

# **RADARS<sup>®</sup> System**

## **Colorado Methamphetamine Task Force**

Jody Green, PhD  
Director of Research  
Rocky Mountain Poison and Drug Center

01 February 2013



# Meeting Objectives

- Brief overview of the RADARS System
- Review Colorado Specific Data
- Current area of FDA interest -  
Abuse Deterrent Formulations (ADFs)

# **RADARS<sup>®</sup> System Goals**

- Measure rates of abuse, misuse and diversion of prescription drugs
- Identify sentinel events involving the abuse, misuse and diversion of prescription drugs nationwide
- Provide experienced and expert analysis and interpretation of the data

# RADARS<sup>®</sup> System Mosaic Approach

College  
Survey

Early  
Experimenters





# RADARS<sup>®</sup> System Mosaic Approach

College  
Survey

Early  
Experimenters

Poison  
Center

Acute Events



# RADARS<sup>®</sup> System Mosaic Approach

**College  
Survey**

**Early  
Experimenters**

**Poison  
Center**

**Acute Events**

**OTP  
Opioid Tx  
Program**

**Patients in  
Treatment**

**SKIP  
Survey of Key  
Informant Pts**

**Patients in  
Treatment**



# RADARS<sup>®</sup> System Mosaic Approach

**College  
Survey**

**Early  
Experimenters**

**Poison  
Center**

**Acute Events**

**OTP  
Opioid Tx  
Program**

**Patients in  
Treatment**

**SKIP  
Survey of Key  
Informant Pts**

**Patients in  
Treatment**

**Drug  
Diversion**

**Criminal Justice/  
Law Enforcement**



# RADARS<sup>®</sup> System Mosaic Approach

**College  
Survey**

**Early  
Experimenters**

**Poison  
Center**

**Acute Events**

**OTP  
Opioid Tx  
Program**

**Patients in  
Treatment**

**SKIP  
Survey of Key  
Informant Pts**

**Patients in  
Treatment**

**Drug  
Diversion**

**Criminal Justice/  
Law Enforcement**

**Street  
Price**

**Users/Buyers**



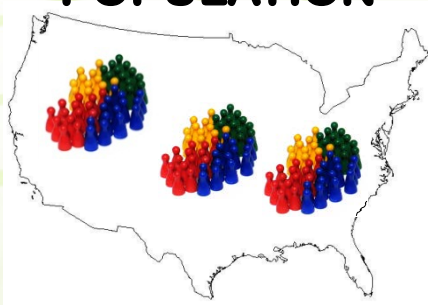


# RADARS<sup>®</sup> System Process

## Tale of Two Denominators

**COUNTS BY SYSTEM**

**UNITED STATES  
POPULATION**



=

**POPULATION RATE**

- Tried and true
- Disease burden on whole population
- Does not account for drug availability

**COUNTS BY SYSTEM**

**URDD**



=

**UNIQUE RECIPIENTS OF  
DISPENSED DRUG (URDD) RATE**

- Number of unique people filling prescription for drug
- Accounts for availability of drug in community
- Relates events to corresponding patient benefit

**RADARS<sup>®</sup>**  
SYSTEM



# RADARS System Fundamentals

- Independent, third party ownership & operation
  - Denver Health/RMPDC controls scientific rigor & integrity
    - Ensures data quality/integrity, sound methodology and expert analysis and interpretation
    - Protects proprietary data of each company while providing product-specific data to each
    - Provides standardized data collection and reporting, including rich historical data for evaluating trends over time
- Guided by External Scientific Advisory Board
  - Independent panel of key opinion leaders (KOL)
  - Minimize conflict of interest
  - Ensure scientific rigor
  - Provide guidance on program development, interpretation of results, future development of RADARS System



# RADARS System Fundamentals

- Qualified Principal Investigator for Each Program
  - Principal investigators provide expertise and credibility
    - Ensures leadership and dedication to success within each program
    - Provides content knowledge, credibility and access to other experts in the field
- Provide Common Ground for Industry, Regulatory Agencies, Academics and Clinicians
  - Host RADARS System Annual Meeting to share current data, trending and new discoveries
  - Meet with each regularly to review data, share ideas, gather feedback about current events, provide guidance

