

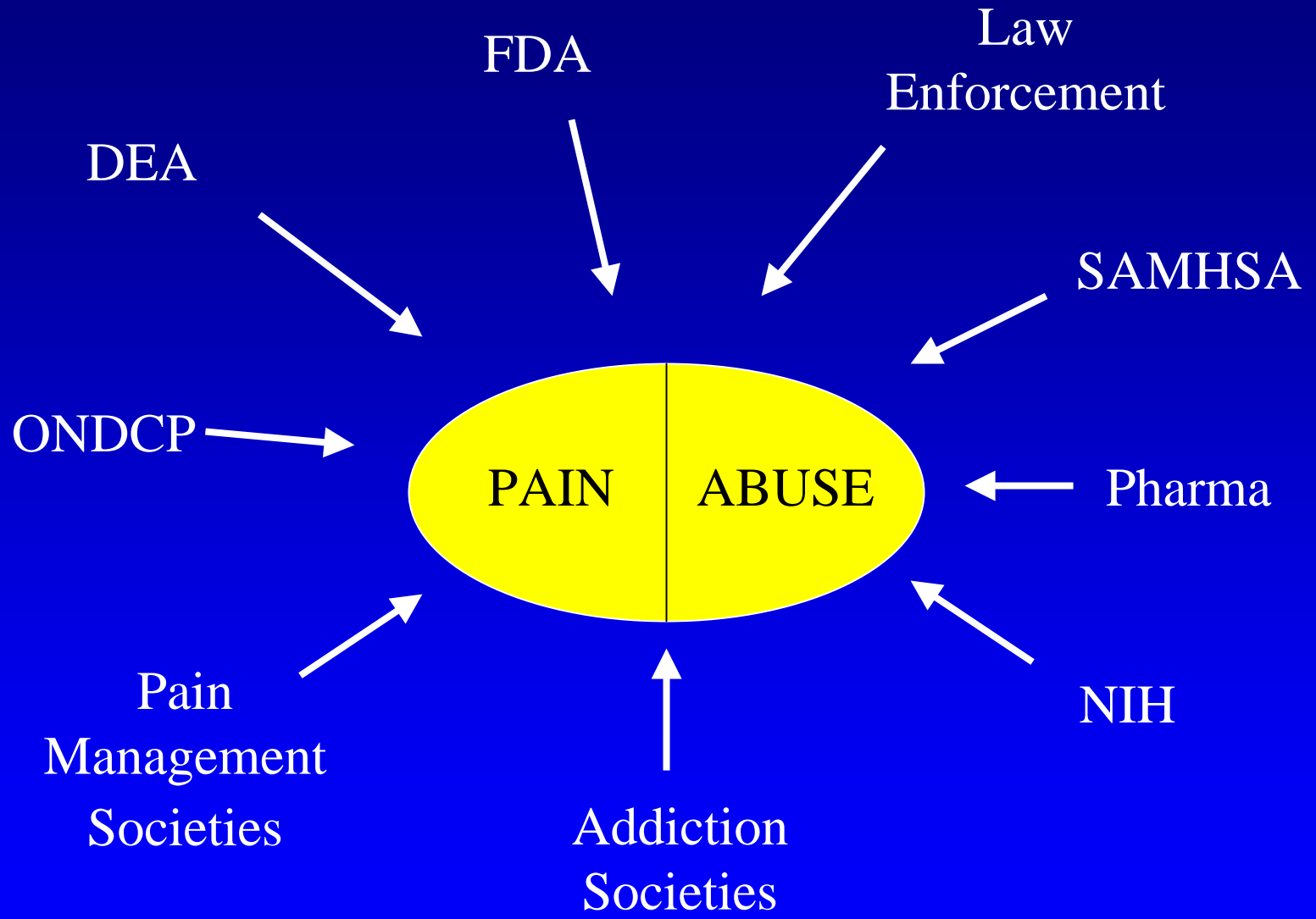
Tufts Health Care Institute
Opioid Risk Management Program

“Best Practices in Opioid Risk
Management”

Tufts Health Care Institute
Boston, MA
November 9-10, 2006

Mission

To address challenges in the development and utilization of opioid analgesics, by engaging a multidisciplinary group of stakeholders focused on optimizing the benefits of opioids for pain management, and minimizing their risks, including abuse and diversion.



