

The Changing Landscape of Prescription Opioid Abuse in the United States

Richard C. Dart, MD, PhD

Executive Director, RADARS System, Denver Health
and Hospital Authority, Denver, Colorado

Professor, University of Colorado School of Medicine

Disclosure

- Most manufacturers of prescription opioids or stimulants subscribe to RADARS System.
- RADARS System is the property of Denver Health and Hospital Authority, a political subdivision of the State of Colorado.
- Subscribers to RADARS System receive information, but do not participate in developing the System, data collection, or analysis. They do not have access to the raw data.
- Employees are prohibited from personal financial relationships with any company.
- **Off-label use will be discussed in this presentation.**

Self-Assessment Question 1

Which statement regarding abuse deterrent opioids analgesics is true?

- A. There is only one product on the US market recognized by FDA as having abuse deterrent features.
- B. The introduction of an abuse deterrent formulation of oxycodone extended release was promptly followed by decreased oral, nasal and intravenous abuse of that drug.
- C. Abuse deterrent formulations can't work because they are intended only for established intranasal or intravenous abuser.
- D. Abuse deterrent formulations are feasible only for extended release formulations of opioid analgesics

Self-Assessment Question 2

What is the relationship between abuse of prescription opioid analgesics and use of heroin in the United States?

- A. Abuse of both heroin and prescription opioid analgesics are increasing
- B. Abuse of heroin is increasing while abuse of prescription opioid analgesics is decreasing.
- C. Abuse of prescription opioid analgesics is increasing while abuse of heroin is decreasing.
- D. Abuse of both heroin and prescription opioid analgesics are decreasing.

Learning Objectives

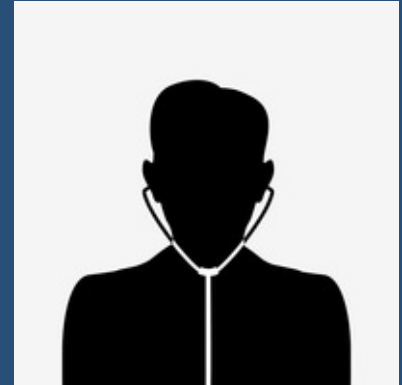
1. The learner will understand the prescription opioid analgesic formulations that are most likely to be abused.
2. The learner will understand trends in the abuse of prescription opioids and heroin in the United States.

Outline

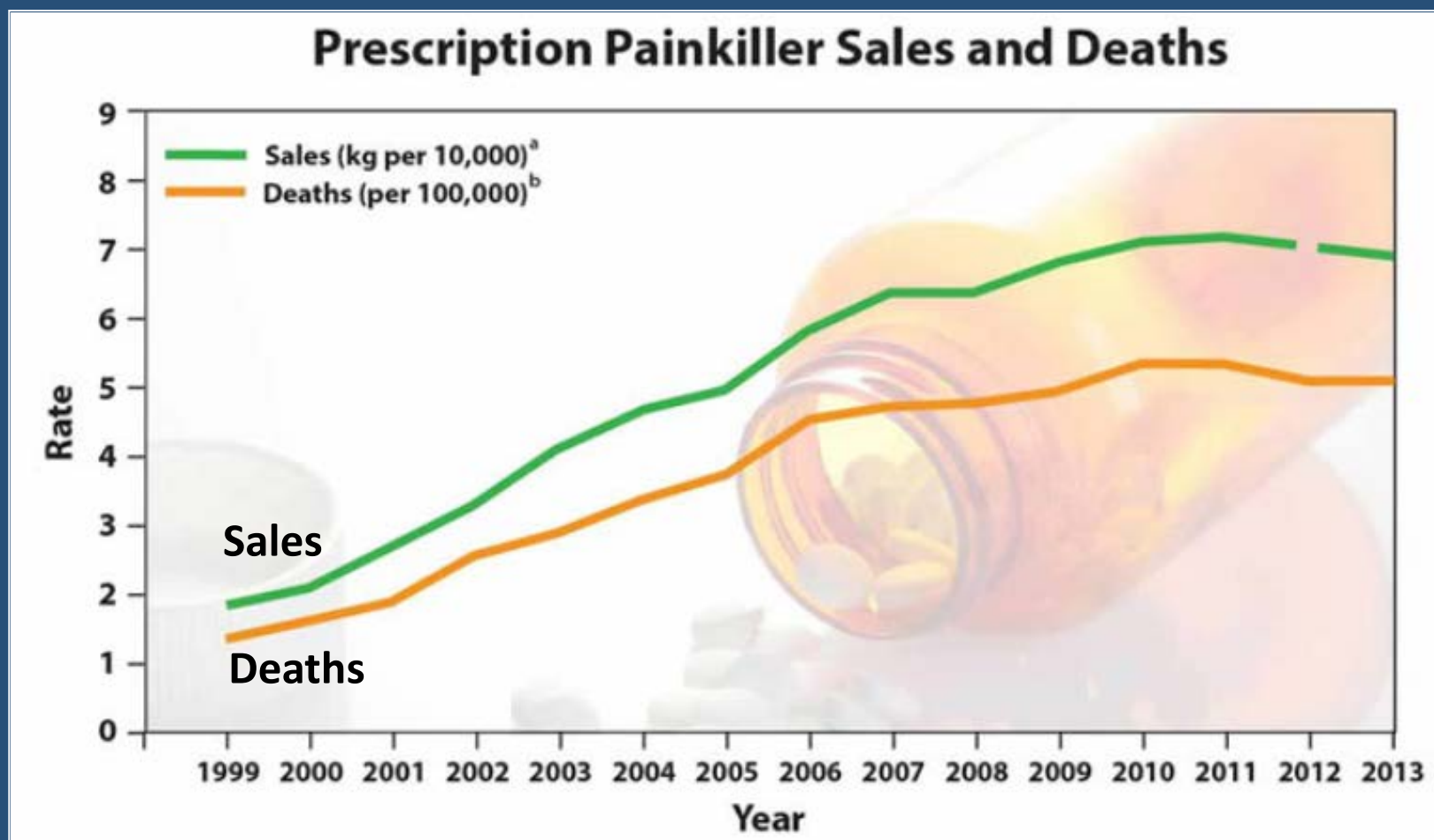
- Background
- Pain and the Downward Spiral
- The Role of Formulations: immediate release, extended release, abuse deterrent (ADFs)
- Potential Implications for the Pain Specialist

Case

- 32 y.o. high performing health care professional receives “Vicodin” for a minor procedure.
- 6 months later, he is arrested for buying hydrocodone-acetaminophen on the street, forging prescriptions, etc.
- What happened?