# **RADARS<sup>®</sup> System**

## **Colorado Data**

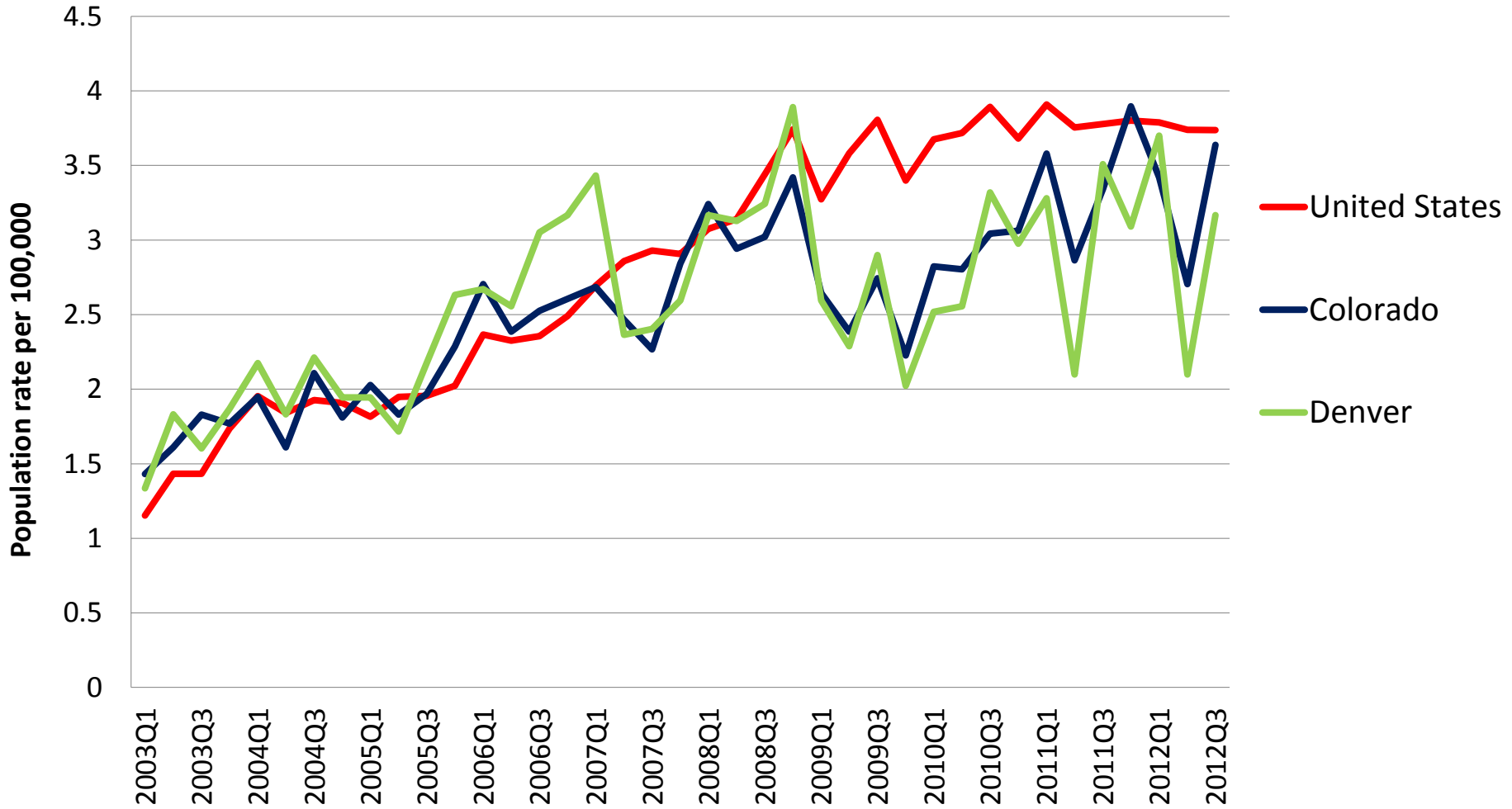




# The RADARS® System Poison Center Program

## Population Rates per 100,000 by region

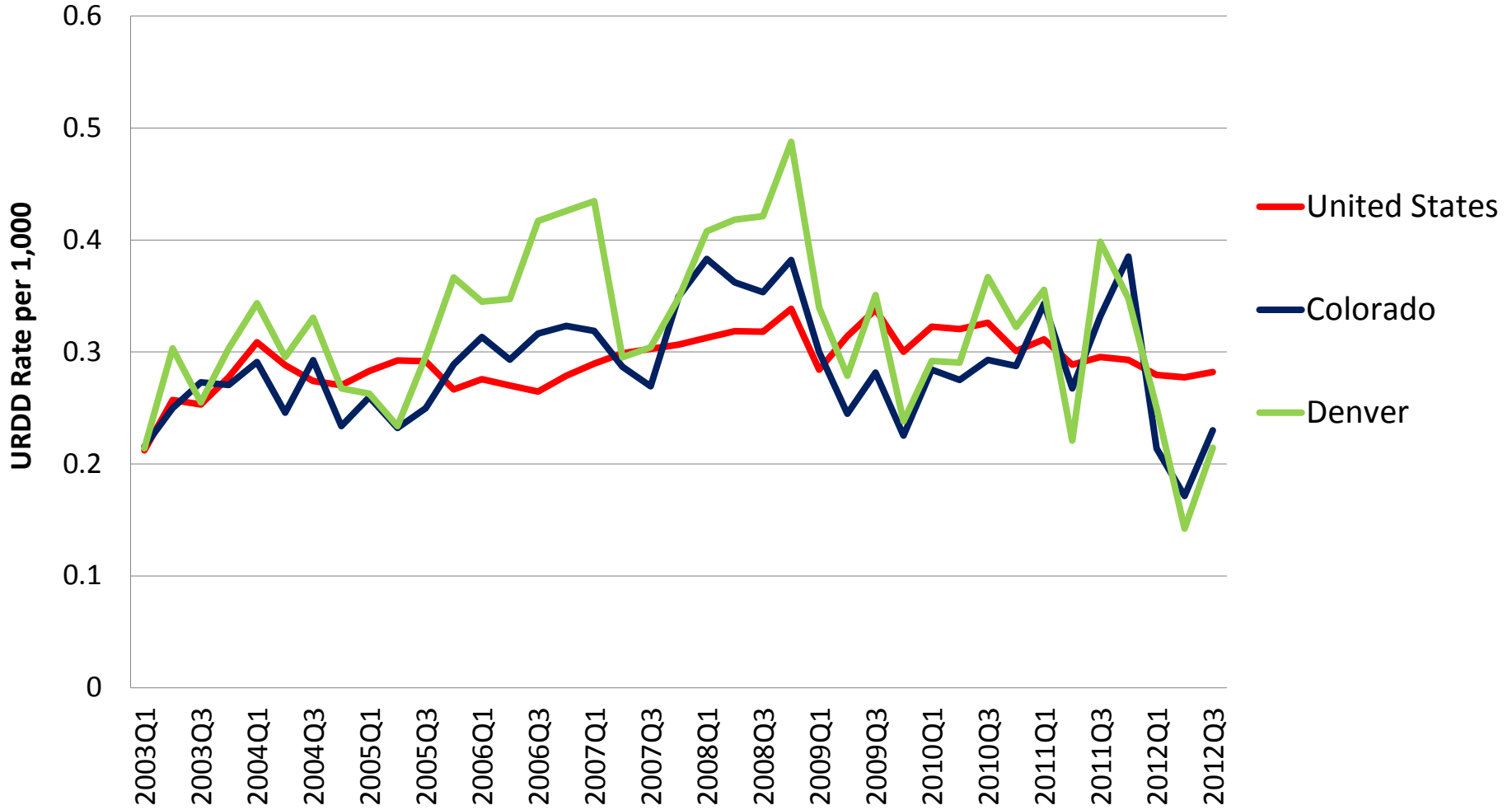
### 1<sup>st</sup> Quarter 2003 through 3<sup>rd</sup> Quarter 2012



