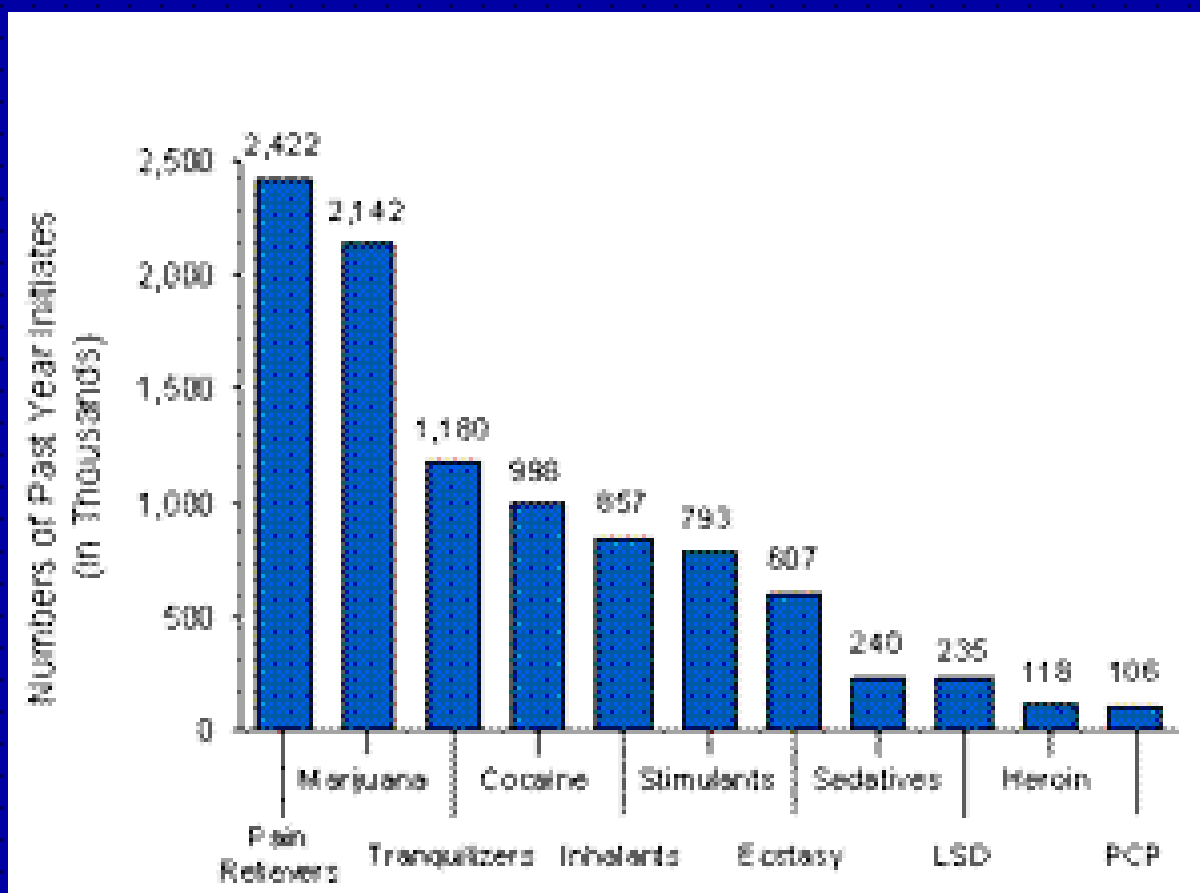


Tufts Health Care Institute  
Opioid Risk Management Program

“Best Practices in Opioid Risk  
Management”

