Emerging Solutions in Pain: The Interface of Pain and Addiction

Saturday, October 27, 2007
Chicago, Illinois

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Program Title: ESP Lecture Series
Mid West Pain Soc.
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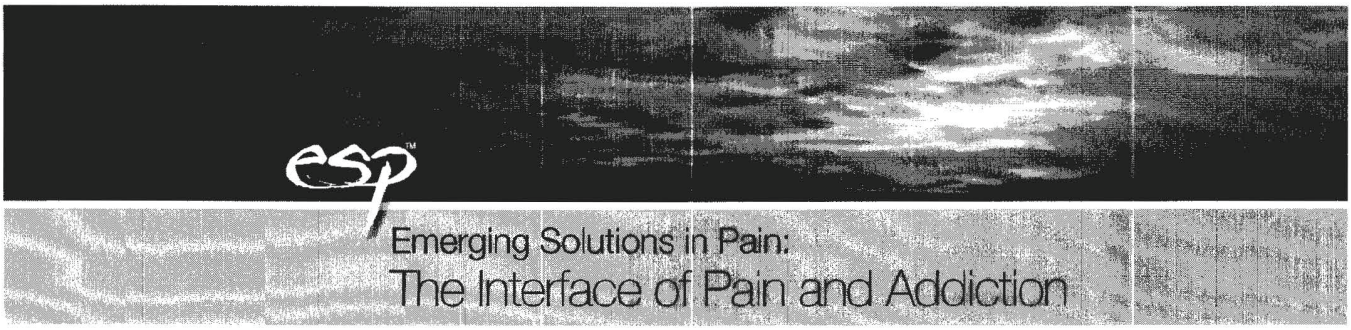
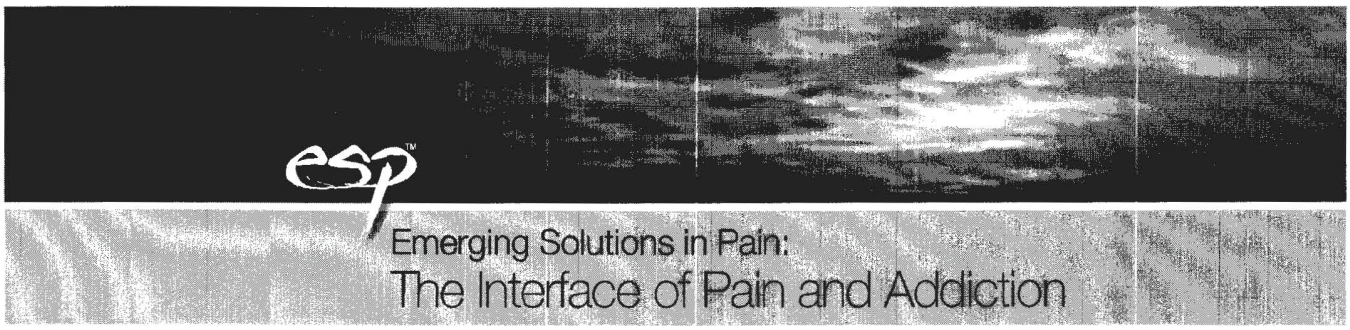
MCS



Saturday, October 27, 2007
Agenda

12:30 pm – 12:35 pm	Welcome and Introductions *Steven Stanos, DO* Program Chair
12:35 pm – 1:20 pm	Universal Precautions *Doug Gourlay, MD*
1:20 pm – 2:05 pm	Regulations Governing Opioid Treatment of Chronic Pain: How Federal and State Law Can Impact Healthcare Practice and Patient Care *Aaron Gilson, PhD*
2:05 pm – 2:50 pm	Understanding the Multidimensional Experience of Pain and Addiction *Lynn Webster, MD*
2:50 pm – 3:20 pm	Question and Answer Session *Panel*
3:20 pm – 3:30 pm	Conclusion and Adjournment *Steven Stanos, DO*

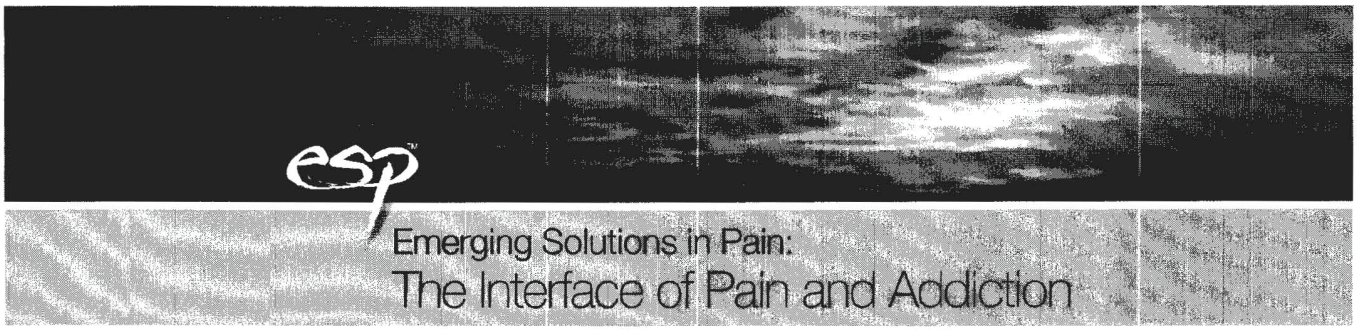


Program Overview
This program will address practical therapeutic strategies for treating chronic pain patients, including those with addictive disorders. Presentations will focus on evidence-based techniques, objective assessment tools and the federal regulations pertaining to controlled substances.

Target Audience
This activity is designed for physicians, nurses and pharmacists who treat patients with chronic pain.

Learning Objectives
At the conclusion of this educational activity, participants should be able to:

- Outline techniques that minimize the risk of misuse, addiction or diversion associated with opioid therapy, and apply these techniques to patients with chronic pain, including those with comorbid addiction
- Identify the ways that federal and state regulations can promote effective pain management or create barriers by restricting medical decision making, conflicting with current knowledge, or creating practice ambiguity
- Develop an effective treatment plan for chronic pain patients, including those patients with the comorbid disease of addiction



Accreditation

CME CREDIT

Accreditation Statement: This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of MediCom Worldwide, Inc. and Medical Learning Solutions. MediCom Worldwide, Inc. is accredited by the ACCME to provide continuing medical education for physicians. *Designation Statement:* MediCom Worldwide, Inc. designates this educational activity for a maximum of 3.0 *AMA PRA Category 1 Credits*™. Physicians should only claim credit commensurate with the extent of their participation in the activity

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NURSING CREDIT

Accreditation Statement: This activity has been planned and implemented through the joint sponsorship of MediCom Worldwide, Inc. and Medical Learning Solutions. MediCom Worldwide, Inc. 101 Washington St., Morrisville, PA 19067 is approved by the California Board of Registered Nursing, Provider Number CEP11380. MediCom designates this CNE activity for 3.0 contact hours.
Program Number: 07-199-194

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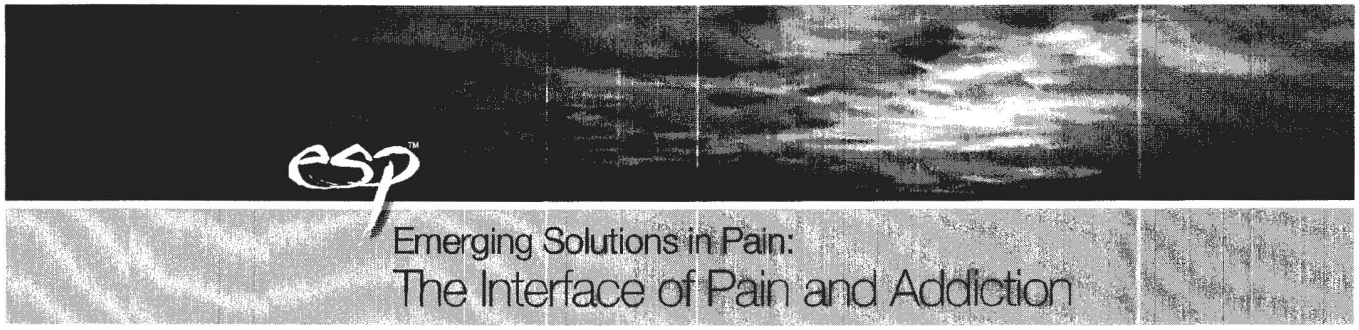
MediCom Worldwide, Inc. has established policies in place that will identify and resolve all conflicts of interest prior to this educational activity.



Faculty Financial Disclosure Statements

The presenting faculty reported the following: Dr. Steven Stanos has received honoraria related to speakers' bureau activities from Pfizer Inc., Cephalon, Inc., and PriCara™ Unit of Ortho-McNeil, Inc., as well as consultant fees from Cephalon, Alpharma Inc., Endo Pharmaceuticals, and Pfizer. He has also received grant support related to research activities from Abbott Laboratories. Dr. Aaron Gilson has received grant support related to research activities from Cephalon, Inc., Endo Pharmaceuticals, and Purdue Pharma L.P. Dr. Doug Gourlay has received honoraria as a consultant from GW Pharmaceuticals, Dominion Diagnostics LLC, Purdue Pharma L.P., Janssen, L.P., and Cephalon, Inc. Dr. Lynn Webster has received honoraria as a consultant from Cephalon, Inc., Elan Corporation, plc, and King Pharmaceuticals, Inc. He has received grant support related to research activities from Advanced Bionics Corporation, TorreyPines Therapeutics, Takeda Pharmaceuticals North America, Inc., Jazz Pharmaceuticals, Inc., ZARS Pharma, Forest Laboratories, Inc., Merck & Co., Inc., Purdue Pharma L.P., DURECT Corporation, Mallinckrodt Inc., GlaxoSmithKline, NeurogesX, Inc., Predix Pharmaceuticals, Elite Pharmaceuticals, Inc., CoMentis, Inc., and Elan.

