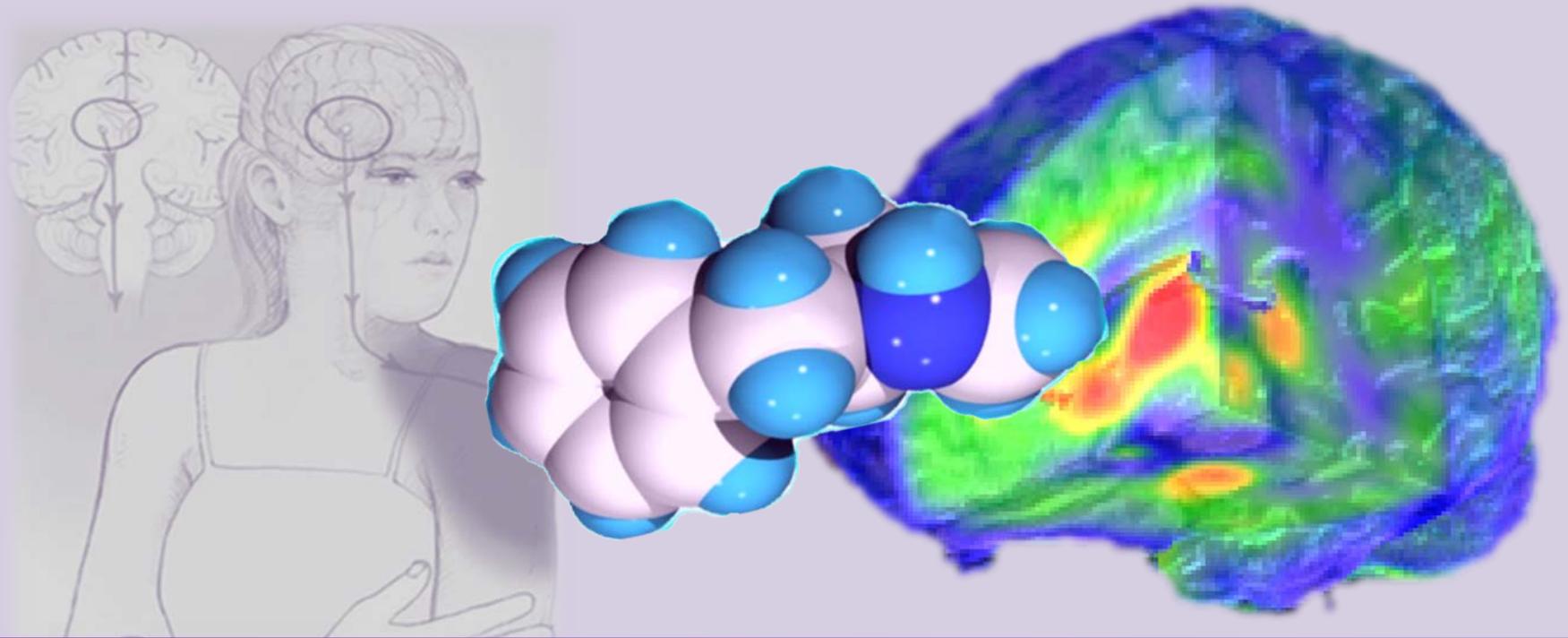


# Update on the Consensus Conference on Chronic Pain and Opioids

(Sponsored by the NIH Consensus Development Program)