Tufts Health Care Institute  
Boston, MA  
September 7-8, 2006

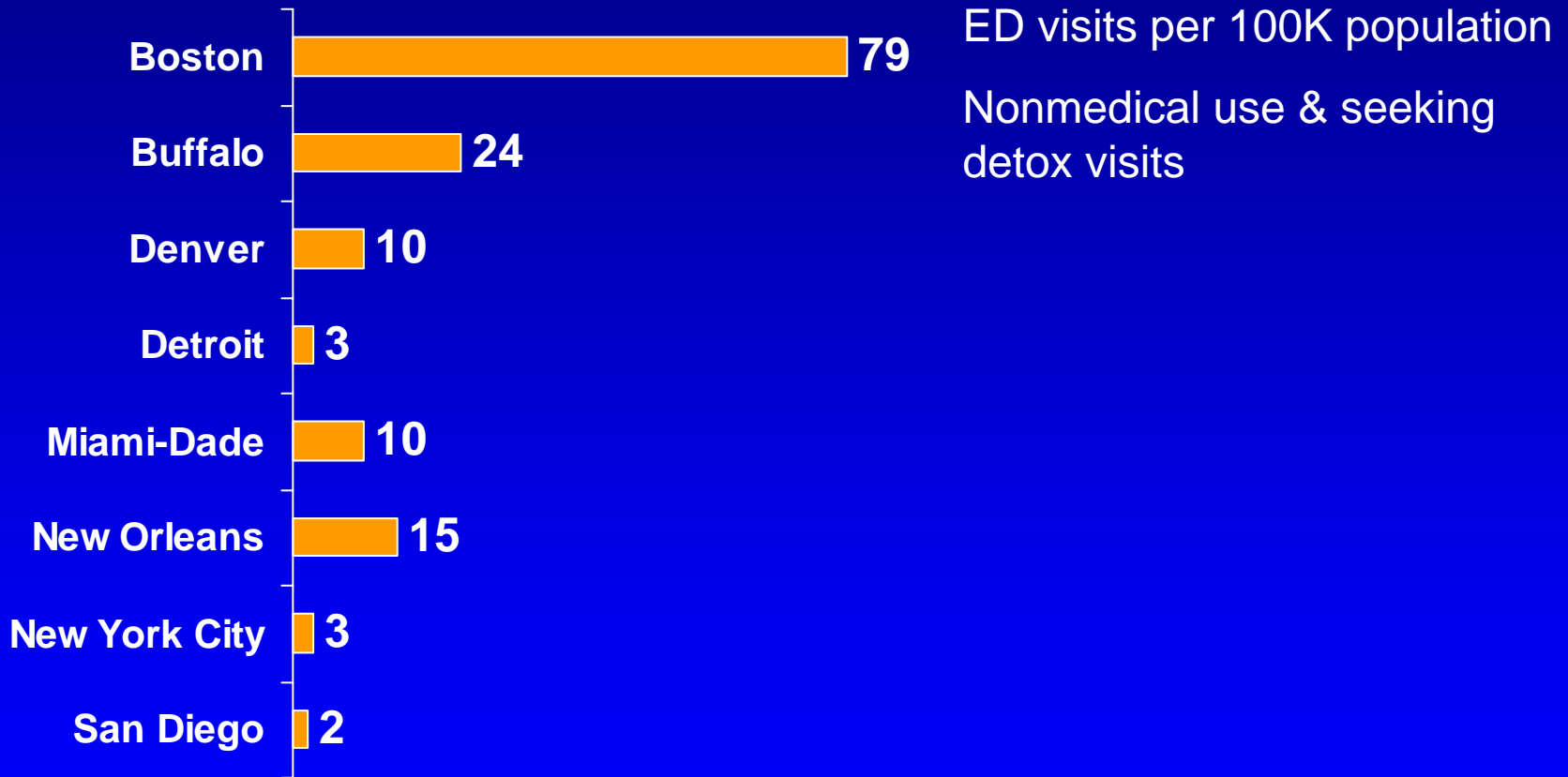
# Past Year Initiates for Illicit Drug Categories: NSDUH 2004



