### Falling Rates of Prescription Opioid Abuse and Death in the United States: Formulations and Ramifications



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# Disclosures

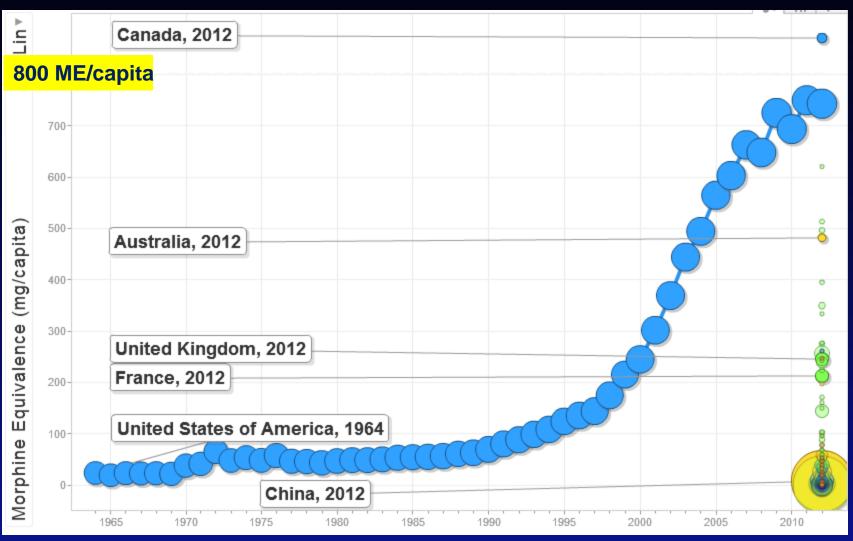
- Most manufacturers of prescription opioids or stimulants subscribe to RADARS System.
- RADARS System is the property of Denver Health and Hospital Authority, a political subdivision of the State of Colorado.
- Subscribers receive information, but do not participate in developing the System, data collection,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

## Outline

- Conceptual Framework for Abuse Deterrent Formulations (ADFs)
- Effectiveness of ADFs
- Unanticipated Consequences?

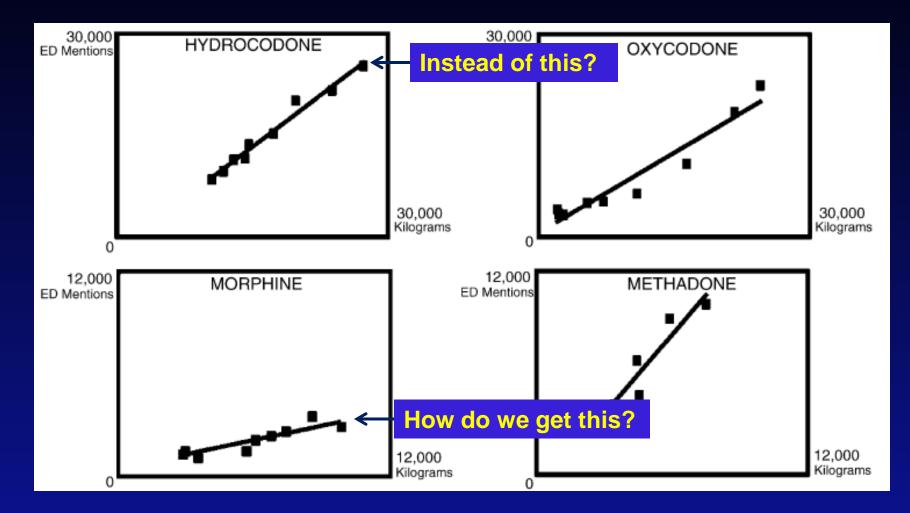
# The Epidemic

#### **US Consumption of Prescription Opioids, 1964 - 2012**



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#### More Drug Production = More Drug Abuse But - the Slope Varies by Drug



Dasgupta N et al. Drug Alcohol Depend. 2006;82(2):135-142.

# How Do Abuse, Addiction and Death Occur?

#### **Progression of Rx Opioid Abuse**

Population of People with Addiction Risk

#### **Exposed to Opioid**



Swallow



\*Crush

Can ADF's Minimize Progression?



