will convey best practices in the initial patient presentation, assessment, diagnosis, and formulation and ongoing refinement of therapeutic plans for chronic pain. Successful completion of a 10-question multiple-choice self-assessment examination based on the content presented is necessary to receive a certificate of completion. Participants must score 70% or higher and are allowed 2 attempts to successfully complete the exam. Upon successful completion of the monograph, physicians may use the CME credit earned toward their licensure and/or certification requirements. The activity will be eligible for 1 hour of credit to physicians for 1 year from the issuance date. Anticipated reach is estimated to be over 45,000 physicians for the print monograph in addition to 5,000-10,000 online recipients.

International Expert Forum and Position Paper on Persistent and Breakthrough Pain Management

Davies and coworkers recently published a task force series of recommendations on the management of breakthrough pain. (Davies, 2008) Interestingly, the experts stopped short of making specific treatment recommendations, and instead provided a conceptual framework to guide decision making. Citing the lack of evidence, the experts emphasized a carefully balanced and ongoing assessment and multimodal strategy for the management of breakthrough pain.

In this proposed expert forum, three prominent US based pain clinicians will explore the findings and implications of the Davies report with and two European leaders (eg Giovambattista Zeppetella, MD, Sebastiano Mercadante, MD). The program will consist of several teleconference calls and/or videoconferences, potentially culminating in a meeting at a medical congress. Salient recommendations would provide the substrate for a 6,500-word position paper on persistent and breakthrough pain management, to be posted on a pain-relevant website, and distributed through PainClinician™, our proprietary database and quarterly distribution vehicle. Based on the response from pain clinicians who participated in an international forum on persistent and breakthrough pain management recently held in Glasgow, Scotland, this expert panel may receive acknowledgement from the International Association for the Study of Pain (IASP). The activity will be eligible for 1+ hour(s) of credit to physicians for 1 year from the issuance date. Anticipated reach is estimated to be over 35,000 physicians for the print portion in addition to over 15,000-20,000 online recipients.

Teleconference Series

A CME audio teleconference brings together the live educational format preferred by many healthcare professionals with the convenience of participating in the activity at home or in the office. Available to a national audience, this format provides clinicians with an opportunity to participate in a lecture led by a thought leader as well as to interact with peers across the country.

This activity will be presented eight (8) times by nationally recognized thought leaders in pain management. Anticipated participation in each broadcast will be 25-50 participants (total n=~200-400), they will be approximately 45 minutes in length, with a 10-minute question-and-answer session completing the program. A teleconference syllabus will be mailed to the participants 48 hours prior to the presentation. Participants will phone in to a reserved line to listen to the lecturer elaborate on the slide content. The activity will be eligible for 1 hour of CME credit to participants.

Teleconference Series Monograph

The teleconferences will be audiotaped and provide commentary ideally suited for a 4,500 word print monograph. The monograph will be posted on a pain-relevant website, distributed to pain specialists through *Pain Medicine News*, a leading trade journal with a wide readership, and direct-mailed to pain practitioners enrolled in PainClinician™, our proprietary database. Written in a narrative style, the case-based monograph will convey best practices in persistent and breakthrough pain management Successful completion of a 10-question multiple-choice self-assessment examination based on the content presented is necessary to receive a certificate of completion. Participants must score 70% or higher and are allowed 2 attempts to successfully complete the exam. Upon successful completion of the monograph, physicians may use the CME credit earned toward their licensure and/or certification requirements. The activity will be eligible for 1 hour of credit to physicians for 1 year from the issuance date. Anticipated reach is estimated to be over 45,000 physicians for the print monograph in addition to over 5,000-10,000 online recipients.

Albert Einstein's Persistent and Breakthrough Pain Reference Compendium

Editor: Russell K. Portenoy, MD Professor of Neurology

Reference manuals provide healthcare professionals with an authoritative educational tool in a condensed format that is easily transported from one clinical setting to another. This reference compendium will provide pain clinicians with practical information in a condensed format for quick reference. Pain and risk screening tools, equianalgesic dosing and other relevant information will be included. This text will include frequently asked questions and answers culled from various fora, including teleconferences and regional meetings. Posed by community pain clinicians, nurses, and psychologists, the questions address the fundamental issues in the management of chronic pain syndromes, from cancer-related pain to osteoarthritis. The responses will be drafted by leading experts in the field; a guest editor for this annual series will provide a preface and additional commentary throughout the text. Exhaustively referenced, this print activity will be available online and eligible for 1-2 hours of continuing education credit to participants. A 10-question multiple-choice self-assessment examination based on the content presented will be included. Successful completion of the posttest is necessary to receive certificate of completion/statement of credit. Anticipated reach is estimated to be over 45,000 physicians for the print monograph in addition to 5,000-10,000 online recipients.

Additional Tactics for Future Consideration

Persistent and Breakthrough Pain: Evidence-Based Practice and Practice Based Evidence

In this print and online series, expert thought leaders will elaborate on the seminal studies supporting the management of persistent and breakthrough pain, conducted over the past twenty years, since Drs Portenoy and Hagen published their seminal work in 1990. Abstracts of select studies will be included, and will help frame the discussion on salient issues in chronic pain management. Randomized controlled studies include patient populations with rigorously defined inclusion and exclusion criteria, often precluding generalizable and practical recommendations. Here, clinicians will discuss several landmark study findings, their limitations and implications for current approaches to assessment and individualization of patient care. Particular emphasis will be placed on the soon-to-be published guidelines from the American Pain Society, providing pain clinicians with guidance on how to interpret and implement their recommendations, bridging the gap between what we know and what we don't know with practice based clinical experience and evidence.

Web-Based Decision Tree (Program Name and URL Will Be Provided Upon Request).

This activity purports to integrate the expert clinical experience with the Level 1 Evidence of randomized controlled studies. Two objectives are served. First, clinicians acquire a more in-depth understanding of the evidence-based recommendations in various guidelines. (Of note, the American Pain Society will be publishing its guidelines in the near term.) This knowledge will help clinicians find a more practical expression of guidelines that too often cannot be implemented. Second, clinicians will refine their clinical judgment by engaging in structured decision making—the art of medicine—that drives patient care, particularly when specific evidence is lacking. In this Web-based activity, clinicians will be presented with case studies representative of the myriad issues in managing patients with persistent and breakthrough pain. Case studies may address chronic pain associated with tumor progression, radiation or chemotherapy-related pain in cancer survivors, diabetic peripheral neuropathy, and chronic low back pain.

Upon reviewing salient data—including, for instance, patient history, comorbidities, prior treatment history, pathophysiology, imaging studies, and laboratory findings—the clinicians will develop in step-by-step fashion a course of action. At each step, from assessment and diagnosis; to the initial and revised treatment, the clinician may choose among several options, each informed by well-designed studies and each having risks and benefits. These data will, of course, only be available to the clinicians upon making their selections. With only one "click," clinicians will gain access to a brief abstract summarizing the available evidence and a video of a thought leader roundtable discussion framing the available evidence. Links to seminal scientific and/or randomized controlled studies will be readily accessible and adjacent to each video presentation. When available, evidence-based outcomes—eg, pain reduction and functional improvement—of each treatment selection will be discussed. This self-directed case-based learning provides a familiar educational format for healthcare professionals based on adult learning principles, and consistently rates as a highly effective means by which to educate clinicians.

Case-In-Point and Accompanying Monograph

This roundtable discussion will feature several pain specialists, two from prominent academic centers and another from private practice. Faculty will present several complicated case studies, elaborating on the evidence for various treatment modalities. Twenty-five community-based clinicians—neurologists, psychologists, physician assistants, and nurses—will be invited to listen and to join in the discussion at appropriate times. This "chronic pain-in-the round" program will be video captured to form the basis for podcasts posted on a pain management Web site (eg, www.pain.edu) that includes practical, evidence-based resources for pain specialists

The recorded sessions are edited professionally and reduced to 10-minute video vignettes, concise and uninterrupted discussions that capture the thought leaders' expert insights into the management of persistent and breakthrough pain. Print editorials written by community pain clinicians will accompany the video vignettes, reinforcing the major themes and providing an opportunity for academic thought leaders to partner with local clinicians, each managing patients with chronic pain. This innovative Web-based format allows clinicians to participate immediately in each activity at a self-directed pace from their computers—accommodating even the busiest of schedules.

A monograph will be developed to provide additional context for the video case studies. A 10-question multiple-choice self-assessment examination will also be included, reflecting the content discussed in each video vignette and accompanying print editorials. Successful completion of the posttest is necessary to receive a certificate of completion, or a statement of credit. Participants must score 70% or higher and are allowed 2 attempts to successfully complete the exam. Upon successful completion of the examination, healthcare professionals may use the CME credit earned toward their licensure and/or certification requirements. Each vignette—prime examples of which may be e-mail blasted to the target audience of pain specialists—will be eligible for 1 hour of credit for 1 year from the issuance date.

Literature Surveillance

Quarterly reports summarizing in an easy-to-read style results from a formal literature surveillance will be shared with select faculty and preceptorship clinicians. Designed to identify new developments in the management of chronic pain, the reports will monitor clinical trial data, guideline updates, FDA approvals and warnings, and emerging issues in pain medicine.

V. Program Recruitment, Awareness, and Distribution

Program Recruitment, Awareness, and Distribution

All live, print, and online programs will have specific recruitment, awareness, and distribution methods contained to ensure that the programs have the best opportunity for educational uptake and acceptance. These recruitment methods have been validated for past programs and have proven cost effective while maximizing reach and distribution to targeted audiences. These methods include live, print, and online components as detailed below.

PainClinician™

PainClinician™ is a compendium of advances in the management of chronic pain, distributed quarterly to pain specialists and other healthcare professionals interested in chronic pain management. Our proprietary database of the same name will ensure distribution to the primary audience of pain practitioners. Distribution methods include direct mail, distribution at AAPM, APS, and other selected pain management meetings throughout the year. Total quarterly distribution is estimated to be over 25,000. In addition to outlining the accredited package contents, each quarter and through an introductory letter, a leading pain management clinician will highlight the most recent and important dialogues and discussions involving pain medicine.

Pain Medicine News

The enduring activity will be a stand alone monograph of 12 journal sized pages distributed with an early 2009 issue of *Pain Medicine News* to its full circulation of approximately 46,500 clinicians. *Pain Medicine News* is a bimonthly publication circulating to physicians in the 12 specialties that most commonly treat patients with pain: emergency medicine physicians; neurologists; oncologists; orthopedic surgeons; pain management, pain medicine, and palliative pain medicine specialists; physical medicine and rehabilitation specialists; primary care physicians; and rheumatologists.

Additional copies of the monograph will be distributed from the *Pain Medicine News* exhibit booth at national conferences. *Pain Medicine News* has a presence at 7 conferences throughout the year at which the monograph may be distributed at:

- American Academy of Pain Medicine
- American Academy of Pain Management
- American Conference on Pain Medicine
- American Pain Society
- American Society of Regional Anesthesia and Pain Medicine Spring Meeting
- American Society of Regional Anesthesia and Pain Medicine Fall Meeting
- North American Neuromodulation Society

Live and Online Components

Live recruitment, awareness, and distributions campaigns will include attendance at various medical congresses and other relevant satellite pain meetings throughout the year. At these meetings, in addition to recruitment, awareness and distribution of ongoing programs to attendees, enrollment into the *PainClinician™* database and program will occur. A thorough online campaign including, but not limited to, MedScape, www.pain.edu, Sermo and other pain-related services, to generate interest in

existing and future educational programs will also ensure maximizing the uptake, awareness, acceptance, and ultimately, participation in the ongoing series of educational programs.

VI. Budgets

Please see attached

Center for Continuing Medical Education

Bridging the Gap Between Education and Practice

Albert Einstein College of Medicine

The University Hospital and Academic Medical Center for the Albert Einstein College of Medicine

Steven Jay Feld

November 6, 2008

Educational Grant Review Committee
Cephalon

Dear Sir and/or Madam:

On behalf of the Albert Einstein College of Medicine & Montefiore Medical Center, Center of Continuing Medical Education (CCME) and our Educational Collaborator and Joint Sponsor, Asante Communications LLC, I am requesting an educational grant from Cephalon in the amount of $1 462,375.00 to be used to help support several CME accredited activities. These activities will focus on the topic of chronic pain management with the goal of providing clinicians with a learning forum to develop practical methods to appropriately assess and manage pain.

CCME, with assistance from its educational collaborator, Asante Communications LLC, an organization with professional staff that have extensive experience in developing and implementing activities such as those being proposed, is planning to develop a series of CME activities to address issues of pain management and to provide physicians with the necessary best-practice skills to be able to better diagnose and treat issues in pain management. The activities will include:

- three (3) cases and commentary live meetings
- one (1) monograph to be developed from materials presented at the cases and commentary meetings
- one (1) on-line monograph (same as above)
- eight (8) live teleconferences available for participation at separate times
- one (1) monograph to be developed from the materials presented during the teleconferences
- one (1) on-line monograph (same as above)
- one (1) live regional meeting
- one (1) satellite webcast which will include highlights from the live regional meeting
- one (1) non-CME international forum of experts, which will be used to develop a CME activity
- one (1) CME position paper developed from the above international forum of experts
- one (1) on-line position paper (same as above)
- one (1) pain/risk management compendium to assist physicians in their clinical settings
- one (1) on-line pain/risk management compendium (same as above)

Each of these activities will include outcomes surveys to measure the practice performance changes of the participants of each activity. A further outcomes study/preceptorship, utilizing a control group to measure and compare the effectiveness of continued educational interventions between the control group's practice performance and the group receiving additional educational interventions will be conducted and will include participants from the cases and commentary, teleconferences and regional meeting. Participants in this outcome study will be given an opportunity to opt in.

3301 Bainbridge Avenue, Bronx, NY 10467

As an additional option we are offering to develop and execute a final outcome study, which will poll from a select group of participants from the above outcome study. The physicians would agree to join a final IRB approved study, which will assess patient satisfaction This study will be developed and overseen by an approved IRB entity and will seek input from patients that agree to be part of the study

The working title of this comprehensive initiative is, *Persistent and Breakthrough Pain. A Multidimensional Assessment and Multimodal Opioid-Based Treatment Strategies Initiative.*

Faculty for this initiative will be chosen to develop unique learning opportunities, which will enable pain management specialists, which will include. neurologists, rheumatologists, physiatrists, primary care physicians, internal medicine physicians, anesthesiologists and oncologists to increase their competence and abilities to treat and appropriately manage pain and learn important methods to incorporate risk management strategies into pain management plans

We will be using the requested grant for all the expenses related to the organization, capture and development of materials and for the accreditation and assessments of these CME activities

The purpose of this letter is to provide you with information on how CCME is planning to organize all the logistics related to the production and accreditation of these activities

The Albert Einstein College of Medicine and Montefiore Medical Center, Center for Continuing Medical Education and its Educational Collaborator and Joint sponsor, Asante Communications LLC. or our agents, will take full responsibility for both the medical content and logistical aspects of the following.

- Select faculty and topics
- Provide a faculty reviewer to make sure that all materials are free of bias and of professional scientific merit
- Develop a marketing plan to reach an audience of appropriate participants
- Provide sponsorship of the activities and maintain all books and records
- File and prepare all appropriate documentation to allow the activities to be certified by Albert Einstein College of Medicine for AMA PRA credit
- Administrate all financial accounting and bookkeeping
- Prepare, distribute and summarize course evaluations
- Develop, distribute and summarize outcomes surveys
- Maintain records of participants, grade quizzes and provide certificates to requesters
- Review and oversee the development of materials to ensure that the enduring material activities are in compliance with the AMA and ACCME Guidelines

Each of the activities will be reviewed by one of our renowned faculty, who is a specialist in the field of pain management They will also be responsible for working with Asante Communications LLC to identify needs, learner gaps, objectives, appropriate faculty and determine topics.

Our tax ID number is 13 1740114 (Montefiore Medical Center)

The provider requires that

- All significant relationships (e g consulting, grant recipient, etc) between Cephalon and faculty members, or any individual in a position to influence content must be disclosed to the participants of its CME activities
- All commercial interest support be disclosed to participants prior to their participation in its CME activities
- All COIs of faculty, or anyone in a position to influence content will be resolved through mechanisms of resolution developed by Einstein for all its CME activities

Einstein requires that its LOA with Cephalon be signed by Victor B Hatcher, PhD, Associate Dean of CME at Albert Einstein College of Medicine and Director of CME at Montefiore Medical Center, or Steven Jay Feld, Associate Director of CME at Albert Einstein College of Medicine & Montefiore Medical Center

Please make checks payable to Montefiore Medical Center

Montefiore Medical Center is the University Hospital for the Albert Einstein College of Medicine and all Albert Einstein College of Medicine, CME finances are handled by Montefiore Medical Center

Check payments should be remitted to
CCME
3301 Bainbridge Avenue
Bronx, NY 10467
Attn Steven Feld

Any unused funds that were received from Cephalon in support of these activities will be retuned to Cephalon upon completion of reconciliation

If you need any further information or have any questions that relate to this grant request, please contact me at 718 920-6674, ext 232

On behalf of Albert Einstein College of Medicine & Montefiore Medical Center I would like to thank Cephalon for consideration of this request

Sincerely

Steven Jay Feld

cc Asante Communications LLC

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.

Cephalon
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www.cephalon.com

Cephalon, Inc.
41 Moores Road
PO Box 4011
Frazer, PA 19355
Phone 610-344-0200
Fax 610-344-0065

INDE (ON TIGRIS (MONTEFIORE) Check Agreement on System - Agreement in TRIM? (ask Connie) PAIN) **ANT AGREEMENT** 2569

This Agr December, 2008, by and
between Cepha , Post Office Box 4011,
Frazer, PA 1935 ") located at CCME, 3301
Bainbridge Aven ations, LLC ("Educational
Partner") located Y 10022.

WHEREAS, Cep t
education progra

WHEREA:)
address educatior

WHEREAS , ensure t
independent, objective, balanced, scientifically rigorous, 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 "Persistent and BTP: Multidimensional Assessment and Multimodal Opioid-Based Treatment Strategies," 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. The name of the Educational Partner is Asante Communications, LLC.

5. Educational Components. The expected components of the Program (e.g., number of live meetings, CD ROM, web-based, etc.) are as follows:

   (a) Thirteen Live National Meetings;
   (b) Two Additional Live Meetings;
   (c) Five Web Tactics;
   (d) One Print Piece;

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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 16th day of December, 2008, by and between Cephalon ("Cephalon"), located at 41 Moores Road, Post Office Box 4011, Frazer, PA 19355, and Montefiore Medical Center ("Provider") located at CCME, 3301 Bainbridge Avenue, Bronx, NY 10467 and Asante Communications, LLC ("Educational Partner") located at 800 Third Avenue, 9th Floor, New York, NY 10022.

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 "Persistent and BTP: Multidimensional Assessment and Multimodal Opioid-Based Treatment Strategies," 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. The name of the Educational Partner is Asante Communications, LLC.

5. Educational Components. The expected components of the Program (e.g., number of live meetings, CD ROM, web-based, etc.) are as follows:

   (a) Thirteen Live National Meetings;
   (b) Two Additional Live Meetings;
   (c) Five Web Tactics;
   (d) One Print Piece;

(e) Three Print Supplements;

6. 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.

7. Grant Amount Funding Arrangements.

(a) Cephalon will provide support for the Program by means of an educational grant in the total amount of $1,316,295, 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.

8. 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.

9. 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.

10. 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

11. 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.

12. Question and Answer Session. To the extent the Program is a presentation, Provider will ensure meaningful opportunities for questioning by the audience.

13. 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.

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 affliated 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.

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 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.

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.

(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.

MONTEFIORE MEDICAL CENTER

By: Steven Jay Feld

Name: STEVEN JAY FELD

Title: ASSOCIATE DIRECTOR, CCHE

The above signatory is a duly authorized corporate officer of the IEP Provider.

Date: 12/23/08

Tax ID #: 13 174 0114

CEPHALON, INC.

SIGN HERE

By:

Name: Robert Kaper, MD

Title: ~~Vice President,~~ Medical Affairs

Date: 12/16/08

APPROVED AS TO LEGAL FORM
CEPHALON LEGAL DEPT.

ASANTE COMMUNICATIONS LLC

By:

Name: PETER HURWITZ

Title: PRESIDENT, MANAGING DIRECTOR

The above signatory is a duly authorized corporate officer of the Educational Partner.

Date: 12/24/08

Tax ID #: 80-0251570

(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.

MONTEFIORE MEDICAL CENTER

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Name: STEVEN JAY FELD

Title: ASSOCIATE DIRECTOR, CCHE

The above signatory is a duly authorized corporate officer of the IEP Provider.

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By: _____

Name: Robert Kaper, MD

Title: Vice President, Medical Affairs

Date: 12/16/08

APPROVED AS TO LEGAL FORM
CEPHALON LEGAL DEPT.

ASANTE COMMUNICATIONS LLC

By: _____

Name: PETER HURWIT

Title: PRESIDENT, MANAGING DIRECTOR

The above signatory is a duly authorized corporate officer of the Educational Partner.

Date: 12/24/08

Tax ID #: 80-0251570

Exhibit A

Copy of Grant Request

Center for Continuing Medical Education

Bridging the Gap Between Education and Practice

Albert Einstein
College of Medicine
of Yeshiva University

The University Hospital and
Academic Medical Center for the
Albert Einstein College of Medicine

Steven Jay Feld
Associate Director

December 8, 2008

Ms. Karen Roy
Director of Medical Education
Cephalon
41 Moores Road
Frazer, PA 19355

Dear Ms. Roy:

Per your request for additional information, please find below a more detailed overview of the Level and Type of data to be collected via the patient questionnaire.

Under the guidance of the Albany Medical Center's Institutional Review Board (IRB), and approved by Albert Einstein College of Medicine, CME, the Stage III Durable Outcomes measurement will be used to gather non-biased, independent and measurable information for the proposed Outcome Study.

As mentioned in the grant, the Stage III patient questionnaire will assess improvements in the management of persistent and breakthrough pain with patients whose physicians participated in the preceptorship program, when compared to patients who were under the care of control group physicians who did not participate in the preceptorship. The questionnaire will consist of 5-multiple choice questions, each inquiring into their perceptions of the clinician's attentiveness to the pain complaint. Sample questions that may be included, pending further discussion and approval by the Albany IRB, Albert Einstein College of Medicine and based on the approach utilized by Dr. Michael Brennan are as follows:

When compared to the beginning of the year has your clinician devoted more time to discuss the "ups-and-downs" in the severity of your chronic pain?

Parameters to be Measured

- 2 Significantly improved
- 1 Improved
- 0 No change

When compared to the beginning of the year has your clinician devoted more time to discuss changes in your pain severity caused by increased activity?

Parameters to be Measured

- 2 Significantly improved
- 1 Improved
- 0 No change

3301 Bainbridge Avenue, Bronx, N.Y. 10467 Phone 718 920 6671 Fax 718 798 2336 mecme.org sfeld@montefiore.org

When compared to the beginning of the year has your clinician devoted more time to discuss how to treat episodes when your pain is at its worst?

Parameters to be Measured

2 Significantly improved
1 Improved
0 No change

Lastly as a point of clarification, the sole data source from patients will be the patient questionnaire. **There aren't any needs for the Durable Outcomes Evaluation to review or collect data from patient charts. Patients will participate in this program on a strictly voluntary basis, can decide not to participate at any time, and will be assured of the confidentiality of their responses.** Dr. Charles Argoff and the Albany Medical Center IRB will supervise the administration and data analysis of Stage III, in collaboration with Dr. Hatcher (Associate Dean of CME at Einstein and Director of Research and CME at Montefiore) and Asante Communications.