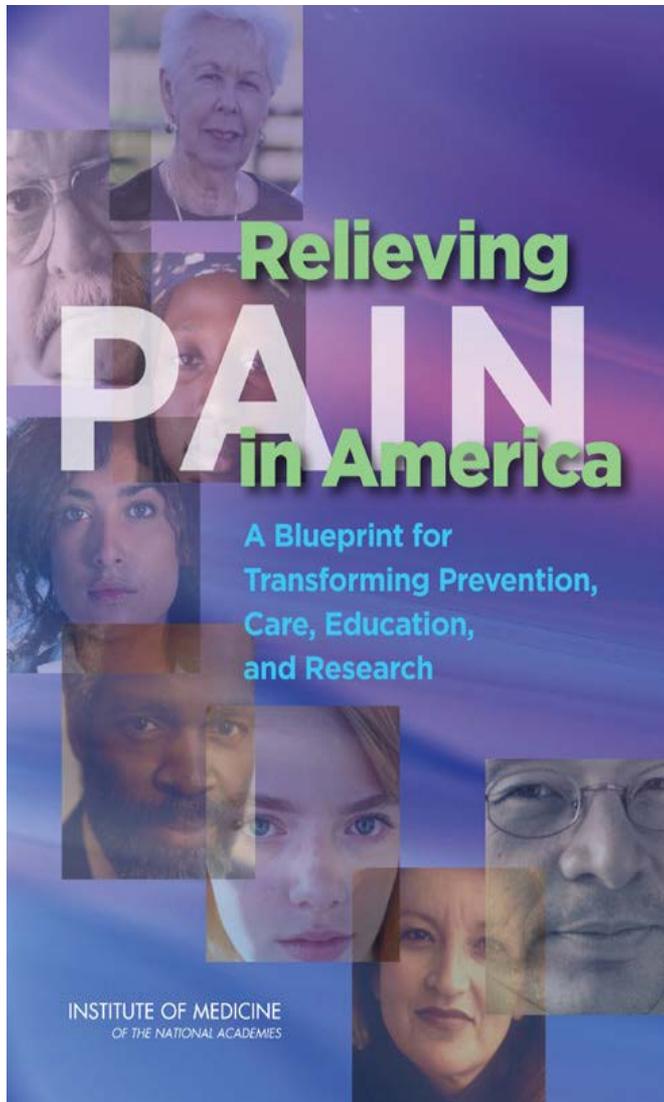
**Nora D. Volkow, M.D.**  
**Director**



**National Institute on Drug Abuse**

# INSTITUTE OF MEDICINE REPORT

## Recommended Adoption of a Comprehensive Plan to



- Heighten awareness about pain and its health consequences
- Emphasize the *prevention* of pain
- Improve pain assessment and management
- Use public health communication strategies to inform patients on how to manage their own pain
- Address disparities in the experience of pain among subgroups of Americans

# Magnitude of the Problem

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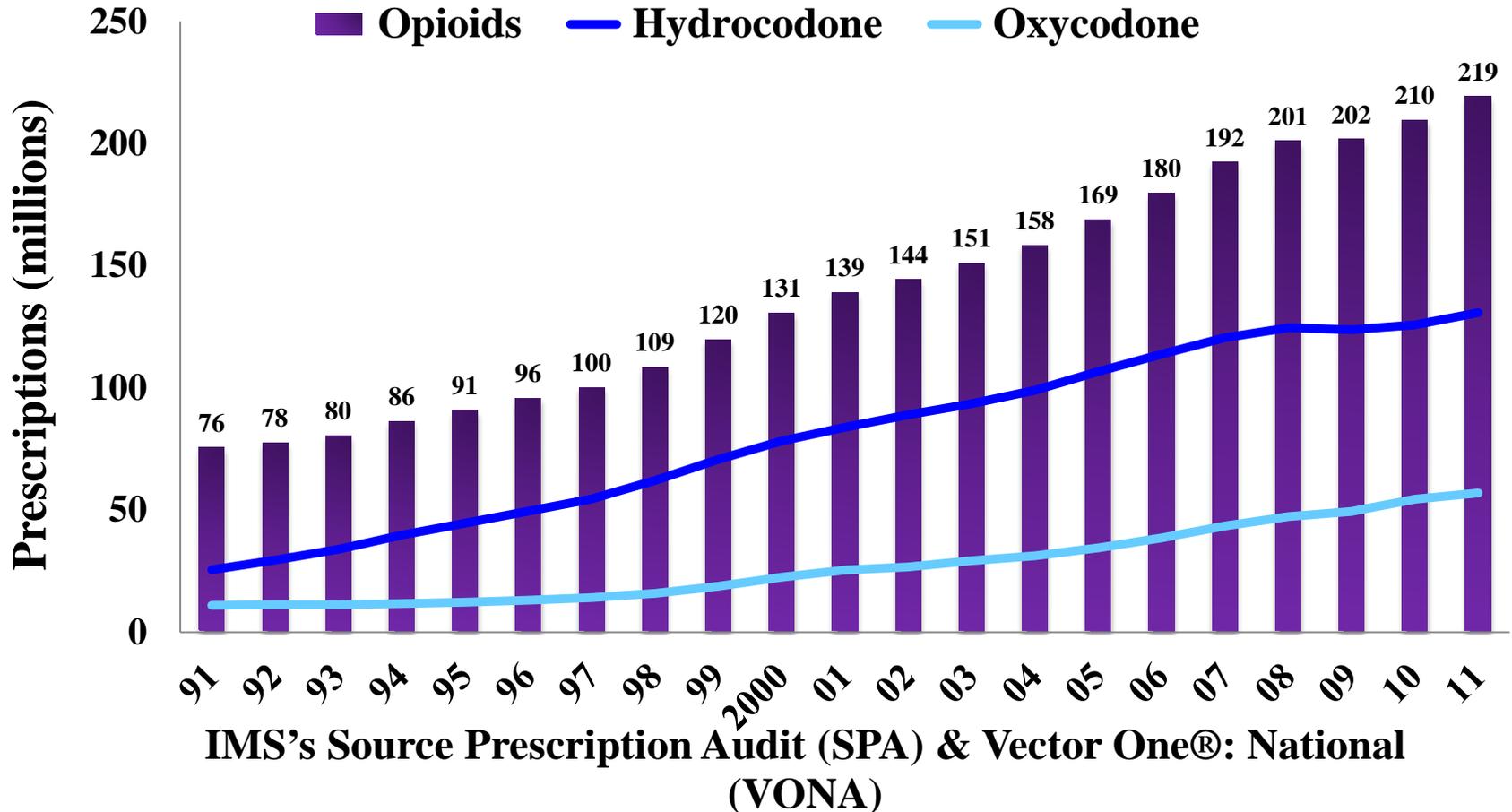
- **100 Million individuals suffer from chronic pain in the US**
- **Costs from pain estimated to be around 560-635 billion dollars annually (medical care and decreased productivity)**
- **Significant percentage of patients suffering from pain are not properly treated (40-70%??)**
- **Prevalence of pain is increasing in the US (associated with increased longevity, increases in obesity and improved survival from trauma)**