# The RADARS<sup>®</sup> System Poison Center Program

## URDD Rates per 1,000 by region

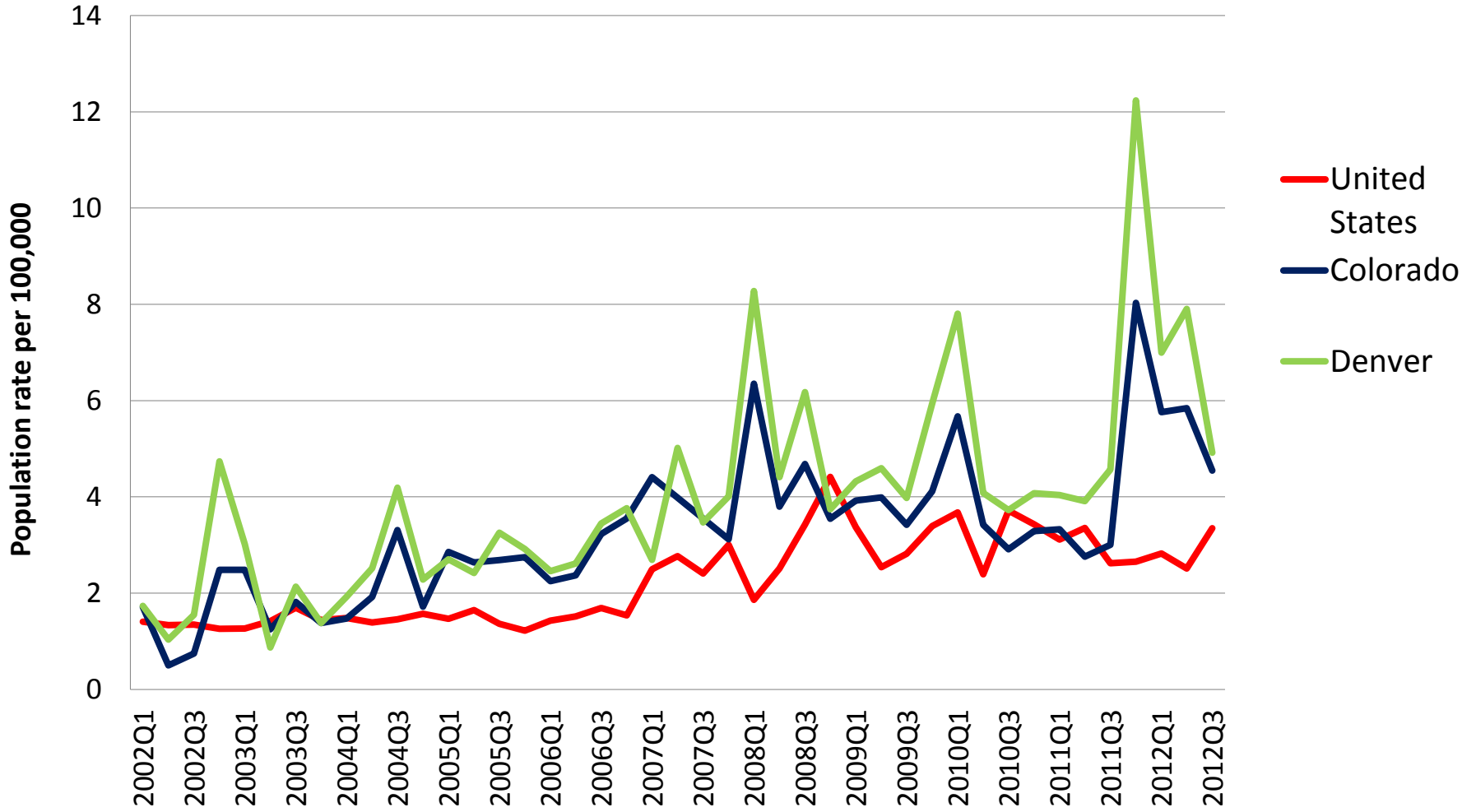
### 1<sup>st</sup> Quarter 2003 through 3<sup>rd</sup> Quarter 2012