We hope this clarifies the Stage III section of the proposed grant. As always, should you have any further questions, please do not hesitate to contact me with any questions.

Sincerely,

Steven Jay Feld

cc: Peter Hurwitz

3301 Bainbridge Avenue, Bronx, N.Y. 10467 Phone 718.920.6674 Fax 718.798.2436 mecme.org sfeld@montefiore.org

Albert Einstein
College of Medicine
of Yeshiva University

Center for Continuing Medical Education

Bridging the Gap Between Education and Practice™

The University Hospital and
Academic Medical Center for the
Albert Einstein College of Medicine

November 20, 2008

Educational Grant Review Committee
Cephalon

Dear Sir and/or Madam:

On behalf of the Albert Einstein College of Medicine & Montefiore Medical Center, Center of Continuing Medical Education (CCME) and our Educational Collaborator and Joint Sponsor, Asante Communications LLC, please find the requested clarification information for Grant #2569.

Albert Einstein would like to reaffirm its commitment to providing high quality education. Of particular importance to us is adapting and refining each successive activity as the year unfolds. Applying our learnings from one program to the next invariably improves the substance of the program, and provides up-to-date insights from the faculty and participants alike.

Upon further discussion with our education collaborator, Asante Communications, in lieu of providing a specific book for the participants, originally suggested to be distributed to after the Full-day Regional Meeting and the Preceptorship program, it would be more prudent to provide a Reference Guide to these participants, in addition to quarterly online updates.

In addition, we see considerable benefits in combining the enduring material of the Teleconferences and the Cases and Commentary into a single enduring material, rather than producing two separate activities. This will limit any overlap that may occur from the content of these two activities. We would like to present this as an attractive option.

Enduring materials posted online will be targeted to pain specialists. Websites that are selected will have an audience which consists of pain specialists, including anesthesiologists, oncologists, neurologists, and physiatrists, among others.

In addition to being an accredited activity, the Position Paper that will be developed from the International Experts Forum will be submitted to a peer-reviewed journal for publication. We will request permission from the journal prior to submission of the article to be published as a CME activity in their journal and elsewhere. This will enhance the current BTP literature.

3301 Bainbridge Avenue Bronx, N.Y. 10467 Phone 718.920.6671 Fax 718.798.2330 meetne.org cme@montefiore.org

We would also like to comment further on two select items. First, as noted in the grant, nurses, nurse practitioners and physician assistants represent an important target audience and as such we will be making a concerted effort to recruit these pain clinicians for each educational activity. In addition, we would like to propose that a *Cases and Commentary* workshop be held at the Oncology Nurses Society (ONS) in 2009. An enduring activity will be developed from this Workshop and will extend the reach of this very valuable educational activity. This activity will be accredited for continuing education (CE) credit for nurses by an approved academic institution or noted medical center, such as Montefiore Medical Center. Further, as noted in the accompanying materials, one of the workshops will be held at the American Pain Society, a multidisciplinary organization that requires triple accreditation for all programs.

The other items uploaded for clarification purposes include:

- Timeline on all proposed activities
- Schematic of Chronic Pain Management Preceptorship (CPMP)
- Full-Day Regional Budget (clarification on Reference Guide)
- Preceptorship Budget (clarification on Reference Guide)

If you need any further information, or have any questions that relate to this grant request, please contact me at 718 920-6674, ext. 232.

On behalf of Albert Einstein College of Medicine & Montefiore Medical Center, I would like to thank Cephalon for the continued consideration of this request.

Sincerely,

Steven Jay Feld

3301 Bainbridge Avenue, Bronx, N.Y. 10467 PHONE 718.920.6674 FAX 718.798.2336 mecme.org cme@montefiore.org

IRB Approved Outcome Study and Manuscript

DESCRIPTION / CATEGORY	ASSUMPTIONS			COST	TOTAL COST
GENERAL - OOP					
	Rate	Persons			
Protocol Director Honorarium	$2,000	1		$2,000	
Faculty Honoraria (Data Review/Interpretation	$2,000	4		$8,000	
				TOTAL	$10,000.00
IRB Academic Center Fees					
Protocol Review and Approval					$5,000.00
Online - OOP					
Technical Programming/Quarterly Webinars					$6,000.00
Online Hosting and Monthly Maintenance					$2,500.00
Email Recruitment Stage II(Control and Participant Groups)					$2,500.00
Data Analysis/Statistician					$5,000.00
Patient Enrollment for Stage III					$1,000.00
MISCELLANEOUS - OOP					
Miscellaneous expenses					$1,500.00
TOTAL OOPs					$33,500.00
FEES					
Management Fee					$15,000.00
Includes:					
* Manage design and production of all materials					
* Grant/Needs development					
*Administer outcomes tools (pre-test, post-test, and follow up questions)					
*Analyze results from pre-test, post-test and follow-up questions					
*Liaise with IRB and faculty					
*Manage all aspects of Patient enrollment under IRB supervision					
* Final reconciliation					
* Internal IRB compliance					
Content Development/Editorial/Creative Fee					$25,000.00
Content Development includes:					
* Development of pre-test, post-test and follow-up questions					
* Liaise with faculty					
*Development of Case Vignettes					
*Development of Patient Survey					
*Development of outcomes report					
*Development of ideas for future educational tactics					
* Editorial/copy editorial review and formatting					
Creative Fee Includes:					
* Design of evaluation survey					
* All costs associated with project design and development					
TOTAL FEES					$40,000.00

GRAND TOTAL	$73,500.00

Variance +/- 10%

SPECIAL NOTE:

Any change in scope will require an approved revised budget. Cancellation of program will be subject to costs-to-date for all expenses and staff hours.

Albert Einstein and Asante Communications — Chronic Pain Management Preceptorship Program

DESCRIPTION / CATEGORY	ASSUMPTIONS			COST		TOTAL COST
GENERAL - OOP						
	Rate	Persons				
Course Director	$3,500	1				$3,500.00
Faculty Honoraria	$2,000	5				$10,000.00
ACCREDITATION FEE						
Albert Einstein Accreditation and Certificate Fee					2.5 hrs.	$12,500.00
LOGISTICS - OOP						
List Purchase						$1,500.00
Survey Distribution						$500.00
Development of Participant Database with tracking software						$3,250.00
Food and Beverage	Cost/Tax/ Gratuity	Persons/ Quantity	Number of Functions			
To Include Breakfast(s)	$40	20	1	$800		
				TOTAL		$800.00
MATERIALS - OOP						
Production/Printing 150 Binders						$1,500.00
Reference Guide	$ 30	200				$6,000.00
Purchase artwork						$750.00
SCIENTIFIC COMMUNICATIONS - OOP						
Transcription Services						$3,000.00
TELECONFERENCE SERVICES - OOP						
Participant Communications (Teleconference/E-Communications)						$2,000.00
Creative Design for Program Template						$2,500.00
MISCELLANEOUS - OOP						
Express Mail Shipping (faculty mailings, materials shipping)						$1,000.00
Postage for panticipant materials		150				$1,000.00
Assembly of participant material		150				$500.00
Miscellaneous expenses other than group						$500.00
OOP TOTAL						**$50,800.00**
FEES						
Management Fee						$32,000 00
Includes:						
* Timeline development & maintenance						
*Manage internal team and project flow						
* Coordinate faculty invitational process including invitations, confirmations, and enrollment process						
* Coordination of participants involvement and gathering of necessary information (Bios, etc)						
* Coordinate all initial faculty, faculty/panticpant, and quarterly teleconference calls						
*Manage the development of database of program and apprpropriate clinician tracking						
* Manage design and production of all meeting materials/reference binders including bios						
* Traffic meeting materials for review and production						
* Arrange for honoraria						
* Grant/Needs development						
*Reconciliation management						
* Certification collaboration (joint sponsorship, compliance review, Albert Einstein liaison)						
* Internal CME compliance						
Content Development/Editorial/Creative Fee						$35,250.00
Includes:						
* Develop learning objectives						
* Collaboration with faculty on agenda and discussion guide development						
* Collaborate with faculty on discussion guide for teleconference calls						
* Liaise with presenters (chair, faculty)						
* Editonal/copy editonal review and formatting						
* Development of program logo						
* All costs associated with meeting content design and development						
FEE TOTAL						**$67,250.00**

GRAND TOTAL	**$118,050.00**

Variance +/- 10%

SPECIAL NOTE:

Any change in scope will require an approved revised budget.
Cancellation of program will be subject to costs-to-date for all expenses and staff hours.

Albert Einstein and Asante Communications
Full-Day Regional Meeting
New York, NY

DESCRIPTION / CATEGORY	ASSUMPTIONS			COST		TOTAL COST
GENERAL - OOP						
	Rate	Persons				
Course Director Honorarium	$3,500	1		$3,500		
Chair Honorarium	$2,500	1		$2,500		
Faculty Honoraria	$2,000	4		$8,000		
				TOTAL		$14,000.00
Albert Einstein Accreditation and Certificate Fee						$9,500.00
Albert Einstein Outcomes Measurement Fee						$3,500.00
LOGISTICS - OOP						
Hotel Accommodations						
	Room & Tax	Persons	Nights			
To Include Faculty	$275	6	1	$1,650		
Accreditor	$275	1	1	$275		
Asante	$275	3	1	$825		
Additional Suppliers	$275	2	1	$550		
				TOTAL		$3,300.00
Airfare	Fare & Tax	Persons	Service			
To Include. Faculty	$600	6	Coach	$3,600		
Accreditor	$600	1	Coach	$600		
Asante	$600	0	Coach	$0		
Additional Suppliers	$600	2	Coach	$1,200		
				TOTAL		$5,400.00
Ground Transportation	Fare & Tax	Persons	Service			
To Include Faculty	$300	6	Sedan	$1,800		
Accreditor	$100	1	Taxi	$100		
Asante	$100	3	Taxi	$300		
Additional Suppliers	$100	2	Taxi	$200		
				TOTAL		$2,400.00
Expenses	Rate	Persons				
To Include Faculty	$100	6		$600		
Accreditor	$100	1		$100		
Asante	$100	3		$300		
Additional Suppliers	$100	2		$200		
				TOTAL		$1,200.00
Food and Beverage	Cost/Tax/ Gratuity	Persons/ Quantity	Number of Functions			
To Include. Continental Breakfast	$40	100	1	$4,000		
Lunch	$55	100	1	$5,500		
Break	$30	100	1	$3,000		
Faculty Dinner	$100	10	1	$1,000		
On-site Slide Review	$250	1	1	$250		
				TOTAL		$13,750.00
Meeting Room(s) Rental	$750	-------	1			$750.00
Business Center	$50	-------	-------			$50.00
Gratuities (Hotel Staff)	$100	-------	-------			$100.00
On-Site Telephone/Fax	$750	-------	-------			$0.00
On-Site Internet Connection	$750	------				$0.00

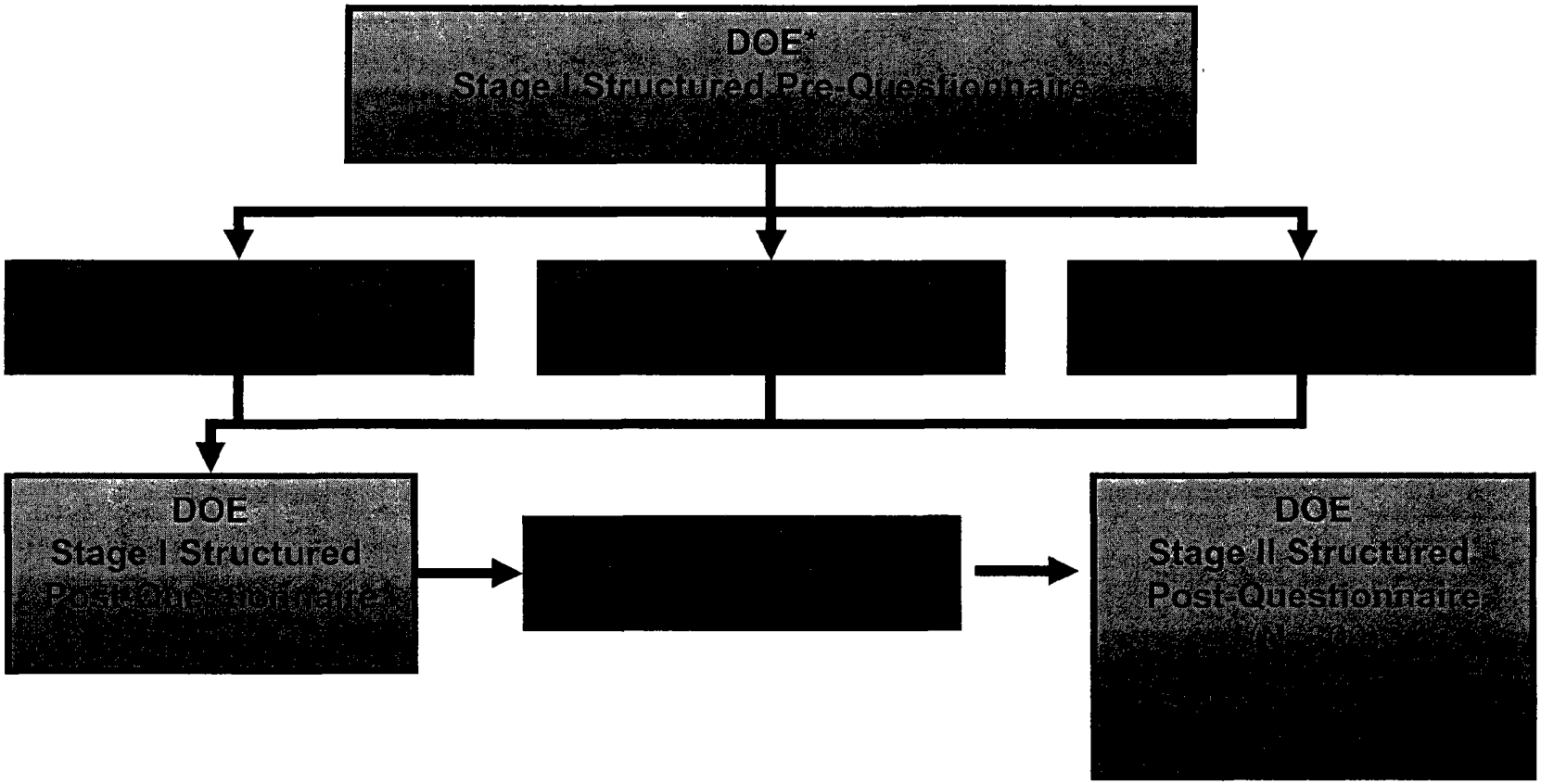
MATERIALS - OOP							
Production/Printing							
Reference Guide			$ 30	100			**$3,000.00**
			Quantity	**Design**			
Services Include:	Printing of syllabus (includes printing & assembly charges for: Agenda, Participant List, Faculty List, color slides, evaluations, etc)		125	4-Color	**$5,250**		
	Printing of self-mailer, wafer-sealed invitation		8,500	4-Color	**$2,750**		
					TOTAL		**$8,000.00**
Signage, Name Badges, Tent Cards							**$1,375.00**
Pens, Pads							**$250.00**
Postage for Invites							**$2,500.00**
Postage for meeting materials							**$250.00**
SCIENTIFIC COMMUNICATIONS - OOP							
Editorial Research (articles/permissions)							**$750.00**
AUDIOVISUAL - OOP							
Audiovisual - All equipment for Slide Review and General Session							**$5,000.00**
Technical Supervisor/Support - Labor/PowerPoint Tech							**$1,500.00**
MISCELLANEOUS - OOP							
Express Mail Shipping (faculty mailings, materials shipping)							**$250.00**
Additional recruitment tactics/purchase lists							**$5,000.00**
Meeting Planner							**$7,000.00**
Creative, Design, and Layout							**$7,000.00**
Transcription							**$1,500.00**
Miscellaneous expenses							**$250.00**
OOP TOTAL							**$97,575.00**
FEES							
Management Fee							**$25,000.00**
Includes: ** Timeline development & maintenance* **Manage internal team and project flow* ** Coordinate faculty invitational process including invitations, confirmations, final and welcome packets* ** Manage attendee recruitment process including invitations, confirmations, final logistical information* ** Oversee coordination of venue selection, negotiation and contracting* ** Oversee all travel, hotel, ground transportation, food functions and AV both pre-meeting and onsite* ** Manage all on-site operations of the program including registration area* ** Manage design and production of all meeting materials including participant handouts, badges, tent cards, etc.* ** Traffic meeting materials for review and production* ** Arrange for honoraria* ** Grant/Needs development* **Reconciliation management* ** Certification collaboration (joint sponsorship, compliance review, Albert Einstein I* ** Internal CME compliance*							
Content Development/Editorial Fee							**$28,000.00**
Includes: ** Collaborate with faculty on learning objectives, agenda and discussion guide development* ** Collaborate with faculty on presentations* ** Liaise with faculty and incorporate faculty comments* ** Liaise with accreditor and incorporate accreditor comments* ** Editorial/copy editorial review and formatting* ** All costs associated with meeting content development*							
FEE TOTAL							**$53,000.00**
GRAND TOTAL							**$150,575.00**

Albert Einstein and Asante Communications Satellite WebCast

DESCRIPTION / CATEGORY	ASSUMPTIONS				COST		TOTAL COST
GENERAL - OOP							
		Rate	Persons				
Course Director Honorarium		$2,500	1		$2,500		
Chair Honorarium		$2,500	1		$2,500		
					TOTAL		$5,000.00
Albert Einstein Accreditation and Certificate Fee							$9,500.00
Albert Einstein Outcomes Measurement Fee							$3,500.00
LOGISTICS - OOP							
MATERIALS - OOP							
Production/Printing							
			Quantity	Design			
	Printing of self-mailer, wafer-sealed invitation, Recruitment and Awareness Campaign To Medscape and Pain Clinician		10,000	4-Color	$3,500		
MISCELLANEOUS - OOP							
Webification (Medscape or Similar Pain Related Website eg. Pain.edu)							$60,000.00
Additional awareness and recruitment tactics							$5,000.00
Creative, Design, and Layout							$7,000.00
Transcription							$2,000.00
Postage							$1,500.00
OOP TOTAL							$93,500.00
FEES							
Management Fee							$20,000.00
Includes: * *Timeline development & maintenance* **Manage internal team and project flow* * *Manage attendee recruitment process including invitations, confirmations, and awareness campaign* * *Manage design and production of all awareness campaign and Medscape Liaison* * *Traffic meeting materials for review and production* * *Arrange for honoraria* * *Grant/Needs development* **Reconciliation management* * *Certification collaboration (joint sponsorship, compliance review, Albert Einstein liaison)* * *Internal CME compliance*							
Content Development/Editorial Fee							$20,000.00
Includes: * *Collaborate with faculty on learning objectives, agenda and discussion guide development* * *Collaborate with faculty on presentations* * *Liaise with faculty and incorporate faculty comments* * *Liaise with accreditor and incorporate accreditor comments* * *Editorial/copy editorial review and formatting* * *All costs associated with meeting content development*							
FEE TOTAL							$40,000.00
GRAND TOTAL							**$133,500.00**

Reference Guide

Chronic Pain Management Preceptorship (CPMP)



*DOE= Durable Outcomes Evaluation

**Control Group for Stage II includes 150 participants from other educational initiatives that do not participate in CPMP

Persistent and Breakthrough Supported Medical Education Initiatives

2009

			J	F	M	A	M	J	J	A	S	O	N	D
International Experts Forum	**Live Event**	**30**	◆→	◆			◆							
Cases and Commentary	**Live Event**	**225**	◆→	◆	◆			◆						
Full-Day Regional Meeting	**Live Event**	**75-100**	◆→	◆										
Teleconference Series	**Live Event**	**200-400**	◆→			◆								
Cases and Commentary Print Monograph/Online	***PMN News*** **PainClinician** **Pain.edu**	**45-60,000**							◆→	◆				
Full-Day Regional Satellite Webcast	**International Forum for Pain Experts** **Pain.edu**	**20-25,000**			◆→		◆							
Teleconference Print Monogrpaph/Online	***PMN News*** **PainClinician** **Pain.edu**	**45-60,000**				◆→		◆						
Pain/Risk Management Compendium	***PMN News*** **PainClinician** **Pain.edu**	**45-60,000**		◆→			◆							
International Experts Forum Position Paper/Online	***PMN News*** **PainClinician** **Pain.edu**	**45-60,000**				◆→		◆						
Preceptorship Program		**300**	◆→					◆			◆			◆→

In order to review your grant request #2569, Cephalon requires the following additional information:

1. **Please explain how HCPs for the outcomes study will be recruited for the Stage I.**

   The participants for the Stage I outcomes study will be recruited through the live educational initiatives proposed in the grant—namely, the *Cases and Commentary* Workshops, Teleconference Series, Full-day Regional Meeting and potentially the International Expert Forum. The latter will be a closed, invitation only meeting that will be held at the 2009 American Pain Society meeting in San Diego, pending availability of select thought leaders.

2. **Will the WebPanel series be accredited?**

   Yes. The quarterly WebPanel series is a component of the Chronic Pain Management Preceptorship (n=~200, pending approval of proposed activities) and will be accredited through Albert Einstein College of Medicine. Of note, participants will complete a Durable Outcomes Evaluation (DOE)* Stage II structured questionnaire upon completion of the WebPanel series. The questionnaire will measure the evolution of thought and practice since completion of the DOE Stage I questionnaire, as measured against control clinicians who limited their education to an enduring material and/or live event and who did not participate in the Preceptorship (Stage II) WebPanel. Notably, clinicians who chose not to participate in the preceptorship, and who have otherwise successfully completed at least one post-test from any of the educational initiatives (Live, Print, and/or Online), may participate in the WebPanel series. Their educational outcomes will not, however, contribute to the DOE Stage II outcomes, which is restricted to preceptorship clinicians only.

3. **How will participants be incentivized to participate in the outcomes study?**

   Incentivization is largely based on the opportunity to participate in a novel educational outcomes study, the results from which will likely be published in a peer-reviewed journal. Requirements will be minimally time consuming. Clinicians attending the live educational initiatives will necessarily complete a structured questionnaire before and after the event, and will therefore provide DOE Stage I study data. After completing the pre-post questionnaire, participants will confirm their interest in joining the Chronic Pain Management Preceptorship, comprising a quarterly WebPanel series facilitated by expert pain clinicians. Preceptorship clinicians (DOE Stage II participants) will have an opportunity to collaborate with their peers and thought leaders during the WebPanel series. In addition, preceptorship clinicians will be invited to a closed, invitation-only International Expert Forum (See Question 1). Qualified clinicians may also serve as adjunct faculty for activities that may be held in 2010, pending evaluation by program faculty

4. **Is the preceptorship a separate activity to the outcomes study? How will participants be recruited for this activity?**

   Preceptorship participants will be required to complete a Stage II structured questionnaire, providing data on the durability of high level outcomes when integrated within an ongoing educational series. Preceptorship participants will be recruited during the registration period through e-mail

correspondence, and during one of the live events—teleconference call, *Cases and Commentary* workshop and/or full-day regional meeting— that they are required to complete.