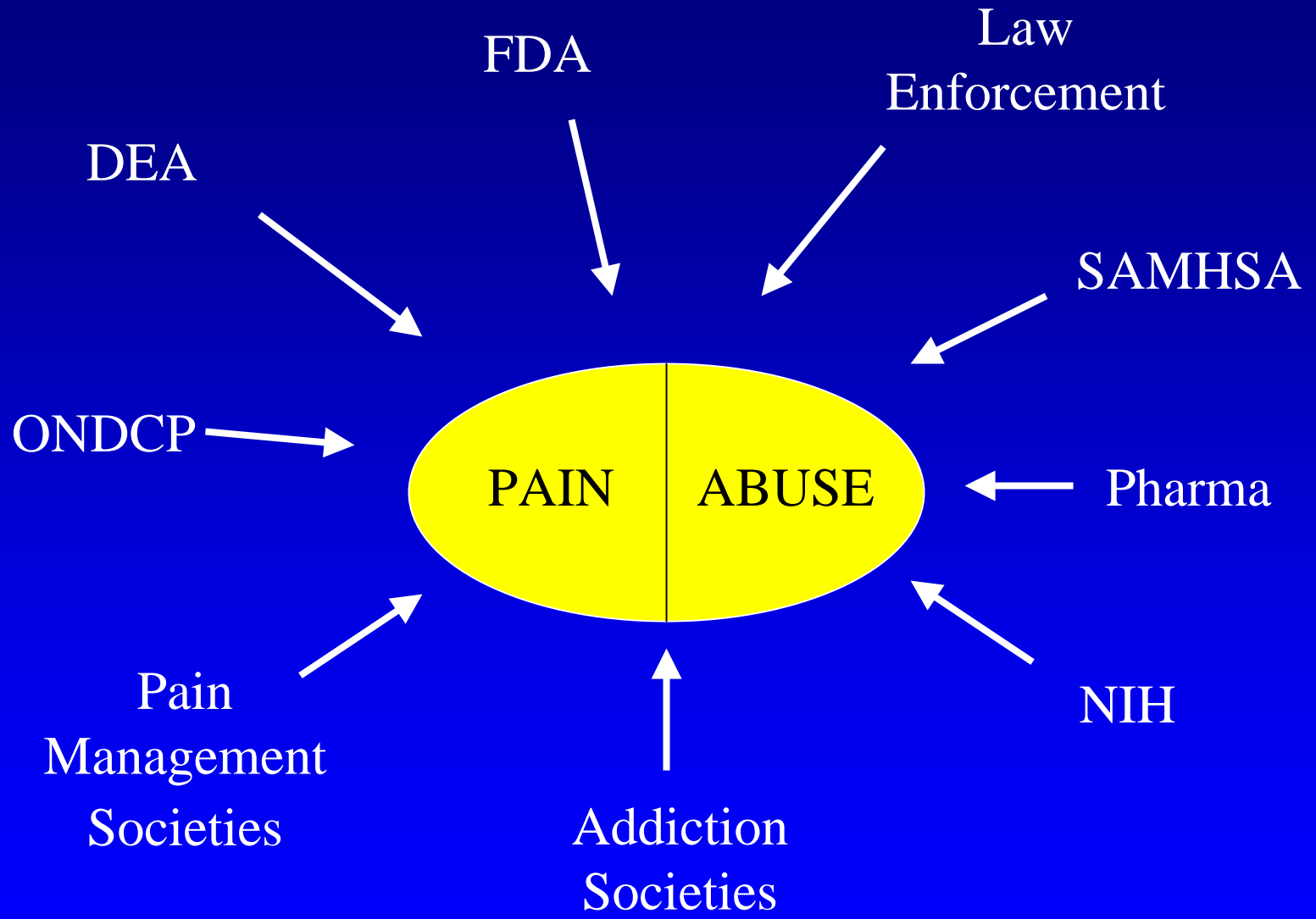
# Volume of Diverted Opioids Study

- Opioids dispensed per yr in US (IMS, 2002- 03)
  - 190 million prescriptions
  - 9.4 billion doses
- Non-medical users in last year (NSDUH 2002-03)
  - 11 million people
  - 430 million non-medical use days
- Number of doses ingested non-medically per yr
  - Floor estimate: 430 million (1 dose/day)
  - Ratio of non-medical use days / medical use days: 0.22
    - 2 billion doses ingested non-medically

# Nonmedical Use: Oxycodone, ED Visit Rates by Area, 2004



Source: DAWN estimates for the U.S., 2004



# 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

# Program Review

- 1<sup>st</sup> Meeting: “Opioid Risk Management,” 3/29/05
  - “Foundations of Opioid Risk Management” article accepted CJP
- 2<sup>nd</sup> Meeting: “Challenges in the Development of Abuse-Resistant Opioid Formulations,” 10/27/05
  - “Challenges in the Development...” review article in progress
  - Consensus to proceed with further meetings:
    - Best Practices in Opioid Use for Chronic Pain
    - Best Practices in Opioid Risk Management
    - Draft Guidance on Development of Abuse-Resistant Products
    - Establishing Standards on Measurement of Extractability
    - Understanding Types of Prescription Opioid Abusers
    - Alcohol Co-Ingestion with Prescription Products
    - Legislative Incentives for Developing Abuse-Resistant Products
- Successful fund-raising, summer 2006
- 3<sup>rd</sup> Meeting: “Best Practices in Opioid Risk Mgt,” 9/7/06



# Program Plans

- Hire part-time program director, fall 2006
- 4<sup>th</sup> Meeting: “Draft Guidance on Development of Abuse-Resistant Products,” 11/9-10/06
- 5<sup>th</sup> Meeting: “Understanding Types of Prescription Opioid Abusers,” April, 2007

# Objectives of Today's Meeting

- To define the regulatory and public health purposes of risk management programs for opioid analgesics
- To identify best practices in the development of risk management action plans, including surveillance, signal detection and verification, prevention, and intervention