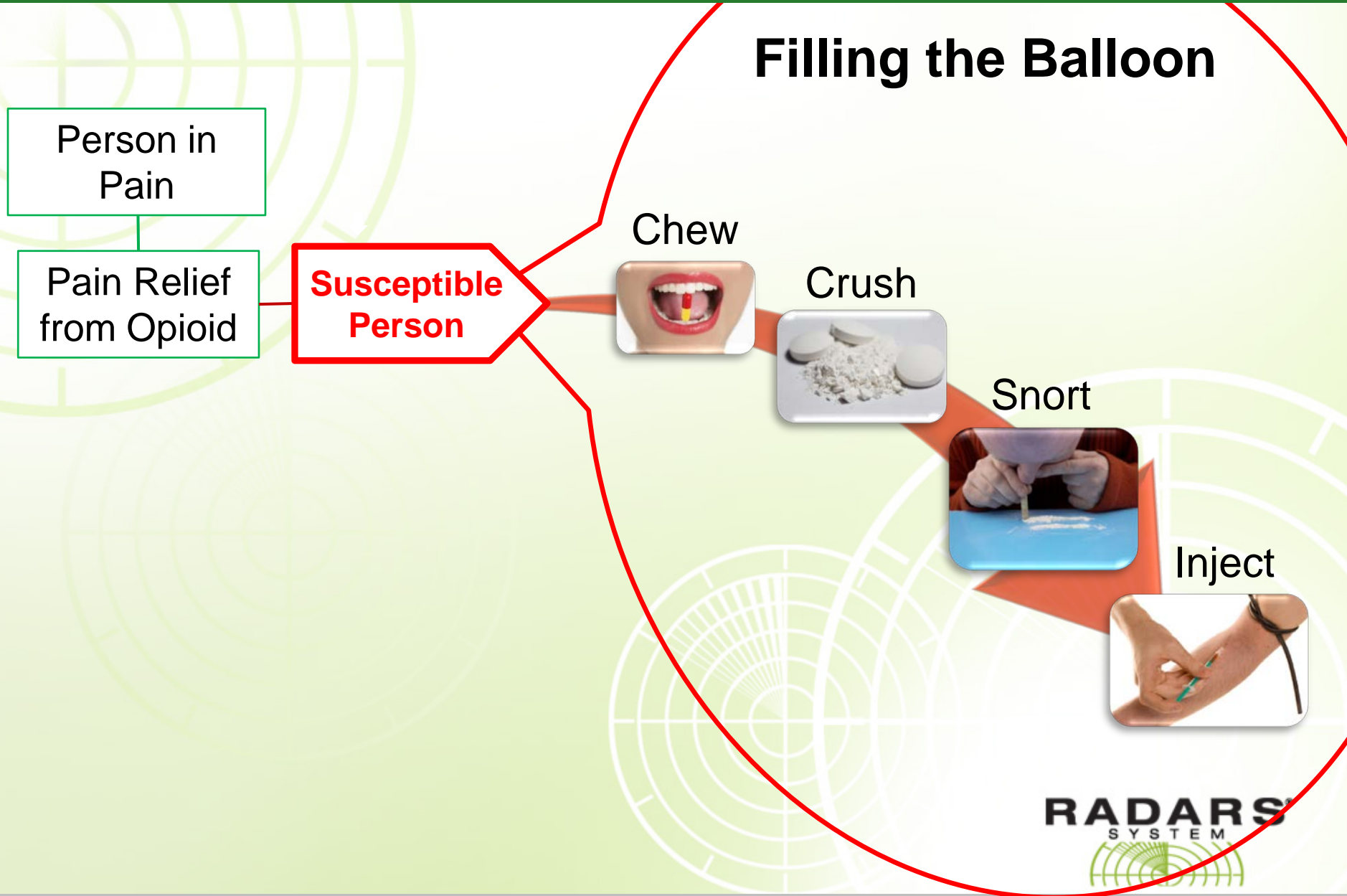


US Epidemic of Prescription Opioid Deaths

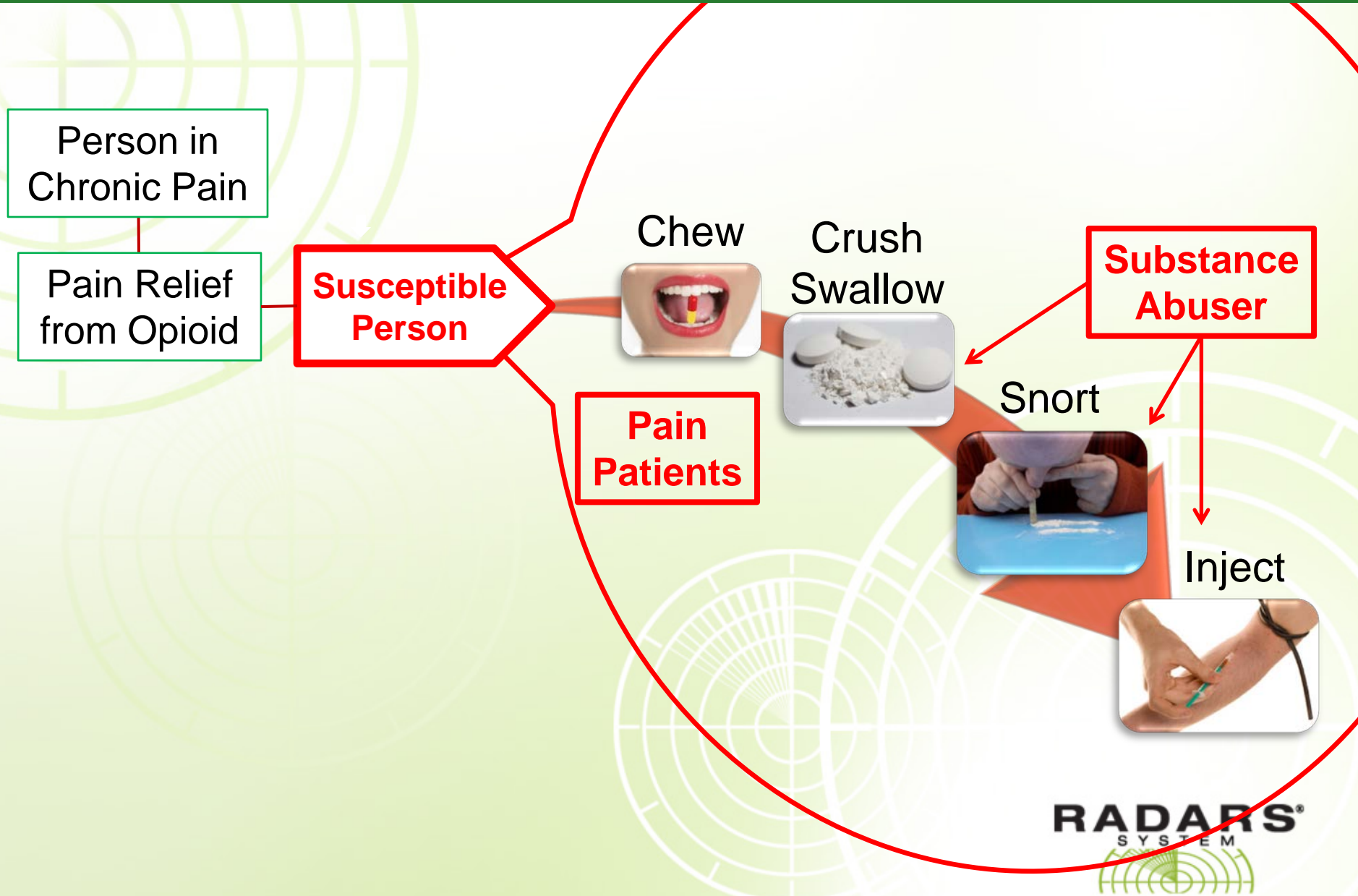


<http://www.cdc.gov/drugoverdose/data/index.html>

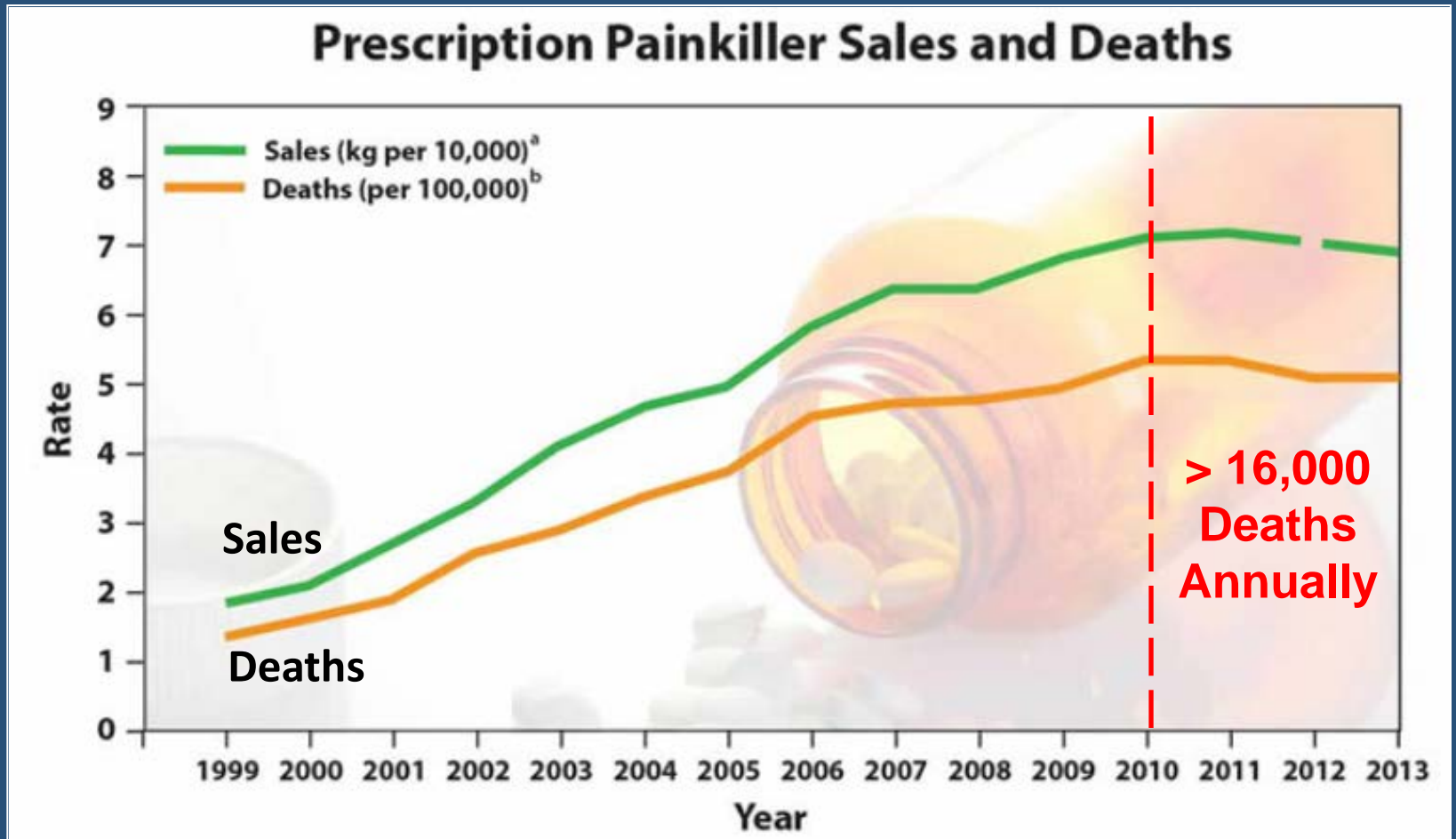
Progression of Opioid Misuse in Pain Patients



How Did We Fill the Balloon?