\*Snort

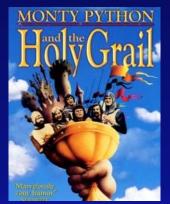
\*Inject

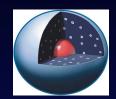
# Abuse Deterrent Formulations

#### **Strategies for Abuse Deterrence**

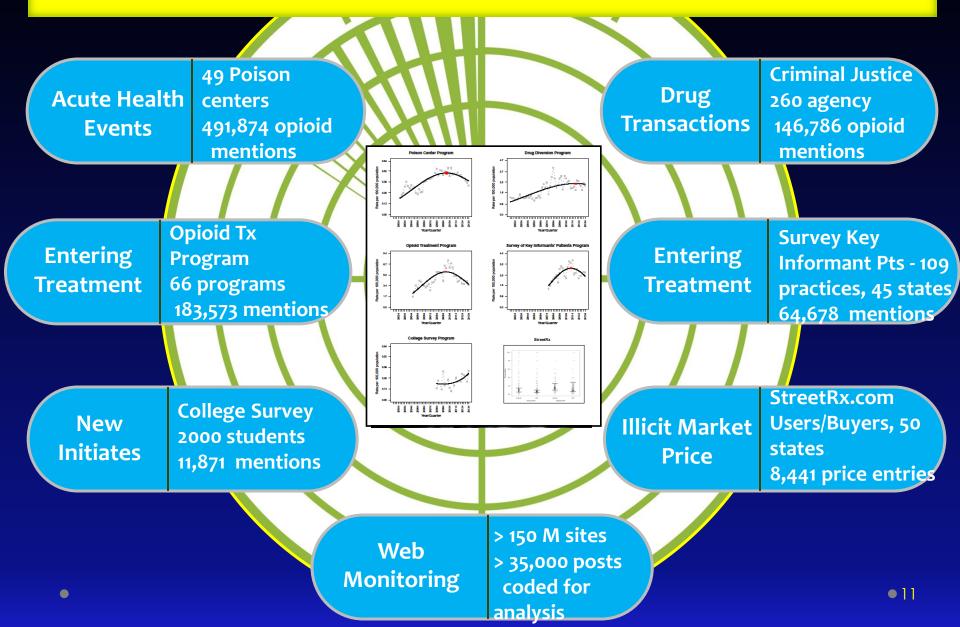
- Physical/Chemical barriers physical form of an oral drug is less amenable to abuse.
- Agonist/Antagonist combinations interfere with euphoria
- Aversion agents unpleasant effect if dosage form is manipulated or a higher dosage is used.
- **Delivery System** depot/implants to reduce release (e.g. SR depot SQ injectable formulation).
- **Prodrug** lacks opioid activity until transformed (e.g. GI tract).
- Combination Two or more methods combined
- *Holy Grail* Overdose only releases therapeutic amount.

http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm334743.

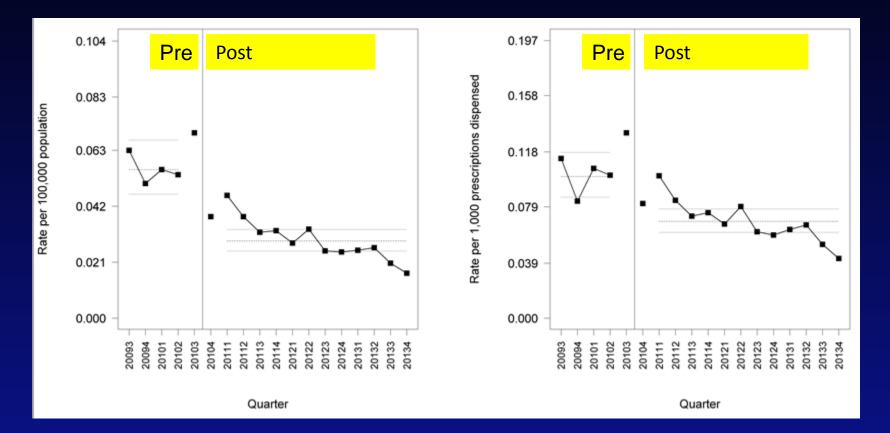




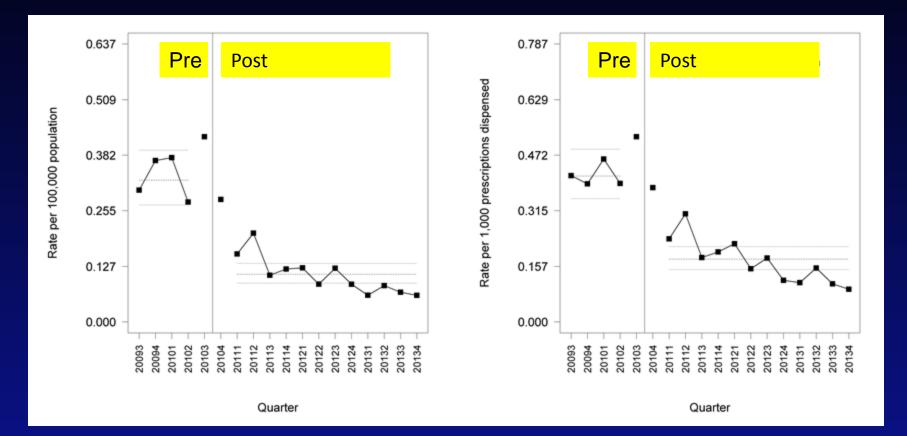
#### **Mosaic Surveillance of Prescription Drug Abuse**