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In accordance with MediCom Worldwide, Inc. policy, the audience is advised of the following disclosures regarding unlabeled or unapproved uses of drugs or devices: At the time of printing, Dr. Gilson, Dr. Gourlay, Dr. Stanos, and Dr. Webster indicated that their presentations would not include the discussion of unlabeled uses of commercial products or investigational products not yet approved by the FDA for any use in the United States.

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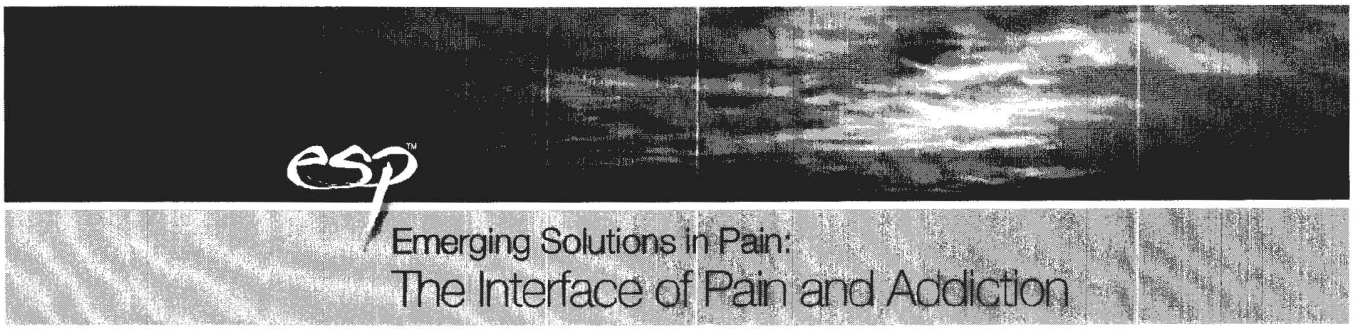
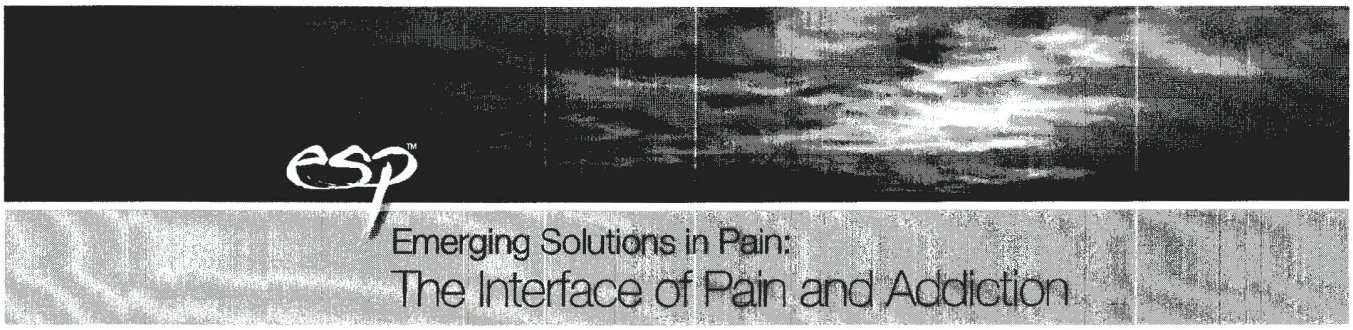
There are no fees for participating in this activity. All participants must complete the Activity Evaluation Form. Participants must receive a minimum score of 70% on the self-assessment portion of the form to qualify for CPE credit. Certificates will be mailed 6 to 8 weeks following receipt of a completed, qualified form.



Aaron M. Gilson, PhD
Associate Director
US Policy Research
Pain & Policy Studies Group
University of Wisconsin
School of Medicine and Public Health
Madison, Wisconsin

Dr. Aaron Gilson received a PhD in social welfare and an MS degree in social work from the University of Wisconsin in Madison, where he had a dual concentration in social policy and in child maltreatment, with emphasis on prevention, theory, and survey research. He also received an MS degree in psychology from Villanova University in Pennsylvania. Dr. Gilson is associate director for US Policy Research at the Pain & Policy Studies Group (PPSG)/WHO Collaborating Center for Policy and Communications in Cancer Care, a division of the Paul P. Carbone Comprehensive Cancer Center at the University of Wisconsin School of Medicine and Public Health.

Dr. Gilson is a member of the American Pain Society, and immediate past chair of its Analgesic Regulatory Affairs Committee. He is a member of the Liaison Committee on Pain and Addiction, the American Academy of Pain Medicine, and the American Society of Addiction Medicine. Dr. Gilson has published and presented about topics relevant to health care professionals and regulators both in the United States and abroad. His recent activities involve developing a methodology to evaluate and quantify federal and state controlled substances and health care practice policies. He currently is examining the extent that prescription opioid analgesics are being diverted by pharmacy thefts, and working to promote a public health approach to prescription medication abuse by identifying the sources of diversion.



Douglas Gourlay, MD, FRCPC, FASAM
Director
Pain and Chemical Dependency
Wasser Pain Management Centre
Mount Sinai Hospital
Toronto, Ontario, Canada

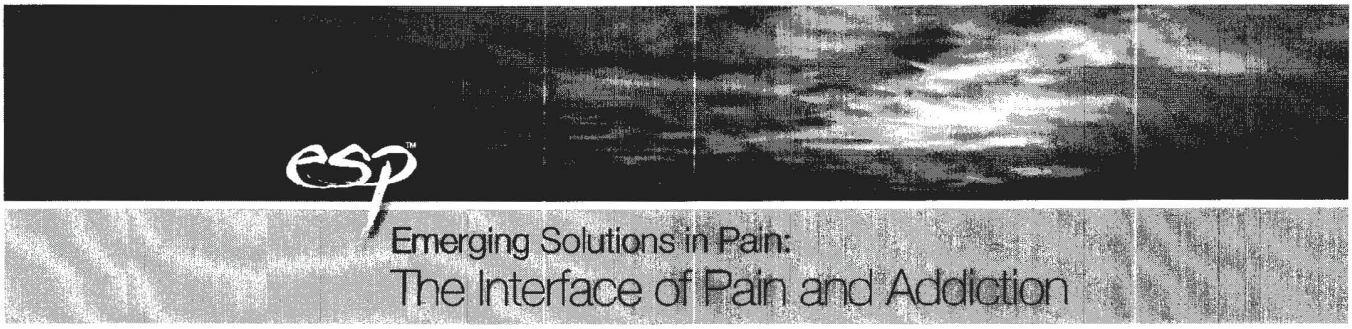
Dr. Doug Gourlay received his medical degree from McMaster University in Hamilton, Ontario. He later completed his fellowship in anesthesiology, was certified in addiction medicine, and became a fellow of the American Society of Addiction Medicine. He is currently the director of the Pain and Chemical Dependency division of the Wasser Pain Management Centre at Mount Sinai Hospital in Toronto, as well as clinical director of laboratory services at the Centre for Addiction and Mental Health.

Dr. Gourlay's practice encompasses the assessment and treatment of patients suffering from pain and addiction, as well as general addiction medicine. He is certified by the American Society of Addiction Medicine, and was the past chair of the Agonist Committee for the American Society of Addiction Medicine. He is also a member of various organizations dedicated to the assessment and treatment of pain, including the American Academy of Pain Medicine and the American Society of Regional Anesthesia. Dr. Gourlay's particular area of expertise is in chronic opioid therapy for the treatment of nonmalignant pain.

Steven Stanos, DO
Medical Director
Chronic Pain Care Center
Rehabilitation Institute of Chicago
Chicago, Illinois

Dr. Steven Stanos earned his doctor of osteopathy degree from Nova Southeastern University in Miami, Florida and went on to complete his internship at Chicago Osteopathic Hospitals and Medical Centers, Midwestern University, Chicago, Illinois. He completed both his residency and pain fellowship in the Department of Physical Medicine and Rehabilitation, Northwestern University Medical School, Rehabilitation Institute of Chicago, where he is currently a clinical instructor. In addition, Dr. Stanos is the medical director at the Chronic Pain Center, Rehabilitation Institute of Chicago.

Dr. Stanos is board certified by the American Board of Physical Medicine & Rehabilitation, as well as a diplomate of the American Board of Pain Medicine and the American Board of Physical Medicine and Rehabilitation with subspecialty certification in pain. In addition Dr. Stanos is co-chairman of the American Academy of Physical Medicine and Rehabilitation Pain Task Force and is on the editorial board of *Pain News*. He has published numerous abstracts and book chapters, and is an active speaker and researcher for studies focusing on pain.



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

Dr. Lynn Webster earned his medical degree from the University of Nebraska Medical Center in Omaha, Nebraska and completed a residency and fellowship in anesthesiology at the University of Utah Medical Center in Salt Lake City. He is medical director of the Lifetree Clinical Research and Pain Clinic, and chief of anesthesiology at the Health South Salt Lake Surgical Center in Salt Lake City.

Dr. Webster is board certified in anesthesiology and pain medicine, and is also certified in addiction medicine. He is president and founding member of the Utah Academy of Pain Medicine. A fellow of the American College of Pain Medicine, Dr. Webster is also a member of professional societies including the American Pain Society, American Neuromodulation Society, American Headache Society, American Medical Association, American Academy of Pain Medicine, American Society of Addiction Medicine, and American Society of Anesthesiologists. He serves on the Board of Directors of the Utah Medical Insurance Association as well.

Dr. Webster is dedicated to treating patients in pain while simultaneously working to minimize the potential for abuse and addiction. His clinical research interests include pain and pain mechanisms, substance abuse, addiction, sleep medicine and cultural and political attitudes toward pain management. His primary focus is the development of novel agents to treat pain. Dr. Webster serves on the editorial advisory board for *Practical Pain Management*, has authored more than 80 scientific abstracts and journal articles, and lectures extensively.

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CE Activity Evaluation

EMERGING SOLUTIONS IN PAIN: THE INTERFACE OF PAIN AND ADDICTION

Saturday, October 27, 2007 • Chicago, Illinois

To receive Continuing Education Credit, all questions and selections must be fully completed. Returned forms with missing answers or entries will be ineligible for CE credit.