5. **The RFP stated that the proposal could cover educational events at national meetings, however none is proposed. Please clarify.**

   Pending availability of the expert pain clinicians, the International Pain Expert Forum may take place at a selected National Congress, currently planned to be held at the American Pain Society (APS; May 2009, San Diego). Preceptorship participants who attend the American Pain Society at their own cost and discretion will be invited to this closed, invitation-only satellite (off-agenda) live event.

   In addition, as a point of clarification, we are planning to hold at least one of the *Cases and Commentary* programs will be held immediately before or after the APS in May 2009 and/or a Regional Chronic Pain meeting (e.g.; **Emerging Practices in Opioid Prescribing for Chronic Pain,** March 2009).

6. **Please clarify the types of HCPS that may take part in the cases workshops.**

   HCPs that will be recruited to take part in the *Cases and Commentary* workshops are pain clinicians, including, among others, neurologists, psychiatrists, anesthesiologists, oncologists, rheumatologists, psychologists, and other general practitioners with an interest in pain management.

7. **Please clarify PainClinician (TM). Is this a quarterly newsletter?**

   PainClinician™ is a proprietary component of a larger educational initiative, *The International Chronic Pain Forum*™, to be formally launched in Q1 2009. The PainClinician quarterly newsletter will drive program recruitment, advertisements, and distribution of accredited pain enduring materials. Our *PainClinician*™ internal database currently includes thousands of practicing pain clinicians who have participated in previous accredited programs, CSNA surveys, or have otherwise expressed an interest in pain education.

8. **Please clarify how you will recruit for the teleconferences and satellite webcasts.**

   Recruitment efforts for the Teleconference and Webcasts will be multifaceted. Reliable tactics include extending invitations to clinicians in our proprietary *PainClinician*™ database, to clinicians identified by the Albert Einstein College of Medicine and to the membership of American Academy of Pain Medicine (AAPM), APS and other medical congresses; announcing the programs in relevant print journals, (e.g., *Pain Medicine News, the Journal of Pain, PainClinician),* and on selected pain-related websites (e.g., WebMD, pain.edu, International Chronic Pain Forum, etc.).

9. **Is the literature surveillance included in the grant costs?**

   The Literature Surveillance program, including monthly written summaries, as detailed in the grant is not included in the total grant costs. However, the Albert Einstein College of Medicine working collaboratively with Asante routinely forwards to the grant supporters select articles from peer-reviewed journals and related reference materials, all of which are relevant to the educational objectives of the proposed grant initiatives.

3301 Bainbridge Avenue, Bronx, N.Y. 10467 Phone 718.920.6674 Fax 718.798.2336 meeinc.org cme@montefiore.org

10. **Please include a timeline of when activities will be disseminated.**

Please see attached.

11. **Additional Information:**

Proposed Payment Schedule: If Albert Einstein College of Medicine is fortunate enough to have its grant approved, the proposed payment schedule is 1/3 of program costs upon LOA acceptance, 1/3 of program costs at a time point identified as approximately 50% through the completion of the grant, and the remaining 1/3 payment during the last 1/3 of the scheduled program completion.

3301 Bainbridge Avenue, Bronx, N.Y. 10467 Phone 718.920.6674 Fax 718.798.2436 necme.org cme@montefiore.org

Albert Einstein and Asante Communications
International Expert Forum with Accredited Position Paper on BTP

DESCRIPTION / CATEGORY	ASSUMPTIONS			COST		TOTAL COST
GENERAL - OOP						
	Rate	Persons				
Course Director	$2,500	1				$2,500.00
Faculty Honoraria	$1,500	4				$6,000.00
ACCREDITATION FEE						
Albert Einstein Accreditation and Certificate Fee						$9,500.00
Albert Einstein Outcomes Measurement Fee						$3,500.00
LOGISTICS - OOP						
Food and Beverage	Cost/Tax/ Gratuity	Persons/ Quantity	Number of Functions			
To Include Breakfast(s)	$40	10	1	$400		
				TOTAL		$400.00
MATERIALS-OOP						
	Quantity	Design				
Production & Printing of Position Paper	35,000	4-Color		$10,800		
Pain Clinician Postage Cost	35,000	n/a		$11,000		
Purchase Mailing Lists AAPM/APS				$4,000		
					Total $25,800.00	
ONLINE CONTENT - OOP						
Webification of enduring materials					$5,000.00	
Purchase artwork						$750.00
SCIENTIFIC COMMUNICATIONS - OOP						
References/Permissions						$750.00
Teleconference - OOP						
Intercall Teleconference Charges						$1,000.00
Transcription Services						$1,500.00
MISCELLANEOUS - OOP						
Express Mail Shipping (faculty mailings, materials shipping)						$250.00
OOP TOTAL						**$56,950.00**
FEES						
Management Fee						$18,000.00

Includes:

** Timeline development & maintenance*
**Manage internal team and project flow*
** Coordinate faculty invitational process including teleconference coordination, confirmations*
** Coordination of venue selection, negotiation and contracting*

* Manage all aspects of program including position paper logistics and trafficking	
* Manage all on-site needs for meetings with faculty	
* Manage design and production of all materials relating to position paper	
* Manage design and production of all materials relating to webification of position paper	
* Arrange for honoraria	
* Grant/Needs development	
*Reconciliation management	
* Certification collaboration (joint sponsorship, compliance review, Albert Einstein liaison)	
* Internal CME compliance	
Content Development/Editorial/Creative Fee	**$23,500.00**
Includes:	
* Develop learning objectives	
* Collaboration with faculty on teleconference agenda and discussion guide development	
*Manage all research associated with identification of prospective Journals for Distribution	
* Collaborate with faculty on position paper	
* Liaise with presenters (chair, faculty)	
* Editorial/copy editorial review and formatting	
FEE TOTAL	**$41,500.00**
GRAND TOTAL	**$98,450.00**
Variance +/- 10%	
SPECIAL NOTE:	
Any change in scope will require an approved revised budget.	
Cancellation of program will be subject to costs-to-date for all expenses and staff hours.	

Albert Einstein and Asante Communications
Pain and Risk Management Reference Compendium

DESCRIPTION / CATEGORY	ASSUMPTIONS			COST		TOTAL COST
GENERAL - OOP						
		Rate	Persons			
Course Director Honorarium		$1,500	1			
Faculty Honoraria		$1,500	2			$4,500.00
Albert Einstein Accreditation and Certificate Fee						$9,500.00
Albert Einstein Outcome Measurement Fee						$3,500.00
MATERIALS - OOP						
Production/Printing						
		Quantity	Design	Total		
Services Include	Printing of Reference Tool for Pain Specialists and Other Clinicians	35000	4-Color	$20,000		
	Printing of Envelope	35000	4-Color	$4,800		
					TOTAL	$24,800.00
ONLINE - OOP						
Webification of Enduring Material						$10,000.00
SHIPPING/POSTAGE - OOP						
Distribution Costs to AAPM and APS Membership						$8,000.00
Pain Clinical Update Costs for Distribtution						$4,000.00
Mail house Handling Fee						$1,750.00
CREATIVE/DESIGN - OOP						
Creative, Design, and Layout						$7,000.00
Purchase Artwork						$250.00
SCIENTIFIC COMMUNICATIONS -OOP						
Permissions/Copyrights						$750.00
MISCELLANEOUS-OOP						
Misc Expenses						$250.00
TOTAL OOPs						**$74,300.00**
FEES						
Management Fee						$22,500.00
Includes:						
** Timeline development & maintenance*						
**Internal team and project management*						
** Arrange for faculty review and honoraria*						
** Traffic Reference Tool for review and production*						
** Manage design and production of reference tool*						
** Liaise with course director & faculty*						
**Review and manage content translation into online format*						
**Develop grant and needs assessment*						
** Certification collaboration (compliance review,Albert Einstein liaison)*						
**Reconciliation management*						
**Ensure internal CME compliance*						
Content Development/Editorial						$30,000.00
Includes:						
** Collaborate with faculty on the development of the content outline, and learning objectives*						
** Collaborate with faculty on the development of the reference tool manuscript*						
**Liaise with faculty & incorporate faculty comments*						
**Liaise with accreditor & incorporate comments*						
** Editorial/copy editorial review and formatting of reference tool*						
** All costs associated with reference tool content development*						
TOTAL FEES						**$52,500.00**
GRAND TOTAL						**$126,800.00**

Albert Einstein and Asante Communications
Teleconference Activity - 8 Presentations

DESCRIPTION / CATEGORY	ASSUMPTIONS				Cost	TOTAL COST
GENERAL-OOP						
		Rate	Persons			
Course Director Honorarium		$2,500	1		$2,500.00	
Faculty Honorarium (per call)		$1,000	1	8	$8,000.00	
					TOTAL	$10,500.00
Albert Einstein Accreditation and Certificate Fee						$15,000.00
Albert Einstein Outcomes Measurement Fee						$3,500.00
PRODUCTION-OOP						
		Quantity	Design			
		syllabus (includes printing & assembly charges for: Agenda, Participant List, Faculty List, color slides.	400	4-Color	$15,000.00	
		Printing of self-mailer, wafer-sealed invitation	45,000	4-Color	$10,000.00	
					TOTAL	$25,000.00
SHIPPING/MAILING COST-OOP						
Invitation Distribution Costs						$14,000.00
Priority mail shipping of syllabus & confirmation letters to participants and faculty						$3,250.00
AUDIO VISUAL/TRANSCRIPTION-OOP						
Teleconference Charges (Total for 8)						$7,500.00
Transcription Services (Total for 8)						$1,500.00
SCIENTIFIC COMMUNICATION-OOP						
Purchase of Articles and Reprints						$1,500.00
RECRUITMENT-OOP						
Additional recruitment tactics/Purchase lists						$5,000.00
CREATIVE/DESIGN-OOP						
Creative, Design, and Layout						$6,500.00
OOP TOTAL						**$93,250.00**
FEES						
Management Fee (Total for 8 teleconferences)						$22,500.00
Includes:						
** Timeline development & maintenance*						
**Manage internal team and project flow*						
**Arrange for faculty honoraria*						
**Coordinate invitational process including confirmations*						
**Develop call schedule*						
**Coordinate with call center to insure appropriate project flow*						
**Develop meeting materials (invites, announcement cards, syllabus, agenda, participant list, faculty bio list, evaluation survey)*						
**Manage design and production of meeting syllabus*						
**Ship meeting materials to participants & faculty*						
**Lead and moderate 8 teleconference sessions*						
**Develop, process and review evaluations & summary report*						
**Liaise with internal teams, faculty, and accreditor*						
** Certification collaboration (joint sponsorship, compliance review, Albert Einstein liaison)*						
**Develop Grants & Needs Assessment*						
**Complete final reconciliation*						
**Ensure internal CME compliance*						
Content Development/Editorial (Total for 8 teleconferences)						$25,000.00

	Includes:	
	** Collaborate with faculty on learning objectives, agenda and discussion guide development*	
	** Collaborate with faculty on presentations*	
	**Liaise with faculty & incorporate faculty comments*	
	**Liaise with accreditor & incorporate comments*	
	**Edit, copyedit, review and format all materials*	
	**Participate in teleconferences*	
	**Pre- and post-teleconference liaise with faculty*	
	FEE TOTAL	**$47,500.00**
	GRAND TOTAL (8 Teleconferences)	**$140,750.00**

Albert Einstein and Asante Communications
Teleconference Spin-off Monograph

DESCRIPTION / CATEGORY	ASSUMPTIONS				COST	TOTAL COST
GENERAL - OOP						
		Rate	Persons			
Course Director Honorarium		$2,500	1		$2,500	
Faculty Honorarium		$1,500	2		$3,000	
					TOTAL	$5,500.00
Albert Einstein Accreditation and Certificate Fee						$9,500.00
Albert Einstein Outcomes Measurement Fee						$3,500.00
MATERIALS - OOP						
Production/Printing						
			Quantity	Design	Cost	
Services Include:	Monograph Printing		45,000	4-Color	$20,000	
					TOTAL	$20,000.00
SHIPPING/MAILING COST-OOP						
Distribution Fee Pain Medicine News/Clinical Updates/Congresses						$14,000.00
Express Mail Shipping (faculty mailings, materials shipping)						$200.00
ONLINE -OOP						
Webification of Monograph						$10,000.00
CREATIVE/DESIGN-OOP						
Creative, Design and Layout						$6,500.00
Purchase Artwork						$250.00
TOTAL OOPs						$69,450.00
FEES						
Management Fee						$17,500.00
Includes:						
* Timeline development & maintenance						
*Internal team and Project management						
* Coordinate faculty review invitational process						
* Arrange for faculty review and honoraria						
* Arrange for honoraria						
* Manage design and production of all materials						
* Traffic materials for review and production						
* Certification collaboration (joint sponsorship, compliance review, Albert Einstein liaison)						
* Evaluation summary development and processing						
* Grant/Needs development						
*Reconciliation management						
Content Development/Editorial						$25,000.00
Content Development includes:						
*Develop learning objectives						
*Develop outline for an 8-page monograph						
*Collaborate with faculty in the development of the monograph manuscript						
*Liaise with faculty & incorporate faculty comments						
*Liaise with accreditor & incorporate comments						
* Editorial/copy editorial review and formatting of special report monograph						
* All costs associated with meeting content development						
TOTAL FEES						$42,500.00
GRAND TOTAL						$111,950.00

Albert Einstein and Asante Communications
Cases and Commentary Workshop #1

DESCRIPTION / CATEGORY	ASSUMPTIONS				COST	TOTAL COST
GENERAL - OOP						
	Rate	Persons				
Course Director Honorarium	$3,500	1			$3,500	
Chair Honorarium	$2,500	1			$2,500	
Faculty Honoraria	$2,000	5			$10,000	
					TOTAL	$16,000.00
Albert Einstein Accreditation and Certificate Fee						$9,500.00
Albert Einstein Outcome Measurement Fee						$3,500.00
LOGISTICS - OOP						
Hotel Accommodations						
	Room & Tax	Persons	Nights			
To Include: Faculty	$275	7	1		$1,925	
Accreditor	$275	1	1		$275	
Asante	$275	3	1		$825	
Additional Suppliers	$275	2	1		$550	
					TOTAL	$3,575.00
Hotel Miscellaneous						$0.00
Airfare	Fare & Tax	Persons	Service			
To Include Faculty	$600	7	Coach		$4,200	
Accreditor	$600	1	Coach		$600	
Asante	$600	0	Coach		$0	
Additional Suppliers	$600	2	Coach		$1,200	
					TOTAL	$6,000.00
Ground Transportation	Fare & Tax	Persons	Service			
To Include Faculty	$300	7	Sedan		$2,100	
Accreditor	$100	1	Taxi		$100	
Asante	$100	3	Taxi		$300	
Additional Suppliers	$100	2	Taxi		$200	
					TOTAL	$2,700.00
Expenses	Rate	Persons				
To Include Faculty	$100	7			$700	
Asante	$100	3			$300	
Accreditor	$100	1			$100	
Additional Suppliers	$100	2			$200	
					TOTAL	$1,300.00
Food and Beverage	Cost/Tax/ Gratuity	Persons/ Quantity	Number of Functions			
To Include: Continental Breakfast	$40	0	1		$0	
Lunch	$65	70	1		$4,550	
Break	$30	70	1		$2,100	
Faculty Dinner	$100	11	1		$1,100	
On-site Slide Review	$250	1	1		$250	
					TOTAL	$8,000.00
Meeting Room(s) Rental	$750	-------	1			$750.00
Gratuities (Hotel Staff)	$100	-------	-------			$100.00
On-Site Telephone/Fax	$750	-------	-------			$750.00
On-Site Internet Connection	$750	------				$750.00
MATERIALS - OOP						
Production/Printing						
		Quantity	Design			

	Services Include	Printing of syllabus (includes printing & assembly charges for Agenda, Participant List, Faculty List, color slides, evaluations, etc)	100	4-Color	$4,500	
		Printing of self-mailer, wafer-sealed invitation	5,000	4-Color	$3,000	
					TOTAL	$7,500.00
	Signage, Name Badges, Tent Cards					$1,375.00
	Pens, Pads					$250.00
	Postage for Invites					$3,500.00
	Postage for meeting materials					$500.00
	AUDIOVISUAL - OOP					
	Audiovisual - All equipment for Slide Review and General Session					$5,000.00
	Technical Supervisor/Support - Labor/PowerPoint Tech					$1,200.00
	MISCELLANEOUS - OOP					
	Express Mail Shipping (faculty mailings, materials shipping)					$250.00
	Additional recruitment tactics/purchase lists					$5,000.00
	Meeting Planner					$7,000.00
	Creative, Design, and Layout					$7,000.00
	Transcription (each table)					$4,000 00
	Miscellaneous expenses					$250.00
	OOP TOTAL					$95,750.00
	FEES					
	Management Fee					$26,000.00
	Includes: * *Timeline development & maintenance* **Manage internal team and project flow* * *Coordinate faculty invitational process including invitations, confirmations, final and welcome packets* * *Manage attendee recruitment process including invitations, confirmations, final logistical information* * *Oversee coordination of venue selection, negotiation and contracting* * *Oversee all travel, hotel, ground transportation, food functions and AV both pre-meeting and onsite* * *Manage all on-site operations of the program including registration area* * *Manage design and production of all meeting materials including participant handouts, badges, tent cards, etc* * *Traffic meeting materials for review and production* * *Arrange for honoraria* * *Grant/Needs development* **Reconciliation management* * *Certification Collaboration (joint sponsorship, compliance review, Albert Einstein liaison)* * *Internal CME compliance*					
	Content Development/Editorial Fee					$31,500.00
	Includes: * *Collaborate with faculty on learning objectives, agenda and discussion guide development* * *Collaborate with faculty on presentations* * *Liaise with faculty and incorporate faculty comments* * *Liaise with accreditor and incorporate accreditor comments* * *Editorial/copy editorial review and formatting* * *All costs associated with meeting content development*					
	FEE TOTAL					$57,500.00
	GRAND TOTAL					$153,250.00

Albert Einstein and Asante Communications
Cases and Commentary Workshop #2

DESCRIPTION / CATEGORY	ASSUMPTIONS			COST	TOTAL COST
GENERAL - OOP					
	Rate	Persons			
Course Director Honorarium	$0	1		$0	
Chair Honorarium	$2,500	1		$2,500	
Faculty Honoraria	$2,000	5		$10,000	
				TOTAL	$12,500.00
Albert Einstein Accreditation and Certificate Fee					$1,000.00
Albert Einstein Outcome Measurement Fee					$0.00
LOGISTICS - OOP					
Hotel Accommodations					
	Room & Tax	Persons	Nights		
To Include Faculty	$275	7	1	$1,925	
Accreditor	$275	1	1	$275	
Asante	$275	3	1	$825	
Additional Suppliers	$275	2	1	$550	
				TOTAL	$3,575.00
Hotel Miscellaneous					$0.00
Airfare	Fare & Tax	Persons	Service		
To Include Faculty	$600	7	Coach	$4,200	
Accreditor	$600	1	Coach	$600	
Asante	$600	3	Coach	$1,800	
Additional Suppliers	$600	2	Coach	$1,200	
				TOTAL	$7,800.00
Ground Transportation (arrival/departure)	Fare & Tax	Persons	Service		
To Include. Faculty	$300	7	Sedan	$2,100	
Accreditor	$100	1	Taxi	$100	
Asante	$100	3	Taxi	$300	
Additional Suppliers	$100	2	Taxi	$200	
				TOTAL	$2,700.00
Expenses	Rate	Persons			
To Include. Faculty	$100	7		$700	
Asante	$100	3		$300	
Accreditor	$100	1		$100	
Additional Suppliers	$100	2		$200	
				TOTAL	$1,300.00
Food and Beverage	Cost/Tax/ Gratuity	Persons/ Quantity	Number of Functions		
To Include. Continental Breakfast	$40	0	1	$0	
Lunch	$65	70	1	$4,550	
Break	$30	70	1	$2,100	
Faculty Dinner	$100	11	1	$1,100	
On-site Slide Review	$250	1	1	$250	
				TOTAL	$8,000.00
Meeting Room(s) Rental	$750	-------	1		$750.00
Gratuities (Hotel Staff)	$100	-------	-------		$100.00
On-Site Telephone/Fax	$750	-------	-------		$750.00
On-Site Internet Connection	$750	------			$750.00

MATERIALS - OOP						
Production/Printing						
			Quantity	**Design**		
Services Include:	(includes printing &		100	4-Color	**$4,500**	
	wafer-sealed invitation		5,000	4-Color	**$3,000**	
					TOTAL	**$7,500.00**
Signage, Name Badges, Tent Cards						**$1,375.00**
Pens, Pads						**$250.00**
Postage for Invites						**$3,500.00**
Postage for meeting materials						**$500.00**
AUDIOVISUAL - OOP						
Audiovisual - All equipment for Slide Review and General Session						**$5,000.00**
Technical Supervisor/Support - Labor/PowerPoint Tech						**$1,200.00**
MISCELLANEOUS - OOP						
Express Mail Shipping (faculty mailings, materials shipping)						**$250.00**
Additional recruitment tactics/purchase lists						**$5,000.00**
Meeting Planner						**$7,000.00**
Creative, Design, and Layout						**$5,000.00**
Transcription (each table)						**$4,000.00**
Miscellaneous expenses						**$250.00**
OOP TOTAL						**$80,050.00**
FEES						
Management Fee						**$26,000.00**
Includes:						
** Timeline development & maintenance*						
**Manage internal team and project flow*						
** Coordinate faculty invitational process including invitations, confirmations, final and welcome packets*						
** Manage attendee recruitment process including invitations, confirmations, final logistical information*						
** Oversee coordination of venue selection, negotiation and contracting*						
** Oversee all travel, hotel, ground transportation, food functions and AV both pre-meeting and onsite*						
** Manage all on-site operations of the program including registration area*						
participant handouts, badges, tent cards, etc						
** Traffic meeting materials for review and production*						
** Arrange for honoraria*						
** Grant/Needs development*						
**Reconciliation management*						
** Certification Collaboration (joint sponsorship, compliance review, Albert Einstein liaison)*						
** Internal CME compliance*						
Content Development/Editorial Fee						**$15,750.00**
Includes:						
** Collaborate with faculty on learning objectives, agenda and discussion guide development*						
** Collaborate with faculty on presentations*						
** Liaise with faculty and incorporate faculty comments*						
** Liaise with accreditor and incorporate accreditor comments*						
** Editorial/copy editorial review and formatting*						
** All costs associated with meeting content development*						
FEE TOTAL						**$41,750.00**