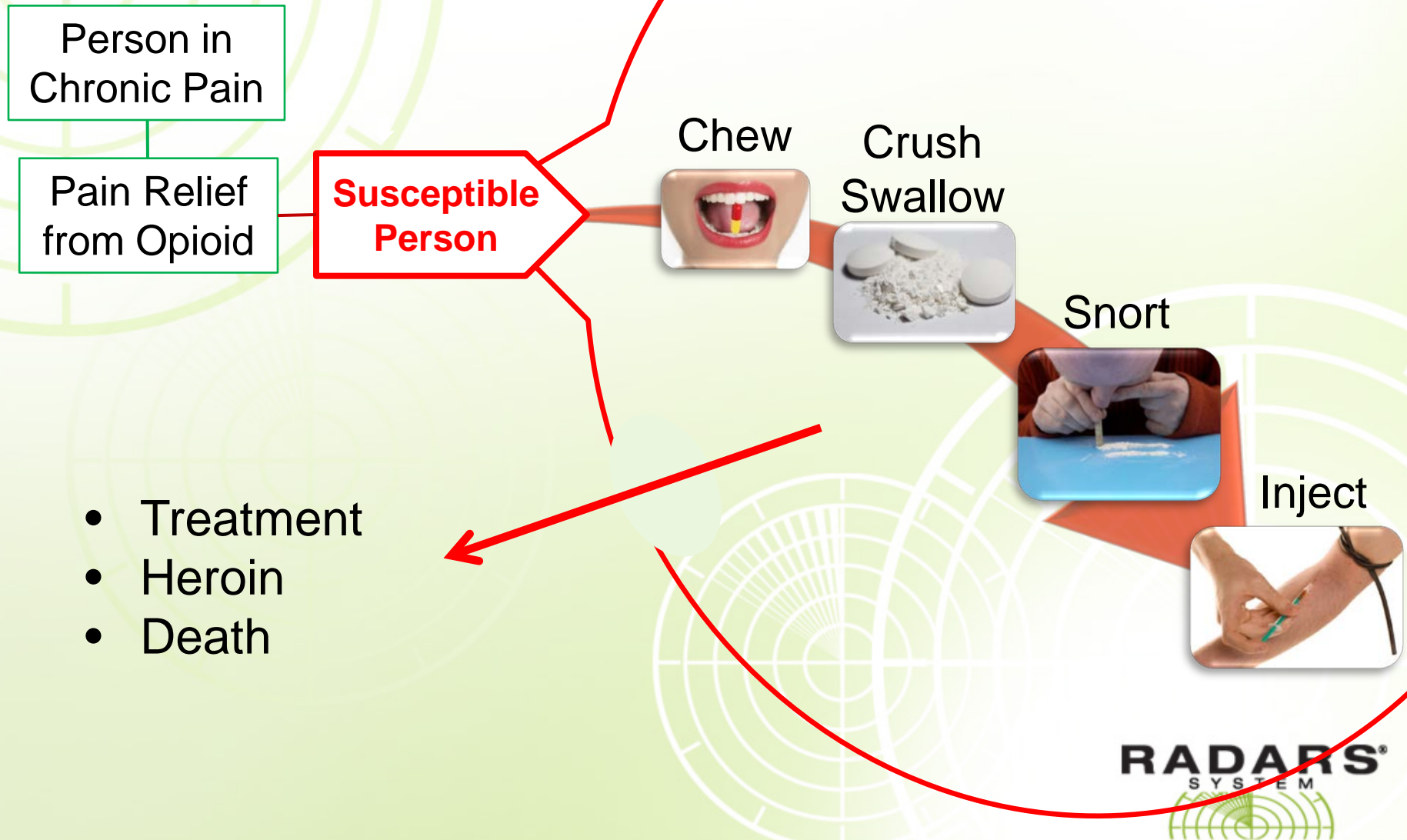


Is Something Working?



How Can We Empty the Balloon?

Rx Opioid Abuse in the US



RADARS System - Mosaic Surveillance of Prescription Drug Abuse - 2015

Acute Health Events

49 Poison centers
46 states
512,609 cases
552,732 opioid mentions

Drug Transactions

Criminal Justice
260 agencies; 49 states
188,635 cases with
194,999 opioid mentions

Entering Treatment

Opioid Tx Program
72 programs; 42 states
43,861 cases with
201,099 opioid mentions

Entering Treatment

SKIP
135 practices, 47 states
12,328 cases with
80,617 opioid mentions

New Initiates

College Survey
2000 students, 50 states
6,201 cases with
15,636 opioid mentions

Illicit Market Price

StreetRx.com
Users/Buyers, 50 states
25,250 price entries for
an opioid

Web Monitoring

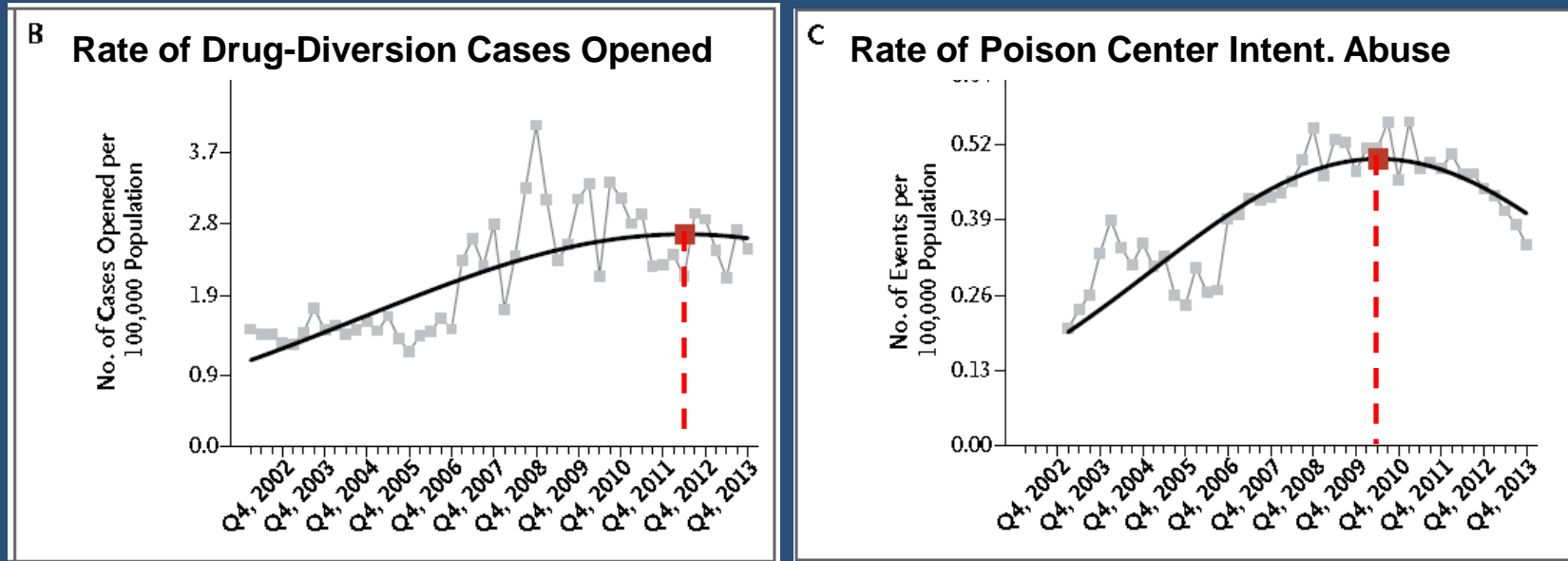
> 150 million sites
monitored



Something is Working

Trends in Abuse of Prescription Opioids in the US

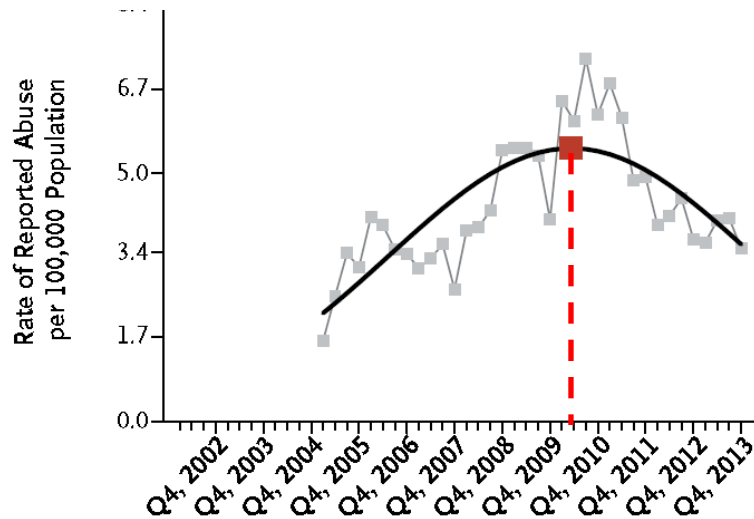
Figure 1. Drug Diversion, Poison Center Program, RADARS System, 2002–2013.



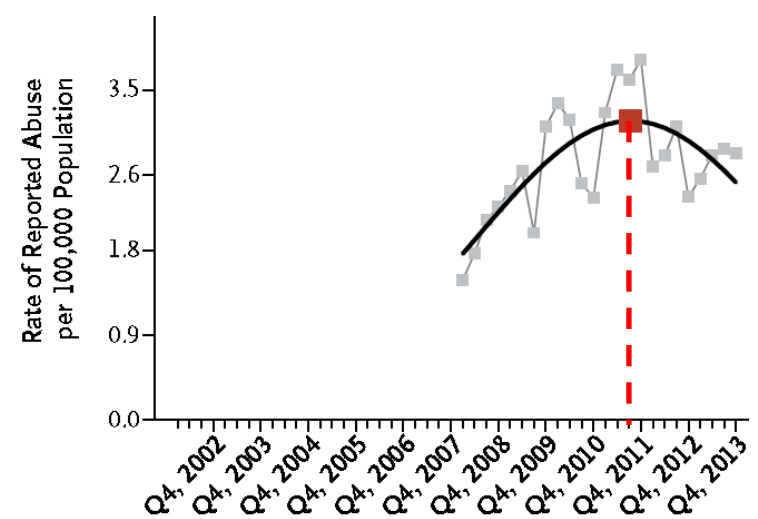
The red boxes in Panels B through E indicate the vertex of the quadratic curve.