# Management of Chronic Pain

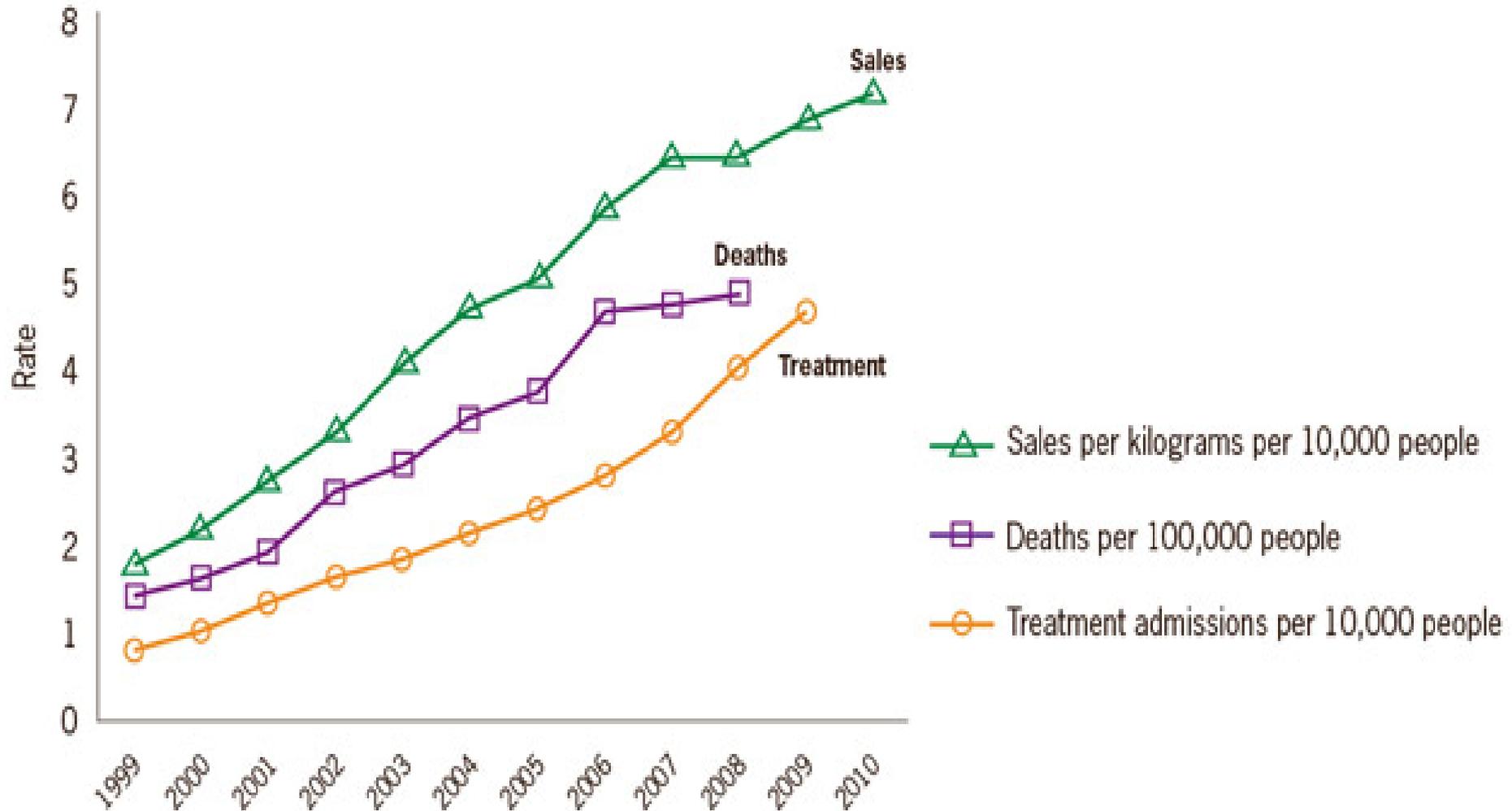
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- **Need for comprehensive treatment – many available treatments are not used**
- **Current treatment algorithms not effective**
- **Increasing reliance on opioids for treatment associated with increases in opioid-related harms...**