GRAND TOTAL	**$121,800.00**

Albert Einstein and Asante Communications
Cases and Commentary Workshop #3

DESCRIPTION / CATEGORY	ASSUMPTIONS			COST	TOTAL COST
GENERAL - OOP					
	Rate	Persons			
Course Director Honorarium	$0	1		$0	
Chair Honorarium	$2,500	1		$2,500	
Faculty Honoraria	$2,000	5		$10,000	
				TOTAL	$12,500.00
Albert Einstein Accreditation and Certificate Fee					$1,000.00
Albert Einstein Outcome Measurement Fee					$0.00
LOGISTICS - OOP					
Hotel Accommodations					
	Room & Tax	Persons	Nights		
To Include: Faculty	$275	7	1	$1,925	
Accreditor	$275	1	1	$275	
Asante	$275	3	1	$825	
Additional Suppliers	$275	2	1	$550	
				TOTAL	$3,575.00
Hotel Miscellaneous					$0.00
Airfare	Fare & Tax	Persons	Service		
To Include. Faculty	$600	7	Coach	$4,200	
Accreditor	$600	1	Coach	$600	
Asante	$600	3	Coach	$1,800	
Additional Suppliers	$600	2	Coach	$1,200	
				TOTAL	$7,800.00
Ground Transportation (arrival/departure)	Fare & Tax	Persons	Service		
To Include Faculty	$300	7	Sedan	$2,100	
Accreditor	$100	1	Taxi	$100	
Asante	$100	3	Taxi	$300	
Additional Suppliers	$100	2	Taxi	$200	
				TOTAL	$2,700.00
Expenses	Rate	Persons			
To Include: Faculty	$100	7		$700	
Asante	$100	3		$300	
Accreditor	$100	1		$100	
Additional Suppliers	$100	2		$200	
				TOTAL	$1,300.00
Food and Beverage	Cost/Tax/ Gratuity	Persons/ Quantity	Number of Functions		
To Include Continental Breakfast	$40	0	1	$0	
Lunch	$65	70	1	$4,550	
Break	$30	70	1	$2,100	
Faculty Dinner	$100	11	1	$1,100	
On-site Slide Review	$250	1	1	$250	
				TOTAL	$8,000.00
Meeting Room(s) Rental	$750	-------	1		$750.00
Gratuities (Hotel Staff)	$100	-------	-------		$100.00
On-Site Telephone/Fax	$750	-------	-------		$750.00
On-Site Internet Connection	$750	------			$750.00

MATERIALS - OOP							
Production/Printing							
				Quantity	Design		
	Services Include:	(includes printing &		100	4-Color	$4,500	
		wafer-sealed invitation		5,000	4-Color	$3,000	
						TOTAL	$7,500.00
Signage, Name Badges, Tent Cards							$1,375.00
Pens, Pads							$250.00
Postage for Invites							$3,500.00
Postage for meeting materials							$500.00
AUDIOVISUAL - OOP							
Audiovisual - All equipment for Slide Review and General Session							$5,000.00
Technical Supervisor/Support - Labor/PowerPoint Tech							$1,200.00
MISCELLANEOUS - OOP							
Express Mail Shipping (faculty mailings, materials shipping)							$250.00
Additional recruitment tactics/purchase lists							$5,000.00
Meeting Planner							$7,000.00
Creative, Design, and Layout							$5,000.00
Transcription (each table)							$4,000.00
Miscellaneous expenses							$250.00
OOP TOTAL							$80,050.00
FEES							
Management Fee							$26,000.00
Includes:							
** Timeline development & maintenance*							
**Manage internal team and project flow*							
** Coordinate faculty invitational process including invitations, confirmations, final and welcome packets*							
** Manage attendee recruitment process including invitations, confirmations, final logistical information*							
** Oversee coordination of venue selection, negotiation and contracting*							
** Oversee all travel, hotel, ground transportation, food functions and AV both pre-meeting and onsite*							
** Manage all on-site operations of the program including registration area participant handouts, badges, tent cards, etc.*							
** Traffic meeting materials for review and production*							
** Arrange for honoraria*							
** Grant/Needs development*							
**Reconciliation management*							
** Certification Collaboration (joint sponsorship, compliance review, Albert Einstein liaison)*							
** Internal CME compliance*							
Content Development/Editorial Fee							$15,750.00
Includes:							
** Collaborate with faculty on learning objectives, agenda and discussion guide development*							
** Collaborate with faculty on presentations*							
** Liaise with faculty and incorporate faculty comments*							
** Liaise with accreditor and incorporate accreditor comments*							
** Editorial/copy editorial review and formatting*							
** All costs associated with meeting content development*							
FEE TOTAL							$41,750.00

GRAND TOTAL	**$121,800.00**

Albert Einstein and Asante Communications
Cases and Commentary Spin-off Monograph

DESCRIPTION / CATEGORY	ASSUMPTIONS				COST	TOTAL COST
GENERAL - OOP						
		Rate	Persons			
Course Director Honorarium		$2,500	1		$2,500	
Faculty Honorarium		$1,500	2		$3,000	
					TOTAL	$5,500.00
Albert Einstein Accreditation and Certificate Fee						$9,500.00
Albert Einstein Outcome Measurement Fee						$3,500.00
MATERIALS - OOP						
Production/Printing						
			Quantity	Design	Cost	
Services Include	Monograph - Printing		45,000	4-Color	$20,000	
					TOTAL	$20,000.00
SHIPPING/MAILING COST-OOP						
Distribution Pain Clinician, Pain Medicine News, and Congresses						$14,000.00
Express Mail Shipping (faculty mailings, materials shipping)						$200.00
ONLINE -OOP						
Webification of Monograph						$10,000.00
CERTIFICATES - OOP						
CREATIVE/DESIGN-OOP						
Creative, Design and Layout						$6,500.00
Purchase Artwork						$250.00
TOTAL OOPs						$69,450.00
FEES						
Management Fee						$17,500.00
Includes: * *Timeline development & maintenance* **Internal team and Project management* * *Coordinate faculty review invitational process* * *Arrange for faculty review and honoraria* * *Arrange for honoraria* * *Manage design and production of all materials* * *Traffic materials for review and production* * *Certification collaboration (joint sponsorship, compliance review, Albert Einstein liaison)* * *Evaluation summary development and processing* * *Grant/Needs development* **Reconciliation management*						
Content Development/Editorial						$25,000.00
Content Development includes: **Develop learning objectives* **Develop outline for an 8-page monograph* **Collaborate with faculty in the development of the monograph manuscript* **Liaise with faculty & incorporate faculty comments* **Liaise with accreditor & incorporate comments* * *Editorial/copy editorial review and formatting of special report monograph* * *All costs associated with meeting content development*						
TOTAL FEES						**$42,500.00**
GRAND TOTAL						**$111,950.00**

PERSISTENT AND BREAKTHROUGH PAIN

MULTIDIMENSIONAL ASSESSMENT AND MULTIMODAL OPIOID-BASED TREATMENT STRATEGIES

An Educational Platform Initiative

Medical Education Grant Request

Presented to | Cephalon, Inc.

Submitted by | Albert Einstein College of Medicine

Submitted on | 11/06/2008

Outline of Request

I. **Overview**

II. **Platform Sponsorship, Management, and Outcomes Measurement**

III. **Educational Platform, Learning Objectives, and Needs Assessment**

IV. **Faculty and Programs**

V. **Program Recruitment, Awareness, and Distribution**

VI. **Budgets**

I. Overview

Albert Einstein College of Medicine (Einstein) in association with its educational collaborator, Asante Communications LLC (Asante), respectfully request a grant for the development, certification, production, and distribution of an educational initiative tentatively entitled "Persistent and Breakthrough Pain: Multidimensional Assessment and Multimodal Opioid-Based Treatment Strategies." This educational platform is intended to provide continuing medical education (CME) credit to healthcare professionals who treat patients with chronic pain.

The sponsors seek support through an educational grant from Cephalon, Inc. A support statement identifying Cephalon, Inc. as the Grantor will be included in the preamble of each activity, as well as in all announcements regarding the platform and individual activities.

Einstein will certify the initiative for CME credit for physicians.

II. Platform Sponsorship, Management, and Outcomes Measurement

Albert Einstein College of Medicine

For more than 5 decades, Einstein has exemplified excellence in medical research, teaching, and patient care. Established in 1955, and guided by the vision of Professor Albert Einstein, the College was one of the first medical schools to integrate bedside experience with classroom study. Einstein also led the way in the development of bioethics as an accepted academic discipline in medical school curricula and was the first private medical school in New York City to establish an academic Department of Family Medicine as well as a residency program in internal medicine with an emphasis on women's health. Today, Einstein is one of the nation's premier institutions for medical education, basic research, and clinical investigation.

Although education is at the heart of Einstein's mission, biomedical research drives its growth. Einstein has 300 research laboratories, which allow it to consistently be on the forefront of medical breakthroughs via development of cutting-edge techniques and clinical trials. A national leader in biomedical research support from the federal government, Einstein received more than $150 million in funding from the National Institutes of Health (NIH) in 2006. Einstein ranks sixth in the nation in terms of NIH awards to basic-science departments, and 7 of its programs are designated as NIH "Centers of Excellence."

Einstein and Montefiore Medical Center (the University Hospital and Academic Medical Center for the Albert Einstein College of Medicine) Center for Continuing Medical Education (CCME) was founded in 1976. It is accredited by the Accreditation Council

for Continuing Medical Education (ACCME) to provide CME for physicians. CCME is committed to the utilization of resources for the advancement of CME throughout the physician's professional career. CCME's mission is to enhance patient care by bringing diagnostic and therapeutic innovations to the clinical environment through professional medical education for physicians that maintains, develops, and increases their knowledge, skills, and competence.

Independence

CCME does not maintain financial relationships with commercial supporters or educational partners outside of the receipt of normal fee for services. Commercial interests are not involved in the development of content, program planning, or budget-determination. Responsibility for assuring that the CME activities meet the highest requirements and standards of Einstein and the ACCME rests solely with the CCME and is not transferable.

Disclosure of Conflict of Interest

CCME requires written, signed disclosure of the existence of relevant financial interests or relationships with commercial interests from any individual contributing to or in a position to influence the content of a CME activity sponsored by Einstein. Individuals not disclosing relevant financial relationships will be disqualified from an association with the CME activity in question.

CCME has established policies that will identify and resolve all conflicts of interest prior to activity certification by applying the disclosed information and activity subject to ACCME's policies.

Content Validation

All scientific research referred to, reported on, or used in a CME activity certified by Einstein in support or justification of a patient care recommendation will conform to the generally accepted standards of experimental design, data collection, and analysis.

Compliance

Asante has retained Hogan & Hartson LLP, an international law firm, to provide Asante with consultancy and expert insights into current federal and state regulations, ACCME codes of conduct, Pharmaceutical Research and Manufacturers of America (PhRMA) code, and their potential impact on the quality and delivery of our medical education programs.

Experts in all relevant accreditation issues, Hogan & Hartson will ensure that the continuing medical education programs Asante proposes and executes—including such full spectrum communications vehicles as regional meetings, teleconferences, web-based and print activities—will be conducted in an irreproachably compliant fashion. By ensuring that the educational programs faithfully adhere to all relevant law and regulations, Hogan & Hartson will help us meet the educational needs of critical therapeutic areas, develop clinicians' skill sets and improve patient care.

As the 2009 educational year unfolds, Hogan & Hartson will continually monitor our policies and programs and may instruct our team accordingly, facilitating any necessary adjustments. Additionally, the global law firm will help Asante develop employee and faculty educational programs.

Asante Communications, LLC

Asante is a full-service medical education company specializing in physician and patient education for the biopharmaceutical industry. Utilizing proprietary research methodologies, the Asante team of scientists, writers, and strategists delivers high quality CME, tailored to the objectives of our accreditors and grantors, grounded in the science of current and investigational treatment options, and shaped by an expert understanding of adult learning principles. In particular, the company integrates the latest insights into disease management with comprehensive preclinical and clinical data, creating coherent and credible educational platforms. Asante provides strategically sharp content across print, live, video, and Web-based outlets and distribution channels,

and leverages its diverse network of pain clinicians to develop, validate and critically review needs assessments and all relevant scientific content. Further, the full spectrum of educational materials proposed in this grant is based on a fundamental tenet that clinicians have idiosyncratic learning preferences and often prefer to self-direct their learning across multiple vehicles. Such a multifaceted, interactive and needs-based approach is critical to instructing clinicians in chronic pain management. Based in New York City, the company is managed by seasoned veterans of the healthcare communications industry.

Platform Management

Asante will be responsible for the development, production, and distribution of the activities within the educational platform under the direction of Einstein. Asante will operate as an extension of the sponsor, working within Einstein's guidelines as well as those of the accrediting organizations and governmental agencies regulating medical education.

Einstein will provide oversight for the development, production, and distribution of the activities within the educational platform as well as the certification for CME credit.

Outcome Levels

Asante reaches Level 4 of Outcomes Measurement as defined by the North American Association of Medical Education and Communication Companies, Inc (NAAMECC) with our standard evaluation process:

Level 1: Participation (via the participant report)

Level 2: Satisfaction (via the activity evaluation)

Level 3: Learning (via the self-assessment exam)

Level 4: Performance (via the commitment-to-change questions on the activity evaluation)

Durable Outcomes Measurement and Evaluation

Einstein and Asante are committed to providing high quality education associated with durable outcomes that promote best practices in pain management and improve patient care. In addition to traditional outcomes measurements reported and evaluated by Einsten for Level 4 Outcomes as noted above, a randomized controlled study approved by Victor Hatcher, PhD, David Kaufman, MD, of Einstein and the Institutional Review Board (IRB) of Albany Medical Center will be conducted to measure the effectiveness of the educational interventions.

Stage I

In this study, clinicians (N=~300~350) will demonstrate their baseline level of attitudes, awareness, knowledge and current practices by completing a structured questionnaire (20-questions; 10 multiple choice and 10 case-based short answer questions). The questionnaire—a self-developed instrument in early stages of psychometric evaluation—will be based on educaticnal deficits initially identified in the Clinical Survey and Needs Assessment (CSNA). After completing the diagnostic, clinicians will participate in a teleconference program and/or live regional meeting, immediately after which they will again complete a similarly structured questionnaire. Pre and post differences in attitudes, awareness and knowledge will be determined, reflecting the extent to which the participants have achieved the learning objectives. To gain additional context, face-to-face focus group discussions will be conducted immediately after the regional meeting as well. Here, participants will have an opportunity to elaborate on self-reported performance indicators that go beyond the structured questionnaire.

Stage II

Upon completion of Stage I, a subset of interested clinicians will be randomized to either an intervention group (~n=150), within which clinicians will participate in a monthly WebPanel series with thought leaders for 6 months, or randomized to a control group of clinicians (~n=150), who will receive no further instruction and provide a benchmark against which the effectiveness of continual intervention may be measured. Adult learning principles suggest that such reinforcement helps translate knowledge into practices with enduring value. Clinicians may benefit from the collegial relationship and outcomes-driven mentoring provided by the WebPanel. Outcome variables for Stage II will include the clinicians' confidence in pain management skills and intent-to-change by: (1) employing functional goals to guide patient care (2) implementing structured pain and risk assessment methodologies (3) monitoring breakthrough and persistent pain longitudinally and (4) documenting level of risk.

Stage III

A more precise measure of effectiveness may be obtained in a third and final stage of this study. A subset of clinicians from the Stage II intervention (n=~5 clinicians) and control groups (~n=5 clinicians) will invite as many as 10 patients each to participate in this stage (~N=100 patients; ~n=50 experimental group; ~n=50 control group). Appropriate disclaimers and IRB approval will be secured for each patient upon initiation of Stage II. Once Stage II is completed, patients in each group will complete a brief questionnaire (5 multiple choice questions). Outcome variables for Stage III will be patients' overall satisfaction with the consultations and satisfaction with the clinician's assessment of the quality, severity and temporal components of chronic pain. Differences in patient outcomes will be compared between the Stage II intervention group and control group. The working hypothesis is that those patients treated by clinicians who received ongoing interventions will have sharper assessment skills, translating into discernable and self-reported differences in patient care.

Importantly, this study design and methodology will provide qualitative and quantitative data longitudinally, throughout each stage of the study. Reported outcomes in physician performance and patient care—particularly those demonstrating sustainability—may constitute publishable data for the *Journal of Continuing Education in the Health Professions*, a peer-reviewed journal specializing in CME.

III. Educational Platform, Learning Objectives, and Needs Assessment

Educational Platform

Guided by an expert panel and comprehensive needs assessment, the educational initiatives within this platform are intended to disseminate chronic pain and risk management strategies to a multidisciplinary audience of clinicians who treat patients with chronic pain, including pain specialists, neurologists, rheumatologists, physical medicine and rehabilitation specialists, family practitioners, oncologists, and internal medicine and general practitioners. In a grant proposal to be submitted subsequently, physician assistants, nurse practitioners, and registered nurses will be addressed as an important secondary audience.

Each activity will provide a venue for healthcare professionals to increase their clinical knowledge and awareness of pain and risk-mitigation strategies in the opioid-based treatment of chronic pain. Upon successful completion of the CME activities, healthcare professionals may use the CME credit(s) earned toward their licensure and/or certification requirements.

Einstein and Asante have completed a thorough analysis of the current state of chronic pain education, researching publications and clinical trials, soliciting in-depth thought-leader feedback, and conducting a survey of potential participants regarding current practice patterns, existing educational opportunities, and the need for focused and targeted activities.

Asante has developed a proprietary approach to identifying unmet educational needs among clinicians, to tailoring educational programs accordingly, and to developing sensitive outcomes-based approaches to evaluating changes in awareness, knowledge and practice. Briefly, working with Einstein, Asante has employed its CSNA data which helps distinguish among clinicians with various levels of expertise. While the psychometric properties have yet to be fully determined, the questions reveal different approaches to the assessment and treatment of specific disorders. After identifying gaps in understanding among responders, specific replies are shared with thought leaders, who are asked to share their insights into a specific educational deficit and how it may be treated through targeted interventions. Finally, teleconference calls are then conducted to confirm identified gaps among target audiences.

Based on this research and feedback, Einstein and Asante have identified specific educational needs within the therapeutic area and recommend addressing those needs via a series of educational approaches to chronic pain and risk management linking evidence-based medicine with expert perspective.

Intended Audience

These activities are developed for pain specialists, neurologists, rheumatologists, physical medicine and rehabilitation specialists, family practitioners, oncologists, and internal medicine and general practitioners

Activity Goals

It is the goal of these activities to increase their competence and abilities to treat and appropriately manage pain and learn important methods to incorporate risk management strategies into pain management plans.

Learning Objectives

At the conclusion of this program, participants will be better prepared to:

1. Define, recognize, and independently assess breakthrough and persistent pain in patients with chronic pain syndromes
2. Implement a multidimensional, continual, and vigilant assessment of persistent and breakthrough pain based, in part, on the phenomenology and inferred pathophysiology of the pain syndrome, patient function, goals, and level of risk
3. Select appropriate patients for opioid-based management of persistent and breakthrough pain
4. Employ multimodal opioid-based therapies tailored to the multidimensional pain assessment of patients with persistent and breakthrough pain
5. Explain the respective roles of long-acting, short acting and rapid onset opioids in the management of persistent and breakthrough pain
6. Distinguish clinical constructs of physical dependence, tolerance, pseudotolerance, addiction, pseudoaddiction and their impact on medical management of patients with chronic pain syndromes

Clinical Survey and Needs Assessment (CSNA)

Two thousand one hundred and thirty five surveys were e-mailed to U.S. based pain clinicians. One hundred and fifty-seven electronic surveys were completed (7% response rate). Respondents provided answers to several yes/no questions and to open-ended questions about breakthrough and persistent pain management. Select questions from the survey are included below.

- Most (82%) of the sample employed multimodal and multidrug approaches

- Nearly 40% of respondents cited the need for more education on multimodal treatment strategies (eg, behavioral, relaxation strategies, cognitive behavioral therapy)
- Approximately 74% of respondents cited a need to learn more about principles of opioid-based therapy, including when to prescribe, how to maintain, and when to discontinue opioids. ("How do I manage a patient with a legitimate pain syndrome who has broken the contract?")
- Nearly half (47%) of the respondents agreed that opioid based therapy is time consuming, poorly reimbursed and increasingly difficult in this environment. Respondents agreed that guidance on formulating a treatment plan within the current 15-minute visit paradigm is needed.
- An estimated 34% of respondents do not risk stratify their patients for problematic opioid use.
- Few subjects (<10%) disagreed with the notion that chronic pain comprises two distinct components (Sample responses below). Rather, the educational need appears to center on definitional issues, and how best to assess and treat the constructs. Operationalizing breakthrough and persistent pain, in other words, appears to be the threshold educational need.
- Most respondents (65%) used the Numeric Rating Scale to evaluate baseline pain, highlighting the need for education on thorough assessment strategies.
- Only 55% of respondents provided an adequate definition of breakthrough pain.

Question: **How do you determine whether baseline persistent pain is controlled? Please elaborate as needed.**

> *"Actually, very complex assessment: I begin with comparing both the peak and average pain scores since last encounter, the frequency and duration, comparing these to values from the previous visit; the total daily long-acting and average short-acting (excluding transmucosal fentanyl) opioid dosages are calculated as oral oxycodone equivalents, and the percentage of short-acting medication of the total of the two components is estimated, and compared with last visit. In the interview, adjustments are made in interpretation of these "hard" data points based on any acute injuries or exacerbations which may have disturbed the balance that month, desirable increases in activity vs. overextension, and the end-effect on mood, sleep, energy, motivation, appetite, and perceived areas of improvement or deterioration are assessed. "*

Question: **How would define breakthrough pain?**

Adequate definitions included:

> *"Sudden onset or rapidly (a relatively soft subjective definition) escalating pain beyond usual tolerable levels (not just above baseline). I do not accept the additional qualification that it is of short duration or even necessarily spontaneously subsides; patients with CRPS I or II, TGN, PHN, or painful MS may experience flares that sustain for hours or even a full day."*
>
> *"Episodic occurrences, commonly related to changes in activity not well controlled by baseline pain medication use that works the majority of the time."*

Inadequate breakthrough pain definitions included:

- *Disturbing pain despite taking long acting opioid*
- *I would just say it is an increase over baseline; the pain is getting worse or it still isn't well controlled in the first place*
- *When a person still has pain on and off, while taking maintenance pain medications*
- *Pain that occurs at the end of dose drop off of the long acting med regimen before the next dose is due*
- *BTP is pain occurring in mid-dose regimen with chronic pain controlled by long acting narcotic*
- *If the baseline pain is not managed then there will be more breakthrough pain. Baseline pain management requires maximizing dosages or other interventions*
- *Pain that unexpectedly breaks through the baseline pain regimen, as distinct from activity related pain and end-of-dose pain*

Critical Assessment of Unmet Educational Needs in Chronic Pain Management

Chronic pain is prevalent, underdiagnosed, often misdiagnosed, and undertreated. (Walid, 2008; Gore, 2006) Previously regarded as a symptom of underlying disorders, the neuroplastic changes that characterize chronic pain constitute a disease state unto itself, a state of peripheral and central sensitization and hyperexcitability that requires comprehensive, continual assessment and treatment. (Woolf, 2007) Chronic pain is a significant burden to the patient, impairing multiple dimensions of function—affective, cognitive, physical, and work-related—which, in turn, adversely affect public health. (McCarberg, 2008) Numerous epidemiologic studies have estimated an annual cost of 80 billion dollars in the United States alone, reflecting the more than 50 million people who have chronic pain syndromes. (APS, 2008) The incidence and prevalence of chronic pain syndromes is projected to increase as the population ages, particularly with such age-related syndromes as osteoporosis, low back pain, osteoarthritis, and multifocal joint pains. (Robinson, 2007) Many patients with chronic pain will be cancer survivors, a group recently estimated to include more than 10.8 million people. (Ries, 2008) The prevalence and cost of chronic pain, and its debilitating signs and symptoms, have driven pain practitioners, academicians and several medical societies to collaboratively develop screening methodologies, validated assessment tools, and multimodal treatment strategies that provide pain relief and improve patient function. All of these approaches require an ongoing commitment to medical education. (Stanos, 2008; Webster, 2005; Passik, 2008) (CSNA; **Learning Objectives 2, 3, 4**)

Chronic pain comprises heterogeneous and frequently complex disorders that often require opioid analgesics, a medication class with an equally complex pharmacology and epidemiology. (Pasternak, 2005) Opioids have long been regarded as a cornerstone in the treatment of cancer pain; numerous randomized controlled studies have documented their safety, tolerability and efficacy across a wide variety of cancer-related syndromes. (Pergolizzi, 2008; Ballantyne, 2005; Miaskowski, 2005; Carr, 2004) Over the past 20 years, opioids have gained increasing, though not unqualified, acceptance for noncancer pain as well. (Ballantyne, 2008; Noble, 2008; Riley, 2008; Portenoy, 2007; Furlan, 2006; Coluzzi, 2005; Nicholson, 2003) Concerns about opioids in the management of moderate to severe pain of noncancerous origin, extensively reviewed elsewhere, help explain, at least in part, an unjustifiable undertreatment of pain, especially in the elderly. (Lin, 20007; Robinson, 2007; APS, 2005; Ballantyne and Mao, 2003) Educational programs are urgently needed to help clinicians select appropriate patients with cancer and noncancer pain syndromes for opioid-based pharmacotherapy, and to develop an individualized therapeutic regimen based

on the pain syndrome, level of risk, and goals of each patient. (Portenoy, 2008; Keeney, 2008; Comley, 2000) (CSNA; **Learning Objectives 3, 4**)

Assessment as Predicate

Multidimensional comprehensive assessment strategies improve patient care and outcomes. (Barbuto, 2008; Breivik H, 2008; Davidson, 2008; Locker, 2007; Yennurajalingam, 2004) Identifying objective findings through a patient work up—including, for example, laboratory electrodiagnostic and imaging studies—remains critical; however, clinicians must operationalize the International Association for the Study of Pain (IASP) definition of pain, which does not require actual tissue damage for pain to be experienced. (Merskey, 1994) Pain is an untestable hypothesis (Fishman, 2008); absent any objective data supporting the pain complaint, clinicians need to rely on patient function and quality of life as goals and benchmarks for success. Listening to the patient is indispensable. By characterizing the quality of the pain, its radiation pattern, and temporal profile—when is the pain minimal, and when is it excruciating?—the patient may help the clinician translate the phenomenology of the pain complaint into a pathophysiology that informs mechanism-based treatment. (Davies, 2008; Maag, 2006; Baron, 2006; Woolf, 2004)

"We need to listen to monitor what's going on with these patients over time, to evaluate the results of therapy, and to control as best we can adherence to the plan of care through a very well thought out monitoring program, and then over time tailor and adjust therapies according to what happens. Because I think if there's one thing we've learned, it is that we really do not have great predictors of either efficacy or safety, except in a very obvious group of high-risk patients."