Figure 1. Methadone Programs (OTP), Other Substance-Abuse Treatment Programs, RADARS System 2004 - 2013

D Rate of Endorsement – OTP



E Rate of Endorsement – SKIP



The red boxes in Panels B through E indicate the vertex of the quadratic curve.

Figure 2: Heroin Use and OxyContin Abuse Before and After OxyContin Reformulation

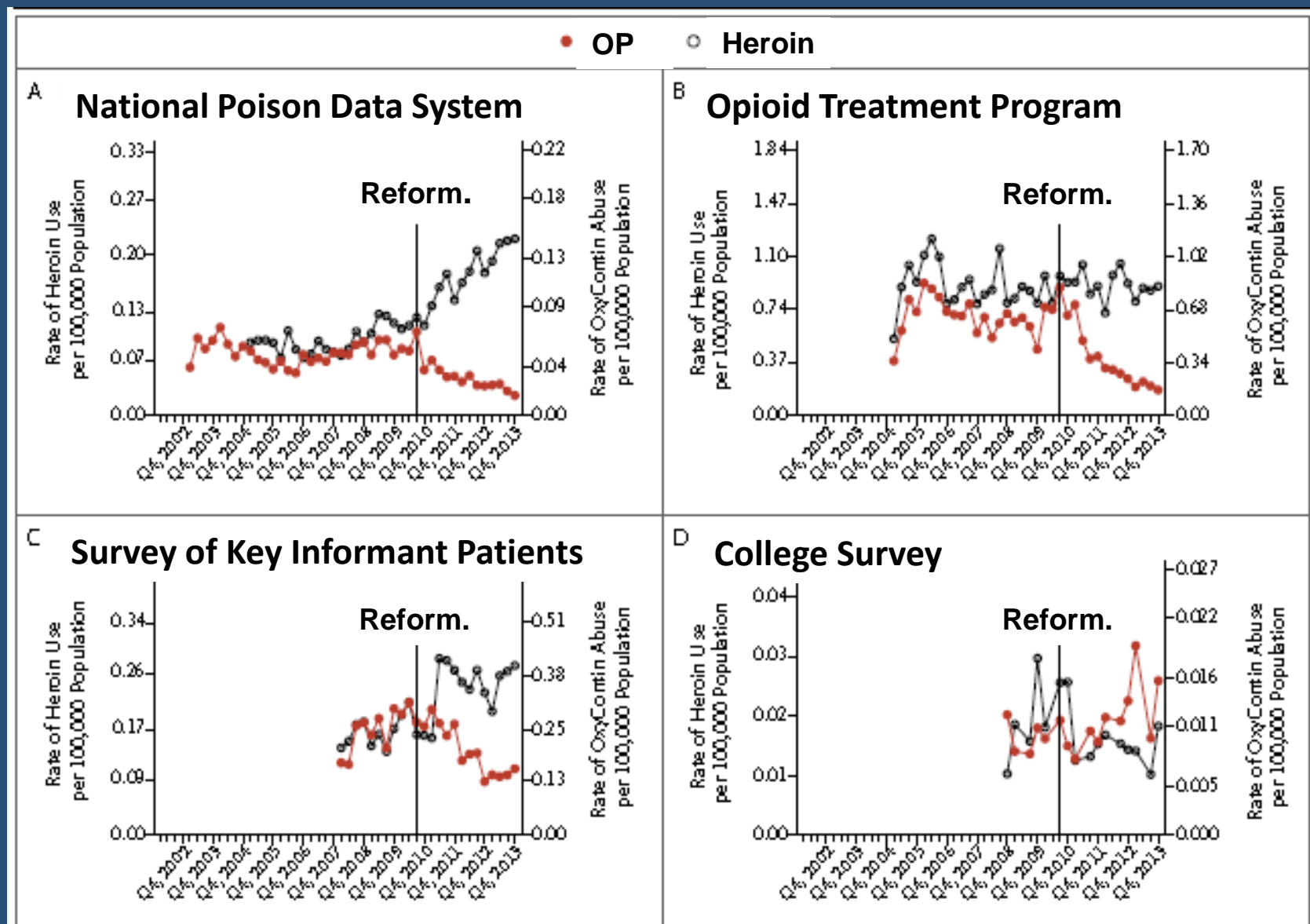
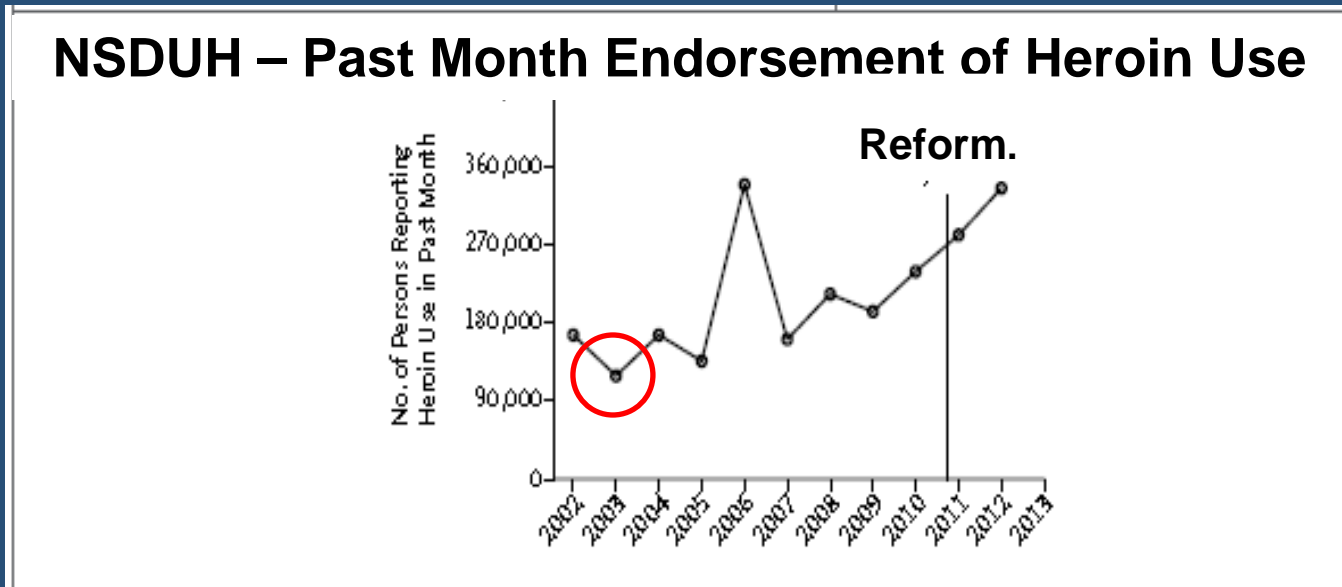


Figure 2. Panel E - Rate of Reported Heroin Use in the National Survey on Drug Use and Health (SAMHSA)