# Number of Opioid Prescriptions Dispensed by U.S. Retail Pharmacies, Years 1991-2011



# Increases in deaths parallel opioid sales increases as well as prescription opioid treatment admissions



# Opioid Therapy for Chronic Pain

Jane C. Ballantyne, M.D., and Jianren Mao, M.D., Ph.D.

*N Engl J Med 2003; 349:1943-1953*

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- **Some physicians argue that opioids are only *marginally* useful in the treatment of chronic pain, have a *minimal* effect on functioning, and may even worsen the outcome**
- **“evidence suggests that prolonged, high-dose opioid therapy may be neither safe nor effective.**

**Studies do not have large number of subjects  
or long duration**

# Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study

*Dunn et al., Ann Intern Med. 2010;152(2):85-92*

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- **Study explored the risk of overdose in patients prescribed opioids for chronic noncancer pain in general health care.**
- **The study links risk of fatal and nonfatal opioid overdose to prescription use -- **strongly associating the risk with the prescribed dose****
- **Because of uncertainties regarding effectiveness and risks, long-term opioids should be prescribed with close patient monitoring, which may not be happening consistently at present**

# Consensus or Workshop Conference

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**Use of opioid medications for the treatment of chronic pain**



**The NIH Consensus Development Program** has organized conferences since 1977 that produce consensus statements **on important and controversial topics in medicine.**

Each conference is sponsored and administered by one or more Institute, Center, or NIH Office and by the NIH Office of Disease Prevention.

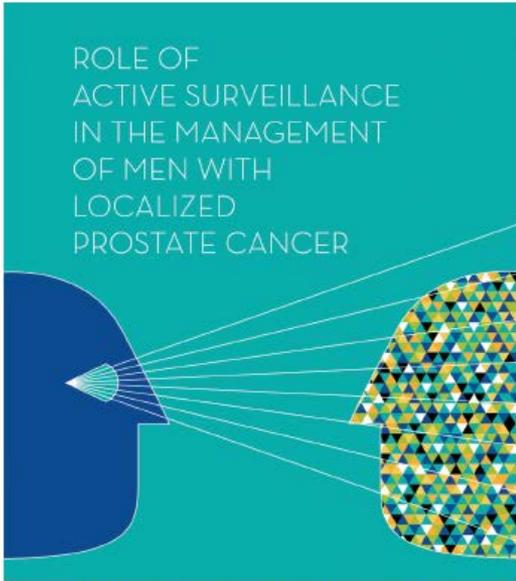
The goal of a Consensus Development Conference is to evaluate the available scientific information and **develop a statement** that advances understanding of the issue in question and will be useful to health professionals and the public at large.