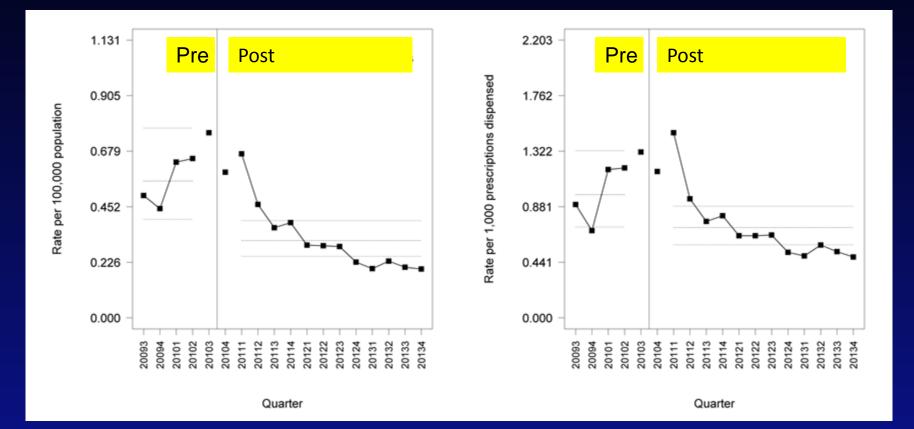
#### Poison Center Program Oxycodone ER Population and Prescription Rates, 2009-2013



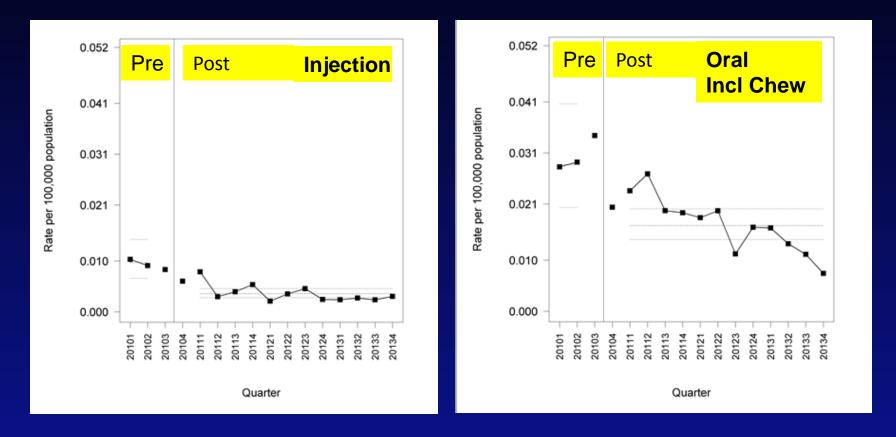
#### Drug Diversion Program Oxycodone ER Population and Prescription Rates, 2009-2013



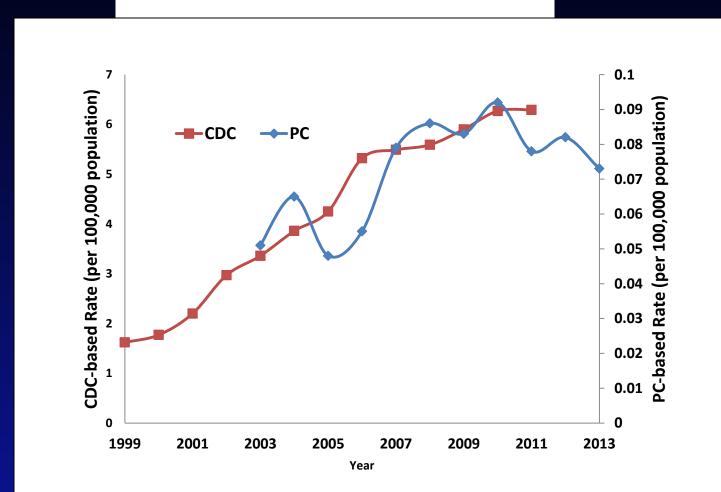
#### Treatment Centers Combined Oxycodone ER Population and Prescription Rates, 2009-2013