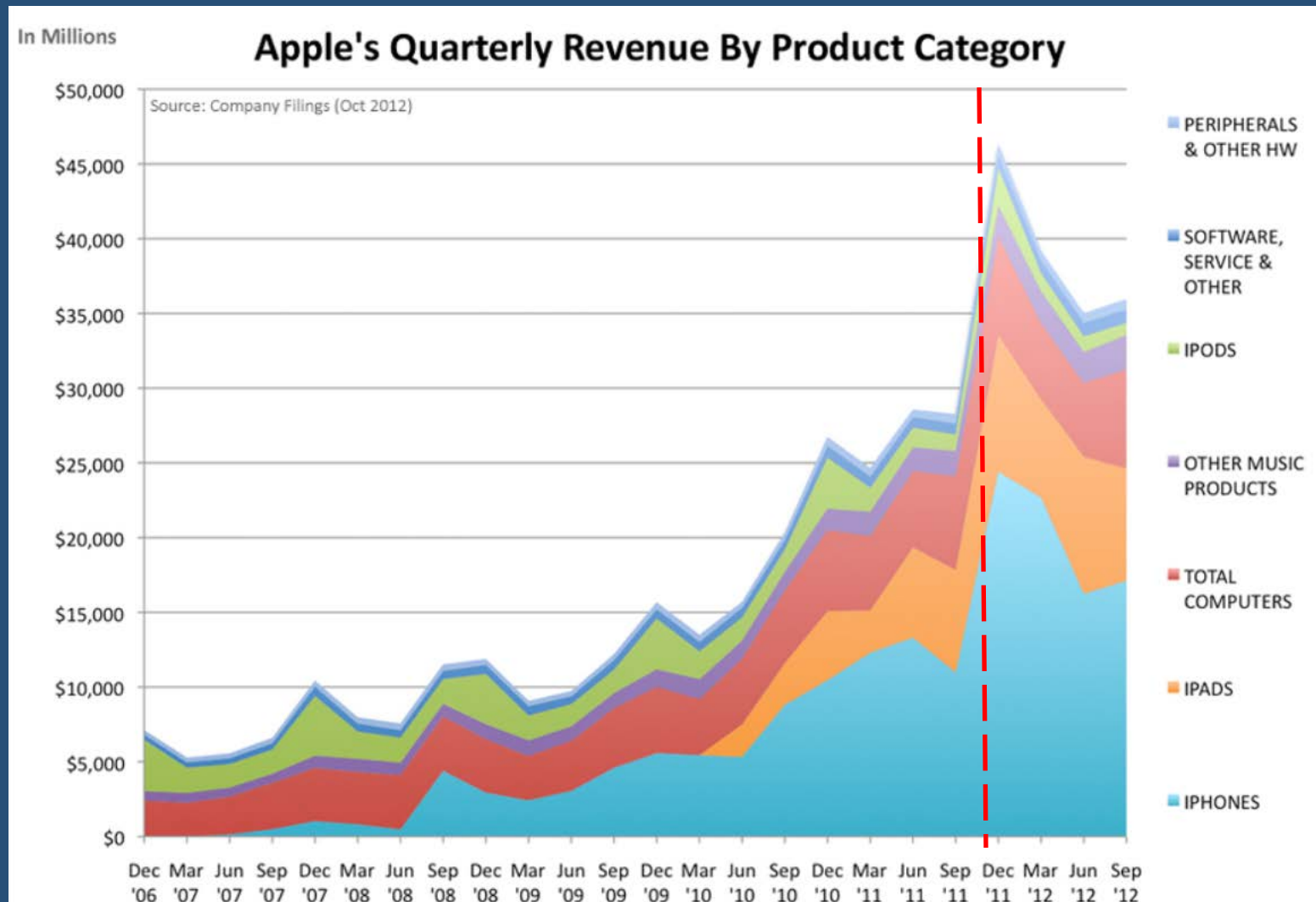
Other Evidence for a Change

- Prescription opioid abuse is decreasing or has flattened in several systems.
 - RADARS System[®], Navipro[®]
 - National Survey of Drug Use and Health (NSDUH)
 - National Vital Statistics (mortality)
 - Several regional analyses (e.g. Kentucky, Florida)
- **Large reservoir of abusers**
 - Switching to alternatives – heroin abuse increasing
 - Entering treatment

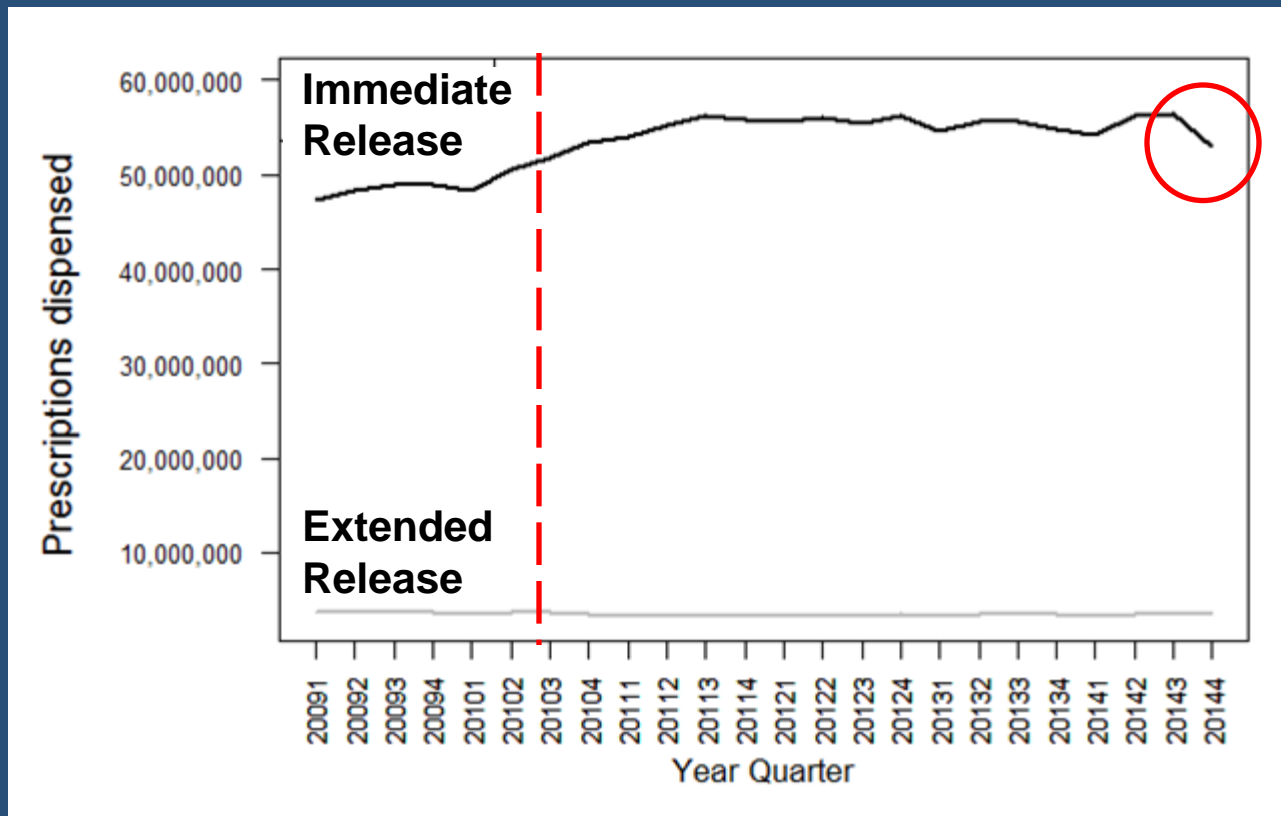
The Role of Formulations

- Preponderance of deaths caused by extended release preparations.
- When the rooster crows, the sun rises...

Apple is the Cause of Deaths from Prescription Drug Abuse?



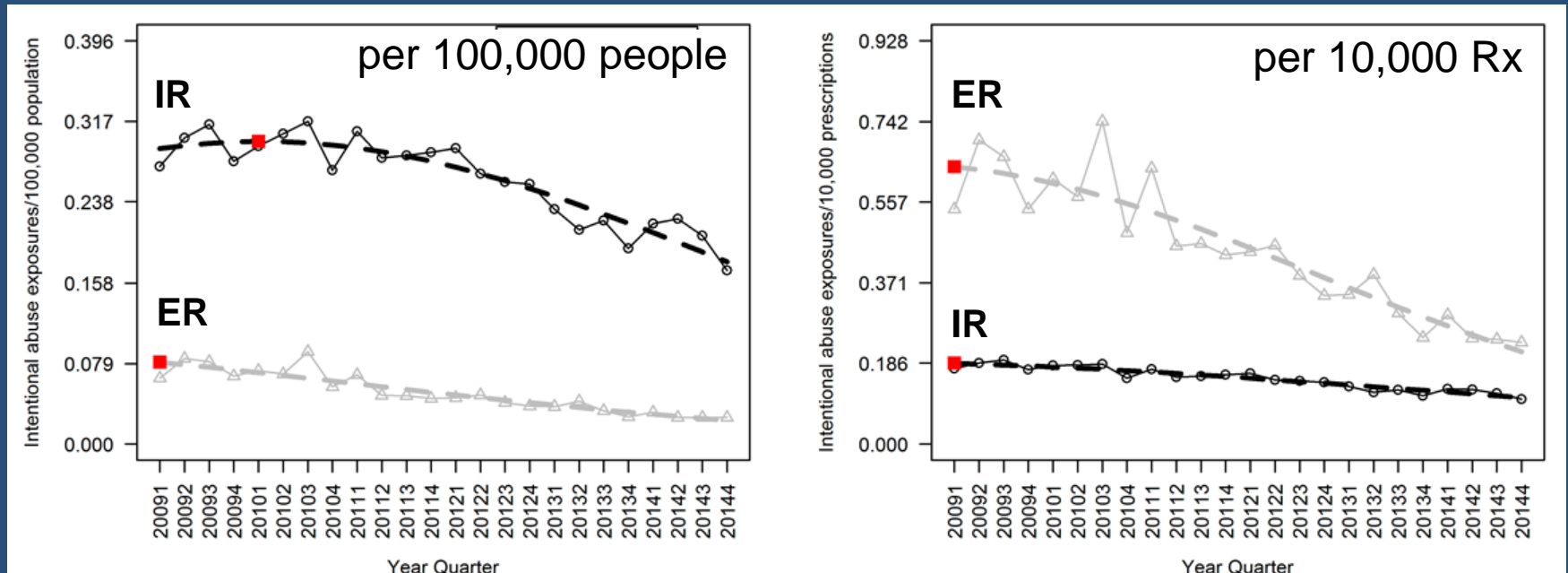
Extended Release vs. Immediate Release Formulations of Opioid Analgesics