# The RADARS® System Drug Diversion Program

## Population Rates per 100,000 by region

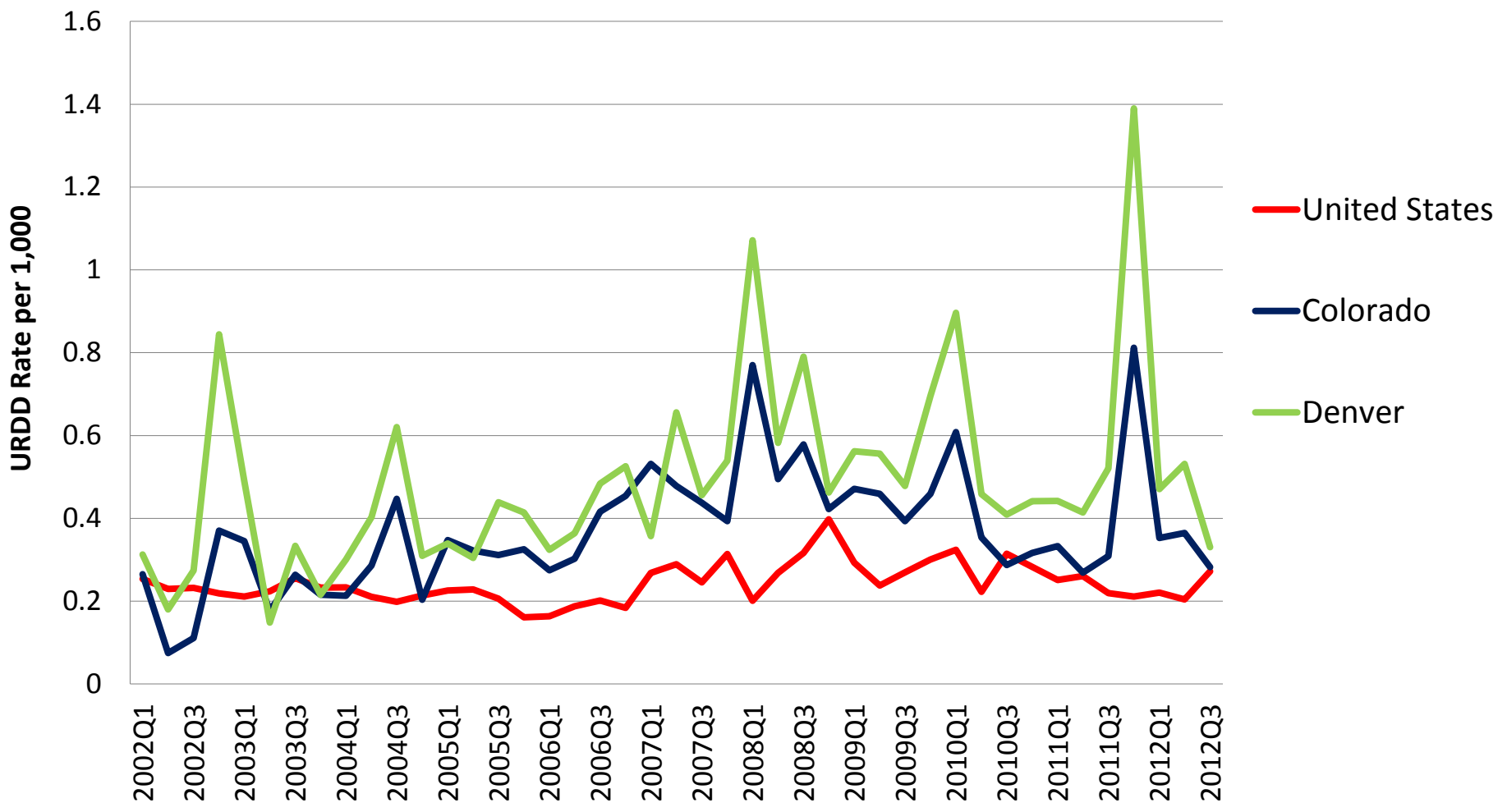
### 1<sup>st</sup> Quarter 2002 through 3<sup>rd</sup> Quarter 2012