Perry G. Fine, MD

In time-constrained clinical practice, reducing irreducibly complex chronic pain syndromes is manifestly challenging; their broad phenomenology must therefore be assessed methodically, through a semi-structured approach over time. (Breiveik, 2008; Guarino, 2007; Passik, 2005) There is an urgent need for educational programs addressing practical solutions for ongoing patient assessment, several of which are briefly discussed below. (CSNA; **Learning Objective 2**)

Assessment is a process that takes time, takes multiple encounters with the patient. And when I discuss with nurses the assessment of pain, I often say for all of us, we have to get the patient's pain story, and in our truncated world of a 15-minute patient visit, that's often a hard thing to achieve, trying to get the patient back with the appropriate frequency so we can detect the subtleties that need to be managed with these types of pain problems."

Christine Miaskowski, PhD, RN

Mechanism-Based Therapy

First, pain must be correctly classified to drive appropriate treatment selection. (Baron, 2008) Underlying etiologies of chronic pain vary considerably. Cancer pain syndromes may involve soft tissue, bones, or joints, and could be related to a polyneuropathy, plexopathy, or another form of nerve injury. (Berger, 2006) Similarly, noncancer pain syndromes may involve chronic tissue injury, inflammatory disorders, or nerve injury. These disease classifications, although helpful, require additional insights into disease mechanisms. Gradually, clinicians are classifying less by disease than by inferred pathophysiology. (Woolf,

2004) Simply, chronic pain syndromes may have a nociceptive (somatic or visceral) component marked by constitutive activation of an otherwise intact nervous system. Inflammatory bowel disease, interstitial cystitis, osteoarthritis, and discogenic back pain are classified as nociceptive. Pain with a predominantly neuropathic component is characterized by reorganization of normal neural circuits, and includes cancer-related neuropathy, complex regional pain syndrome (CRPS), post-laminectomy syndrome, HIV-related neuropathy, central post-stroke pain, post-herpetic neuralgia, diabetic neuropathy, and phantom limb pain, among others. (Argoff, 2006; McMahon & Koltzenburg, 2005) Matching treatment to disease is gradually being eclipsed by matching treatment to mechanism. (Woolf, 2008; de Leon-Casasola, 2008; Baron, 2008) Clinicians require concerted educational efforts to understand this paradigm shift. (CSNA; **Learning Objective 2**)

Temporal Dimensions of Chronic Pain

Second, temporal characteristics of chronic pain must be captured during each visit. Chronic pain is dynamic, ebbing and flowing as a function of movement, stress, and other idiosyncratic factors. (Davies, 2008; Bennett, 2005) The persistent, baseline component of pain, even when controlled, fluctuates; often, the pain breaks through an otherwise effective analgesic regimen. (Bennett, 2007) Breakthrough pain, the second temporal component of chronic pain, is an often overlooked clinical construct. (William, 2008; Swanwick, 2001) Recently discussed by an expert panel, breakthrough pain is a transitory pain more severe than the persistent baseline pain that adversely affects function or quality of life in patients who are receiving analgesic therapy on most days. (Expert Panel on Breakthrough Pain, 2006) The requirement for an adverse functional impact is essential for the management of BTP, and mirrors the increasing focus on function in the Federation of State Medical Boards (FSMB) model policy. (Fishman, 2008) Clinicians require expert guidance on how best to employ patient function as a standard by which to measure treatment success. (CSNA; **Learning Objectives 2, 5**)

> *"An important question in pain management: Does an observed reduction in pain intensity translate into clinically relevant functional improvement? That is to say, because a patient says, "Yes, in fact I am experiencing an analgesic effect," does that lead to demonstrable, meaningful accomplishment of certain goals that we may say, other than pain relief, are very important from a clinical or therapeutic standpoint?"* **Perry G. Fine, MD**

Epidemiologic studies have demonstrated that the majority of patients experience breakthrough pain; the prevalence in cancer patients is estimated at 64%, and that in noncancer pain patients is closer to 74%. (Portenoy 1990; Portenoy, 2006) Patients with breakthrough pain have decreased satisfaction with their analgesic regimen, increased healthcare utilization and associated costs, increased hospital visits and hospitalization, increased mood disturbances, and impaired function. (Abernethy, 2008; Taylor, 2007; Fortner, 2003; Fortner, 2002) Independent assessment and treatment of this clinical entity is therefore critical to patient care. (Taylor, 2007) Clinicians face formidable challenges, however. Breakthrough pain is a highly variable clinical construct—its duration, frequency, severity, and predictability vary among and within patients. (Portenoy, 2006; Mercadante, 2002; Portenoy, 1990; Portenoy, 1989) Continual assessment helps characterize these temporal features and distinguish breakthrough pain from uncontrolled baseline pain. Clinicians require educational programs that help clarify breakthrough pain as a measurable and treatable clinical construct. (CSNA; **Learning Objectives 1, 4**)

Risk Mitigation

Third, a careful consideration of the risk-benefit relationship of opioids in the context of other pharmacologic and nonpharmacologic treatment options is critical to individualized patient care. (Fine and Portenoy, 2007) Russell K. Portenoy, MD and colleagues have developed a conceptual framework within which clinicians can decide to initiate, maintain, or discontinue opioid-based therapy. Specifically, the "Portenoy principles" require identifying the conventional therapeutic approach for the pain syndrome; evaluating the risk-benefit ratios of all feasible treatment options; assessing the risk of opioid-related adverse

pharmacologic outcomes (eg, gastrointestinal distress, sedation, endocrine dysfunction); and stratifying the risk of nonmedical opioid use. This approach helps structure opioid-based therapy consistent with risk, an increasingly critical driver of chronic pain management. (Portenoy, 2004) Clinicians can benefit from an educational program that helps them incorporate the principles suggested by Dr Portenoy into their clinical practice. (CSNA; **Learning Objective 1, 4**)

> *"Conventional management may not be evidence based and may not be appropriate for the individual person. But we all exist in a network of relationships with other physicians, other health care providers, a regulatory network, a legal network, a managed care network. And you need to have that understanding of conventional practices, within the network, in order to make an informed judgment. If you decide not to do what is conventional, from my perspective, that's totally okay. We do that every day as clinicians. We decide to do something that's not conventional. But, if it's not conventional, you need three things. You need a good reason. You need informed consent. And you need documentation."* **Russell K. Portenoy, MD**

Understanding the social milieu in which the patient lives and works, and obtaining the personal and/or family history of medical and psychiatric comorbidities, especially substance use disorders, creates a three-dimensional, biopsychosocial representation of the patient. (Wasan, 2007; Adams, 2006; Wool, 2005) Validated screening tools—including the Opioid Risk Tool and the Screener and Opioid Assessment for Patients With Pain—are available to help stratify the risk of inappropriate opioid use. (Belgrade, 2006; Akbig, 2006; Webster, 2005) Such problematic opioid use includes failure to use the opioid as prescribed (misuse), the deliberate use of a drug for nonmedical reasons, in particular for psychotropic effects (abuse), and the willful or accidental transfer of the medication to others (diversion). (Katz, 2008; Katz, 2007) Amid the escalating epidemic of prescription opioid abuse, clinicians need expert insights into balancing the benefits of opioid medications with the risk of abuse, misuse, and diversion. (CASA, 2008; CASA 2005; SAMHSA, 2004) There is an unmet medical and educational need for thorough and careful assessment of biological, psychological, and social dimensions of patients with chronic pain. (Denisco, 2008; Martelli, 2004; Marcus, 2000) (CSNA; **Learning Objective 2**)

Patients with chronic pain who are assessed as high risk may require a highly structured plan. (Gourlay, 2005) Pill counts, urine drug screening, weekly visits for prescription refills, pharmacy monitoring plans and treatment agreements are all available options. Risk mitigation is an inherently imprecise methodology, as familiar as it is essential. Patients with diabetes, hypertension, or schizophrenia all require careful stratification of risk. The universal applicability of risk stratification to all disciplines of medicine underscores its central importance and the need for ongoing education. (CSNA; **Learning Objectives 2, 3**)

> *"In every sector of medicine, we always have to balance the risk or burdens of treatment against the benefits. The benefits in analgesic treatment are going to be pain relief, improved functionality, and decreased or at least more appropriate healthcare utilization. The risks include the side effects of the medication, diminution of quality of life as a result, and abuse behaviors, which can be problematic not only to the patient, but for our society."* **Neal E. Slatkin, MD**

Multimodal Opioid Based Management of Persistent and Breakthrough Pain

Multidisciplinary, collaborative pain management is often required, particularly for complex chronic pain syndromes with demonstrable biopsychosocial elements. (Stanos, 2007; Wiedemer, 2007) Clinical data and experience support the use of opioids, often in combination with behavioral, psychosocial, rehabilitative, and interventional treatments, customized to the individual patient's pain complaint, risk status, and goals. (Pergolizzi, 2008; de Leon-Casasola, 2008; Soares, 2007; Jensen, 2006) Further, patient care is often improved by combining opioids with nonopioid analgesics—$\alpha_2\delta$, tricyclic antidepressants, serotonin norepinephrine reuptake inhibitors, or nonsteroidal anti-inflammatory drugs. (Gilron, 2008) By targeting therapies at distinct neuraxial sites that transduce, transmit, modulate, and perceive pain signals, patients may receive opioid-sparing and additive analgesic effects. (Baron, 2008)

The rationale for multidrug therapy has considerable face validity, although few randomized controlled studies have been performed to date. (Dworkin, 2007; Backonja, 2006; Kalso, 2005) As discussed, classifying pain as neuropathic or nociceptive significantly influences these combination treatment approaches. (Horowitz, 2007; Argoff, 2006) Recently, Gilron and coworkers reported the benefits of a morphine sulfate-gabapentin combination for neuropathic pain. (Gilron, 2005) Many questions remain. Is there differential benefit to sequential or concurrent combination strategies? Should the maximal tolerated dose for monotherapy be achieved before combining a second agent? How should breakthrough pain be treated within this multidrug treatment paradigm? (Raja, 2005) These and other issues require educational fora to foster peer-to-peer learning and to capture the clinical experience with opioid-based multimodal approaches for persistent and breakthrough pain management. (CSNA; **Learning Objectives 4, 5**)

Orchestrating an Opioid Trial

In his recently published text, *Responsible Opioid Prescribing: A Physician's Guide,* Scott Fishman, MD, describes the model policy of the Federation of State Medical Boards (FSMB) for safe, rational, and transparent prescribing of opioids. (Fishman, 2008) Briefly, the FSMB reinforces the need for thorough assessment and ongoing evaluation of the patient on the formulation and continual refinement of a therapeutic plan. Further, FSMB policy highlights the central importance of tailoring opioid-based therapy commensurate with the degree of risk, and based on a transparent, beneficent, and vigilant relationship with the patient. The paradigm for an opioid trial has been extensively documented, though rarely evaluated in randomized controlled studies. (APS Annual Meeting, 2008) Presently, experts recommend that physicians initiate a trial with predefined functional goals: to achieve control of the baseline pain and to assess and treat fluctuations that break through the multimodal analgesic regimen. (Dy, 2008; Pergolizzi, 2008; Davies, 2008; Portenoy, 2004) There is an urgent need for physicians to integrate this approach into their daily care of patients with chronic pain syndromes. (CSNA; **Learning Objectives 1, 4, 5**)

> *"Clinicians should make sure that their records are generally complete, but the key is not to just document everything that's going on, but to be transparent about risk management, to recognize that every patient has risk, whether or not they are taking opioids, whether they are being treated for pain or treated for infections with antibiotics. There is risk in doing nothing, and there is risk in doing the treatment. Recognize the risk and have a plan for follow-up. If there is a problem, then there is a risk management plan."* **Scott M. Fishman, MD**

Numerous guidelines and consensus statements recommend the use of regularly scheduled opioid agonists for cancer-related persistent pain. (Pergolizzi, 2008; Moulin, 2007; Trescot, 2006) In addition, "rescue" doses of short-acting and rapid-onset opioids are recommended for the intense fluctuations that often occur despite adequate control of baseline pain—namely, breakthrough pain. (Fishbain, 2008; Aronoff, 2005) For the past 20 years, evidence-based guidelines and empirical decision making in cancer pain management have become the basis by which to evaluate the roles and risks of opioid medications in chronic noncancer pain. (Ballantyne, 2007) Data continue to emerge demonstrating the utility of opioids for common noncancer pain syndromes. (Furlan, 2007; Eisenberg, 2005) Still, more rigorously controlled studies are needed; meanwhile, clinicians must balance evidence-based medicine with practice-based evidence when initiating and maintaining opioid-based therapies. (Davis, 2004; Carr, 2004)

Maintenance of the long-acting opioid (LAO)–based regimen requires continual monitoring and occasional baseline medication adjustments to achieve a measure of dose stability. (Portenoy, 2004) Robust trial data have demonstrated that pharmacologic outcomes—a favorable balance between analgesia and side effects—improve when, during this maintenance phase, breakthrough pain episodes are recognized, assessed, and treated. (Hagen, 2008; Portenoy, 2007; Simpson, 2007; Portenoy, 2006; Zeppetella, 2006; Coluzzi, 2001; Portenoy, 1999; Christie, 1998) Challenges persist, however, and educational programs are required to provide guidance for clinicians to identify well-controlled baseline pain through continual assessment, allowing the independent and tight therapeutic management of breakthrough pain. (CSNA; **Learning Objectives 1, 2, 5**)

> *"When clinicians see people who have inadequate pain relief back in their offices, and they're on a long-acting opioid, what it really boils down to during that visit is: Do you decide to raise the background opioid or do you add on another drug, and what drives your decision making at that critical point? And it will depend on how you view the pain phenomenology, the patient, and other factors. And I don't think it's a straightforward question in a disease state in which the best therapies only reduce the background pain by 57 percent."* **Steven D. Passik, PhD**

Breakthrough pain is not a unitary phenomenon; rather, several subtypes have been evaluated clinically and shown to have telltale characteristics that aid assessment and treatment. (Webster, 2008; Caraceni, 2004; Gutgsell, 2003) First, incident breakthrough pain may be precipitated by volitional (eg, gardening) or nonvolitional (eg, spasm) activity. (Svendsen, 2005) Second, breakthrough pain attributed to end-of-dose failure emerges with a periodicity that coincides roughly with the pharmacokinetic troughs of the baseline medication, typically an LAO. (McCarberg, 2001) Baseline dose adjustments may reduce the frequency and severity of these episodes, although the LAO may reach dose-limiting toxicities, causing some clinicians to switch opioid baseline medications or to prescribe a short-acting opioid to compensate for the drop in LAO serum levels. (Dy, 2008; De Leon-Casasola, 2008) Finally, idiopathic breakthrough pain is associated with paroxysmal spikes that may reach peak intensity in as little as 3-5 minutes. (Portenoy, 2006; Simon, 2006; Bennett, 2005; Portenoy, 1990)

Clinical studies on the differential phenomenology of breakthrough pain subtypes have been limited. The threshold frequency for breakthrough pain episodes that warrants baseline medication adjustments has not been well established. (Svendsen, 2005) Absent clear experimental evidence, clinicians need guidance on the differential diagnosis of breakthrough pain, and the respective roles of long-acting, short-acting, and rapid-onset opioids. (Davies, 2008; Hagen, 2008; Portenoy, 2008) Case-based workshops, reviews of the evidence, and other expert insights into breakthrough pain management are urgently needed. (CSNA; **Learning Objectives 1, 5**)

"Can we add some questions to the concept of a comprehensive assessment that speak more to clinical meaningfulness of breakthrough pain and treatment selection? So, for instance, the time to onset, time to severe, or time to clinically meaningful effect. And activities you avoid in an attempt to prevent episodes may help define a scope of fluctuations that should be called breakthrough pain that aren't now described as such?" **Russell K. Portenoy, MD**

Pain management perspectives continue to evolve. In particular, several concerns are often noted: lack of data supporting long-term opioid therapy; the occurrence of addictive disease in a subset of patients; inexact risk mitigation methodologies; and the potential for hyperalgesia and for endocrine and immune dysfunction with long-term opioid exposure. (Korff, 2008; Ballantyne, 2007) For some patients, opioids are associated with side effects (eg, constipation, pruritis, and sedation), poor tolerability, and serious adverse events such as respiratory depression and, as discussed, misuse, abuse, and diversion. (Harris, 2007) In addition, clinicians need to clarify the nomenclature and clinical constructs of physical dependence, tolerance, pseudotolerance, addiction, and pseudoaddiction. (Jage, 2005; Savage, 2003) (CSNA; **Learning Objective 6**) These and other safety concerns—identifying opioid-tolerant patients, for instance—rightly rank as paramount among clinicians, and demand continual and comprehensive evaluation of patient compliance and therapeutic response, informed by predefined functional goals. (Rosenblum, 2008) Educational programs should raise awareness of these issues and provide practical guidance to minimize their impact on patient care. (CSNA; **Learning Objectives 2, 4**)

"For some patients, the therapeutic window is the size of the Texas plains and you can give them medicines without much worry. But there are individuals who are extremely sensitive to medicines and instead of being the size of the Texas plains, the window is the size of a New York City street during rush hour: tight, small, and difficult to manage. When you're trying to treat these patients, you need very precise control of the medications." **Michael J. Brennan, MD**

Clearly, patient selection is the linchpin of effective opioid-based therapy. (Portenoy, 2008; Antoin, 2004) Individuals vary across multiple dimensions: in their response to nonpharmacologic and pharmacologic treatment options; in their pain phenomenology; in their affective behavior during therapy; and in their propensity for irresponsible medication use. Despite current and emerging data, no one opioid molecule—oxycodone, fentanyl, or morphine, for instance—has an *a priori* advantage over another. And data delineating the respective roles of long-acting, short-acting, and rapid-onset opioids in managing the persistent and breakthrough components of chronic pain are only beginning to emerge. (Simon, 2005) Clinicians thus need expert input on how best to structure opioid-based therapy in the context of a well orchestrated N-of-1 trial.

Multidimensional assessment governs multimodal therapeutic decision making, but the gap between evidence-based medicine and the practical, day-to-day management of patients with persistent and breakthrough pain is considerable and, for some, even prohibitive. Rational, transparent prescribing of opioids among appropriately selected patients thus presents formidable challenges that can only be met by rigorous educational efforts. (CSNA; **Learning Objectives 3, 4**)

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IV. Faculty and Programs

Potential Faculty

Under the direction of David Kaufman, MD, Professor of Neurology and Psychiatry at Albert Einstein College of Medicine, and the Albert Einstein College of Medicine, qualified faculty will be selected and may include the following:

Michael J. Brennan, MD
Chief of Rehabilitation Medicine
Bridgeport Hospital
Bridgeport, Connecticut

David A. Fishbain, MD
Professor of Psychiatry, Adjunct Professor of
Anesthesiology and Neurological Surgery
Leonard M. Miller School of Medicine
University of Miami
Miami, Florida

Scott M. Fishman, MD
Professor of Anesthesiology
Chief, Division of Pain Medicine
University of California, Davis
Sacramento, California

Gordon Irving, MD
Medical Director, Swedish Pain Center
747 Broadway
Seattle, Washington Seattle, WA 98122

Bill McCarberg, MD
Founder, Chronic Pain Management Program
Kaiser Permanente
Escondido, California

Sebastiano Mercadante, MD
La Maddalena Cancer Center
University of Palermo
Pain Relief & palliative care
Via S. Lorenzo Colli 312
90146 Palermo, ITALY.