Please evaluate this educational activity as a whole by checking the appropriate circle.

Overall Evaluation

	Excellent	*Very Good*	*Good*	*Fair*	*Poor*
Usefulness	◯	◯	◯	◯	◯
Quality of Content	◯	◯	◯	◯	◯
Environment Conducive to Learning	◯	◯	◯	◯	◯
Audio-Visual	◯	◯	◯	◯	◯
Food & Beverage	◯	◯	◯	◯	◯

Course Objectives and Context

Were the following overall course objectives met?

- Outline techniques that minimize the risk of misuse, addiction or diversion associated with opioid therapy, and apply these techniques to patients with chronic pain, including those with comorbid addiction — Yes ◯ No ◯
- Identify the ways that federal and state regulations can promote effective pain management or create barriers by restricting medical decision making, conflicting with current knowledge, or creating practice ambiguity — Yes ◯ No ◯
- Develop an effective treatment plan for chronic pain patients, including those patients with the comorbid disease of addiction — Yes ◯ No ◯

1. Do you feel this activity was fair, balanced and free of commercial bias? Yes ◯ No ◯

If no, please state reasons:

_____

_____

_____

2. On a scale of 1 to 5, with 5 being the highest, how do you rank this activity overall? ◯1 ◯2 ◯3 ◯4 ◯5

3. As part of our continuous quality improvement effort, we conduct post-activity follow-up surveys to assess impact of our CME/CE activities. Are you willing to participate in such a survey? Yes ◯ No ◯

Faculty Evaluation

Speaker: *Douglas Gourlay, MD*
Activity Title: *Universal Precautions*

	Excellent	*Very Good*	*Good*	*Fair*	*Poor*
Content of presentation	○	○	○	○	○
Ability to convey the subject matter clearly	○	○	○	○	○

Speaker: *Aaron Gilson, PhD*
Activity Title: *Regulations Governing Opioid Treatment of Chronic Pain: How Federal and State Law Can Impact Healthcare Practice and Patient Care*

	Excellent	*Very Good*	*Good*	*Fair*	*Poor*
Content of presentation	○	○	○	○	○
Ability to convey the subject matter clearly	○	○	○	○	○

Speaker: *Lynn Webster, MD*
Activity Title: *Understanding the Multidimensional Experience of Pain and Addiction*

	Excellent	*Very Good*	*Good*	*Fair*	*Poor*
Content of presentation	○	○	○	○	○
Ability to convey the subject matter clearly	○	○	○	○	○

Needs Assessment

Of the following assessment, treatment, and monitoring tools, which do you utilize in your practice?

Assessment, Treatment or Monitoring Tool	Currently use	Plan to implement after learning this new information	Need additional information
1. Differential pain assessment (intermittent, & breakthrough)	○	○	○
2. Numeric rating scale	○	○	○
3. Physical Disability Index (PDI)	○	○	○
4. Abilities of Daily Living (ADL)	○	○	○
5. CAGE questionnaire	○	○	○
6. Opioid Risk Tool (ORT)	○	○	○
7. 4 A's	○	○	○
8. Urine drug testing	○	○	○
9. Pre- and post-therapy physical functioning assessment	○	○	○
10. Patient informed consent	○	○	○
11. Treatment/Opioid agreement	○	○	○

Needs Assessment continued...

12. Of the topics covered, which area do you feel is most important to you in your practice setting?

❍ Epidemiology	❍ Assessment/Diagnosis	❍ Urine Drug Testing
❍ Neurobiology	❍ Interface of Pain & Addiction	❍ Federal Regulations
❍ Pharmacology	❍ Non-Medication Tx Approach	❍ Universal Precautions

13. Do you feel the concept of patient assessment and triage as described in the "Universal Precautions" presentation will assist you in knowing when to refer a patient to an addiction medicine specialist or establishing multi- or interdisciplinary teams in your treatment of patients with pain? Yes ❍ No ❍

If no, why do you feel this concept is not clinically effective? _____

_____

_____

14. Has the information in this program provided you with practical experience based recommendations that have increased your confidence in prescribing opioid analgesics for your patients with pain? Yes ❍ No ❍

If no, what other information would you find helpful? _____

_____

_____

15. This educational activity has contributed to my professional effectiveness and improved my ability to:

	Strongly Agree	Agree Somewhat	Neutral	Disagree Somewhat	Strongly Disagree
Treat/manage patients	❍	❍	❍	❍	❍
Communicate with patients	❍	❍	❍	❍	❍
Communicate with other clinicians	❍	❍	❍	❍	❍
Manage my medical practice	❍	❍	❍	❍	❍
Enhance my current knowledge base	❍	❍	❍	❍	❍
Provided new ideas or information I expect to use	❍	❍	❍	❍	❍

16. In looking forward to future programs, are there additional areas of interest that we should be covering that have not been included or that need to be covered in greater depth?

❍ Keep topics as they currently are
❍ Drop the following topic area: _____

Other Suggestions: _____

17. Please list at least two things you learned from today's meeting that you plan on incorporating into your practice.

_____

_____

_____

Request for CE Credit

To receive CE credit, please fully complete the following information (please print):

First Name Last Name Degree

Address

City State Zip

Phone Number

- -

Email _____

☐ MD ☐ DO ☐ RN ☐ LPN ☐ PhD ☐ Other _____

☐ PharmD ☐ RPh ☐ PA

Pharmacists/Nurses, please provide License Number

☐ Please contact me regarding upcoming medical education opportunities!

Physicians

- ☐ I participated in the entire activity and claim 3.0 credits
- ☐ I participated in only part of the activity and claim _____ credits

Pharmacists

- ☐ I participated in the entire activity and claim 3.0 credits
- ☐ I participated in only part of the activity and claim _____ credits

Nurses

- ☐ I participated in the entire activity and claim 3.0 credits
- ☐ I participated in only part of the activity and claim _____ credits

Participant information is collected for issuance of CE certification only, and will not be provided to any third party.

Signature Date

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CPE Activity Posttest

EMERGING SOLUTIONS IN PAIN: THE INTERFACE OF PAIN AND ADDICTION

October 27, 2007 • Chicago, Illinois

Name: _____

(Please Print)

*To receive **pharmacy credit** for this educational activity, please complete this posttest. All participants must achieve a minimum score of 70% on the posttest to qualify for CPE credit. Certificates will be mailed 6 to 8 weeks following receipt of a completed, qualified form.*

*Please circle the **best** answer for each question.*

1. Universal Precautions should be applied in the treatment of which population of pain patients?
   a. Those who begin to display aberrant behavior
   b. All new and current patients in a pain practice
   c. Those with a history of addiction

2. The utility of opioid agreements is limited to patients with a history of addiction or to those who exhibit aberrant behavior during treatment.
   a. True
   b. False

3. Opioid agreements that have clear, inflexible boundaries provide the best level of protection for the physician and medical care for the patient.
   a. True
   b. False

4. Addictive drugs activate the reward system by:
   a. Monoamine uptake
   b. Increasing dopamine transmission
   c. Cross tabulation and multinomial regression
   d. Decreasing dopamine transmission

5. Which of the following statements best describes addiction?
   a. Addiction is a social condition that is mainly influenced by environmental factors
   b. Addiction is a personal weakness resulting from moral failing
   c. Addiction is a neurobiologic disease with a neurochemical basis and a genetic component

6. Immunoassays can:
   a. Identify a specific drug or drug metabolite
   b. Detect the presence of a drug class
   c. Provide quantitative results
   d. Only be performed in a testing laboratory

7. When federal law differs from state law in regard to Schedule II controlled substance prescribing, the more stringent rule applies.
   a. True
   b. False

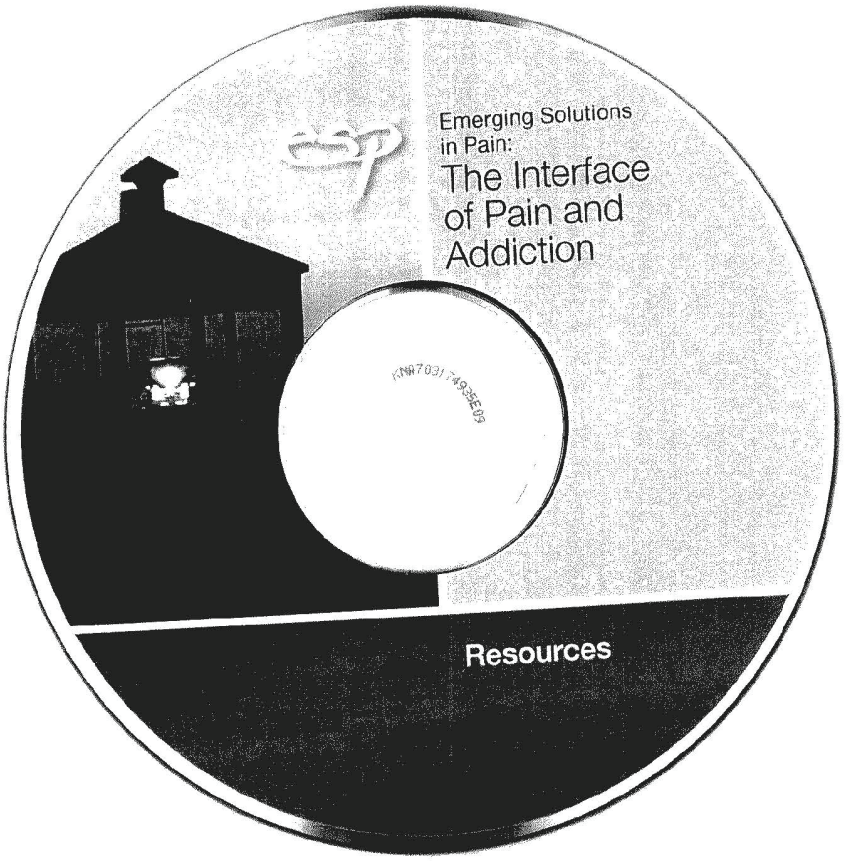
8. State policies regarding Schedule II controlled substance prescribing are important for all but which of the following?
   a. Authorize health care practice, medical use of drugs
   b. Define unprofessional conduct and prohibit unauthorized distribution of controlled substances
   c. Encourage pain management
   d. Defines criminal charges and sets punitive sentences for unauthorized controlled substance misuse

9. Which of the following is not considered an objective to achieving the Principle of Balance concerning controlled substance prescribing?
   a. Review and revise laws that deter effective pain relief
   b. Clarify misconceptions about dependence/addiction
   c. Reform state health care regulatory policies
   d. Refrain from prescribing controlled substances

Signature: _____

Mandatory to receive credit.