# **Basic Criteria for a Consensus Development Conference**

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- **Clinical and broad public health importance**
- **Gap between knowledge and practice**
- **There is scientific information from which to answer conference questions**
- **Issue is of cross-cutting concern to a variety of NIH Institutes, Centers, or Offices**

**NIH State-of-the-Science Conference Statement on  
Role of Active Surveillance in the Management  
of Men With Localized Prostate Cancer**



NIH Consensus and State-of-the-Science Statements

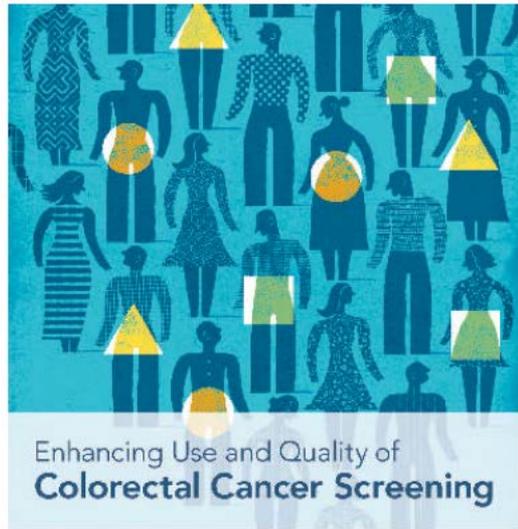
Volume 28, Number 1  
December 5-7, 2011

NATIONAL INSTITUTES OF HEALTH  
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NIH...Turning Discovery Into Health

**NIH State-of-the-Science Conference Statement on  
Enhancing Use and Quality of  
Colorectal Cancer Screening**



Enhancing Use and Quality of  
**Colorectal Cancer Screening**

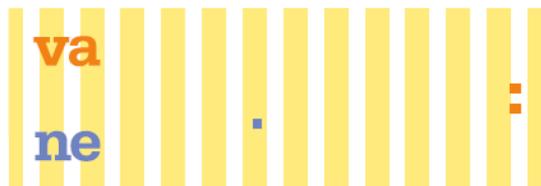
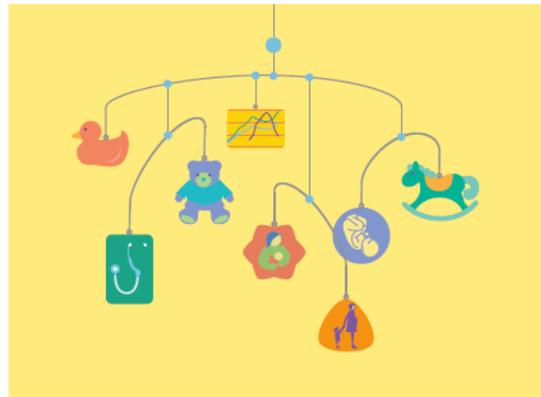
NIH Consensus and State-of-the-Science Statements

Volume 27, Number 1  
February 2-4, 2010

NATIONAL INSTITUTES OF HEALTH  
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**NIH Consensus Development Conference Statement on  
Vaginal Birth After Cesarean: New Insights**



NIH Consensus and State-of-the-Science Statements

Volume 27, Number 3  
March 8-10, 2010

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# *Types of Conferences:*

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- **State of the Science – Designed to find gaps in research.**
- **Consensus Conference – 2.5 day long conference to review all the scientific literature and determine and answer to a complex scientific question.**
- **Workshop Conferences – shorter than the consensus conference. Can be developed in about one year (vs. 2 for consensus conference), and answer a scientific question where less literature is available.**



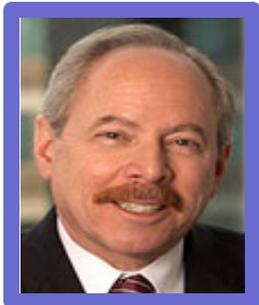
*NIH's Office of Disease Prevention incurs all financial costs for conferences*

# Submission to Consensus Development Program

Opioids are widely used for chronic pain, often without evidence-based clinical guidelines. Complicating this is an epidemic of prescription opioid abuse.

PC proposed a consensus conference on **the efficacy of opioids for chronic non-malignant pain** (6-2012), which was accepted. PC (with FDA involvement) established a working group to develop content for the conference.

