

# Responding to Signals of Prescription Opioid Abuse

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Colonnade Hotel  
Boston, MA  
March 29-30, 2007

DEATH

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THERAPEUTIC  
ACCESS

CRIME

INITIATION OF  
DRUG USE

Prescription  
Opioid Abuse

TEENAGE  
SUICIDE

ADDICTION

ECONOMIC  
COST

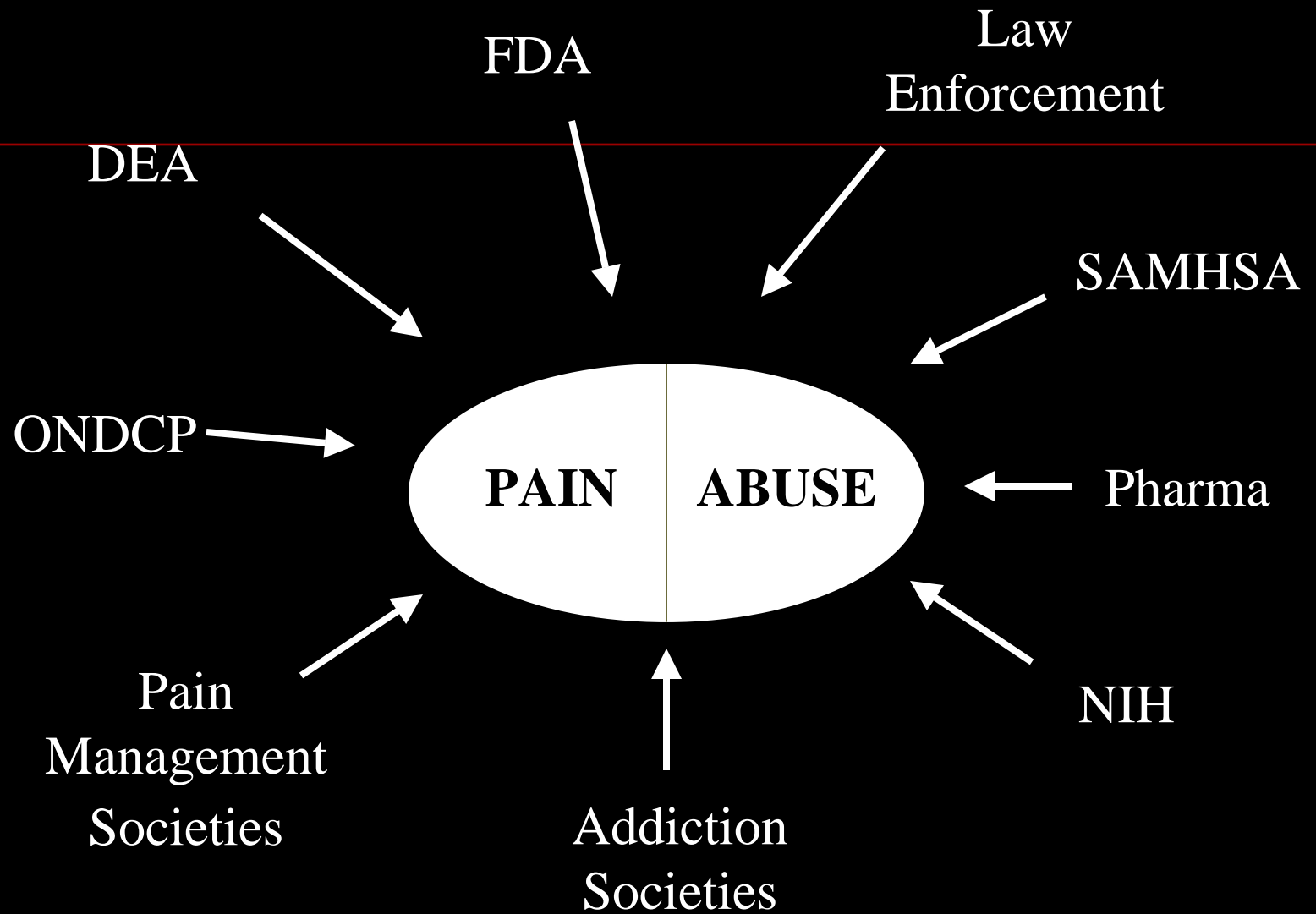
MEDICAL  
EMERGENCIES

# Differences between prescription opioid abuse and other drug abuse

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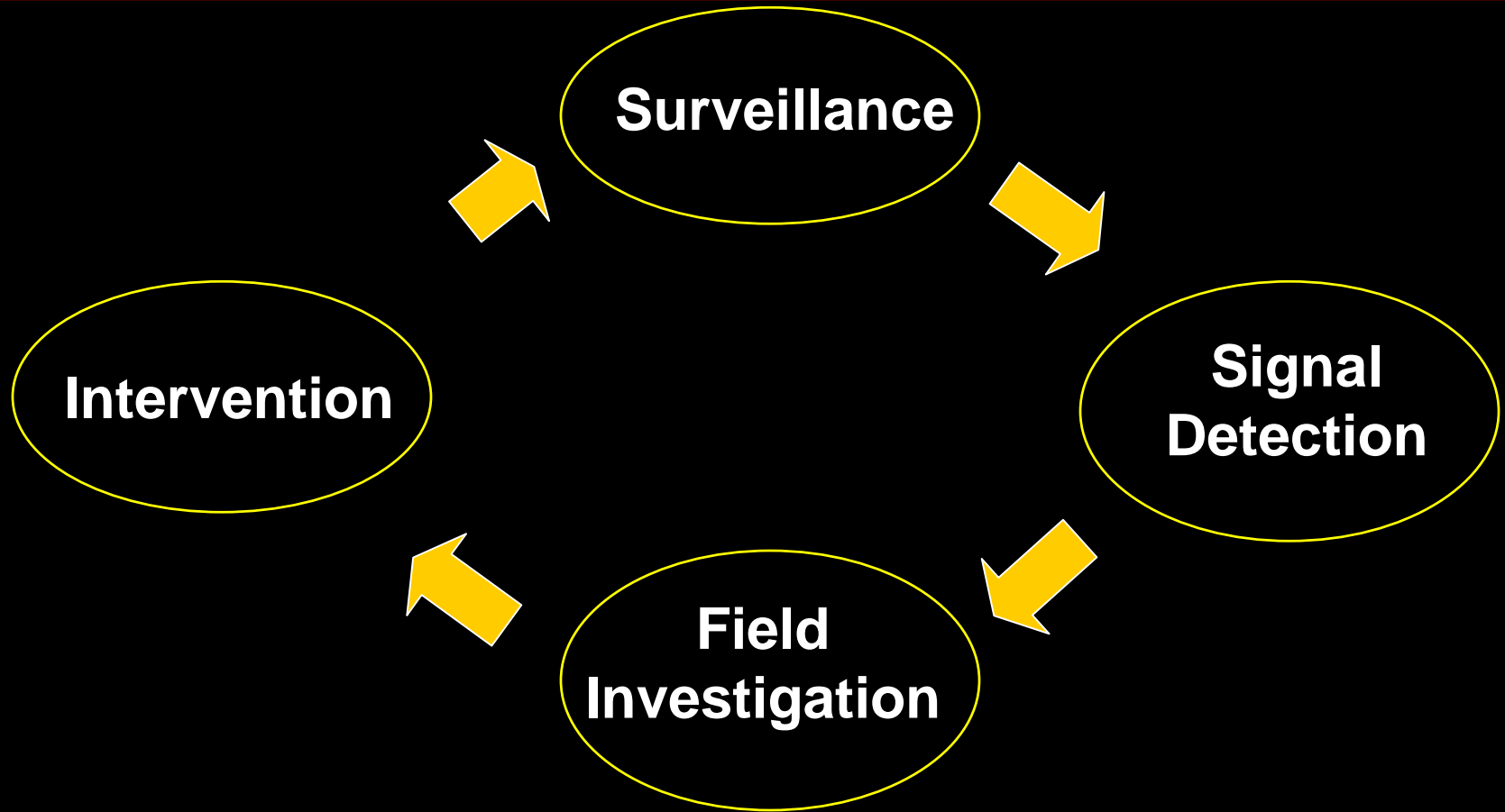
- Product manufactured by pharmaceutical industry
- Much of diverted prescription opioids generated by prescriptions for pain

SOURCE	NSDUH 2005	NAVIPPRO	Mass PMP	Joranson, 2005	AATOD	RADARS <21	RADARS >51
Dealer	4.8%	63%			85%	76%	10%
Own script	14%	55%			29%	19%	55%
1 doctor	12.7%						
Mult. doctors	1.3%	9%	2.5 million DU* 75 million DU**				
Forged or stolen						33%	10%
Forged		9%			3%		
Stolen		3%			7%		
Internet		8%			3%	2%	6%
Friend or relative	-	49%			53%	61%	22%
Friend/Relative Free	53.0%						
Friend/relative bought	10.6%						
Friend/relative Stole	3.8%						
Pharmacy Robberies				14 million DU***			
Emerg Dept					13%		



# Opioid Risk Management

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# THCI Program in Opioid Risk Management: Mission

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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 Milestones

## Foundations of Opioid Risk Management

*Nathaniel P. Katz, MD, MS,\* † Edgar H. Adams, ScD, † James C. Benneyan, PhD, ‡  