### Oral and Non-oral Abuse Decrease after Oxycodone ADF - Poison Center Program



#### Deaths Associated with Oxycodone ER Decreased Poison Center Program, 2008 - 2013



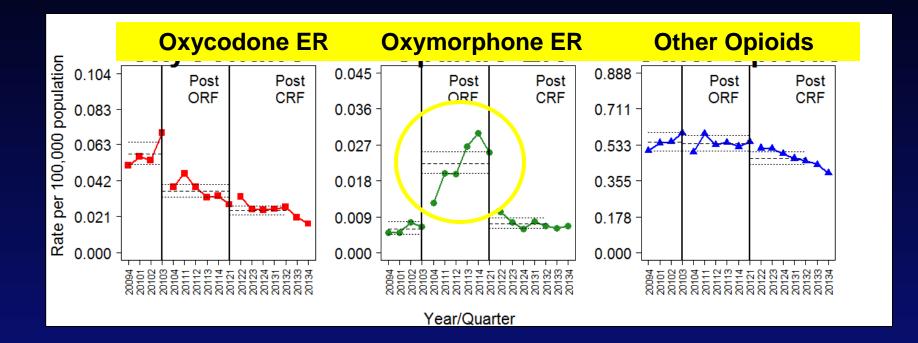
**Refining Our Understanding of** Abuse Deterrent Formulations

### Squeezing the Balloon: ADFs Have Limited Impact Unless All Opioids Included

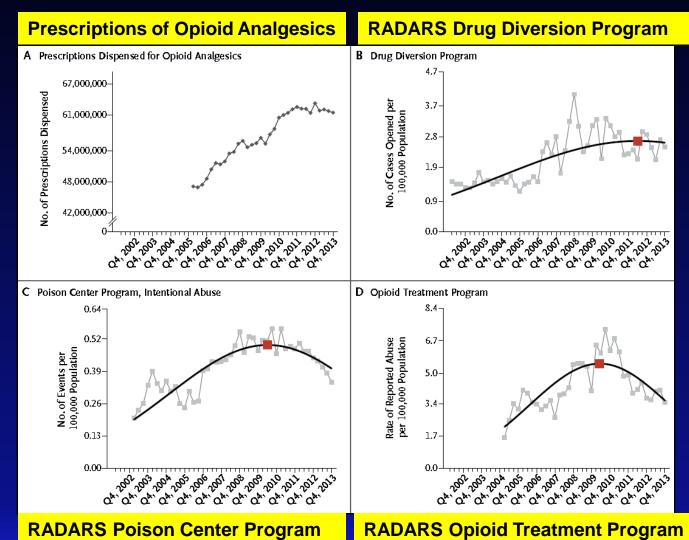
Switch opioid or enter treatment program

New opioidaddicted patients

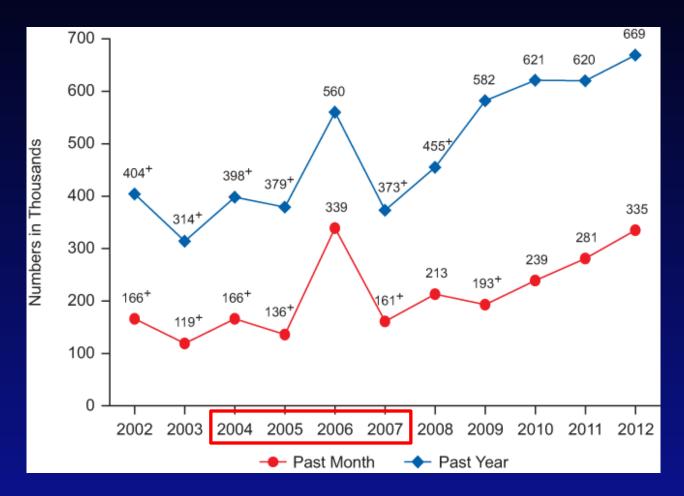
#### Poison Center Program Population Rate, 2009-2013



#### National Trends in Opioid Abuse and Diversion



#### Endorsement of Heroin Use National Survey of Drug Use and Health



#### **Progression of Rx Opioid Abuse**

Population of People with Addiction Risk

#### **Exposed to Opioid**



Swallow



\*Crush



ADFs are not for the addicted \*Snort

 More drug = more abuse, but formulation can change relation

- Need ADFs for IR as well as ER
- Need greater treatment capacity for opioid addiction



\*Inject

#### **Need to Stop Inflating the Balloon**

Switch opioid or enter treatment program

ADFs?

Ne

add

## **Questions?**