IMS, 2015

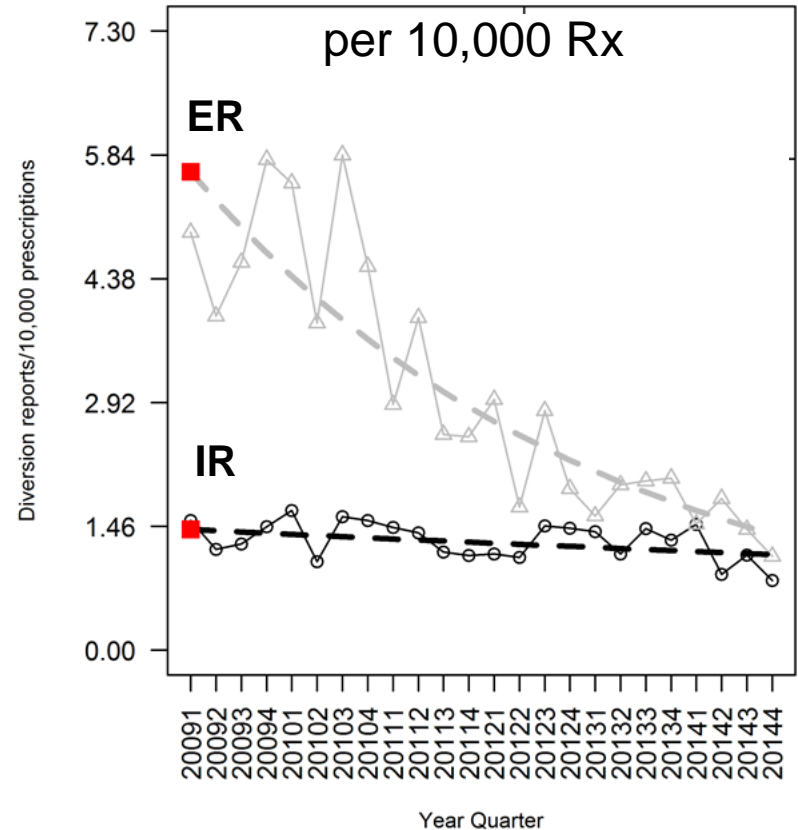
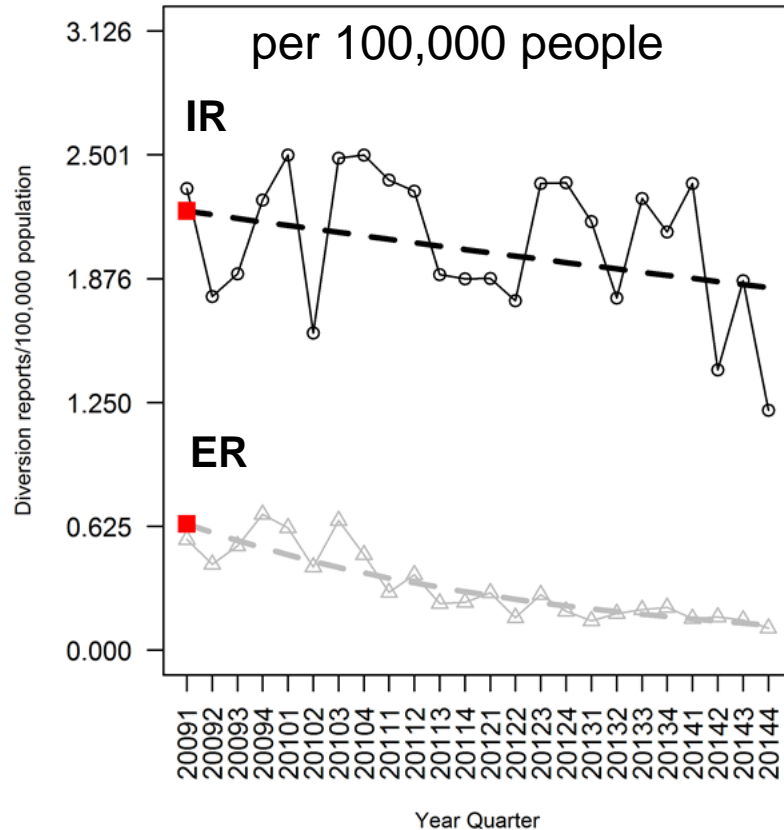
Poison Center Program - Abuse Exposures

Oxycodone ER, 2009-2013



Drug Diversion Program

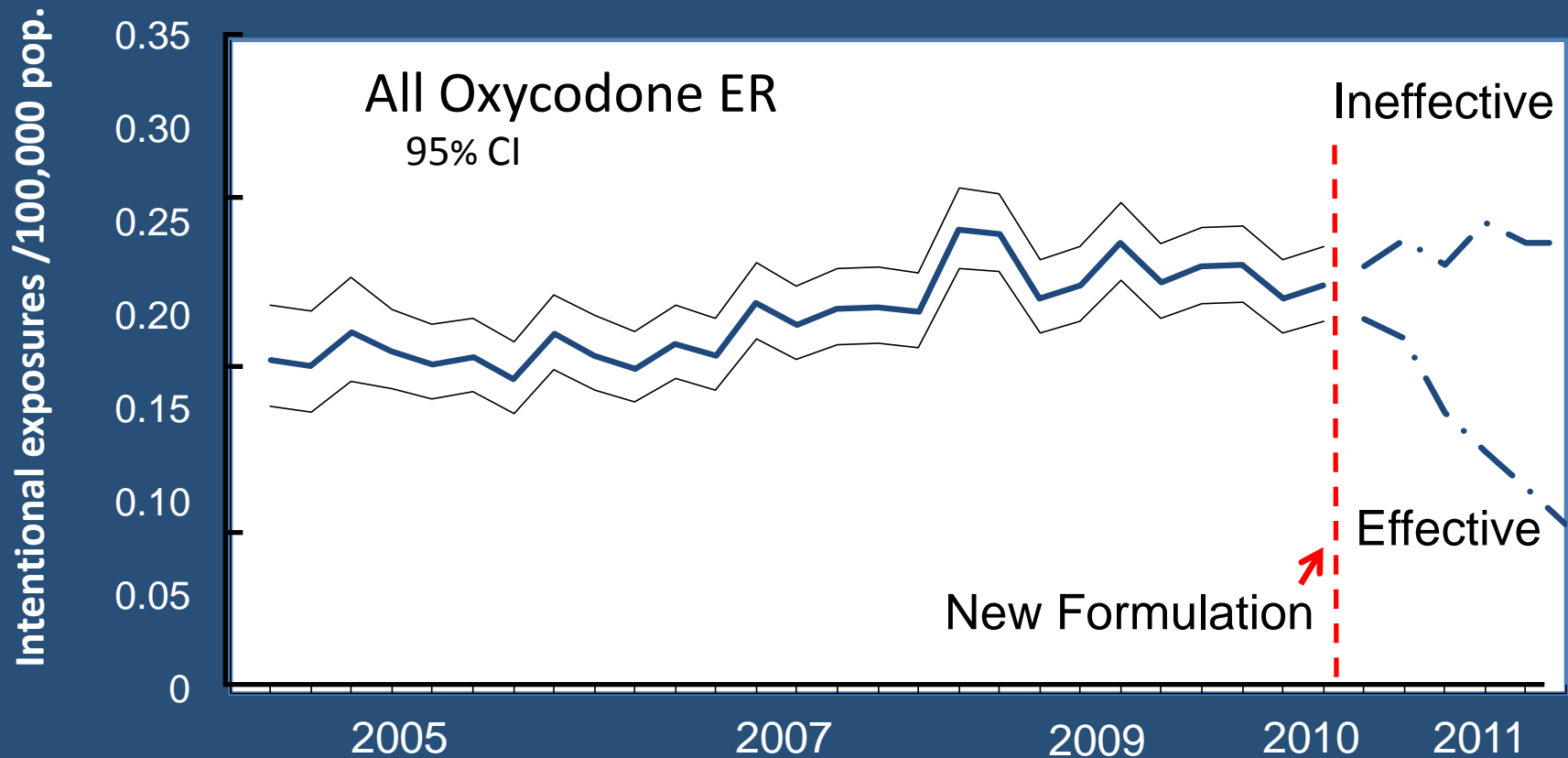
Oxycodone ER, 2009-2013



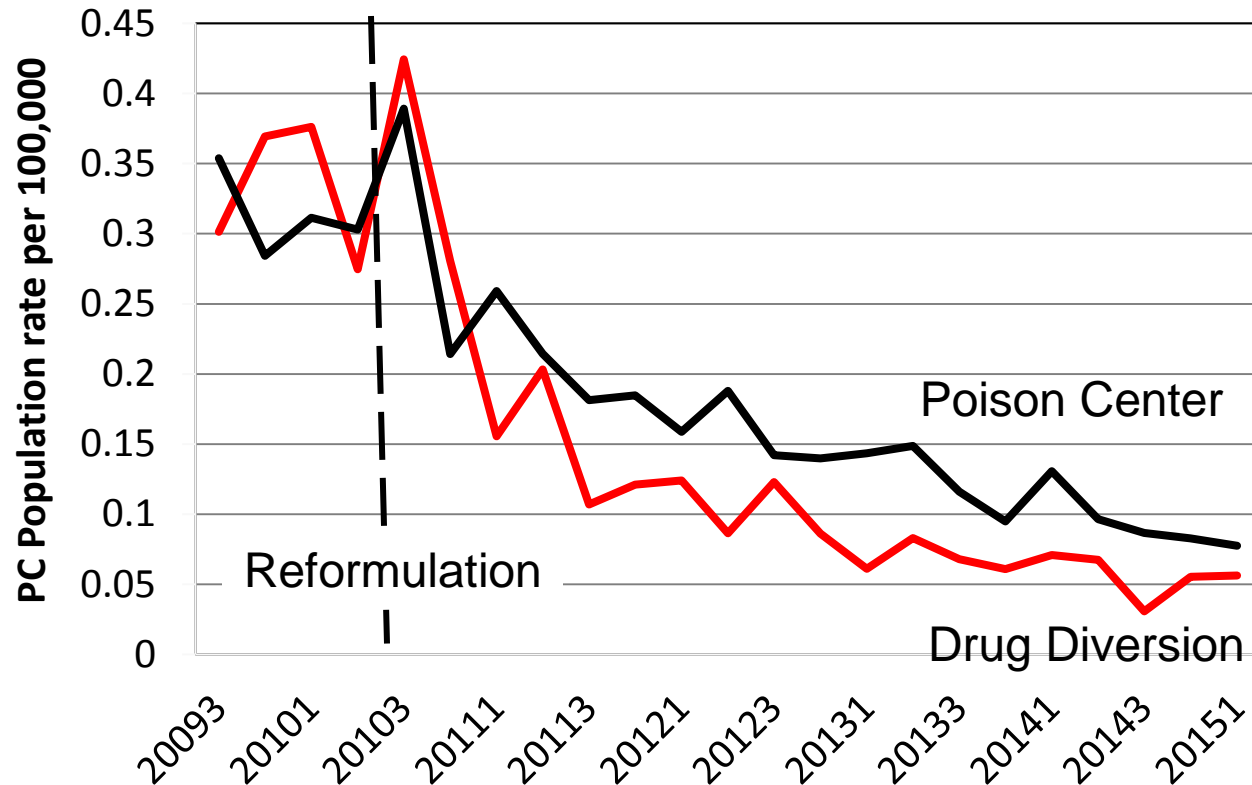
Role of Abuse Deterrent Formulations?