Christine Miaskowski, RN, PhD, FAAN
Professor and Chair
Department of Physiological Nursing
UCSF School of Nursing,
San Francisco, California

Judith A. Paice, RN, PhD
Research Professor
Northwestern University Feinberg School of Medicine
Chicago, Illinois

Steven D. Passik, PhD
Clinical Psychologist
Memorial Sloan-Kettering Cancer Center
New York, New York

John Peppin, DO, FACP
Director
Iowa Pain Management Clinic
Des Moines, Iowa

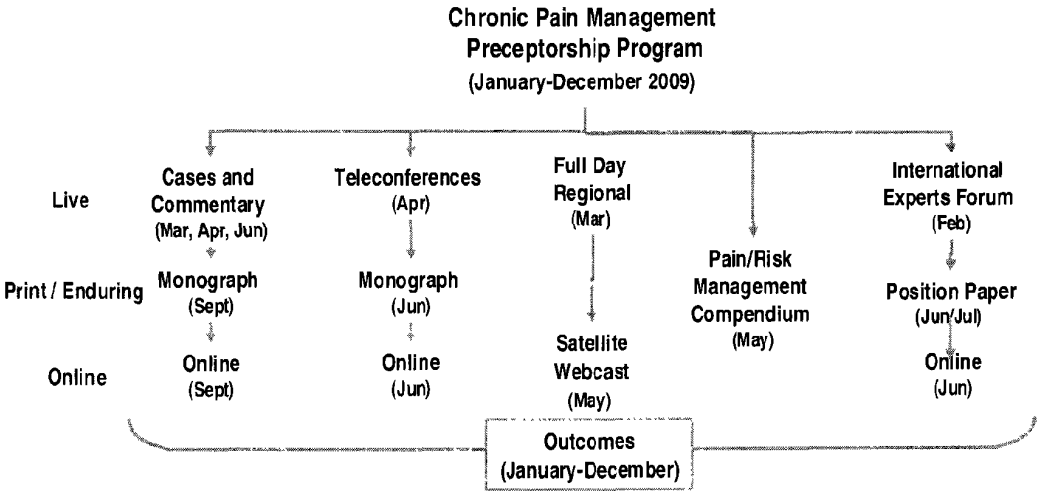
Russell K. Portenoy, MD
Chairman
Department of Pain Medicine and Palliative Care
Beth Israel Medical Center
New York, New York

Neil E. Slatkin, MD, DABPM
Director
Department of Supportive Care, Pain & Palliative Medicine
City of Hope Medical Center
Duarte, California

Lynn R. Webster, MD, FACPM, FASAM
Medical Director
Chief Executive Officer
Lifetree Clinical Research and Pain Clinic
Salt Lake City, Utah

Giovambattista Zeppetella, MD
St Clare Hospice
Hastingwood Road
Hastingwood, Essex CM17 9JX, UK

Einstein and Asante recommend developing a comprehensive, accredited, and integrated CME initiative comprising each of the proposed tactics. Further, we recommend folding the educational programs and materials under a unifying and meaningful acronym, linking them conceptually, and assuring clinicians of their quality, accuracy, and clinical relevance.



Chronic Pain Management Preceptorships

In this pilot program, approximately two-hundred (~n=200) US-based pain management clinicians will participate in a preceptorship focusing on opioid-based care of patients with chronic pain. The program will provide a forum for each clinician to interact with national thought leaders via monthly WebPanel series. The interactions will be structured around previously identified areas of educational need and interest, as determined by CSNA and as described in the learning objectives. An initial 30-minute teleconference call with the community-based pain clinicians and national thought leader will launch the pilot program, followed by 15-30 minute quarterly WebPanel calls and, potentially, a meeting at a major medical congress, half-day or full-day regional meeting. Participants will be required to participate in at least three distinct activities; and would be encouraged to participate in a live regional meeting, to be held near to a Pain Center of Excellence identified by the American Pain Society (see below). Upon completion of this program, participants will receive up to 4 hours of CME credit and a complimentary copy of *Rational Opioid Prescribing, A Physician's Guide*, by Scott Fishman, MD, and/or a copy of *Diagnosis and Treatment of Breakthrough Pain*, by Perry Fine, MD. Together, the books effectively summarize the essential elements in developing opioid-based regimens for patients with chronic pain syndromes.

Participants will be encouraged to share their newly acquired knowledge with their colleagues, potentially through a variety of outlets, including, but not limited to, in-services, lectures, and institutional publications. Upon completion of the educational series, and demonstration of improved and durable improvements in awareness, knowledge and performance (see Outcomes Measurement), select clinicians may be invited to participate as adjunct faculty for 2010 educational programs held in their respective regions. Working with national thought leaders, each adjunct faculty member will contribute to educational offerings—some in their local communities—on the assessment, differential diagnosis, and individualization of care for patients with persistent and breakthrough pain, potentially creating regional centers of excellence in pain management.

"This proposed preceptorship is superb! This is exactly what many of us have been discussing as a significant need—both for pain and for palliative care. The link to the centers of excellence is great—these are wonderful clinical centers. Some are more academic (NYU, Brigham) and others are more of a private practice model. This would allow participants a wider array of experiences. The outcomes described are perfect." **Judith A. Paice, PhD, RN**

Persistent and Breakthrough Pain Management in Cancer Survivors: Mechanism-Based Treatment for a Growing Patient Population (A Full-Day Regional Meeting)

Chronic pain in cancer survivors is an important yet under-studied problem. The prevalence of patients in long-term remission from a variety of cancer syndromes continues to grow, as does the need for guidance on how best to manage their complex pain states, particularly those with other medical and psychiatric comorbidities. Chronic pain and other long-term sequelae related to the disease and to medical, surgical, and radiation treatments significantly impair patient function and healthcare utilization, increasing the burden of illness on patients, their families, and society. This full-day workshop will consist of a morning lecture and panel session with veteran clinicians either currently or formerly associated with Memorial Sloan-Kettering Cancer Center (MSKCC). Their tenure at this premier facility will serve as a backdrop against which cancer survivorship and advances in the care of patients with cancer-related pain will be evaluated. In the afternoon session, participants will engage in a *Cases and Commentary* roundtable discussion.

Participants will receive a complimentary copy of *Rational Opioid Prescribing, A Physician's Guide,* by Scott Fishman, MD, and a copy of *Diagnosis and Treatment of Breakthrough Pain,* by Perry Fine, MD. The activity will be eligible for up to 8 hours of CME credit to physicians. Anticipated attendance is 75-100 physicians.

Satellite Web-Broadcast

Presently, the projection for attendance is 75-100 participants per full-day workshop, drawn primarily from the local and regional communities. To ensure access to other interested clinicians from across the country, a Web cast posted on Medscape or similar pain-related website (eg, www.pain.edu) is proposed. Distance learning is now turnkey, and each participant will be able to access the slide deck, related materials online, and highlights from the meeting. The activity will be eligible for up to 3 hours of CME credit to physicians. Anticipated reach is estimated to be over 20,000 physicians for the online activity.

Cases & Commentary™ Workshop

The ***Cases & Commentary***™ Workshop format is based, in part, on a small group case-based learning (SGCBL) model, allowing attendees to discuss therapeutic decision making across several case studies. Participants will benefit from the peer-to-peer design of the roundtable discussions, empowering them to listen, to probe, and to proffer solutions with their peers. The workshop provides a forum for exchange of insights into current diagnostic and therapeutic strategies. For those participants whose approach to decision making is aligned with that of their peers and thought leaders, the workshop will validate their own practice. Most participants will acquire knowledge across multiple facets of complicated disease states and patient care.

Eligible for 4 hours of CME credit each, the workshop will include no more than 50-75 participants (total n=~225), who will engage in small group discussions to evaluate best practices in persistent and breakthrough pain management. Each study group may include neurologists, physiatrists, anesthesiologists, and psychologists, and will be facilitated by a key thought leader

in pain medicine. In evaluations of previous workshops, most attendees rated the overall activity as "excellent," providing favorable comments regarding both the faculty and learning environment.

The meetings will be presented at regional locations across the country, selected from the 2007 American Pain Society Centers of Excellence. Suggested venues therefore may include the following:

- NYU Medical Center / Hospital for Joint Diseases, Bellevue Hospital Center, Comprehensive Pain Management Center, New York
- The Rosomoff Comprehensive Pain Center, Miami
- Brigham and Women's Hospital, Pain Management Center, Department of Anesthesiology, Perioperative and Pain Medicine, Boston
- UCSF Pain Management Center and UCSF PainCARE, Center for Advanced Research and Education, San Francisco
- Cincinnati Children's Hospital Medical Center, Division of Pain Management

Cases & Commentary Monograph

The case-based discussions will be audiotaped and provide substantial commentary ideally suited for a 4,500 word print monograph. The monograph will be posted on a pain-relevant website (eg www.medscape.com; www.pain.edu), distributed to pain specialists through *Pain Medicine News*, a leading trade journal with a wide readership, and/or through PainClinician™, our proprietary database and quarterly distribution vehicle. Written in a narrative style, the case-based monograph will convey best practices in the initial patient presentation, assessment, diagnosis, and formulation and ongoing refinement of therapeutic plans for chronic pain. Successful completion of a 10-question multiple-choice self-assessment examination based on the content presented is necessary to receive a certificate of completion. Participants must score 70% or higher and are allowed 2 attempts to successfully complete the exam. Upon successful completion of the monograph, physicians may use the CME credit earned toward their licensure and/or certification requirements. The activity will be eligible for 1 hour of credit to physicians for 1 year from the issuance date. Anticipated reach is estimated to be over 45,000 physicians for the print monograph in addition to 5,000-10,000 online recipients.

International Expert Forum and Position Paper on Persistent and Breakthrough Pain Management

Davies and coworkers recently published a task force series of recommendations on the management of breakthrough pain. (Davies, 2008) Interestingly, the experts stopped short of making specific treatment recommendations, and instead provided a conceptual framework to guide decision making. Citing the lack of evidence, the experts emphasized a carefully balanced and ongoing assessment and multimodal strategy for the management of breakthrough pain.

In this proposed expert forum, three prominent US based pain clinicians will explore the findings and implications of the Davies report with and two European leaders (eg Giovambattista Zeppetella, MD, Sebastiano Mercadante, MD). The program will consist of several teleconference calls and/or videoconferences, potentially culminating in a meeting at a medical congress. Salient recommendations would provide the substrate for a 6,500-word position paper on persistent and breakthrough pain management, to be posted on a pain-relevant website, and distributed through PainClinician™, our proprietary database and quarterly distribution vehicle. Based on the response from pain clinicians who participated in an international forum on persistent and breakthrough pain management recently held in Glasgow, Scotland, this expert panel may receive acknowledgement from the International Association for the Study of Pain (IASP). The activity will be eligible for 1+ hour(s) of credit to physicians for 1 year from the issuance date. Anticipated reach is estimated to be over 35,000 physicians for the print portion in addition to over 15,000-20,000 online recipients.

Teleconference Series

A CME audio teleconference brings together the live educational format preferred by many healthcare professionals with the convenience of participating in the activity at home or in the office. Available to a national audience, this format provides clinicians with an opportunity to participate in a lecture led by a thought leader as well as to interact with peers across the country.

This activity will be presented eight (8) times by nationally recognized thought leaders in pain management. Anticipated participation in each broadcast will be 25-50 participants (total n=~200-400), they will be approximately 45 minutes in length, with a 10-minute question-and-answer session completing the program. A teleconference syllabus will be mailed to the participants 48 hours prior to the presentation. Participants will phone in to a reserved line to listen to the lecturer elaborate on the slide content. The activity will be eligible for 1 hour of CME credit to participants.

Teleconference Series Monograph

The teleconferences will be audiotaped and provide commentary ideally suited for a 4,500 word print monograph. The monograph will be posted on a pain-relevant website, distributed to pain specialists through *Pain Medicine News*, a leading trade journal with a wide readership, and direct-mailed to pain practitioners enrolled in PainClinician™, our proprietary database. Written in a narrative style, the case-based monograph will convey best practices in persistent and breakthrough pain management. Successful completion of a 10-question multiple-choice self-assessment examination based on the content presented is necessary to receive a certificate of completion. Participants must score 70% or higher and are allowed 2 attempts to successfully complete the exam. Upon successful completion of the monograph, physicians may use the CME credit earned toward their licensure and/or certification requirements. The activity will be eligible for 1 hour of credit to physicians for 1 year from the issuance date. Anticipated reach is estimated to be over 45,000 physicians for the print monograph in addition to over 5,000-10,000 online recipients.

Albert Einstein's Persistent and Breakthrough Pain Reference Compendium

Editor: Russell K. Portenoy, MD Professor of Neurology

Reference manuals provide healthcare professionals with an authoritative educational tool in a condensed format that is easily transported from one clinical setting to another. This reference compendium will provide pain clinicians with practical information in a condensed format for quick reference. Pain and risk screening tools, equianalgesic dosing and other relevant information will be included. This text will include frequently asked questions and answers culled from various fora, including teleconferences and regional meetings. Posed by community pain clinicians, nurses, and psychologists, the questions address the fundamental issues in the management of chronic pain syndromes, from cancer-related pain to osteoarthritis. The responses will be drafted by leading experts in the field; a guest editor for this annual series will provide a preface and additional commentary throughout the text. Exhaustively referenced, this print activity will be available online and eligible for 1-2 hours of continuing education credit to participants. A 10-question multiple-choice self-assessment examination based on the content presented will be included. Successful completion of the posttest is necessary to receive certificate of completion/statement of credit. Anticipated reach is estimated to be over 45,000 physicians for the print monograph in addition to 5,000-10,000 online recipients.

Additional Tactics for Future Consideration

Persistent and Breakthrough Pain: Evidence-Based Practice and Practice Based Evidence

In this print and online series, expert thought leaders will elaborate on the seminal studies supporting the management of persistent and breakthrough pain, conducted over the past twenty years, since Drs Portenoy and Hagen published their seminal work in 1990. Abstracts of select studies will be included, and will help frame the discussion on salient issues in chronic pain management. Randomized controlled studies include patient populations with rigorously defined inclusion and exclusion criteria, often precluding generalizable and practical recommendations. Here, clinicians will discuss several landmark study findings, their limitations and implications for current approaches to assessment and individualization of patient care. Particular emphasis will be placed on the soon-to-be published guidelines from the American Pain Society, providing pain clinicians with guidance on how to interpret and implement their recommendations, bridging the gap between what we know and what we don't know with practice based clinical experience and evidence.

Web-Based Decision Tree (Program Name and URL Will Be Provided Upon Request).

This activity purports to integrate the expert clinical experience with the Level 1 Evidence of randomized controlled studies. Two objectives are served. First, clinicians acquire a more in-depth understanding of the evidence-based recommendations in various guidelines. (Of note, the American Pain Society will be publishing its guidelines in the near term.) This knowledge will help clinicians find a more practical expression of guidelines that too often cannot be implemented. Second, clinicians will refine their clinical judgment by engaging in structured decision making—the art of medicine—that drives patient care, particularly when specific evidence is lacking. In this Web-based activity, clinicians will be presented with case studies representative of the myriad issues in managing patients with persistent and breakthrough pain. Case studies may address chronic pain associated with tumor progression, radiation or chemotherapy-related pain in cancer survivors, diabetic peripheral neuropathy, and chronic low back pain.

Upon reviewing salient data—including, for instance, patient history, comorbidities, prior treatment history, pathophysiology, imaging studies, and laboratory findings—the clinicians will develop in step-by-step fashion a course of action. At each step, from assessment and diagnosis; to the initial and revised treatment, the clinician may choose among several options, each informed by well-designed studies and each having risks and benefits. These data will, of course, only be available to the clinicians upon making their selections. With only one "click," clinicians will gain access to a brief abstract summarizing the available evidence and a video of a thought leader roundtable discussion framing the available evidence. Links to seminal scientific and/or randomized controlled studies will be readily accessible and adjacent to each video presentation. When available, evidence-based outcomes—eg, pain reduction and functional improvement—of each treatment selection will be discussed. This self-directed case-based learning provides a familiar educational format for healthcare professionals based on adult learning principles, and consistently rates as a highly effective means by which to educate clinicians.

Case-In-Point and Accompanying Monograph

This roundtable discussion will feature several pain specialists, two from prominent academic centers and another from private practice. Faculty will present several complicated case studies, elaborating on the evidence for various treatment modalities. Twenty-five community-based clinicians—neurologists, psychologists, physician assistants, and nurses—will be invited to listen and to join in the discussion at appropriate times. This "chronic pain-in-the round" program will be video captured to form the basis for podcasts posted on a pain management Web site (eg, www.pain.edu) that includes practical, evidence-based resources for pain specialists.

The recorded sessions are edited professionally and reduced to 10-minute video vignettes, concise and uninterrupted discussions that capture the thought leaders' expert insights into the management of persistent and breakthrough pain. Print editorials written by community pain clinicians will accompany the video vignettes, reinforcing the major themes and providing an opportunity for academic thought leaders to partner with local clinicians, each managing patients with chronic pain. This innovative Web-based format allows clinicians to participate immediately in each activity at a self-directed pace from their computers—accommodating even the busiest of schedules.

A monograph will be developed to provide additional context for the video case studies. A 10-question multiple-choice self-assessment examination will also be included, reflecting the content discussed in each video vignette and accompanying print editorials. Successful completion of the posttest is necessary to receive a certificate of completion, or a statement of credit. Participants must score 70% or higher and are allowed 2 attempts to successfully complete the exam. Upon successful completion of the examination, healthcare professionals may use the CME credit earned toward their licensure and/or certification requirements. Each vignette—prime examples of which may be e-mail blasted to the target audience of pain specialists—will be eligible for 1 hour of credit for 1 year from the issuance date.

Literature Surveillance

Quarterly reports summarizing in an easy-to-read style results from a formal literature surveillance will be shared with select faculty and preceptorship clinicians. Designed to identify new developments in the management of chronic pain, the reports will monitor clinical trial data, guideline updates, FDA approvals and warnings, and emerging issues in pain medicine.

V. Program Recruitment, Awareness, and Distribution

Program Recruitment, Awareness, and Distribution

All live, print, and online programs will have specific recruitment, awareness, and distribution methods contained to ensure that the programs have the best opportunity for educational uptake and acceptance. These recruitment methods have been validated for past programs and have proven cost effective while maximizing reach and distribution to targeted audiences. These methods include live, print, and online components as detailed below.

PainClinician™

PainClinician™ is a compendium of advances in the management of chronic pain, distributed quarterly to pain specialists and other healthcare professionals interested in chronic pain management. Our proprietary database of the same name will ensure distribution to the primary audience of pain practitioners. Distribution methods include direct mail, distribution at AAPM, APS, and other selected pain management meetings throughout the year. Total quarterly distribution is estimated to be over 25,000. In addition to outlining the accredited package contents, each quarter and through an introductory letter, a leading pain management clinician will highlight the most recent and important dialogues and discussions involving pain medicine.

Pain Medicine News

The enduring activity will be a stand alone monograph of 12 journal sized pages distributed with an early 2009 issue of *Pain Medicine News* to its full circulation of approximately 46,500 clinicians. *Pain Medicine News* is a bimonthly publication circulating to physicians in the 12 specialties that most commonly treat patients with pain: emergency medicine physicians; neurologists; oncologists; orthopedic surgeons; pain management, pain medicine, and palliative pain medicine specialists; physical medicine and rehabilitation specialists; primary care physicians; and rheumatologists.

Additional copies of the monograph will be distributed from the *Pain Medicine News* exhibit booth at national conferences. *Pain Medicine News* has a presence at 7 conferences throughout the year at which the monograph may be distributed at:

- American Academy of Pain Medicine
- American Academy of Pain Management
- American Conference on Pain Medicine
- American Pain Society
- American Society of Regional Anesthesia and Pain Medicine Spring Meeting
- American Society of Regional Anesthesia and Pain Medicine Fall Meeting
- North American Neuromodulation Society

Live and Online Components

Live recruitment, awareness, and distributions campaigns will include attendance at various medical congresses and other relevant satellite pain meetings throughout the year. At these meetings, in addition to recruitment, awareness and distribution of ongoing programs to attendees, enrollment into the *PainClinician™* database and program will occur. A thorough online campaign including, but not limited to, MedScape, www.pain.edu, Sermo and other pain-related services, to generate interest in

existing and future educational programs will also ensure maximizing the uptake, awareness, acceptance, and ultimately, participation in the ongoing series of educational programs.

VI. Budgets

Please see attached

Center for Continuing Medical Education

Bridging the Gap Between Education and Practice

Albert Einstein
College of Medicine
of Yeshiva University

The University Hospital and
Academic Medical Center for the
Albert Einstein College of Medicine

November 6, 2008

Steven Jay Feld
Associate Director

Educational Grant Review Committee
Cephalon

Dear Sir and/or Madam:

On behalf of the Albert Einstein College of Medicine & Montefiore Medical Center, Center of Continuing Medical Education (CCME) and our Educational Collaborator and Joint Sponsor, Asante Communications LLC, I am requesting an educational grant from Cephalon in the amount of $1,462,375.00 to be used to help support several CME accredited activities. These activities will focus on the topic of chronic pain management with the goal of providing clinicians with a learning forum to develop practical methods to appropriately assess and manage pain

CCME, with assistance from its educational collaborator, Asante Communications LLC, an organization with professional staff that have extensive experience in developing and implementing activities such as those being proposed, is planning to develop a series of CME activities to address issues of pain management and to provide physicians with the necessary best-practice skills to be able to better diagnose and treat issues in pain management. The activities will include:

- three (3) cases and commentary live meetings
- one (1) monograph to be developed from materials presented at the cases and commentary meetings
- one (1) on-line monograph (same as above)
- eight (8) live teleconferences available for participation at separate times
- one (1) monograph to be developed from the materials presented during the teleconferences
- one (1) on-line monograph (same as above)
- one (1) live regional meeting
- one (1) satellite webcast which will include highlights from the live regional meeting
- one (1) non-CME international forum of experts, which will be used to develop a CME activity
- one (1) CME position paper developed from the above international forum of experts
- one (1) on-line position paper (same as above)
- one (1) pain/risk management compendium to assist physicians in their clinical settings
- one (1) on-line pain/risk management compendium (same as above)

Each of these activities will include outcomes surveys to measure the practice performance changes of the participants of each activity. A further outcomes study/preceptorship, utilizing a control group to measure and compare the effectiveness of continued educational interventions between the control group's practice performance and the group receiving additional educational interventions will be conducted and will include participants from the cases and commentary, teleconferences and regional meeting. Participants in this outcome study will be given an opportunity to opt in.

3301 Bainbridge Avenue, Bronx, NY 10467 Phone (718) 920-6071 Fax (718) 798-2336 ace@aecme.org sfeld@montefiore.org

As an additional option we are offering to develop and execute a final outcome study, which will poll from a select group of participants from the above outcome study. The physicians would agree to join a final IRB approved study, which will assess patient satisfaction. This study will be developed and overseen by an approved IRB entity and will seek input from patients that agree to be part of the study.

The working title of this comprehensive initiative is, *Persistent and Breakthrough Pain: A Multidimensional Assessment and Multimodal Opioid-Based Treatment Strategies Initiative.*

Faculty for this initiative will be chosen to develop unique learning opportunities, which will enable pain management specialists, which will include: neurologists, rheumatologists, physiatrists, primary care physicians, internal medicine physicians, anesthesiologists and oncologists to increase their competence and abilities to treat and appropriately manage pain and learn important methods to incorporate risk management strategies into pain management plans.

We will be using the requested grant for all the expenses related to the organization, capture and development of materials and for the accreditation and assessments of these CME activities

The purpose of this letter is to provide you with information on how CCME is planning to organize all the logistics related to the production and accreditation of these activities

The Albert Einstein College of Medicine and Montefiore Medical Center, Center for Continuing Medical Education and its Educational Collaborator and Joint sponsor, Asante Communications LLC, or our agents, will take full responsibility for both the medical content and logistical aspects of the following:

- Select faculty and topics
- Provide a faculty reviewer to make sure that all materials are free of bias and of professional scientific merit
- Develop a marketing plan to reach an audience of appropriate participants
- Provide sponsorship of the activities and maintain all books and records
- File and prepare all appropriate documentation to allow the activities to be certified by Albert Einstein College of Medicine for AMA PRA credit
- Administrate all financial accounting and bookkeeping
- Prepare, distribute and summarize course evaluations
- Develop, distribute and summarize outcomes surveys
- Maintain records of participants, grade quizzes and provide certificates to requesters
- Review and oversee the development of materials to ensure that the enduring material activities are in compliance with the AMA and ACCME Guidelines

Each of the activities will be reviewed by one of our renowned faculty, who is a specialist in the field of pain management They will also be responsible for working with Asante Communications LLC to identify needs, learner gaps, objectives, appropriate faculty and determine topics.