Program Structure

- Meetings in neutral, educational environment for free exchange of information and ideas
- Non-for-profit organizational structure; cost neutral financial model; multi-pharma support
- Meetings organized informally through networking, literature, organizational requests
- Emphasis on engaging medical and scientific communities through publications
- Emerging policy and advocacy agenda

Program Accomplishments

Foundations of Opioid Risk Management

Nathaniel P. Katz, MD, MS, † Edgar H. Adams, ScD, ‡ James C. Benneyan, PhD, §
Howard G. Birnbaum, PhD, ¶ Simon H. Budman, PhD, ¶¶ Ronald W. Buzzco, RPh, **
Daniel B. Carr, MD, * Theodore J. Cicero, PhD, † † Douglas Gourlay, MD, ‡ ‡
James A. Inciardi, PhD, §§ David E. Joranson, MSSW, || James Kesslick, MS, ¶ ¶ and
Stephen D. Lande, PhD, ¶ ¶ ¶*



Program Accomplishments

Challenges in the Development of Prescription Opioid Abuse-Deterrent Formulations

Authors:

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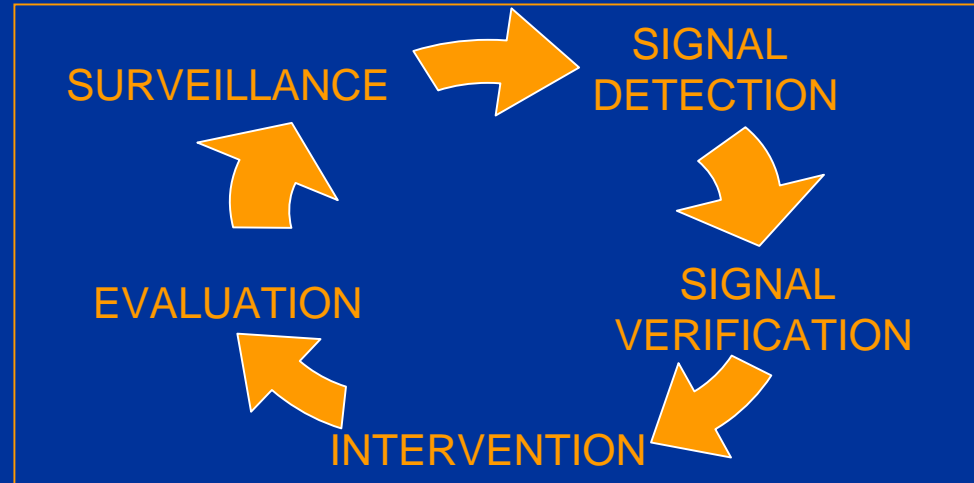
Program Accomplishments

\$ Fundraising \$



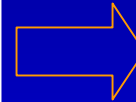
Program Accomplishments

“Best Practices in Opioid Risk Management”

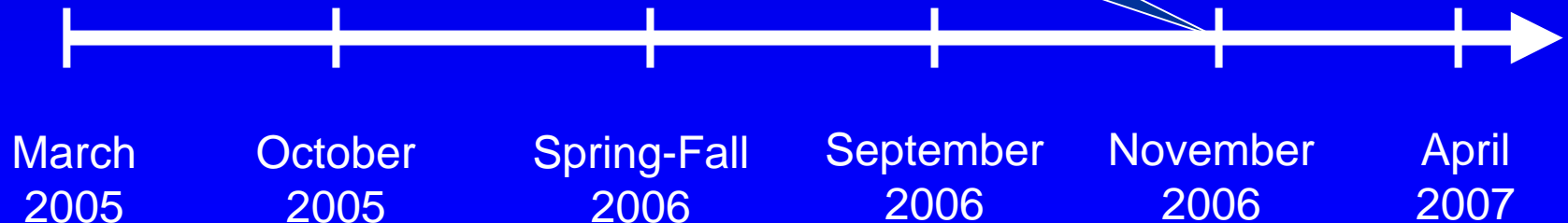


Program Accomplishments

“FDA Guidance on Developing Abuse-Deterrent Opioid Formulations”



CITIZEN'S
PETITION
SCIENTIFIC
BACKGROUND
DOCUMENT



Program Accomplishments

Responding to Signals of Prescription Opioid Abuse

Signal Prioritization
Signal Verification: Ultra-rapid Assessment
Cost-effective Interventions
Evaluation of Interventions



Goal of Today's Meeting

To initiate a process that will end with the FDA producing a guidance document on the development of abuse-deterrent opioid formulations

*“You create change by
announcing your intention”*

Andrea Barthwell, MD

Prescription Opioid Abuse/Misuse is Not One Phenomenon

- Converting controlled-release formulations into immediate-release formulations
 - PO, nasal, IV, buccal, smoking, etc.
- Overdosing on intact formulations
- Harm from co-ingestion with alcohol
- Ingesting intact formulations for recreational purposes

Objectives of Today's Meeting

- To begin the drafting of a Citizen's Petition to FDA requesting that FDA develop a guidance on the development of ADFs
 - See initial “outline” in your packet
 - We will discuss (but not work on) the CP during this meeting
 - Final document to be completed by the group within 1 month
- To draft a scientific background paper to support the Citizen's Petition
 - Key elements of this background paper to be produced by workgroups today
 - Input by the larger group will take place today and tomorrow
 - Input by the broad THCI ORM community to be captured over next few weeks as document is finalized
 - To be provided as part of the Citizen's Petition, and published as a consensus paper
- We are not writing the guidance itself