Answers: 1. b, 3. a, 5. c, 7. a, 9. d


Emerging Solutions
in Pain:
The Interface
of Pain and
Addiction
Resources

Pain, Dependency and Universal Precautions

Douglas Gourlay MD, MSc, FRCPC, FASAM
Director, Pain and Chemical Dependency Division
Wasser Pain Management Centre
Mount Sinai Hospital
Toronto Canada

Declaration of Potential Conflict of Interest

- The content of this presentation is non-commercial and does not represent any conflict of interest
- I have been compensated for my participation on various advisory boards for several drug companies

Universal Precautions in Infectious Disease

- Need to protect both the health worker (infection) AND the patient (unnecessary stigmatization)
- Inability to accurately identify the "at-risk" patient
- 1985 CDC published 'Universal Precautions'
  - A set of recommendations if applied to all patients, would reduce the risk of transmission of infectious disease

Centers for Disease Control. *MMWR*. 1988;37:377-3 82,387-38 8.
Gourlay D, Heit H. et al. *Pain Medicine*. 2005;5(2):107-1 12.

Universal Precautions in Infectious Disease

- The elements already existed
  - But not collected together in one document
  - Not universally applied
- By applying to all patients, three goals achieved:
  - Reduced risk to health workers
  - Decreased stigmatization of patients
  - Didn't have to 'know' who was at risk

Gourlay D, Heit H, et al. *Pain Medicine*. 2005;6(2):107-112.

Universal Precautions in Pain Medicine

- Striking similarity to infectious disease model
  - At risk population hard to identify
  - Incorrect assessment can lead to patient and practitioner harm
  - All elements of the model currently exist
  - Physicians reluctant to implement due to personal prejudice and bias

Gourlay D, Heit H, et al. *Pain Medicine*. 2005;6(2):107-112.

Assessment

Open Communication Between Clinician and Patient

Comprehensive Initial Assessment

- Management of all patients with pain
- Detailed history and physical exam
  - Focus on potential pain generators
  - Review of diagnostic tests
  - Past treatment history, including nonopioid therapeutic trial
- Pain and physical function assessment
- Psychological function assessment
- Abuse/addiction risk assessment

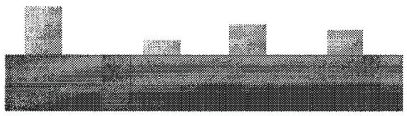
Pain and Physical Function Assessment

- 10-point numeric rating scale (10 = worst pain imaginable)
- Establish the type of pain
- Pain Disability Index
- Activities of Daily Living

TARGET Chronic Pain Pocket Card. *American Pain Foundatio n.*

Pain and Physical Function Assessment

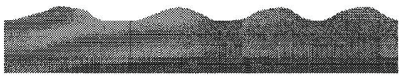
- Establish the type of pain
  - Intermittent pain
    - Episodic
    - Occurs in waves or patterns



TARGET Chronic Pain Pocket Card. *American Pain Foundatio n.*

Pain and Physical Function Assessment

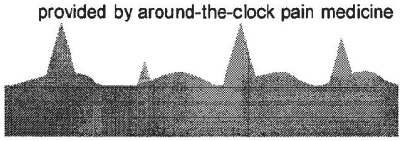
- Establish the type of pain
  - Persistent pain
    - Static, constant or continuous
    - Pain lasts 12 or more hours every day



TARGET Chronic Pain Pocket Card. *American Pain Foundatio n.*

Pain and Physical Function Assessment

- Establish the type of pain
  - Breakthrough pain
    - Dynamic, sudden, or incidental
    - Pain flares up or breaks through the relief provided by around-the-clock pain medicine

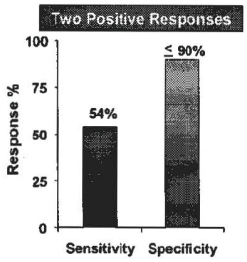


TARGET Chronic Pain Pocket Card. *American Pain Foundatio n.*

The CAGE Questionnaire

1. Have you felt [Do you feel] the need to **C**ut down on your alcohol or drug use?
2. Have people **A**nnoyed [Do people Annoy] you by criticizing your use of alcohol or drugs?
3. Have you ever felt [Do you feel] bad or **G**uilty about your alcohol or drug use?
4. Have you ever needed [Do you ever need] an **E**ye-opener to steady your nerves or get rid of alcohol or drug aftereffects?

Evaluating Responses



- Two positive responses of the four CAGE questions indicates a risk of an abuse or addiction problem
- Even greater sensitivity with three or four positive responses

Fiellin DA, et al. *Ann Intern Med*. 2000;133(10):815-827.

The Opioid Risk Tool

- Five-question clinical interview or patient questionnaire to assess patierts at risk prior to treatment initiation
- Specifically developed to screen patients with chronic pain who will be using opioids as part of their treatment plan
- Quantifies the level of risk for patient
- Easy to use format

Webster LR, Webster RM. *Pain Medicine*. 2005;6(6):432- 442.

The ORT Form

Mark each box that applies

	Female	Male
1. Family history of substance abuse		
Alcohol	[ ] 1	[ ] 3
Illegal drugs	[ ] 2	[ ] 3
Prescription drugs	[ ] 4	[ ] 4
2. Personal history of substance abuse		
Alcohol	[ ] 3	[ ] 3
Illegal drugs	[ ] 4	[ ] 4
Prescription drugs	[ ] 5	[ ] 5
3. Age (mark box if between 16-45)	[ ] 1	[ ] 1
4. History of preadolescent sexual abuse	[ ] 3	[ ] 0
5. Psychological disease		
Attention deficit disorder, obsessive-compulsive disorder, bipolar, schizophrenia	[ ] 2	[ ] 2
Depression	[ ] 1	[ ] 1
Scoring Totals		

Webster LR, Webster RM. *Pain Medicine*. 2005;6(6):432-442.

Scoring the ORT

- Total score is calculated by adding the point values for each of the risk factors
- Three risk categories
  - Low: 0 - 3 points
  - Moderate: 4 - 7 points
  - High: 8 points and above

Webster LR, Webster RM. *Pain Medicine*. 2005;6(6):432-442.

Customize the Assessment Process

Only 6% of interaction between physician and patient are questions to patients

- Find the approach that works best for you and your staff
  - Open-ended questions
  - Standardized templates
  - Combination

Roter D. *Communicating with Medical Patients*. Ed: Stewart M, Roter D. Newbury Park, CA: Sage Series. 1989: 183-196.

Routine Use of Assessment Tools

- Which tools are used is less important than when they are used
- Routine implementation of assessment
  - Provides valuable information
  - Contributes to positive relationship between the clinician and patient
  - Supports compliance with state and federal regulations

Patient Triage

- Group I – primary care patients
- Group II – primary care patient with specialist support
- Group III – specialty care patients/pain and addiction management

Gourlay D, Heit H, et al. *Pain Medicine*. 2005;6(2):107-112.

Group I: Primary Care Patients

- No past or current history of substance use disorders
- Lack major or untreated psychopathology
- Noncontributory family history with respect to substance use disorders
- Majority of patients will present to a health care professional

Gourlay D, Heit H, et al. *Pain Medicine*. 2005;6(2):107-112.

Group II: Primary Care Patient With Specialist Support

- May have a past history of a treated substance use disorder or a significant family history of problematic drug use
- May also have a past or concurrent psychiatric disorder
  - Not actively addicted, but do represent increased risk, which may be managed in consultation with appropriate specialist support
  - Consultation may be formal and ongoing (co-managed) or with the option for referral back for reassessment should the need arise

Gourlay D, Heit H, et al. *Pain Medicine*. 2005;6(2):107-112.

Group III: Specialty Care Patients/ Pain and Addiction Management

- Most complex cases to manage due to an active substance use disorder or major untreated psychopathology
- Actively addicted and pose significant risk to both themselves and to the health care professional who often lacks the resources or experience to manage them

Gourlay D, Heit H, et al. *Pain Medicine*. 2005;6(2):107-112.

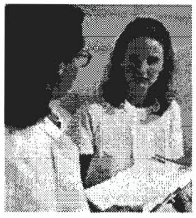
Patient Triage

- It is important to remember that **Groups II** and **III** can be dynamic
  - **Group II** can become **Group III** with relapse to active addiction
  - **Group III** patients can move to **Group II** with appropriate treatment
  - In some cases, as more information becomes available to the health care professional, the patient who was originally thought to be low risk (**Group I**) may become **Group II** or even **Group III**
- ***It is important to continually reassess risk over time***

Gourlay D, Heit H, et al. *Pain Medicine*. 2005;6(2):107-112.

Treatment Plan Elements

Informed Consent



- Two-way communication between physician and patient regarding
  - Risks and benefits of medications
  - Treatment plan
  - Terminology
    - Addiction
    - Physical dependence
    - Tolerance

AAPM, APS, ASAM. Definitions Related to the Use of Opioids for the Treatment of Pain. [consensus document] 2001.

Treatment/Opioid Agreement

- Can improve the therapeutic relationship
- Must be based on mutual trust and honesty between patient and physician that is initiated with the first visit
- Must be part of an environment of care that emphasizes truthful, open dialogue
- Purpose of agreement
  - To facilitate informed consent
  - Patient education
  - Compliance

Heit HA. *Care Management: Disease Management Digest*. 2003;7(1):2-3.