# The RADARS® System Drug Diversion Program

## URDD Rates per 1,000 by region

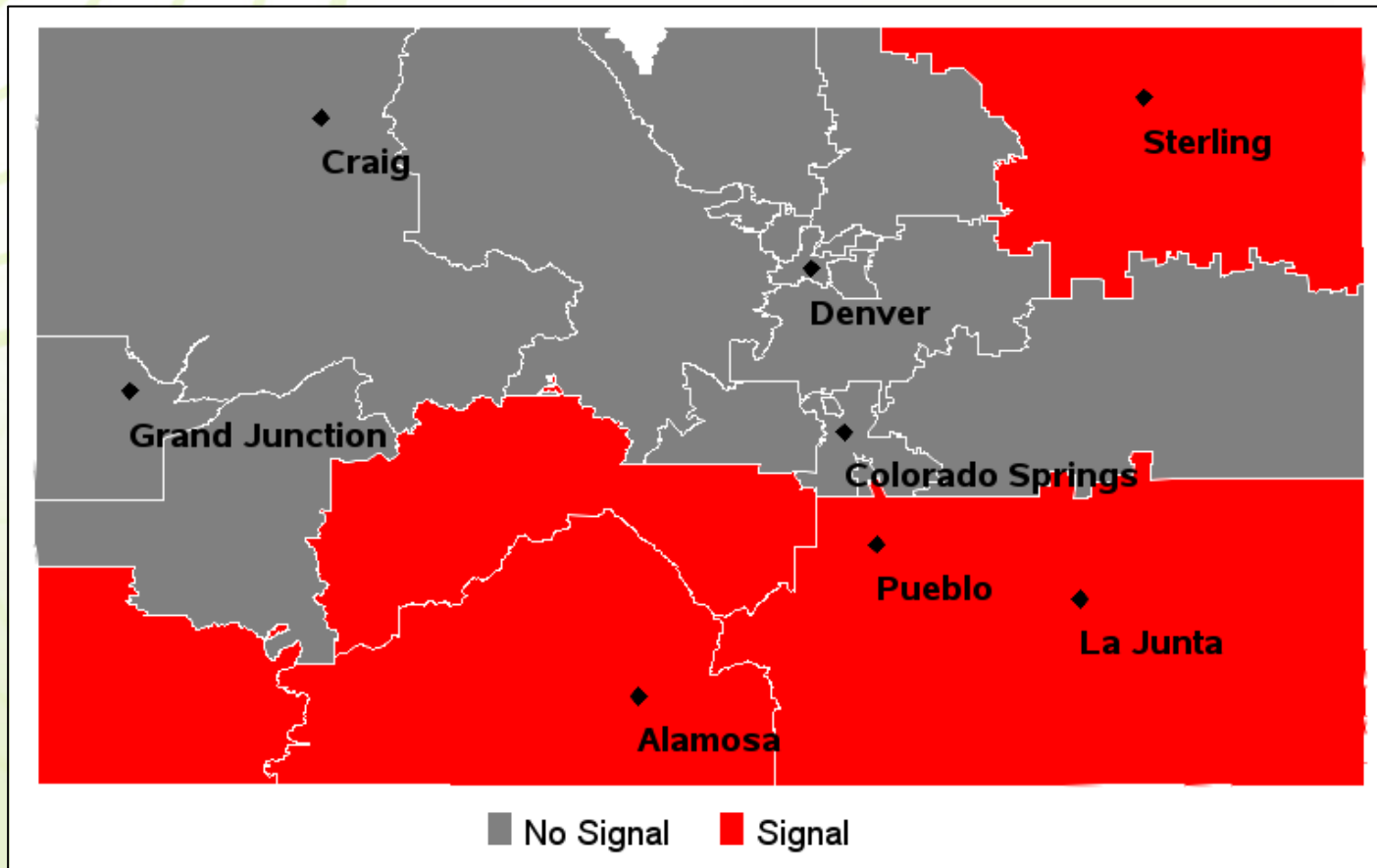
### 1<sup>st</sup> Quarter 2002 through 3<sup>rd</sup> Quarter 2012