Howard G. Bimbauan, 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 Kessler, MS, ¶ ¶ and  
Stephen D. Locke, PhD, §§*





# Program Milestones

## Challenges in the Development of Prescription Opioid Abuse-Deterrent Formulations

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*IMPLICIT  
CLAIMS*

*EXPLICIT  
CLAIMS*

March  
2005

October  
2005

Spring-Fall  
2006

September  
2006

November  
2006

April  
2007

# Program Milestones

## “Best Practices in Opioid Risk Management”

SURVEILLANCE

SIGNAL  
DETECTION

EVALUATION

SIGNAL  
VERIFICATION

INTERVENTION

March  
2005

October  
2005

Spring-Fall  
2006

September  
2006

November  
2006

April  
2007

# Program Milestones

“FDA Guidance on  
Developing Abuse-  
Deterrent Opioid  
Formulations”

CITIZEN'S  
PETITION  
SCIENTIFIC  
BACKGROUND  
DOCUMENT



# Program Milestones

## Responding to Signals of Prescription Opioid Abuse

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



# Objectives of Today's Meeting

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- To develop recommendations for how to respond to a “signal” of prescription opioid abuse
  - To develop a signal management algorithm for pharmaceutical companies
  - To describe options for signal assessment studies
  - To develop a menu of assessment findings and matched interventions
  - To develop policy considerations around collaborations between pharma and other stakeholders
  - To propose a vision for the evolution of roles and responsibilities of the key stakeholders in opioid risk management