- Plausible ADF Formulations
 - OxyContin[®], Opana ER[®] (Intac[®]), Nucynta ER (Intac[®])
 - Exalgo[®], Oxecta[®], Embeda[®]
 - Suboxone[®], buprenorphine/naloxone combos
- Do they affect rates of abuse in a meaningful manner over large portion of United States?
- Do they affect outcomes?
 - Injection? Mortality?
- Supportive studies
 - Street Price?
 - Behaviors?
 - Adverse Events?

Model for Oxycodone Extended Release RADARS System Poison Centers

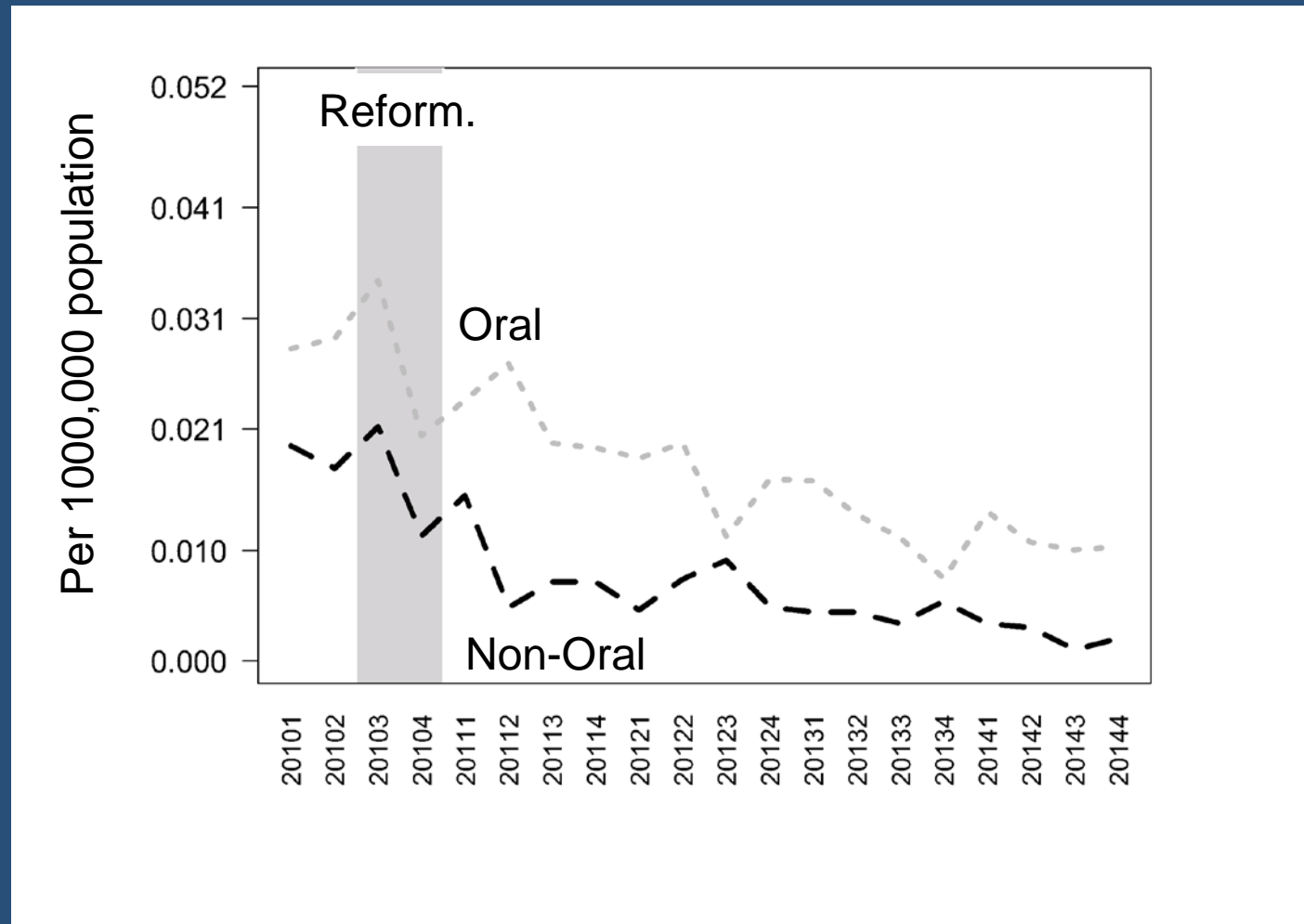


Poison Center and Drug Diversion Programs Oxycodone ER, 2009 - 2015



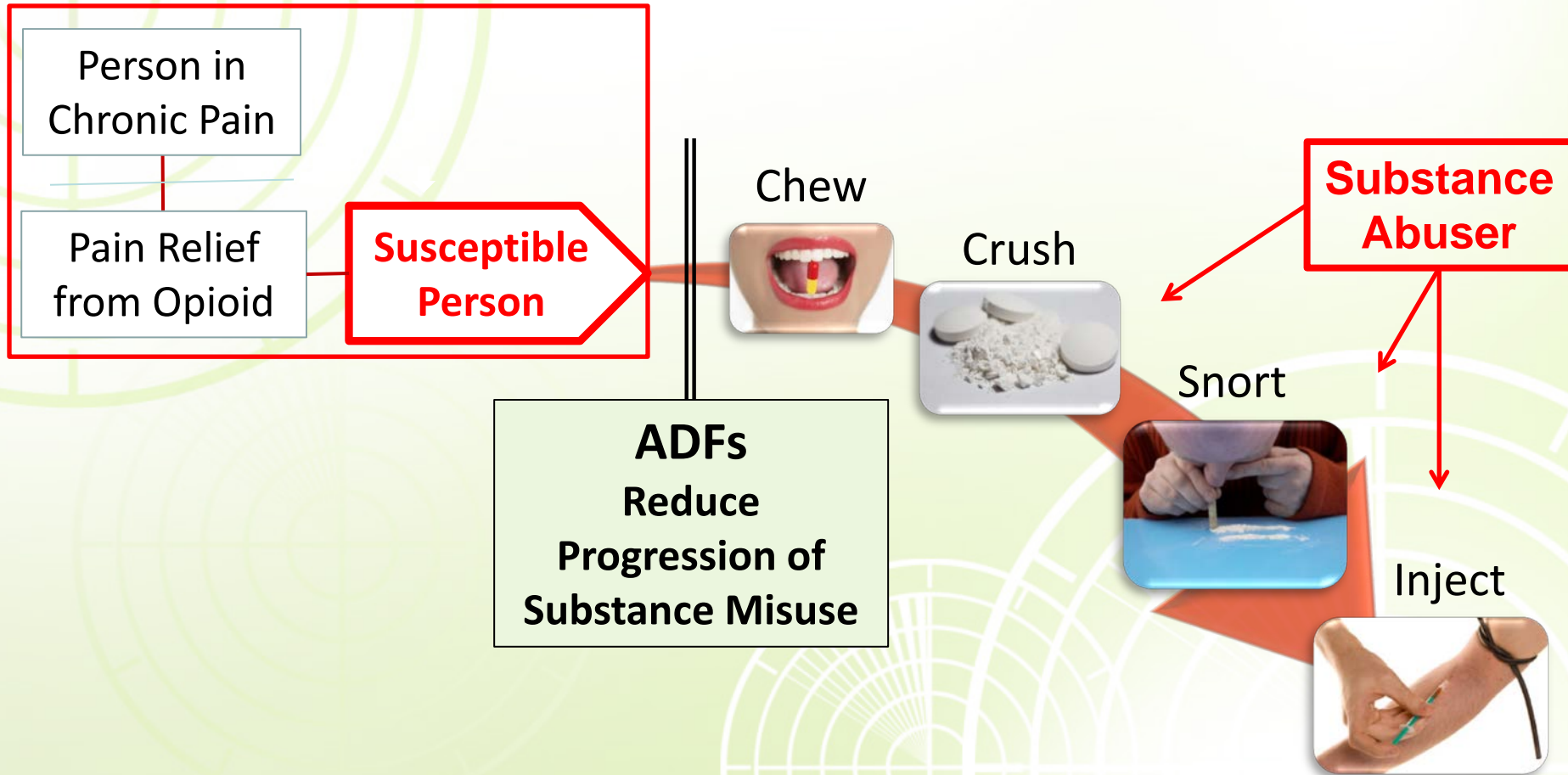
Poison Center Program

Oxycodone ER, Route of Use, 2009 - 2015



What is the Role of Pain Practitioner?