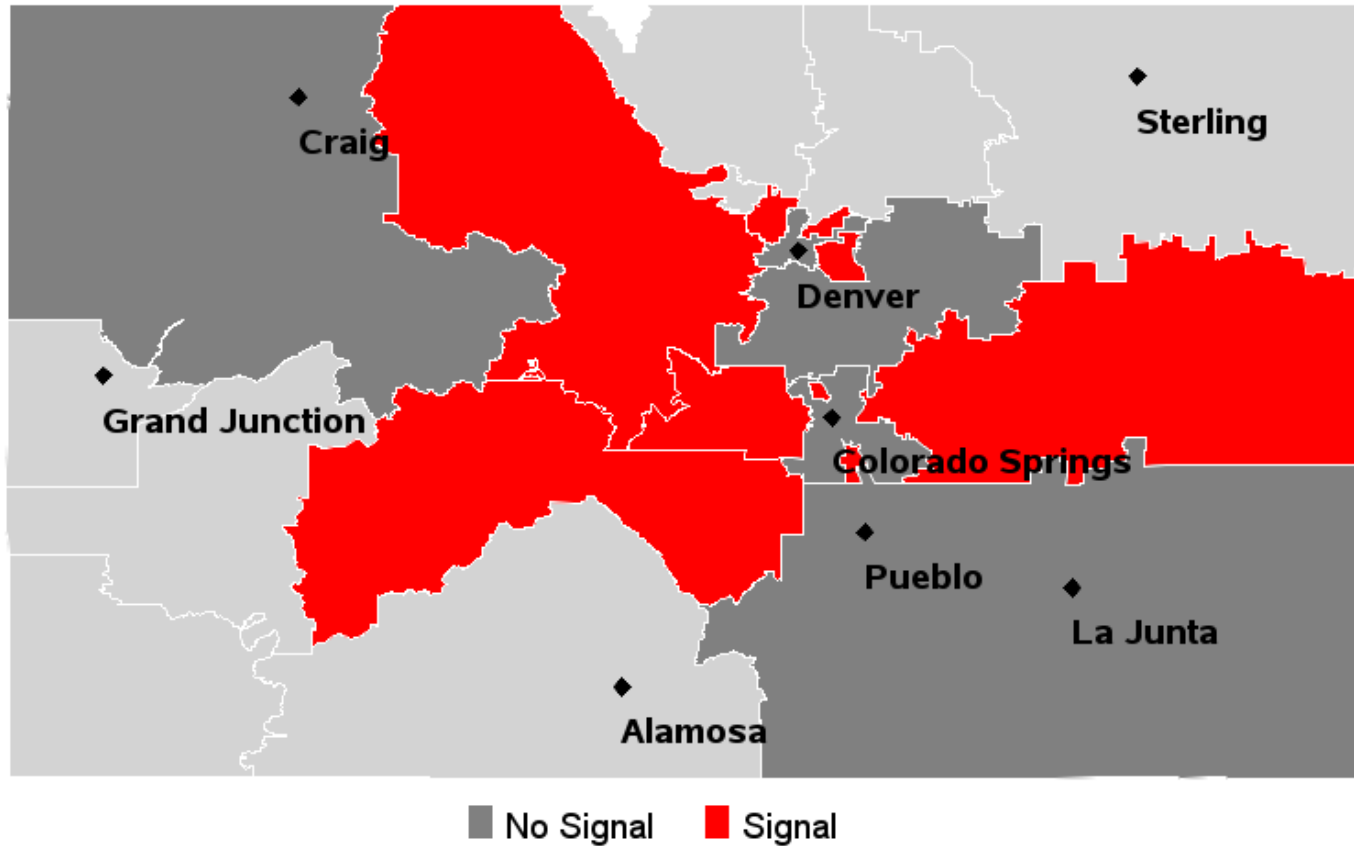
# Poison Center Oxycodone Signals

## 3<sup>rd</sup> Quarter 2011 – 2<sup>nd</sup> Quarter 2012



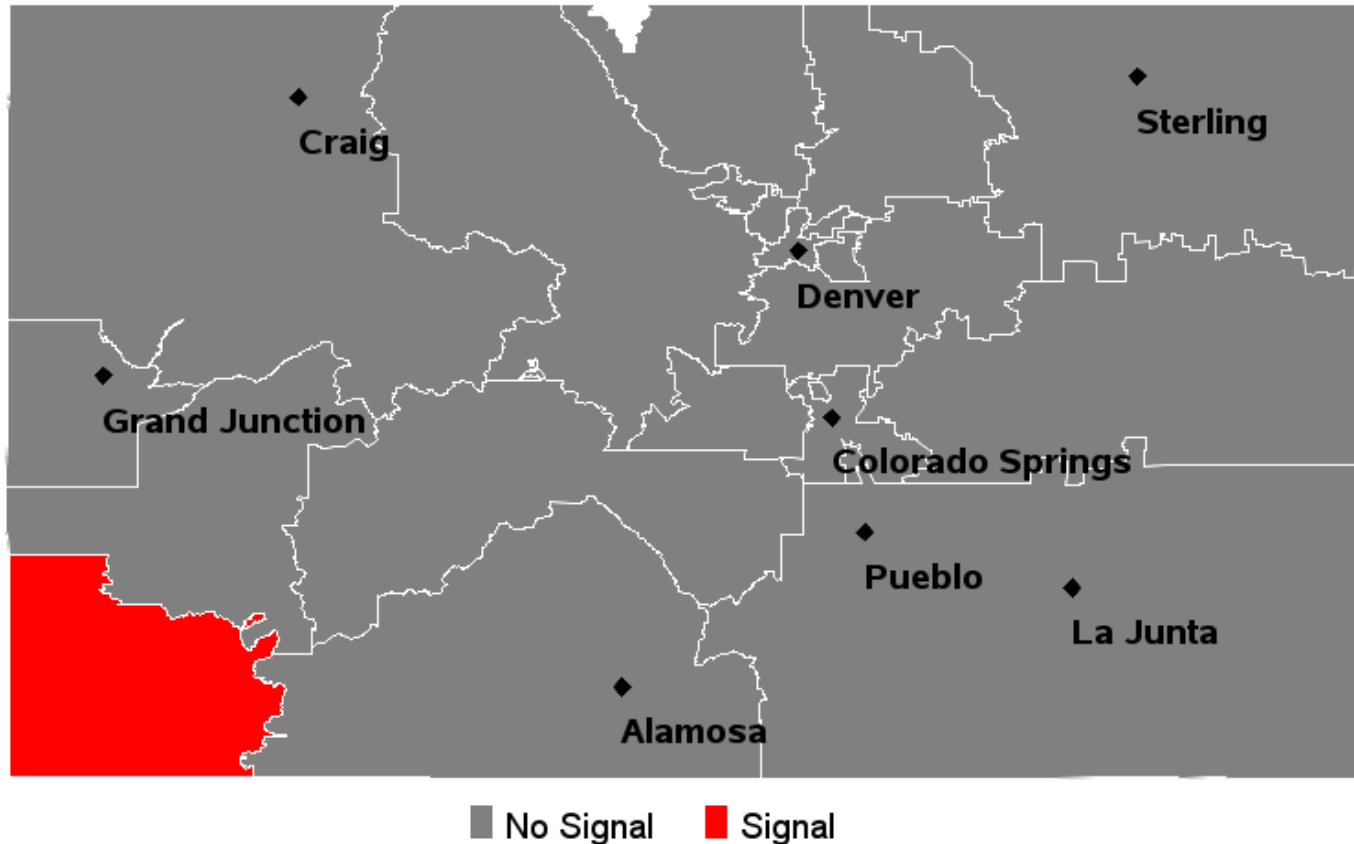
# Drug Diversion Oxycodone Signals

## 3<sup>rd</sup> Quarter 2011 – 2<sup>nd</sup> Quarter 2012



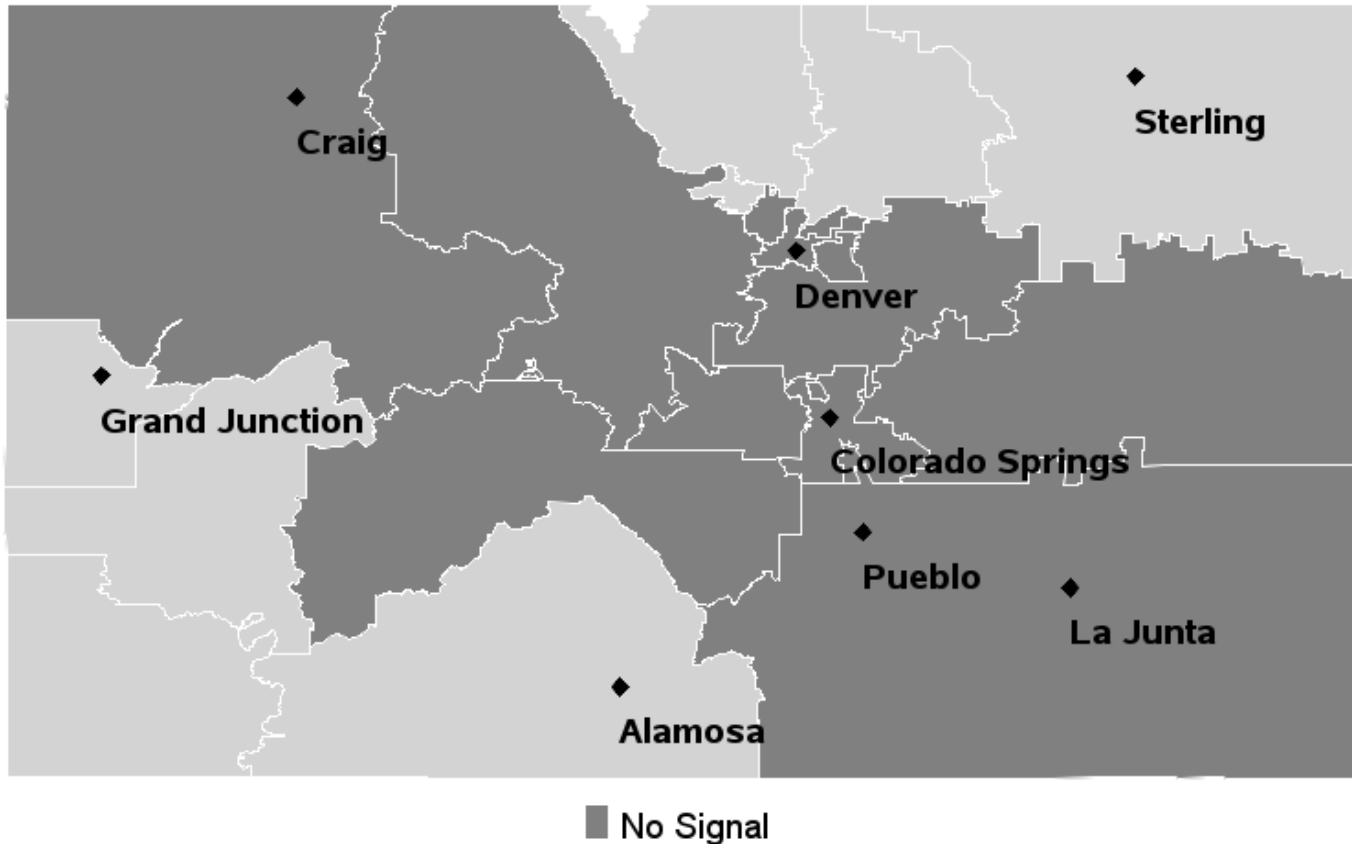
# Poison Center Hydrocodone Signals

## 3<sup>rd</sup> Quarter 2011 – 2<sup>nd</sup> Quarter 2012



# Drug Diversion Hydrocodone Signals

## 3<sup>rd</sup> Quarter 2011 – 2<sup>nd</sup> Quarter 2012





# Colorado Summary

- Poison Center trends indicate Colorado rates have been **similar to or lower than** national rates
- Drug Diversion trends indicate Colorado rates have been **similar to or higher than** national rates
- Multiple oxycodone signals detected in both Poison Center and Drug Diversion
  - Signals detected in different 3 Digit Zip Codes depending on program
- Minimal hydrocodone signals detected in Colorado
  - Only signal in southwest corner of state and no diversion signals