The conference will be a hybrid of consensus conference (strong evidence), and state-of-the-science (data is inconclusive).



**Proposed Chair : Alan I. Leshner, Ph.D.**  
Chief Executive Officer AAAS  
Executive Publisher, *Science*.

## **WORKING GROUP MEMBERS**

**Thomas Aigner, NIDA/NIH**

**Houman Araj, NEI/NIH**

**Ann Berger, CC/OD/NIH**

**Catherine Bushnell, NCCAM/NIH**

**Wen Chen, NIA/ERP/NIH**

**Richard Denisco, NIDA/NIH**

**Raymond Dionne, NINR/NIH**

**John H. Ferguson, NCATS/NIH**

**Mike Iadarola, NIDCR/NIH**

**Edward Ivy, NHLBI/NIH**

**Petra Jacobs, NIDA/NIH**

**Cheryl Kitt, CSR/NIH**

**Ann Knebel, NINR/NIH**

**John Kusiak, NIDCR/NIH**

**Yu Lin, NIDA/NIH**

**Susan Maier, OD/NIH**

**Sue Marden, NINR/NIH)**

**Ann O'Mara, NCI/NIH**

**Linda Porter, NINDS/NIH**

**Bridgett Rahim-Williams, NIMHD/NIH**

**Bob A. Rappaport, CDER/FDA**

**Wendy Smith, OD/NIH**

**Michael Steinmetz, NEI/NIH**

**Michele Straus, NIDA/NIH**

**David Thomas, NIDA/NIH**

**Douglas C. Throckmorton, CDER/FDA**

**James Witter, NIAMS/NIH**

## POTENTIAL TOPICS/QUESTIONS:

### *Efficacy of opioids for treating chronic pain:*

- 1) Are there **types of pain for which opioids are most/least effective**, e.g. neuropathic, musculoskeletal, sickle cell, pain due to inflammation, backache, headache?
- 2) Are opioids effective for treating prolonged pain driven by insult, trauma or active disease processes versus **chronic pain which persists after the original insult/trauma or disease has healed**?
- 3) Should opioids be used for pain resulting from or exacerbated by **treatment-induced pain** (e.g. analgesics, chemotherapies...)?
- 4) In chronic opioid-treated patients, what are **the treatment options for flare-ups** (e.g., sickle cell disease) or **breakthrough pain** (e.g., as a result of tolerance or illness progression)?

- **Opioid use for optimal efficacy/minimal adverse effects:**

- 1) Can doses of opioids be adjusted to take advantage of known circadian variations in pain?

- 2) Are certain **regimens or formulations** more or less likely to cause tolerance? (e.g. short- versus long-acting opioids, continuous versus intermittent prescriptions).

- 3) Are there treatment combinations (e.g. pharmacological, behavioral, complementary approaches) that could be used with opioids to increase analgesic efficacy, reduce tolerance, and decrease dosage needed?

- **Risks for opioid addiction:**

- 1) Are certain dosing regimens or formulations more or less likely to cause addiction? (e.g. short- vs. long-acting opioids, continuous versus intermittent prescriptions.)

- 2) How does severity/chronicity of pain relate to risk for addiction?

- ***Curtailing* opioid treatment when it has been determined that its no longer effective:**

- 1) How should pain be managed if it has not resolved at the time of the reduction in the opioid regimen?

- 2) How can one distinguish between **physical dependence** (which will occur in chronically treated patients) **versus addiction**; and how should patients falling into either or both categories be managed?

- ***Populations differences:***

- 1) What are the risks of opioids **in older adults**, taking into account co-morbid medical conditions, poly-pharmacy, diminished neuronal plasticity and potentially weakened immune and metabolic systems?

- 2) Should there be special consideration to using non-opioid pain medications in **children and adolescents**?

- 3) Given the extensive data **on sex-related differences** in analgesic efficacy and side effects of mu and kappa agonists, what are the best ways to treat pain with opioids in men versus women?

## POTENTIAL TOPICS/QUESTIONS:

- **What *training* is available (other than that offered by industry) for teaching how and what type of opioids should be used in managing chronic pain?**
- **What *future research directions* need to be pursued to determine the best approaches for managing chronic pain conditions with opioid therapies?**

**For identified research gaps, what are the *research priorities*?**