Our tax ID number is 13 1740114 (Montefiore Medical Center).

3301 Bainbridge Avenue Bronx, N.Y. 10467 Phone 718.920.6071 Fax 718.796.2536 meetcme.org sfeldmancme@aol.com

The provider requires that:

- All significant relationships (e.g. consulting, grant recipient, etc.) between Cephalon and faculty members, or any individual in a position to influence content must be disclosed to the participants of its CME activities
- All commercial interest support be disclosed to participants prior to their participation in its CME activities
- All COIs of faculty, or anyone in a position to influence content will be resolved through mechanisms of resolution developed by Einstein for all its CME activities

Einstein requires that its LOA with Cephalon be signed by Victor B. Hatcher, PhD, Associate Dean of CME at Albert Einstein College of Medicine and Director of CME at Montefiore Medical Center, or Steven Jay Feld, Associate Director of CME at Albert Einstein College of Medicine & Montefiore Medical Center.

Please make checks payable to Montefiore Medical Center.

Montefiore Medical Center is the University Hospital for the Albert Einstein College of Medicine and all Albert Einstein College of Medicine, CME finances are handled by Montefiore Medical Center.

Check payments should be remitted to:
CCME
3301 Bainbridge Avenue
Bronx, NY 10467
Attn: Steven Feld

Any unused funds that were received from Cephalon in support of these activities will be returned to Cephalon upon completion of reconciliation.

If you need any further information or have any questions that relate to this grant request please contact me at 718 920-6674, ext. 232.

On behalf of Albert Einstein College of Medicine & Montefiore Medical Center, I would like to thank Cephalon for consideration of this request.

Sincerely,

Steven Jay Feld

cc: Asante Communications LLC

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.

2569

Persistent and Breakthrough Pain

Multidimensional Assessment and Multimodal Opioid Based Treatment Strategies

An Educational Platform Initiative

EINSTEIN

MONTEFIORE Medical Center
The University Hospital for the Albert Einstein College of Medicine

Jasonic Communications

Cephalon

Cephalon, Inc.

October 26, 2009

Interventions, Outcomes, and Status Meeting

Table of Contents

Compendium. Release. 2009
APS
AAPM
AAPMR.
Painclinician data.

October 26, 2009

Educational Grant Review Committee
Cephalon, Inc.

Dear Sir and/or Madam:

On behalf of the Albert Einstein College of Medicine & Montefiore Medical Center, Center of Continuing Medical Education (CCME) and our Educational Collaborator and Joint Sponsor, Asante Communications LLC, I wish to present some information for Grant #2569, titled *Persistent and Breakthrough Pain: Multidimensional Assessment and Multimodal Opioid-Based Treatment Strategies.*

Please find enclosed synopses and/or evaluation summaries from these educational tactics that have been completed to date: 1 Teleconference Series (April 2009), 3 Cases and Commentary™ Workshops (April, May, and September 2009), 1 Full-Day Regional Meeting (June 2009), 3 Live-Streaming Web-Based Tutorials (August and September 2009), 1 International Experts Forum (September 2009), and 1 Spin-off Satellite Webcast (October 2009). These documents will serve as reference materials for this meeting.

Kindly please note that based on faculty recommendations and/or availability, the timing for several initiatives has been revised from the timeline included in the original grant request. The following schematic reflects the revised timeline of the platform deliverables.

Programs	Distribution	Total reach	Quarter 1			Quarter 2			Quarter 3			Quarter 4		
			J	F	M	A	M	J	J	A	S	O	N	D
International Experts Forum	Live Event	30							◆	———	◆		◆	
Cases and Commentary	Live Event	225	◆	———	◆	◆	◆				◆			
Full-Day Regional Meeting	Live Event	75-100	◆	———	———	———	———	◆						
Teleconference Series	Live Event	200-400	◆	———	———	◆								
Full-Day Regional Satellite Webcast	PAINClinician.com™	20-25,000								◆	———	◆		
Teleconference Print Monograph/Online	APS, AAPM, AAPM&R PAINClinician.com™	45-60,000								◆	———	◆		
Pain/Risk Management Compendium	APS, AAPM, AAPM&R PAINClinician.com™	45-60,000								◆	———	———	◆	
International Experts Forum Position Paper/Online	APS, AAPM, AAPM&R PAINClinician.com™	45-60,000								◆	———	———	◆	
Preceptorship Program		300	◆	———	———	———	———	———	———	———	———	———	———	◆

Finally, the following educational tactics are in development and will be delivered in Q4 2009: 1 Cases and Commentary™/Teleconference Series Spin-off Monograph, 1 International Experts Forum Monograph, 1 Pain and Risk Compendium.

Sincerely,

Steven Jay Feld

Teleconference Schedule

Date	Time	Faculty
Monday, April 20, 2009	NOON–1:00 PM	Perry G. Fine, MD
Monday, April 20, 2009	6:30 PM–7:30 PM	Perry G. Fine, MD
Tuesday, April 21, 2009	6:30 PM–7:30 PM	Lynn R. Webster, MD
Tuesday, April 21, 2009	8:00 PM–9:00 PM	Michael J. Brennan, MD
Wednesday, April 22, 2009	NOON–1:00 PM	Michael J. Brennan, MD
Wednesday, April 22, 2009	6:30 PM–7:30 PM	Lynn R. Webster, MD
Thursday, April 23, 2009	NOON–1:00 PM	David M. Simpson, MD
Thursday, April 23, 2009	8:00 PM–9:00 PM	David M. Simpson, MD

Faculty

Perry G. Fine, MD—PROGRAM CHAIR
Salt Lake City, Utah

Michael J. Brennan, MD
Fairfield, Connecticut

David M. Simpson, MD
New York, New York

Lynn R. Webster, MD
Salt Lake City, Utah

CCME Reviewer

David M. Kaufman, MD
Bronx, New York

Learning Objectives

At the completion of this initiative, participants should be better prepared to:

- Implement a continuous, multidimensional, and vigilant assessment of persistent and breakthrough pain based, in part, on the phenomenology and inferred pathophysiology of the pain syndrome, patient function, goals, and level of risk
- Select appropriate patients for opioid-based management of persistent and breakthrough pain
- Employ multimodal treatment strategies tailored to the multidimensional pain assessment of patients with persistent and breakthrough pain
- Explain the respective roles of long-acting, short-acting, and rapid-onset opioids in the management of persistent and breakthrough pain

Participation and Metrics

Total registrants and certifications issued to date: **280**

170-180

Course Evaluation

April 20-23, 2009

Number of Registrants: 280

1. **Did the learning objectives, which clarify specific steps to address educational gaps (current vs best practices, meet the overall purpose of the activity?**

		Response Rate
Objective 1:	Implement a continuous, multidimensional, and vigilant assessment of persistent and breakthrough pain based, in part, on the phenomenology and inferred pathophysiology of the pain syndrome, patient function, goals, and level of risk	
	Yes	97.22%
	No	2.78%
Objective 2:	Select appropriate patients for opioid-based management of persistent and breakthrough pain	
	Yes	98.61%
	No	1.39%
Objective 3:	Employ multimodal treatment strategies tailored to the multidimensional pain assessment of patients with persistent and breakthrough pain	
	Yes	97.22%
	No	2.78%
Objective 4:	Explain the respective roles of long-acting, short-acting, and rapid-onset opioids in the management of persistent and breakthrough pain	
	Yes	98.59%
	No	1.41%

2. **What percentage of the presentation was effective in teaching you something new?**

90%	11.27%
70%	26.76%
50%	28.17%
30%	23.94%
10%	9.86%

3. **This activity provided evidence-based information that will be useful to me in my job or practice.**

Yes	97.26%
No	2.74%

4. **Did the information received today confirm how you treat/manage patients?**

Yes	95.89%
No	4.11%

5. **Will you make changes that will benefit patient care as a result of information received? If yes, please describe.**

Yes	80.95%
No	19.05%

Comments

1. Teach other professionals
2. Education
3. Include education materials
4. Better counseling
5. Identify opioid tolerant patients
6. Get the opioid agreements instituted in any office
7. More aware of BTP
8. Will reevaluate my use of opioids in my clinical practice
9. Screening patients more often
10. Better prepared to share this info with my patients and peers
11. Get additional assistance managing medium-risk patients
12. Consider rapid-onset opioids for breakthrough pain in more circumstances
13. Ratio between long- and short-acting opioids
14. Better assessment and management of BTP
15. Assessment of BTP
16. Drug rotation
17. Carefully consider benefits and risks of opioid therapy for chronic pain
18. Better assessment/asking about BTP
19. Consider other options
20. More accurate categorization of patient's status
21. SOAPP-R score outcome
22. Risk stratification
24. Better techniques for BTP assessment
25. Update assessment on chronic pain patients
26. Assess and listen to patient
27. Consider using fentanyl for BTP
28. Reaffirmation of current practice parameters
29. Evaluate patients more thoroughly before prescribing
30. Use combination therapies more frequently
31. Better assess and follow patient on pain treatments
32. Use of newer delivery forms of fentanyl for breakthrough pain
33. Prescribe more TCAs than SSRIs for neuropathic pain

6. What subject matter not presented in this activity do you think should be included in future activities?

Comments

1. More highlights about fentanyl
2. Complex & difficult topic, managing the uninsured a terrible problem
3. Focus on the pediatric patient
4. Methods of opioid rotation, side effect management
5. More focus on etiology of BTP
6. More detail about dosing rapid-onset fentanyl for patients including starting doses
7. More case studies
8. How to handle pain in methadone clinic patients
9. Pain management in a patient with consistent multiple medical problems
10. Pain management in psychiatric patients
11. More detailed discussion of specific drugs

12. Management of addicted patients
13. Side effects
14. Opioid rotation/Dose conversion
15. Details regarding prescribed monitoring program
16. In depth review of non-pharmacological modalities effective for treatment of neuropathic pain or BTP
17. Pediatric pain
18. Dosages for medications
19. Integrate/share risk assessment (Universal Precaution Paradigm) in chronic pain setting
20. Factors in opting for long-acting opioids when a patient is controlled by short acting opioids
21. Non-addictive, non-toxic naturalization medications as in German literature "Lipoic Acid", "Tumeric" for pain
22. Use of breakthrough medications in patients on intrathecal therapies

7. Was this CME activity "free of commercial bias" for or against any product?

Yes	87.88%
No	12.12%

Optional Questions

8. In comparison with other similar activities, how would you rate this activity?

Excellent:	55.88%
Good:	35.29%
Average:	7.35%
Fair:	1.47%
Poor:	0.00%

9. How would you rate this activity in the quality of its organization and professional manner in which it was conducted?

Excellent:	65.22%
Good:	31.88%
Average:	2.90%
Fair:	0.00%
Poor:	0.00%

My Customer Service Experience

10. Pre-/Off-site Registration

Excellent:	76.12%
Good:	23.88%
Average:	0.00%
Fair:	0.00%
Poor:	0.00%

11. Other:

Excellent:	67.65%
Good:	23.53%
Average:	2.94%
Fair:	5.88%
Poor:	0.00%

12. I wash my hands before and after each patient encounter.

Always:	64.18%
Most of the Time:	31.34%
Sometimes:	4.48%
Never:	0.00%

13. As of today, I will wash my hands before and after each patient encounter.

Always:	78.79%
Most of the Time:	15.15%
Sometimes:	6.06%
Never:	0.00%

Speaker Evaluation

April 20-23, 2009

	Ability to Communicate	How Well Was Topic Covered?	Objectivity, Balance, & Scientific Rigor	Relevance to Your Practice
Michael J. Brennan, MD				
Superior	40%	43.48%	33.33%	34.78%
Excellent	52%	43.48%	58.33%	52.17%
Satisfactory	8%	13.04%	8.33%	13.04%
Unsatisfactory	0%	0%	0%	0%
Presentation Addressed Gaps in Changing Your				
Competence:	29.03%			
Performance:	32.26%			
Patient Outcomes:	38.71%			
Perry G. Fine, MD				
Superior	41.67%	54.55%	54.55%	27.27%
Excellent	41.67%	18.18%	18.18%	36.36%
Satisfactory	8.33%	27.27%	18.18%	36.36%
Unsatisfactory	8.33%	0%	9.09%	0%
Presentation Addressed Gaps in Changing Your				
Competence:	22.22%			
Performance:	44.44%			
Patient Outcomes:	33.33%			
David M. Simpson, MD				
Superior	42.86%	38.46%	38.46%	53.85%
Excellent	50%	61.54%	53.85%	38.46%
Satisfactory	7.14%	0%	7.69%	7.69%
Unsatisfactory	0%	0%	0%	0%
Presentation Addressed Gaps in Changing Your				
Competence:	30%			
Performance:	50%			
Patient Outcomes:	20%			

	Ability to Communicate	How Well Was Topic Covered?	Objectivity, Balance, & Scientific Rigor	Relevance to Your Practice
Lynn R. Webster, MD				
Superior	47.62%	52.38%	57.14%	52.38%
Excellent	42.86%	42.86%	38.10%	42.86%
Satisfactory	9.52%	4.76%	4.76%	4.76%
Unsatisfactory	0%	0%	0%	0%
Presentation Addressed Gaps in Changing Your				
Competence:	30.77%			
Performance:	38.46%			
Patient Outcomes:	30.77%			

Persistent and Breakthrough Pain

Multidimensional Assessment and Multimodal Opioid-Based Treatment Strategies

Cases and Commentary™ Workshop

Saturday, April 25, 2009 | 8:00 am–12:00 pm
The Westin Copley Place | Boston, Massachusetts

Faculty

Charles E. Argoff, MD—PROGRAM CHAIR
Albany, New York

Daniel Brookoff, MD, PhD
Denver, Colorado

Michael G. Byas-Smith, MD
Atlanta, Georgia

James P. Rathmell, MD
Boston, Massachusetts

B. Todd Sitzman, MD, MPH
Hattiesburg, Mississippi

CCME Reviewer

David M. Kaufman, MD
Bronx, New York

Learning Objectives

At the completion of this initiative, participants should be better prepared to:

- Define, recognize, and independently assess breakthrough and persistent pain in patients with chronic pain syndromes
- Implement a multidimensional, continual, and vigilant assessment of persistent and breakthrough pain based, in part, on the phenomenology and inferred pathophysiology of the pain syndrome, patient function, goals, and level of risk
- Select appropriate patients for opioid-based management of persistent and breakthrough pain
- Employ multimodal opioid-based therapies tailored to the multidimensional pain assessment of patients with persistent and breakthrough pain
- Explain the respective roles of long-acting, short-acting, and rapid-onset opioids in the management of persistent and breakthrough pain

Participation and Metrics

Total attendee and certifications issued to date: **38**

Course Evaluation

April 25, 2009 | Boston, Massachusetts
Total Number of Attendees: 38

1. **Did the learning objectives, which clarify specific steps to address educational gaps (current vs best practices), meet the overall purpose of the activity?**

		Response Rate
Objective 1:	Define, recognize, and independently assess breakthrough and persistent pain in patients with chronic pain syndromes	
	Yes	100%
	No	0%
Objective 2:	Implement a multidimensional, continual, and vigilant assessment of persistent and breakthrough pain based, in part, on the phenomenology and inferred pathophysiology of the pain syndrome, patient function, goals, and level of risk	
	Yes	100%
	No	0%
Objective 3:	Select appropriate patients for opioid-based management of persistent and breakthrough pain	
	Yes	100%
	No	0%
Objective 4:	Employ multimodal opioid-based therapies tailored to the multidimensional pain assessment of patients with persistent and breakthrough pain	
	Yes	100%
	No	0%
Objective 5:	Explain the respective roles of long-acting, short-acting, and rapid-onset opioids in the management of persistent and breakthrough pain	
	Yes	100%
	No	0%

2. **What percentage of the presentation was effective in teaching you something new?**

0%	45%
70%	20%
50%	20%
30%	15%
10%	0%

3. **This activity provided evidence-based information that will be useful to me in my job or practice.**

Yes	100%
No	0%

4. **Did the information received today confirm how you treat/manage patients?**

Yes	100%
No	0%

5. Will you make changes that will benefit patient care as a result of information received?

Yes	100%
No	0%

If yes, please describe.

Comments

1. Better use of standardized risk assessment tools
2. Prescribe opioids
3. More formal upfront assessment using a tool to assess for potential dependence and/or abuse
4. More patient education regarding issues
5. Better viewpoint of where opioids fit on a continuum of care
6. Use of charts

6. What subject matter not presented in this activity do you think should be included in future activities?

Comments

1. Urine drug testing
2. Pharmacodynamics and pharmacokinetics of pain drugs
3. A little more interdisciplinary approach, although I realize this was not purpose of program
4. Alternative pain therapies
5. Interventional role-IT/SCS
6. Apply and document risk stratification

7. Was this CME activity "free of commercial bias" for or against any product?

Yes	100%
No	0%

Optional Questions

8. In comparison with other similar activities, how would you rate this activity?

Excellent:	90%
Good:	10%
Average:	0%
Fair:	0%
Poor:	0%

9. How would you rate this activity in the quality of its organization and professional manner in which it was conducted?

Excellent:	80%
Good:	20%
Average:	0%
Fair:	0%
Poor:	0%

My Customer Service Experience

10. Pre-/Off-site Registration

Excellent:	89.47%
Good:	10.53%
Average:	0%
Fair:	0%
Poor:	0%

11. Onsite Registration

Excellent:	100%
Good:	0%
Average:	0%
Fair:	0%
Poor:	0%

12. Interaction With Staff/Workshop Facilitators

Excellent:	89.47%
Good:	10.53%
Average:	0%
Fair:	0%
Poor:	0%

13. Conference Facilities

Excellent:	90%
Good:	10%
Average:	0%
Fair:	0%
Poor:	0%

14. Other:

Excellent:	100%
Good:	0%
Average:	0%
Fair:	0%
Poor:	0%

Comments

I did not expect this format to be as useful as it was—very practical. I can use this information.

15. I wash my hands before and after each patient encounter.

Always:	75%
Most of the Time:	25%
Sometimes:	0%
Never:	0%

16. As of today, I will wash my hands before and after each patient encounter.

Always:	75%
Most of the Time:	25%
Sometimes:	0%
Never:	0%

Speaker Evaluation

April 25, 2009 | Boston, Massachusetts

	Ability to Communicate	How Well Was Topic Covered?	Objectivity, Balance, & Scientific Rigor	Relevance to Your Practice
Charles E. Argoff, MD				
Superior	100%	100%	100%	100%
Excellent	0%	0%	0%	0%
Satisfactory	0%	0%	0%	0%
Unsatisfactory	0%	0%	0%	0%
Presentation Addressed Gaps in Changing Your				
Competence:	33%			
Performance:	34%			
Patient Outcomes:	33%			
Daniel Brookoff, MD, PhD				
Superior	100%	100%	100%	100%
Excellent	0%	0%	0%	0%
Satisfactory	0%	0%	0%	0%
Unsatisfactory	0%	0%	0%	0%
Presentation Addressed Gaps in Changing Your				
Competence:	33%			
Performance:	34%			
Patient Outcomes:	33%			
Michael G. Byas-Smith, MD				
Superior	100%	100%	100%	100%
Excellent	0%	0%	0%	0%
Satisfactory	0%	0%	0%	0%
Unsatisfactory	0%	0%	0%	0%
Presentation Addressed Gaps in Changing Your				
Competence:	34%			
Performance:	33%			
Patient Outcomes:	33%			

	Ability to Communicate	How Well Was Topic Covered?	Objectivity, Balance, & Scientific Rigor	Relevance to Your Practice
James P. Rathmell, MD				
Superior	100%	100%	100%	100%
Excellent	0%	0%	0%	0%
Satisfactory	0%	0%	0%	0%
Unsatisfactory	0%	0%	0%	0%
Presentation Addressed Gaps in Changing Your				
Competence:	40%			
Performance:	30%			
Patient Outcomes:	30%			
B. Todd Sitzman, MD, MPH				
Superior	80%	67%	78%	75%
Excellent	20%	33%	11%	13%
Satisfactory	0%	0%	11%	12%
Unsatisfactory	0%	0%	0%	0%
Presentation Addressed Gaps in Changing Your				
Competence:	38%			
Performance:	31%			
Patient Outcomes:	31%			

Persistent and Breakthrough Pain

Multidimensional Assessment and Multimodal Opioid-Based Treatment Strategies

Cases and Commentary™ Workshop

Saturday, May 30, 2009 | 8:00 AM–12:00 PM

Parc 55 Hotel | San Francisco, California

Faculty

Perry G. Fine, MD—PROGRAM CHAIR
Salt Lake City, Utah

Michael J. Brennan, MD
Fairfield, Connecticut

Scott M. Fishman, MD
Sacramento, California

David M. Simpson, MD, MPH
New York, New York

Mark S. Wallace, MD
San Diego, California

Donna S. Zhukovsky, MD
Houston, Texas

CCME Reviewer

David M. Kaufman, MD
Bronx, New York

Learning Objectives

At the completion of this initiative, participants should be better prepared to:

- Define, recognize, and independently assess breakthrough and persistent pain in patients with chronic pain syndromes
- Implement a multidimensional assessment of persistent and breakthrough pain based, in part, on the phenomenology and inferred pathophysiology of the pain syndrome, patient function, goals, and level of risk
- Select appropriate patients for opioid-based management of persistent and breakthrough pain
- Employ multimodal opioid-based therapies for patients with persistent and breakthrough pain
- Explain the respective roles of long-acting, short-acting, and rapid-onset opioids in the management of persistent and breakthrough pain

Participation and Metrics

Total attendees and certifications issued to date: **34**

Course Evaluation

May 30, 2009 | San Francisco, California

Total Number of Attendees: 34

1. **Did the learning objectives, which clarify specific steps to address educational gaps (current vs best practices), meet the overall purpose of the activity?**

		Response Rate
Objective 1:	Define, recognize, and independently assess breakthrough and persistent pain in patients with chronic pain syndromes	
	Yes	100%
	No	0%
Objective 2:	Implement a multidimensional assessment of persistent and breakthrough pain based, in part, on the phenomenology and inferred pathophysiology of the pain syndrome, patient function, goals, and level of risk	
	Yes	100%
	No	0%
Objective 3:	Select appropriate patients for opioid-based management of persistent and breakthrough pain	
	Yes	100%
	No	0%
Objective 4:	Employ multimodal opioid-based therapies for patients with persistent and breakthrough pain	
	Yes	100%
	No	0%
Objective 5:	Explain the respective roles of long-acting, short-acting, and rapid-onset opioids in the management of persistent and breakthrough pain	
	Yes	100%
	No	0%

2. **What percentage of the presentation was effective in teaching you something new?**

90%	40%
70%	47%
50%	7%
30%	6%
10%	0%

3. **This activity provided evidence-based information that will be useful to me in my job or practice.**

Yes	100%
No	0%

4. **Did the information received today confirm how you treat/manage patients?**

Yes	100%
No	0%

5. Will you make changes that will benefit patient care as a result of information received today? If yes, please describe.

Yes	67%
No	33%

Comments

1. Less likely to image back pain patients; will try pregabalin
2. Consider using scales
3. Opioid dosing for chronic pain (x2)
4. Better use of screening tools

6. What subject matter not presented in this activity do you think should be included in future activities?

Comments

1. Providing scales (i.e., Brief Pain Inventory) would be helpful, so I can use them in my practice

7. Was this CME activity "free of commercial bias" for or against any product?

Yes	93%
No	7%

Optional Questions

8. In comparison with other similar activities, how would you rate this activity?

Excellent:	67%
Good:	33%
Average:	0%
Fair:	0%
Poor:	0%

9. How would you rate this activity in the quality of its organization and professional manner in which it was conducted?