Treatment/Opioid Agreement

- Establishes the responsbilities of physician-to-patient and patient-to-physician
- Delineates the treatment plan to manage pain
- Gives informed consent about side effects and risks of opioids
- Establishes boundaries and consequences for opioid misuse or diversion
  - Noncompliance with the agreement can aid in the diagnoses of the disease of addiction or substance misuse relapse

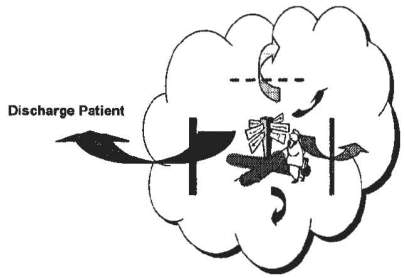
Heit HA. *Care Management:Disease Management Digest*. 2003;7(1):2-3.

Boundary Setting

- 90%+ of patients don't need strict boundary setting
  - Most patients have their own internal set
- For remaining ~10%, strict boundary setting is essential
- Treatment agreements, urine testing, interval/contingency dispensing, etc.

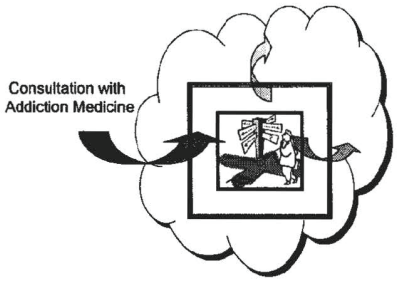
Gourlay D, Heit H, et al. *Pain Medicine*. 2005;6(2):107-112.

Boundaries – Identification and Enforcement



Gourlay D, Heit H, et al. *Pain Medicine*. 2005;6(2):107-112.

Boundaries – Identification and Enforcement



Gourlay D, Heit H, et al. *Pain Medicine*. 2005;6(2):107-112.

Setting Boundaries

- Treatment agreements
  - Avoid term "contract"
  - Purpose is not to "give MD an out", with difficult patients
  - Used to clearly set out patient AND physician expectations/responsibilities
  - Effective boundary setting tool
- Must be readable, reasonable and flexible

Gourlay D, Heit H, et al. *Pain Medicine*. 2005;6(2):107-112.

Monitoring Standards

- Consider urine drug testing (UDT) in all patients
  - Especially those starting opioid therapy
  - When making major changes in therapy
  - When pain persists despite reasonable opioid therapy
  - In response to aberrant behavior
- Cheap, effective and well tolerated by patients
  - Only patients 'philosophically opposed' to UDT are those patients with problems who don't want help
- Use for advocacy, motivate/support behavioral change, identify abuse/addiction: avoid "gotcha" syndrome

Gourlay D, Heit H, et al. *Pain Medicine*. 2005;6(2):107-112.

Monitoring Standards

- UDT is not particularly useful for compliance testing
  - Absence of prescribed drug MAY indicate a behavioral problem (ie, bingeing, diversion)
  - Presence of illicit substance MAY indicate a substance use disorder
- Develop relationship with testing lab to assist in interpretation of results

Gourlay D, Heit H, et al. *Pain Medicine*. 2005;6(2):107-112.

Universal Precautions in Pain Medicine

1. Diagnosis with appropriate differential
2. Psychological assessment including risk of addictive disorders
3. Informed consent (verbal vs. written/signed)
4. Treatment agreement (verbal vs. written/signed)
5. Pre-trial assessment of pain/function
6. Appropriate trial of opicid therapy +/- adjuvants
7. Reassessment of pain score and level of function
8. Regular assess the "Four A's" of pain medicine
9. Periodically review Pain Diagnosis and co morbid conditions including addictive disorders
10. **DOCUMENT, DOCUMENT, DOCUMENT**

Gourlay D, Heit H, et al. *Pain Medicine*. 2005;6(2):107-112.

Summary

- By consistently applying a basic set of principles to chronic noncancer pain patients
  - Patient care is improved
  - Stigma is reduced
  - Overall risk is contained
- Universal precautions is not about opioids – its about good medical care

Gourlay D, Heit H, et al. *Pain Medicine*. 2005;6(2):107-112.

Regulations Governing Opioid Treatment of Chronic Pain: How Federal and State Law Can Impact Healthcare Practice and Patient Care

Aaron M. Gilson, MS, MSSW, PhD
Director of U.S. Policy Research
University of Wisconsin Pain & Policy Studies Group

October 27, 2007
12:30 – 3:30 PM
Northwestern Medical Center
Chicago, IL

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- At the time of printing, Dr. Gilson indicated that his presentation would not include the discussion of unlabeled uses of commercial products or investigational products not yet approved by the FDA for any use in the United States.

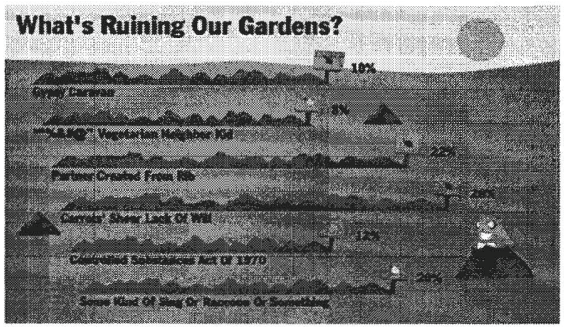
Review of Learning Objectives

Attendees should be better able to:

- ✓ Know the requirements that federal law establishes for the medical use of controlled substances
- ✓ Define quality of and disparities in the content of state pain policies
- ✓ Describe how state policies have changed over time

Policies Affect the Regulatory Environment for Pain Management

- Federal controlled substances law (i.e., both legislation and regulations)
  - Controlled Substances Act (legislation)
  - Code of Federal Regulations, Part 1300 (regulations)
- State legislation and regulations
  - Controlled substances
  - Medical and pharmacy practice
  - Intractable Pain Treatment Acts, etc
- Official state regulatory agency policies
  - Guidelines (not clinical practice guidelines)
  - Policy statements



Medical Value of Controlled Substances (21 USC §801(1))

- "Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people."

Prescribing a Controlled Substance (21 CFR 1306.04(a))

- A prescription for a controlled substance, to be lawful, must be issued:
  - For a legitimate medical purpose
  - By an individual practitioner acting in the usual course of professional practice

Treating Pain (21 CFR 1306.07(c))

- "This section is not intended to impose any limits on a physician or authorized hospital staff to...administer or dispense [including prescribe] narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts."

Basis of Intractable Pain Treatment Acts

Prescribing to Patients with Pain and an Addictive Disease

"A practitioner may prescribe methadone *or any other narcotic* to a narcotic addict for analgesic purposes."

Drug Enforcement Administration
Pharmacist's Manual
April, 2004, p. 54

Concept of Addiction

"...pharmacists should recognize that drug tolerance and physical dependence may develop as a consequence of the patient's sustained use of opioid analgesics for the legitimate treatment of chronic pain."

Drug Enforcement Administration
Pharmacist's Manual
April, 2004, p. 55

Concept of Addiction

"Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction."

Federation of State Medical Boards
Model Policy for the Use of Controlled Substances for the Treatment of Pain
May, 2004, p. 5

Concept of Addiction

"The term 'drug dependent person' means a person who is using a controlled substance...and who is in a state of psychic or physical dependence, or both, arising from the use of that substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects or to avoid the discomfort caused by its absence."

U.S. Public Health and Welfare
42 USCS §201

Federal vs. State Requirements

- Healthcare professionals must comply with the requirements from both federal and state laws that govern controlled substances prescribing
- When federal law differs from state law, the more stringent rule applies
  - State laws can be more restrictive than federal requirements but, ultimately, they cannot be less restrictive

Federal vs. State Requirements

- Length of time a Schedule II controlled substances prescription is valid
  - Federal requirement
    - No limit
  - State requirements
    - Wisconsin = 2 month limit
    - Illinois = 7 day limit
    - Hawaii = 3 day limit

Federal vs. State Requirements

- Amount or duration of a Schedule II controlled substance that can be prescribed at once
  - Federal requirement
    - No limit
  - State requirements
    - Illinois = no limit
    - South Carolina = 31-day supply
    - New Hampshire = 34-day supply/100 dosage units

Status of Federal Prescription Limits

"The CSA and DEA regulations contain no specific limits on the number of days worth of a Schedule II controlled substance that a physician may authorize per prescription."

Drug Enforcement Administration
Federal Register
August 26, 2005, p. 50409

Concern About Practice Scrutiny

"It would be a disservice to many patients if exaggerated statements regarding the likelihood of a DEA investigation resulted in physicians mistakenly concluding that they must scale back their patients' use of controlled substances to levels below that which is medically appropriate."

Drug Enforcement Administration
Policy Statement
Federal Register: Sept. 6, 2006, p. 52720

Concern About Practice Scrutiny

"Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice."

Federation of State Medical Boards
Model Policy for the Use of Controlled Substances for the Treatment of Pain
May 2004, p. 6

Parameters of Federal Law

- Federal law does not regulate healthcare practice
  - Prescribing requirements
- State authority to regulate healthcare practice
  - Licensing and disciplinary boards

Why State Policies are Important

- Authorize healthcare practice, medical use of drugs
- Define unprofessional conduct, and prohibit unauthorized distribution of controlled substances
- Restrict prescriptive practices

Policies can also

- Recognize value of controlled substances
- Encourage pain management
- Address barriers, i.e. fear of regulatory scrutiny

Need to Evaluate State Policies

- Drug control and professional practice policies impact pain management
- Identify regulatory barriers
  - Contradict medical knowledge
  - Impose excessive limits on professional practice
  - Introduce ambiguity
- Identify ways to improve policy
  - Encourage pain management
  - Address fears of regulatory scrutiny
  - Avoid excessive limits
- Compare states on same basis
- Baseline to evaluate progress

The Principle of *Balance*

A principle central to medicine, controlled drugs, and the protection of public health and safety

- Opioids are necessary medicines for pain relief
- Opioids pose risks, need to be controlled
- "Controlled substance" does not diminish medical usefulness
- Health care professionals: relieve pain/avoid contributing to abuse
- Law enforcement/regulation: address diversion/avoid interfering in medical practice and patient care

Law Enforcement on the Principle of *Balance*

"...the prevention of drug abuse is an important societal goal that can and should be pursued without hindering patient care..."