Good Clinical Practice



Battle of the ADFs





Responding to an Epidemic

Rx Nonmedical Use in Florida

James N. Hall

**Center for Applied Research on
Substance Use and Health Disparities
Nova Southeastern University**

Florida Legislative Actions

- 2009: **FL Senate Bills 462** and **440** – PDMP
- July 2010 – **Senate Bill 2272** to **shut down illicit pain management clinics...**
- August 2010 – New **tamper-resistant** reformulated OxyContin OP shipped.
- February 2011 – Operation Pill Mill:
South Florida
- March 2011 – Florida Law Enforcement
Drug Strike Force created

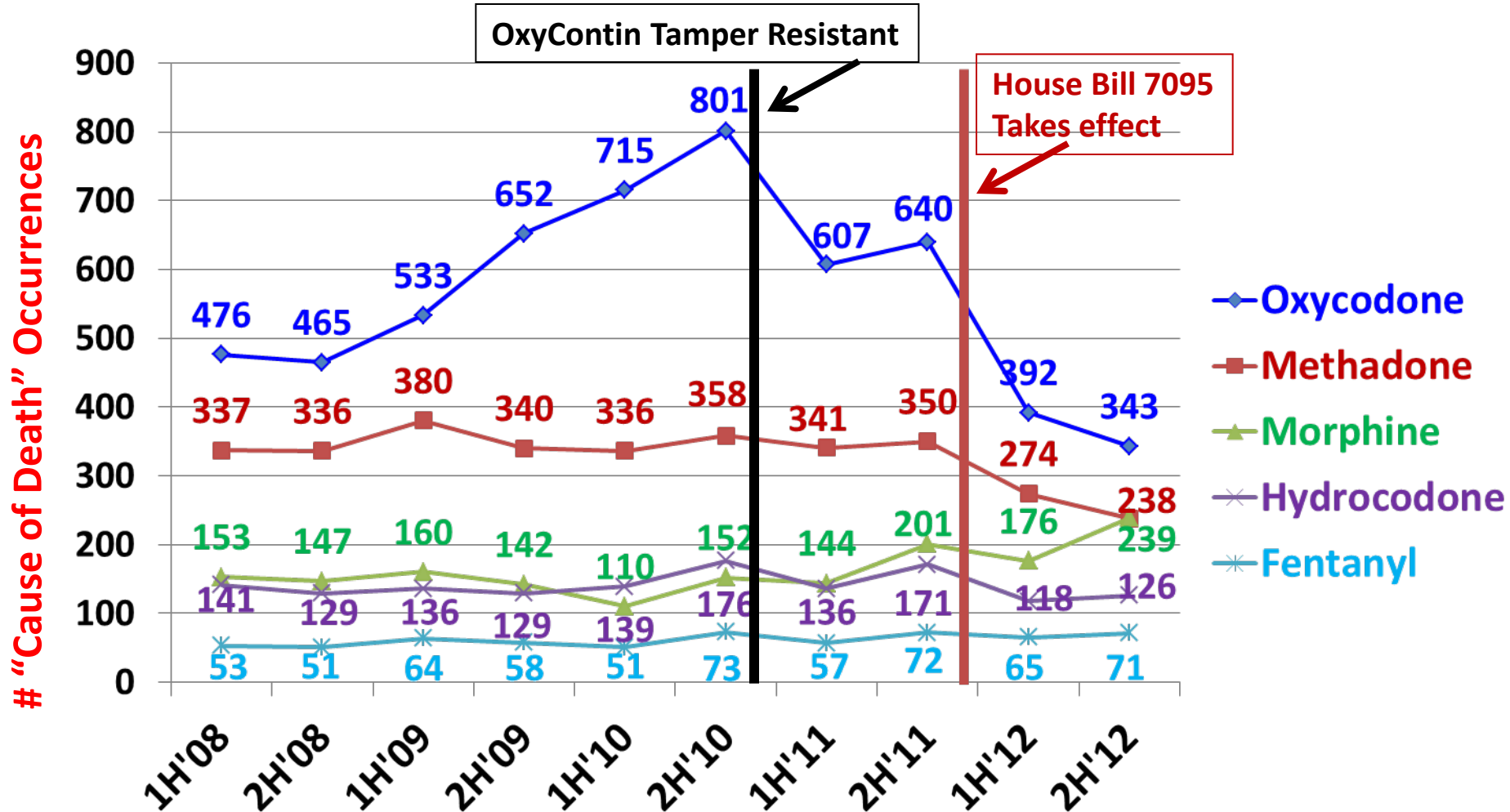


2011

July 1, 2011 - House Bill 7095 goes into effect. It

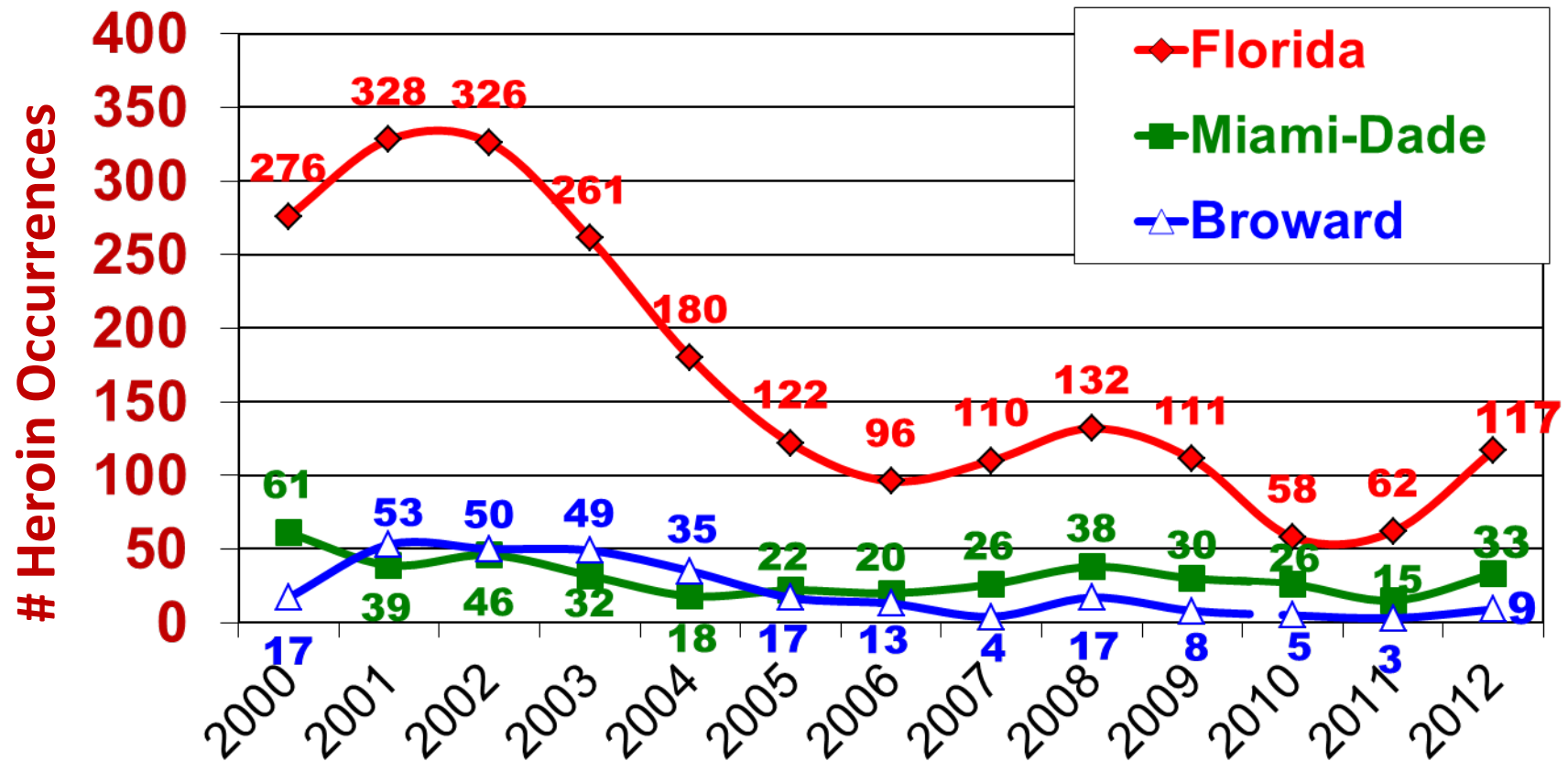
- Bans direct dispensing by medical practitioners,
- New permitting & inspection regulations for pharmacies,
- Shortening from 15 days to 7 days the PDMP dispensing reporting requirement,
- Codified new patient standard of care measures for physicians with enhanced penalties,
- \$ 3 million for law enforcement Strike Force to close pill mills

Number of Selected **Lethal Rx Opioid Occurrences** Among Deceased Persons in Florida Jan 2008 to Jun 2012



Source: FDLE – Drugs Identified In Deceased Persons by Florida Medical Examiners
Jan 2008 - Dec 2012 Reports

Number of Heroin-related Deaths in Florida: 2000 – 2012



SOURCE: Florida Medical Examiners Commission Reports 2000-2012

Implications

- Prescription opioid drug abuse “improving.”
- Focus on the true pain patient’s transition to abuse and addiction
- Clinical care seems most important in prevention.
- ADF’s have meaningful role, but not panacea. Not just for the high-risk patient?
- More focus on IR opioid formulations is needed.

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Question and Answer

Thank you!

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