Excellent:	73%
Good:	27%
Average:	0%
Fair:	0%
Poor:	0%

My Customer Service Experience

10. Pre-/Off-site Registration

Excellent:	73%
Good:	27%
Average:	0%
Fair:	0%
Poor:	0%

11. Onsite Registration

Excellent:	60%
Good:	40%
Average:	0%
Fair:	0%
Poor:	0%

12. Interaction With Staff/Workshop Facilitators

Excellent:	86%
Good:	14%
Average:	0%
Fair:	0%
Poor:	0%

13. Conference Facilities

Excellent:	64%
Good:	29%
Average:	7%
Fair:	0%
Poor:	0%

14. Other:

Excellent:	100%
Good:	0%
Average:	0%
Fair:	0%
Poor:	0%

Comments

1. Good onsite signage directing participants to registration.

15. I wash my hands before and after each patient encounter.

Always:	79%
Most of the Time:	21%
Sometimes:	0%
Never:	0%

16. As of today, I will wash my hands before and after each patient encounter.

Always:	91%
Most of the Time:	9%
Sometimes:	0%
Never:	0%

Speaker Evaluation

May 30, 2009 | San Francisco, CA

	Ability to Communicate	How Well Was Topic Covered?	Objectivity, Balance, & Scientific Rigor	Relevance to Your Practice
Michael J. Brennan, MD				
Superior	29%	20%	20%	40%
Excellent	71%	80%	80%	60%
Satisfactory	0%	0%	0%	0%
Unsatisfactory	0%	0%	0%	0%
Perry G. Fine, MD				
Superior	60%	63%	63%	75%
Excellent	40%	37%	25%	25%
Satisfactory	0%	0%	12%	0%
Unsatisfactory	0%	0%	0%	0%
Scott M. Fishman, MD				
Superior	50%	33%	33%	33%
Excellent	50%	67%	67%	67%
Satisfactory	0%	0%	0%	0%
Unsatisfactory	0%	0%	0%	0%
David M. Simpson, MD, MPH				
Superior	40%	33%	33%	33%
Excellent	60%	67%	67%	67%
Satisfactory	0%	0%	0%	0%
Unsatisfactory	0%	0%	0%	0%
Mark S. Wallace, MD				
Superior	50%	50%	67%	67%
Excellent	50%	33%	33%	33%
Satisfactory	0%	17%	0%	0%
Unsatisfactory	0%	0%	0%	0%

	Ability to Communicate	How Well Was Topic Covered?	Objectivity, Balance, & Scientific Rigor	Relevance to Your Practice
Donna S. Zhukovsky, MD				
Superior	100%	100%	100%	100%
Excellent	0%	0%	0%	0%
Satisfactory	0%	0%	0%	0%
Unsatisfactory	0%	0%	0%	0%

Persistent and Breakthrough Pain

Multidimensional Assessment and Multimodal Opioid-Based Treatment Strategies

Cases and Commentary™ Workshop

Friday, September 11, 2009 | 4:30 PM–8:30 PM

The Hyatt Regency Jacksonville Riverfront | Jacksonville, Florida

Faculty

B. Todd Sitzman, MD, MPH—PROGRAM CHAIR
Hattiesburg, Mississippi

Paul M. Arnstein, RN, PhD
Boston, Massachusetts

Patricia M. Bruckenthal, PhD, RN, ANP-C
Stony Brook, New York

Deb B. Gordon, RN, MS
Madison, Wisconsin

Keela A. Herr, PhD, RN
Iowa City, Iowa

April Hazard Vallerand, PhD, RN
Detroit, Michigan

CCME Reviewer

David M. Kaufman, MD
Bronx, New York

@ASPMN

Learning Objectives

At the completion of this initiative, participants should be better prepared to:

- Define, recognize, and independently assess breakthrough and persistent pain in patients with chronic pain syndromes
- Perform multidimensional and continual assessments of persistent and breakthrough pain based, in part, on the phenomenology and inferred pathophysiology of the pain syndrome, as well as patient function and treatment goals
- Discuss important steps in the implementation, optimization, and long-term monitoring of multimodal opioid-based therapies for persistent and breakthrough pain with patients, families, caregivers, and physicians
- Explain the respective roles of long-acting, short-acting, and rapid-onset opioids in the management of persistent and breakthrough pain

Participation

Total attendees and certifications issued to date: **60**

Course Evaluation

September 11, 2009 | Jacksonville, Florida

Total Number of Attendees: 60

1. **Did the learning objectives, which clarify specific steps to address educational gaps (current vs best practices), meet the overall purpose of the activity?**

	Response Rate
Objective 1: Define, recognize, and independently assess breakthrough and persistent pain in patients with chronic pain syndromes	
Yes	96%
No	4%
Objective 2: Perform multidimensional and continual assessments of persistent and breakthrough pain based, in part, on the phenomenology and inferred pathophysiology of the pain syndrome, as well as patient function and treatment goals	
Yes	96%
No	4%
Objective 3: Discuss important steps in the implementation, optimization, and long-term monitoring of multimodal opioid-based therapies for persistent and breakthrough pain with patients, families, caregivers, and physicians	
Yes	98%
No	2%
Objective 4: Explain the respective roles of long-acting, short-acting, and rapid-onset opioids in the management of persistent and breakthrough pain	
Yes	96%
No	4%

2. **What percentage of the presentation was effective in teaching you something new?**

90%	33%
70%	27%
50%	32%
30%	8%
10%	0%

3. **This activity provided evidence-based information that will be useful to me in my job or practice.**

Yes	100%
No	0%

4. **Did the information received today confirm how you treat/manage patients?**

Yes	100%
No	0%

5. **Will you make changes that will benefit patient care as a result of information received today?**

Yes	89%
No	11%

If yes, please describe.

Comments

1. *Comprehensive risk assessments (x3)*
2. *Implement urine drug screening*
3. *Try to implement more specific pain rating questions*
4. *Use SOAPP-R and Passik's 5 A's*
5. *Implement opioid agreements for all patients (x2)*
6. *Use more pain evaluation tools*
7. *Better assessment of breakthrough pain (x2)*
8. *Try to question actual medication-taking protocol*
9. *Consider screening all patients, universally*
10. *Use new medications*
11. *Consider use of rapid-onset medications in lieu of short-acting opioids for breakthrough pain*

6. **What subject matter not presented in this activity do you think should be included in future activities?**

Comments

1. *None (x4)*
2. *We had a great table—nothing!*
3. *Posttraumatic stress disorder and traumatic brain injury*
4. *Nursing/legal responsibilities in pain management*
5. *Chemical dependency and mental illness in pain management*
6. *Nonopioid management of chronic pain*

7. **Was this CME activity "free of commercial bias" for or against any product?**

Yes	100%
No	0%

8. **The provider of the activity has disclosed in writing or verbally the conflict of interest or lack thereof declared by the planners and presenters/content specialists.**

Yes	100%
No	0%

Optional Questions

9. **In comparison with other similar activities, how would you rate this activity?**

Excellent:	88%
Good:	10%
Average:	2%
Fair:	0%
Poor:	0%

10. How would you rate this activity in the quality of its organization and professional manner in which it was conducted?

Excellent:	73%
Good:	27%
Average:	0%
Fair:	0%
Poor:	0%

My Customer Service Experience

11. Pre-/Off-site Registration

Excellent:	65%
Good:	31%
Average:	4%
Fair:	0%
Poor:	0%

12. Onsite Registration

Excellent:	76%
Good:	19%
Average:	5%
Fair:	0%
Poor:	0%

13. Interaction With Staff/Workshop Facilitators

Excellent:	70%
Good:	28%
Average:	2%
Fair:	0%
Poor:	0%

14. Conference Facilities

Excellent:	77%
Good:	19%
Average:	2%
Fair:	2%
Poor:	0%

15. Other:

Excellent:	100%
Good:	0%
Average:	0%
Fair:	0%
Poor:	0%

Comments

1. Excellent method of teaching
2. Dr Sitzman was excellent and encouraged our group to maximize our learning
3. This was fun!

16. I wash my hands before and after each patient encounter.

Always:	84%
Most of the Time:	16%
Sometimes:	0%
Never:	0%

If you did not answer "Always," please list any factors acting as barriers.

1. Not when I meet patients in the hall
2. Emergency situations
3. Short on time
4. Also use topical antiseptics

17. As of today, I will wash my hands before and after each patient encounter.

Always:	93%
Most of the Time:	7%
Sometimes:	0%
Never:	0%

Speaker Evaluation

	Ability to Communicate	How Well Was Topic Covered?	Objectivity, Balance, & Scientific Rigor	Relevance to Your Practice
Paul M. Arnstein, RN, PhD				
Superior	56%	50%	78%	63%
Excellent	44%	50%	22%	37%
Satisfactory	0%	0%	0%	0%
Unsatisfactory	0%	0%	0%	0%
Patricia M. Bruckenthal, PhD, RN, ANP-C				
Superior	88%	88%	88%	88%
Excellent	12%	12%	12%	12%
Satisfactory	0%	0%	12%	0%
Unsatisfactory	0%	0%	0%	0%
Deb B. Gordon, RN, MS				
Superior	50%	60%	50%	50%
Excellent	50%	40%	50%	50%
Satisfactory	0%	0%	0%	0%
Unsatisfactory	0%	0%	0%	0%
Keela A. Herr, PhD, RN				
Superior	91%	100%	82%	82%
Excellent	9%	0%	18%	18%
Satisfactory	0%	0%	0%	0%
Unsatisfactory	0%	0%	0%	0%
April Hazard Vallerand, PhD, RN				
Superior	71%	61%	71%	65%
Excellent	29%	33%	29%	35%
Satisfactory	0%	6%	0%	0%
Unsatisfactory	0%	0%	0%	0%
B. Todd Sitzman, MD, MPH				
Superior	60%	60%	70%	70%
Excellent	40%	40%	30%	30%
Satisfactory	0%	0%	0%	0%
Unsatisfactory	0%	0%	0%	0%

Persistent and Breakthrough Pain

Multidimensional Assessment and Multimodal Opioid-Based Treatment Strategies

Full-Day Regional Meeting

Saturday, June 13, 2009 | 8:00 AM–3:05 PM

The Grand Hyatt | New York, New York

Faculty

Russell K. Portenoy, MD—PROGRAM CHAIR
New York, New York

Michael J. Brennan, MD
Fairfield, Connecticut

Nathan I. Cherny, MBBS
Jerusalem, Israel

Subhash Jain, MD
New York, New York

Srinivas Nalamachu, MD
Overland Park, Kansas

Steven D. Passik, PhD
New York, New York

David M. Simpson, MD, MPH
New York, New York

Steven P. Stanos, DO
Chicago, Illinois

Theodore Wein, MD
Montréal, Québec, Canada

Sharon M. Weinstein, MD
Salt *Lake City, Utah*

CCME Reviewer

David M. Kaufman, MD
Bronx, New York

Learning Objectives

At the completion of this initiative, participants should be better prepared to:

- Define, recognize, and independently assess breakthrough and persistent pain in cancer survivors
- Implement a multidimensional, continual, and vigilant assessment of persistent and breakthrough pain based, in part, on the phenomenology and inferred pathophysiology of the pain syndrome, patient function, goals, and level of risk
- Select appropriate patients for opioid-based management of cancer- or treatment-related persistent and breakthrough pain
- Employ multimodal opioid-based therapies tailored to the multidimensional pain assessment of patients with persistent and breakthrough pain
- Explain the respective roles of long-acting, short-acting, and rapid-onset opioids in the management of persistent and breakthrough pain

Participation

Total attendees and certifications issued to date: **80**

Course Evaluation

June 13, 2009 | The Grand Hyatt | New York, New York

Total Number of Attendees: 80

1. **Did the learning objectives, which clarify specific steps to address educational gaps (current vs best practices) meet the overall purpose of the activity?**

		Response Rate
Objective 1:	Define, recognize, and independently assess breakthrough and persistent pain in cancer survivors	
	Yes	100%
	No	0%
Objective 2:	Implement a multidimensional, continual, and vigilant assessment of persistent and breakthrough pain based, in part, on the phenomenology and inferred pathophysiology of the pain syndrome, patient function, goals, and level of risk	
	Yes	100%
	No	0%
Objective 3:	Select appropriate patients for opioid-based management of cancer- or treatment-related persistent and breakthrough pain	
	Yes	100%
	No	0%
Objective 4:	Employ multimodal opioid-based therapies tailored to the multidimensional pain assessment of patients with persistent and breakthrough pain	
	Yes	98%
	No	2%
Objective 5:	Explain the respective roles of long-acting, short-acting, and rapid-onset opioids in the management of persistent and breakthrough pain	
	Yes	100%
	No	0%

2. **What percentage of the presentation was effective in teaching you something new?**

90% effective	30%
70% effective	32%
50% effective	21%
30% effective	14%
10% effective	3%

3. **This activity provided evidence-based information that will be useful to me in my job or practice.**

Yes	96%
No	4%

4. **Did the information received today confirm how you treat/manage patients?**

Yes	98%
No	2%

5. Will you make changes that will benefit patient care as a result of information received?

Yes	83%
No	17%

If yes, please describe.

Comments

1. *Assess risk for opioid abuse and addiction*
2. *Use multiple adjuvants*
3. *Use of new mandatory tools*
4. *Use of many newer agents to modify patient's pain*
5. *I treat patients who are on opioids for various reasons but I do not prescribe them myself*
6. *More likely to use a contract*
7. *More specific classification of patient application of modalities*
8. *Use of risk stratification*
9. *Risk stratify patients with chronic organic illness or BTP that will need opioid treatment*
10. *Maximize therapeutic regimen*
11. *Increased efficacy of therapy*
12. *Goal setting/evaluation of pain, even in long-time pain patients with chronic opioid use*
13. *Prescribe lower opioid dose in patients with uncertain etiology of pain*
14. *Evaluation of risk factors for potential abuse*
15. *Ceiling of opioid dosage*
16. *Fibromyalgia and migraine headache*
17. *Consider use of opioid risk tool*
18. *Improve risk stratification process; reassess for risk*
19. *Re-examine discharge and exit policy*
20. *APS-AAPM guidelines recommendations will help patients*
21. *Use risk assessment tools*
22. *Review treatment of patients in which risk outweighs benefit*
23. *Manage cancer pain*
24. *Will question patients about adherence*
25. *Thoroughly apply new guidelines*
26. *Will evaluate prior history of addiction and psychological problems*
27. *Start regularly using SOAPP*
28. *Increased frequency of UDT*
29. *Better assessment of addiction, diversion*
30. *Manage chronic cancer pain with baseline long-acting opioid analgesic*

6. What subject matter not presented in this activity do you think should be included in future activities?

Comments

1. *Additional presenters that incorporate other modalities that affect pain and its management*
2. *Very satisfied with program*
3. *Review of drug testing*
4. *How to communicate exit strategies to patients*
5. *Neuropathic pain*
6. *Specific prescription treatment for types of chronic pain*
7. *Use of adjunctive medications that can reduce dose of opioids*

8. PCA and intrathecal pumps
9. Practicality of information in real life
10. Pain practice
11. Treatment of acute pain
12. Noncancer pain management
13. Hospice pain

7. Was this CME activity "free of commercial bias" for or against any product?

Yes	98%
No	2%

Optional Questions

8. In comparison with other similar activities, how would you rate this activity?

Excellent:	58%
Good:	35%
Average:	5%
Fair:	2%
Poor:	0%

9. How would you rate this activity in the quality of its organization and professional manner in which it was conducted?

Excellent:	69%
Good:	27%
Average:	4%
Fair:	0%
Poor:	0%

My Customer Service Experience

10. Pre-/Off-site Registration

Excellent:	63%
Good:	32%
Average:	4%
Fair:	0%
Poor:	0%

11. Onsite Registration

Excellent:	60%
Good:	36%
Average:	4%
Fair:	0%
Poor:	0%

12. Interaction With Staff/Workshop Facilitators

Excellent:	58%
Good:	38%
Average:	4%
Fair:	0%
Poor:	0%

13. Conference Facilities

Excellent:	63%
Good:	29%
Average:	7%
Fair:	1%
Poor:	0%

14. Other

Excellent:	50%
Good:	50%
Average:	0%
Fair:	0%
Poor:	0%

15. I wash my hands before and after each patient encounter.

Always:	73%
Most of the Time:	20%
Sometimes:	5%
Never:	2%

16. As of today, I will wash my hands before and after each patient encounter.

Always:	78%
Most of the Time:	20%
Sometimes:	0%
Never:	2%

Speaker Evaluation

June 13, 2009 | The Grand Hyatt | New York, New York

	Ability to Communicate	How Well Was Topic Covered?	Objectivity, Balance, & Scientific Rigor	Relevance to Your Practice
Michael J. Brennan, MD				
Superior	38%	31%	38%	38%
Excellent	44%	49%	42%	44%
Satisfactory	18%	20%	20%	18%
Unsatisfactory	0%	0%	0%	0%
Nathan I. Cherny, MBBS				
Superior	25%	18%	24%	22%
Excellent	44%	52%	46%	53%
Satisfactory	31%	30%	30%	25%
Unsatisfactory	0%	0%	0%	0%
Subhash Jain, MD				
Superior	31%	28%	28%	33%
Excellent	44%	44%	47%	39%
Satisfactory	23%	28%	25%	28%
Unsatisfactory	2%	0%	0%	0%
Srinivas Nalamachu, MD				
Superior	27%	24%	21%	17%
Excellent	52%	52%	52%	52%
Satisfactory	18%	24%	27%	31%
Unsatisfactory	3%	0%	0%	0%
Steven D. Passik, PhD				
Superior	62%	52%	52%	52%
Excellent	35%	44%	42%	35%
Satisfactory	3%	4%	6%	13%
Unsatisfactory	0%	0%	0%	0%

	Ability to Communicate	How Well Was Topic Covered?	Objectivity, Balance, & Scientific Rigor	Relevance to Your Practice
Russell K. Portenoy, MD				
Superior	55%	52%	52%	54%
Excellent	37%	38%	35%	31%
Satisfactory	8%	10%	13%	15%
Unsatisfactory	0%	0%	0%	0%
David M. Simpson, MD, MPH				
Superior	31%	23%	27%	24%
Excellent	55%	57%	57%	59%
Satisfactory	15%	20%	16%	17%
Unsatisfactory	0%	0%	0%	0%
Steven P. Stanos, DO				
Superior	32%	27%	27%	20%
Excellent	54%	57%	57%	63%
Satisfactory	14%	16%	16%	17%
Unsatisfactory	0%	0%	0%	0%
Theodore Wein, MD				
Superior	27%	21%	21%	28%
Excellent	59%	62%	59%	55%
Satisfactory	14%	17%	20%	17%
Unsatisfactory	0%	0%	0%	0%
Sharon M. Weinstein, MD				
Superior	38%	36%	36%	37%
Excellent	45%	45%	47%	43%
Satisfactory	17%	19%	17%	20%
Unsatisfactory	0%	0%	0%	0%

International Experts Forum

Tuesday, September 1, 2009 | 8:00 AM–2:00 PM
Asante Communications, LLC | New York, New York

Stage I Faculty

Perry G. Fine, MD—PROGRAM CO-CHAIR
Salt Lake City, Utah

Russell K. Portenoy, MD—PROGRAM CO-CHAIR
Boston, Massachusetts

Roger Chou, MD
Portland, Oregon

Stage II Faculty

Andrew Davies, MD, MBBS
Surrey, United Kingdom

Sebastiano Mercadante, MD
Palermo, Italy

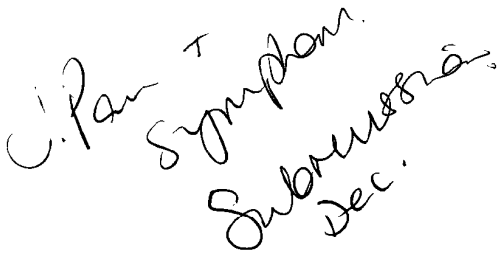
Christine A. Miaskowski, RN, PhD
San Francisco, California

Thomas Smith, MD
Richmond, Virginia

Giovambattista Zeppetella, MD
Essex, United Kingdom

CCME Reviewer

David M. Kaufman, MD
Bronx, New York



Full-Day Regional Meeting Satellite Webcast

Faculty

Russell K. Portenoy, MD—PROGRAM CHAIR
New York, New York

Steven D. Passik, PhD
New York, New York

Michael J. Brennan, MD
Fairfield, Connecticut

CCME Reviewer

David M. Kaufman, MD
Bronx, New York

Learning Objectives

At the completion of this initiative, participants should be better prepared to:

- Define, recognize, and independently assess breakthrough and persistent pain in cancer survivors
- Implement a multidimensional, continual, and vigilant assessment of persistent and breakthrough pain based, in part, on the phenomenology and inferred pathophysiology of the pain syndrome, patient function, goals, and level of risk
- Select appropriate patients for opioid-based management of cancer- or treatment-related persistent and breakthrough pain
- Employ multimodal opioid-based therapies tailored to the multidimensional pain assessment of patients with persistent and breakthrough pain
- Explain the respective roles of long-acting, short-acting, and rapid-onset opioids in the management of persistent and breakthrough pain

Persistent and Breakthrough Pain

Multidimensional Assessment and Multimodal Opioid-Based Treatment Strategies

Durable Outcomes Study Webcast Series

Monday, August 17, 2009 | 2:00 PM–2:30 PM
Monday, August 31, 2009 | 2:00 PM–2:30 PM
Monday, September 14, 2009 | 2:00 PM–2:30 PM

5-10 pee live intervention done. but less interactive 2nd were

Faculty

Perry G. Fine, MD
Salt Lake City, Utah

David M. Simpson, MD
New York, New York

Michael J. Brennan, MD
Fairfield, Connecticut

CCME Reviewer

David M. Kaufman, MD
Bronx, New York

Learning Objectives

At the completion of this initiative, participants should be better prepared to:

- Define, recognize, and independently assess breakthrough and persistent pain in patients with chronic pain syndromes
- Implement a multidimensional assessment of persistent and breakthrough pain based, in part, on the phenomenology and inferred pathophysiology of the pain syndrome, patient function, goals, and level of risk
- Select appropriate patients for opioid-based management of persistent and breakthrough pain
- Employ multimodal opioid-based therapies for patients with persistent and breakthrough pain
- Explain the respective roles of long-acting, short-acting, and rapid-onset opioids in the management of persistent and breakthrough pain

PAINClinician.com™

Overview

PAINClinician.com™ is an independently funded forum committed to improving clinician access to high quality pain education. PAINClinician.com™ provides clinicians with an opportunity to share their insights and experience managing patients with debilitating acute and chronic pain disorders. By consolidating resources already available and generating new educational materials tailored to the needs of the community—all identified through ongoing surveys posted throughout the site—this forum will, we believe, facilitate the exchange of ideas, help clinicians practice the art and science of pain medicine, and ultimately improve patient care. Primary care physicians, pain specialists, emergency room clinicians, surgeons, physiatrists, anesthesiologists, neurologists, pharmacists, physician assistants, nurse practitioners, nurses, and the countless other healthcare providers who treat pain are all invited to participate in this global community.

Editorial Board

Video Interviews

Visit **www.painclinician.com** to access our library of video commentary.

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