National Association of Attorneys General
2003

U.S. Drug Enforcement Administration
2001 Joint Policy Statement

Imperative to Achieve *Balance*

- World Health Organization
- International Narcotics Control Board
- Institute of Medicine
- National Cancer Institute
- American Medical Association
- American Pain Society
- American Cancer Society
- American Academy of Pain Medicine
- Alliance of State Pain Initiatives
- Federation of State Medical Boards
- National Association of Attorneys General
- Drug Enforcement Administration

How to Achieve Balance

- Review and revise laws that deter effective pain relief
- Clarify misconceptions about dependence/addiction
- Reform state healthcare regulatory policies

What Can Healthcare Practitioners Do?

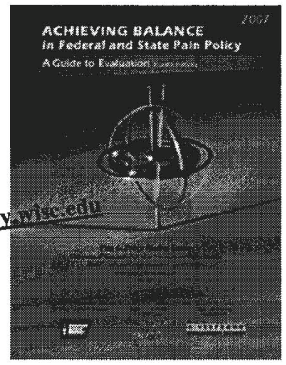
- Maintain expertise
- *Know the law*
- Respond to pharmacist inquiries
- Use one pharmacy; patient choice
- Incompetent, unethical conduct
  - Med Societies; Peer review orgs; Licensing boards
- Illegal attempts to acquire controlled substances
  - Law Enforcement; First-hand knowledge

Physicians' Knowledge of Policy

California Medical Board

- **1994:** Rx Guidelines for opioids and chronic pain
- **1994-1996:** Mailed to physicians three times
- **1997:** UCSF/Stanford survey
  - 230 physicians
  - 161 responded (70%)
  - **39% remembered reading the Guidelines**

Potter et al. Opioids for chronic nonmalignant pain: Attitudes and practices in the UCSF/Stanford Collaborative Research Network. *The Journal of Family Practice*. 2001;50(2):145-151.



(+) Criteria: Policy Language That Can *Enhance* Pain Management

1. Controlled substances necessary for the public health
2. Pain management is general medical practice
3. Medical use of opioids is legitimate professional practice
4. Pain management is encouraged
5. *Practitioners' concerns about regulatory scrutiny are addressed*
6. Prescription amount is insufficient to determine legitimacy
7. *Addiction is not confused with physical dependence or analgesic tolerance*
8. Other positive language

(-) Criteria: Policy Language That Can *Impede* Pain Management

9. *Opioids are a last resort*
10. Opioids are outside legitimate professional practice
11. *Addiction is confused with physical dependence or analgesic tolerance*
12. Medical decisions are restricted
    - *Restrictions based on patient characteristics*
    - Mandated consultation
    - *Restrictions regarding quantity prescribed or dispensed*
    - Undue prescription limitations
13. Prescription validity are restricted
14. Additional prescription requirements (i.e., PMPs)
15. Other restrictive language
16. Ambiguous language

Do State Policies Address Physician Fear of Regulatory Scrutiny?

Alabama	Maine	New Mexico*	South Dakota
Arizona	Maryland	New York	Tennessee
Arkansas*	Massachusetts	North Carolina	Texas
California	Michigan	North Dakota	Utah
Colorado	Minnesota	Ohio	Vermont
Florida	Missouri	Oklahoma	Virginia
Idaho	Montana	Oregon	Washington
Iowa	Nebraska	Pennsylvania	West Virginia*
Kansas	Nevada	Rhode Island	Wisconsin
Kentucky	New Hampshire	South Carolina	*(39 states)*

* Also establishes immunity from criminal prosecution

Pain & Policy Studies Group. *Achieving balance in federal and state pain policy: A guide to evaluation* (4th edition). University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, WI, 2007.

Clarifies the Difference Between Addiction and Physical Dependence

Alabama	Kansas*	Nebraska	South Dakota
Arizona	Kentucky	Nevada	Tennessee
California	Louisiana	New Mexico	Texas
Colorado	Maine	New York	Utah
Connecticut	Maryland	North Carolina	Vermont
DC	Massachusetts	Ohio	Virginia
Florida	Michigan*	Oklahoma	Washington*
Hawaii	Mississippi	Pennsylvania	West Virginia*
Idaho	Missouri	South Carolina	Wisconsin *(36 states)*

* Policies endorsed by nursing boards

Pain & Policy Studies Group. *Achieving balance in federal and state pain policy: A guide to evaluation* (4th edition). University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, WI, 2007.

Example: "Health care providers authorized by law to prescribe, administer or dispense drugs, including controlled substances, should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction."

Kansas Joint Policy Statement by the Boards of Healing Arts, Nursing, and Pharmacy
July, 2002

Confuses Addiction and Physical Dependence

Arizona	Louisiana	Oklahoma
Colorado	Maryland	Pennsylvania
Georgia	Missouri	Tennessee
Hawaii	Nevada	Wyoming
Idaho	New Jersey	
Indiana	North Carolina	*(16 states)*

Pain & Policy Studies Group. *Achieving balance in federal and state pain policy: A guide to evaluation* (4th edition). University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, WI, 2007.

Further Confuses Concept of Addiction

Arizona	Missouri
Colorado	Nevada
Hawaii	North Carolina
Idaho	Oklahoma
Louisiana	Pennsylvania
Maryland	Tennessee *(12 states)*

Pain & Policy Studies Group. *Achieving balance in federal and state pain policy: A guide to evaluation* (4th edition). University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, WI, 2007.

Restrict Rx to Patients with Pain and an Addictive Disease

Arkansas
Missouri
Nebraska
New York
Oklahoma
Tennessee
Texas
Wyoming *(8 states)*

Pain & Policy Studies Group. *Achieving balance in federal and state pain policy: A guide to evaluation* (4th edition). University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, WI, 2007.

Uniquely Restrictive Policy

"Every practitioner that provides treatment or rehabilitation services to a *person dependent upon drugs* shall periodically as required by the Secretary of the North Carolina Department of Health and Human Services commencing January 1, 1972, make a statistical report to the Secretary of the North Carolina Department of Health and Human Services in such form and manner as the Secretary shall prescribe for each such person treated or to whom rehabilitation services were provided."

North Carolina General Statutes § 90-109.1(c)

Restrict Rx Quantity

Delaware	100 dosage units or 31-day supply
Massachusetts	30-day supply
New Hampshire	100 dosage units or 31-day supply
New Jersey	120 dosage units or 30-day supply
New York	30-day supply
Rhode Island	250 dosage units or 30-day supply
South Carolina	120 dosage units or 30-day supply
Utah	one month supply
	(8 states)

Pain & Policy Studies Group. *Achieving balance in federal and state pain policy: A guide to evaluation* (4th edition). University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, WI, 2007.

Requires Opioids to be Treatment of Last Resort

Georgia
Kentucky
Louisiana
Mississippi
Montana
Tennessee
Washington
(7 states)

Pain & Policy Studies Group. *Achieving balance in federal and state pain policy: A guide to evaluation* (4th edition). University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, WI, 2007.

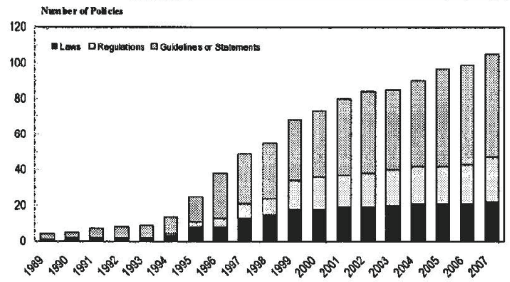
State Pain Policies (March 2007)

- 47 states (including DC) have a pain policy
  - Totaling more than 100 policies
- 4 states do not have any pain policy
  - Alaska
  - Delaware
  - Illinois
  - Indiana

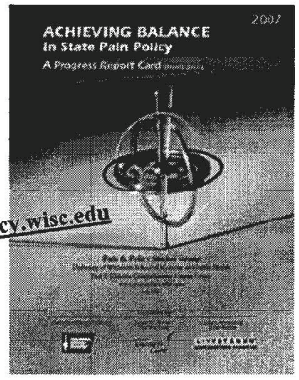
Pain & Policy Studies Group. *Achieving balance in federal and state pain policy: A guide to evaluation* (4th edition). University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, WI, 2007.

State Pain Policies

1989 - 2007



Pain & Policy Studies Group. *Database of state laws, regulations, and other official governmental policies governing pain management.* University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, WI, 2007.



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Why a Progress Report Card?

- Simplification of complex evaluation
- Single index of quality to compare states
- Positive context for critical evaluation
- Simplifies measurement of progress
- Supports goal setting
- Increases visibility of the need to improve pain policy

Are State Policies Becoming More Balanced? (2003-2006)

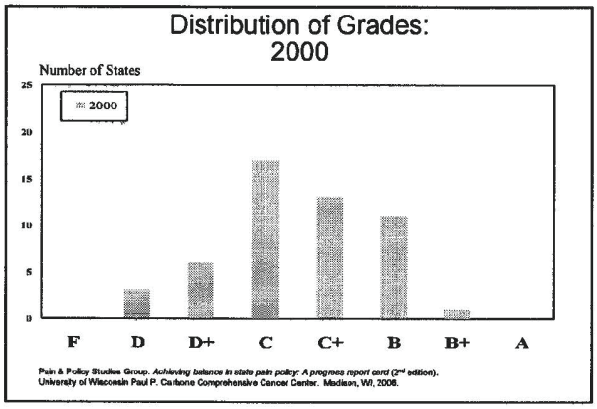
Alabama	New Jersey
Arkansas	North Dakota
Colorado	Oregon
Connecticut	Rhode Island
District of Columbia	Utah
Hawaii	Vermont
Idaho	Virginia
Kentucky	Wisconsin
Minnesota	Wyoming
Mississippi	*(19 states)*

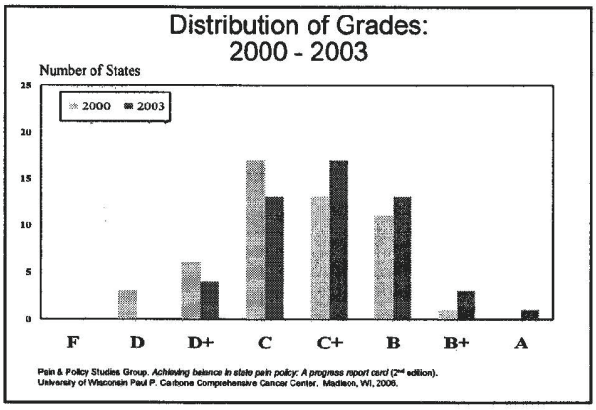
Pain & Policy Studies Group. *Achieving balance in state pain policy: A progress report card* (2nd edition). University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, WI, 2006.

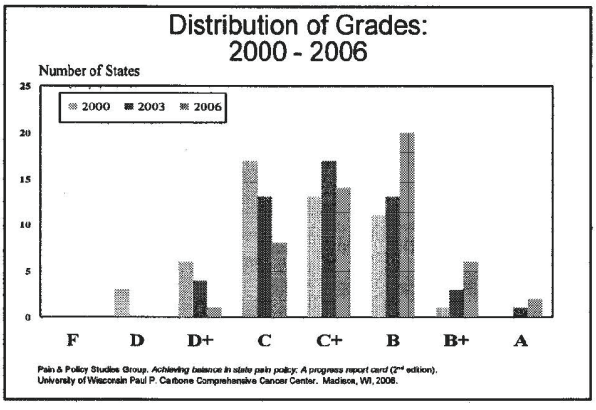
Are State Policies Becoming More Balanced? (2006-2007)

Arizona	Kansas
California	Massachusetts
Colorado	New Hampshire
Connecticut	Wisconsin
	(8 states)

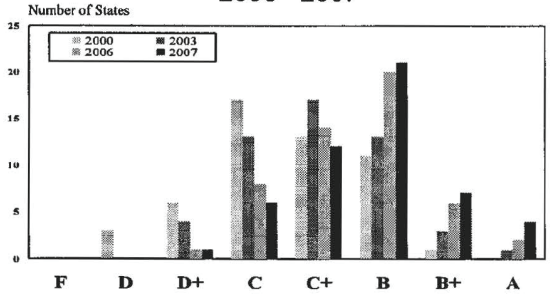
Pain & Policy Studies Group. *Achieving balance in state pain policy: A progress report card* (2nd edition). University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, WI, 2007.







Distribution of Grades: 2000 - 2007



Pain & Policy Studies Group. *Achieving balance in state pain policy: A progress report card* (3rd edition). University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, WI, 2007.

What Contributed to Positive Change?

- Addition of positive provisions
  - Board policies based on the Model Guidelines
  - Joint board policy statements
  - Board palliative care and end-of-life care guidelines
- Repeal of negative provisions
  - Archaic addiction-related terminology
  - Restrictions to patients with an addictive disease
  - Quantity/duration limits
  - Last resort language
- Use of models

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"Circumstances that contribute to the prevalence of undertreated pain include...lack of understanding of regulatory policy..."

FSMB Model Policy
May, 2004, p. 1

FSMB Model Policy

- Controlled substances are necessary for public health
- Access to appropriate and effective pain relief
- Pain management is part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness
- Physicians should not fear regulatory sanctions
- Dosage or duration of prescriptions will not solely determine legitimacy of treatment
- Physical dependence is not synonymous with addiction

Prescription Monitoring Programs

Historically

- Used government-issued serialized forms (MCPPs)
- Applied only to Schedule II medications
- Administered by law enforcement
- Data were not compiled timely
- MCPPs associated with decreased prescribing of Schedule II medications
  - "Chilling effect," "stigmatization," "substitution effect"
  - Evidence of program effectiveness
- No evidence of decreased diversion

Prescription Monitoring Programs

Recently

- Use electronic data transfer systems (EDTs)
- Applies to multiple schedules of medications
  - Less chance of "stigmatization" or "substitution effect"
- Administered by health agencies
- Clear statements that these programs are not meant to hinder patient care
- Data are compiled more timely (still not real time)
- No evidence of effect on prescribing
- No evidence of decreased diversion

Prescription Monitoring Programs

- Today, 33 states have an EDT system for multiple drug schedules
  - Only Texas continues to require a serialized form for Schedule II controlled substances only
- 50% of states established EDT in last three years
- Effect of National All Schedules Prescription Electronic Reporting Act (NASPER)
  - Signed into federal law in 2005
  - Provides formula grants: EDTs for Schedules II-IV
  - Mandate for SHHS to evaluate safety and efficacy
- No evidence of effect on prescribing
- No evidence of decreased diversion

How to Achieve and Maintain *Balance*

- Continued state policy improvement
  - Adopt policies that encourage appropriate use of controlled substances for pain management
  - Revise laws that can deter effective pain relief
- Healthcare facility licensing regulations
- Advisory Councils (created by statute)
- Greater understanding of policy content
  - Communicate/educate
- Collaboration between healthcare and law enforcement

Milestones in State Pain Policy

1988 – FSMB *Modern Medical Practice Act* includes pain
1989 – PPSG begins study of regulatory issues
1994 – Medical Board pain management workshops
1997 – IOM recommends evaluating state laws and reforming state medical board policies
1998 – FSMB *Model Guideline*
2000 – PPSG 1st *Evaluation Guide*
2003 – PPSG 1st *Progress Report Card* & 2nd *Evaluation Guide*
2004 – FSMB *Model Policy*
2006 – PPSG 2nd *Progress Report Card* & 3rd *Evaluation Guide*
2007 – *Responsible Opioid Prescribing: A Physician's Guide*
2007 – PPSG 3rd *Progress Report Card* & 4th *Evaluation Guide*
2008? – *Bonica's Management of Pain*

Emerging Solutions for Avoiding Opioid Abuse While Managing Pain

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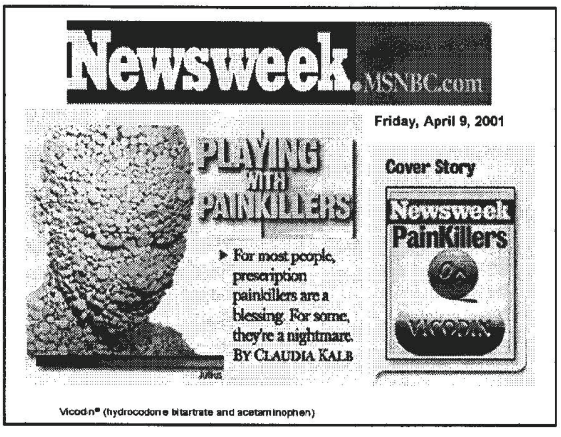
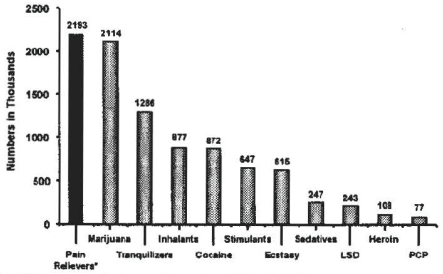


Who Abuses

- Illicit use (reward seekers)
  - Recreational abusers
  - Patients with the disease of addiction
- Licit use (escape harsh reality of pain)
  - Pain patients trying find more pain relief
  - Pain patients escaping the emotional pain

New Illicit Drug Use in the United States: 2005



*526,000 n ew nonmedical users of Oxycodone CR (OxyContin®)
SAMHSA. *Results From the 2005 National Survey on Dr ug Use and Health*. DHHS Publication No. SMA 06-4194. 2006

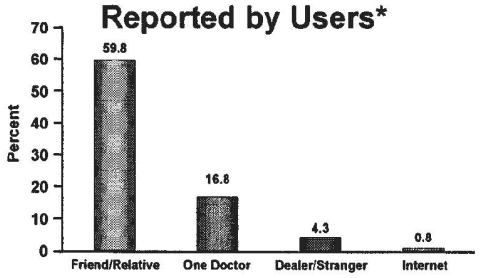
Increasing Deaths From Opioid Analgesics

	1999	2002	% Change
Opioid Analgesics	1942	4451	+129.2
Cocaine	2215	2569	+16.0
Heroin	858	1061	+23.7

Licit drugs have recently replaced illicit drugs as the most common cause of fatal drug poisoning in the United States

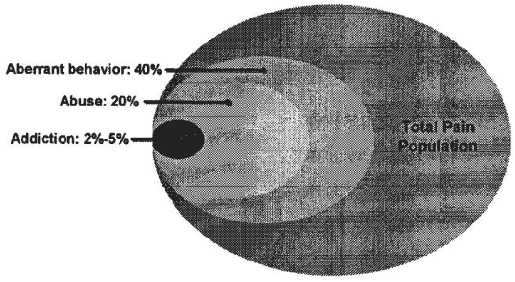
Adapted from: Paulozzi LJ, et al. *Pharmacoepidemiol Drug Saf*. 2006;15:618-627.

Pain Relievers Obtained for Nonmedical Use: Sources Reported by Users*



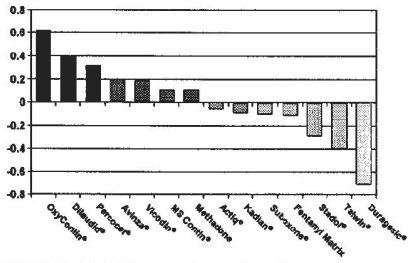
*Source of drugs for the most recent nonmedical use of pain relievers reported by persons aged 12 or older in the United States 2005.
SAMHSA. *Results From the 2005 National Survey on Drug Use and Health.* DHHS Publication No. SMA 06-4194, 2006.

Risk of Aberrant Behaviors



Webster LR, Webster RM. *Pain Med.* 2005;6:432-442.

Average Effect Size for Each Drug with All Other Drugs



Effect size = Cohen's D for each drug averaged across all other drugs
Butler SF, et al. *Harm Reduct J.* 2006;3:5.

"Holy Grail" for Opioids

- Potent dose-related analgesia
- Minimal side effects
- Minimal withdrawal
- Minimal tolerance
- No hyperalgesia
- No euphoria
- No craving

Formulations

- Rapid onset
- SAOs
- LAOs
- Abuse resistance
- Abuse deterrence

SAOs = short-acting opioids; LAOs = long-acting opioids

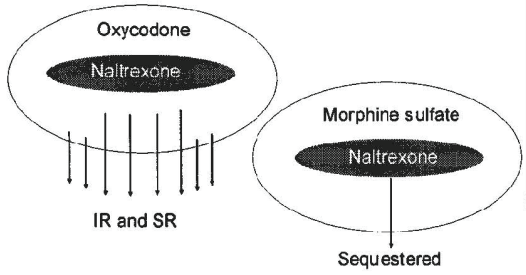
Areas of Abuse Deterrent Research

- Pharmacokinetic
  - Modify route of administration
  - Modify delivery system
- Pharmacodynamic
  - Receptor specific function
  - Combination with opioid antagonist
- Genetic/molecular
  - Targeting intracellular pathways and processes

Abuse-Deterrent Opioid Formulations in Development

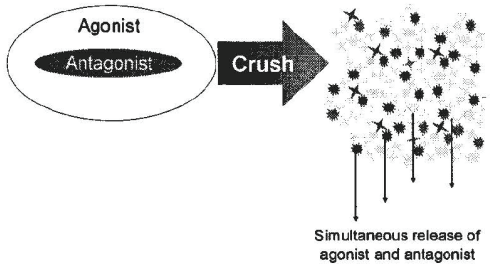
Technology	Company
Oxycodone + low-dose naltrexone	Pain Therapeutics, Inc. (PTI)
Morphine + antagonist	Alpharma
Oxycodone + naltrexone	Elite Pharma
Controlled-release gel capsule	PTI/King Pharma
Secure-release formulation	TheraQuest

Agonist-Antagonist Formulations



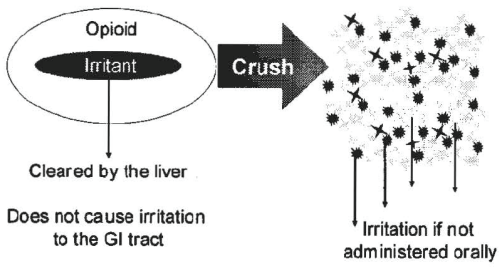
IR = immediate-release; SR = sustained-release
Gershell L, Goater JJ. *Nature Rev.* 2006;5:889-890.

Agonist-Antagonist Formulations



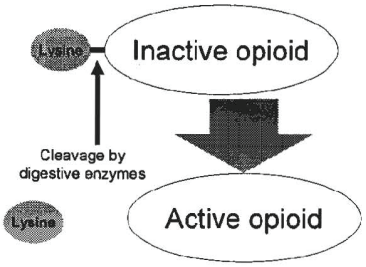
Gershell L, Goater JJ. *Nature Rev.* 2006;5:889-890.

Irritant in Abuse Deterrent



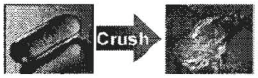
Woolf CJ, Hashmi M. *Curr Opin Investig Drugs.* 2004;5:61-66.

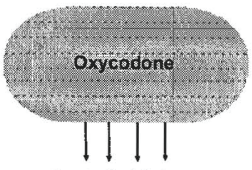
Prodrugs: Inactive Until Digestion



Gershell L, Goater JJ. *Nature Rev.* 2006;5 889-890.

Abuse-Resistant Formulation



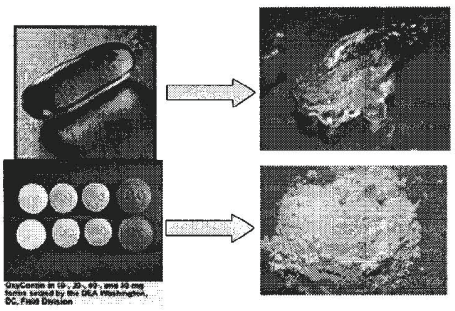


- Resists physical and mechanical manipulation aimed at disrupting the CR feature
- Cannot be chewed or crushed
- Cannot be snorted
- Cannot be injected

CR = controlled-release

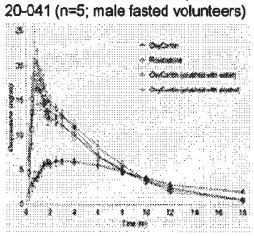
Gershell L, Goater JJ. *Nature Rev.* 2006;5:889-890.; Webster LR. *Expert Opin Investig Drugs.* 2007;16:359-366.

Clinical Abuse Resistance

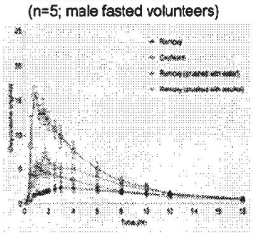


Oxycodone Controlled-Release Gel Capsule (Remoxy™): Abuse Deterrence Study Results

Mean (SEM) oxycodone plasma concentrations in LifeTree protocol 20-041 (n=5; male fasted volunteers)



Mean (SEM) oxycodone plasma concentrations in PTI-821-CE (n=5; male fasted volunteers)



SEM = standard error of the mean

Opioid Agonist and "Ultra-Low Dose" Antagonist

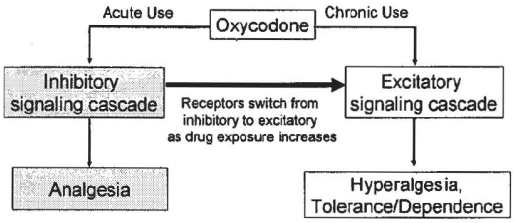
- Enhance and prolong acute analgesia
- Decrease the euphoria effect
- Prevent opioid tolerance
- Decrease physical dependence (withdrawal)
- Lessen side effects

Mechanism of Action: Opioid Receptors and Tolerance

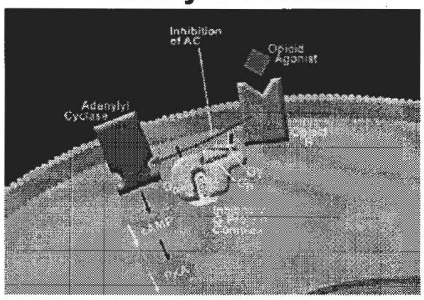
- After chronic exposure, opioid receptors adapt to counteract an opiate drug
- Initial theories: number of opioid receptors decrease, or simply stop signaling
- Crain and Shen: receptors have extreme adaptation, ie, *excitatory* rather than *inhibitory* signaling

Inhibitory ⟶ Excitatory

Opioid Tolerance/Dependence Is a Switch in Signaling



Normal Coupling to Inhibitory G Proteins



Webster LR. *Expert Opin Investig Drugs.* 2007;16:1277-1283.

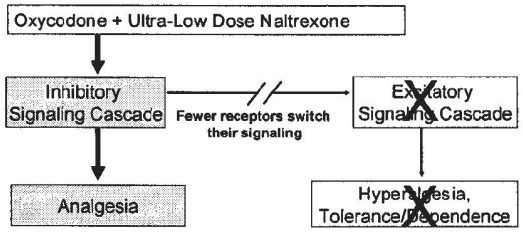
The Switch in G Proteins

- Opioid receptors are GPCRs that normally couple to inhibitory G proteins
- Excitatory signaling is caused by a switch in G protein coupling from inhibitory G proteins (Gi and Go) to the excitatory Gs

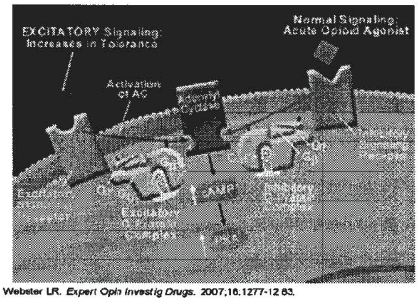
GPCRS = G-protein coupled receptors

Inhibitory —//→Excitatory

Ultra–Low Dose Antagonist Prevents Excitatory Signaling



Tolerance: Switch to Excitatory G Protein Coupling



Webster LR. *Expert Opin Investig Drugs.* 2007;16:1277-1283.

Oral Oxycodone + Ultra-Low Dose Naltrexone: Same Pain Relief

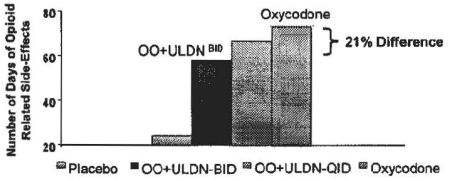
	Placebo (N = 101)	Oxycodone (N = 206)	Oral Oxycodone + Ultra-Low Dose Naltrexone (N = 206) QID	BID
Baseline Pain Scores (0-10)	7.7	7.6	7.3	7.6
Week 12	5.2	4.0	4.2	4.3
Δ Pain Scores	32%	47%	42%	43%
Study Drug Dose	41.5 mg	39.0 mg	*34.5 mg	**34.7 mg
Drop-out Rate	58%	51%	58%	52%

*P = .027
**P = .035

All drug groups separate from placebo.
All drug groups have statistically similar reduction in pain scores.

Webster LR, et al. *J Pain*. 2006;12:937-946.

Oral Oxycodone + Ultra-Low Dose Naltrexone (OO+ULDN) Less Side-Effects



- Significantly less moderate-severe constipation, somnolence, and pruritus
- Significantly less physical dependence/withdrawal

OO+ULDN = oral oxycodone + ultra-low dose naltrexone

Conclusions

- There is a large unmet need to control pain and opioids are a necessary therapy
- Opioid abuse is a growing concern that needs new solutions
- New abuse resistance and abuse deterrent formulations may lead to some decrease in abuse and diversion