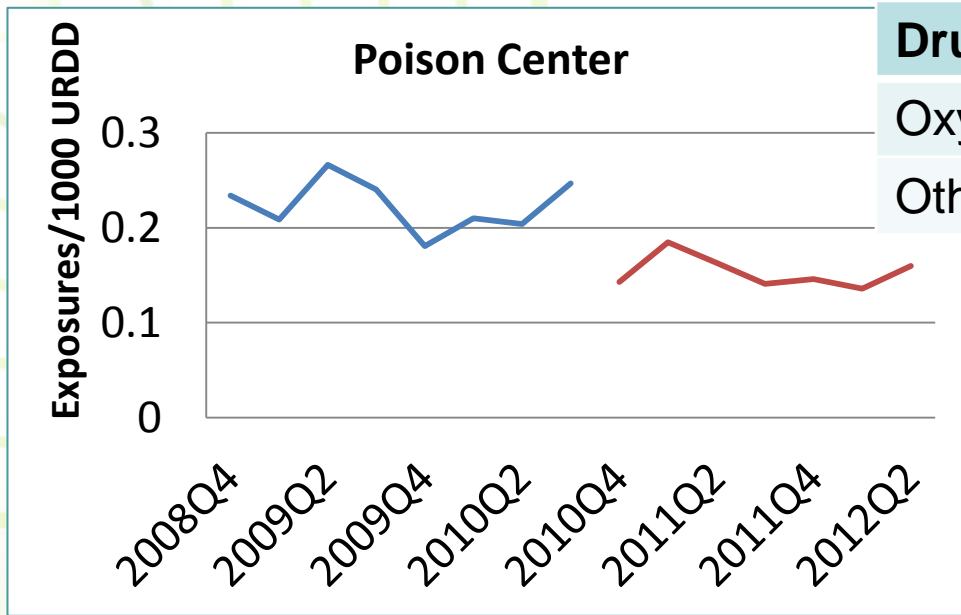
# Abuse Deterrent Opioids

# Abuse Deterrent Formulations

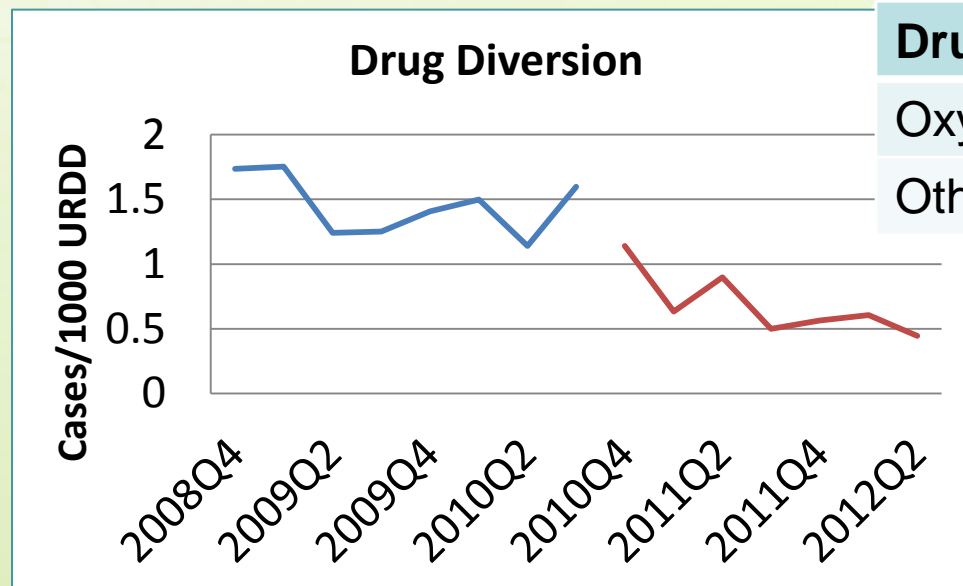
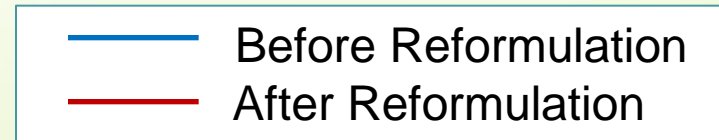
- FDA Draft Guidance on evaluation and labeling for abuse deterrent opioids
  - Specifies that these formulations only address non-oral routes of abuse (i.e. injection, snorting, crushing; oral route of abuse not impacted)
  - Types: physical/chemical barriers, antagonist/agonist combinations, aversion, delivery system, prodrug, combination of >1 type
- Currently several products on the market:

|                                       |  |   |
|---------------------------------------|--|---|
| OxyContin <sup>®</sup><br>(oxycodone) | Opana <sup>®</sup><br>(oxymorphone)    | Suboxone <sup>®</sup><br>(buprenorphine/naloxone) |
| Nucynta <sup>®</sup><br>(tapentadol)  | Exalgo <sup>®</sup><br>(hydromorphone) |   |

# OxyContin<sup>®</sup> Rates per 1,000 URDD



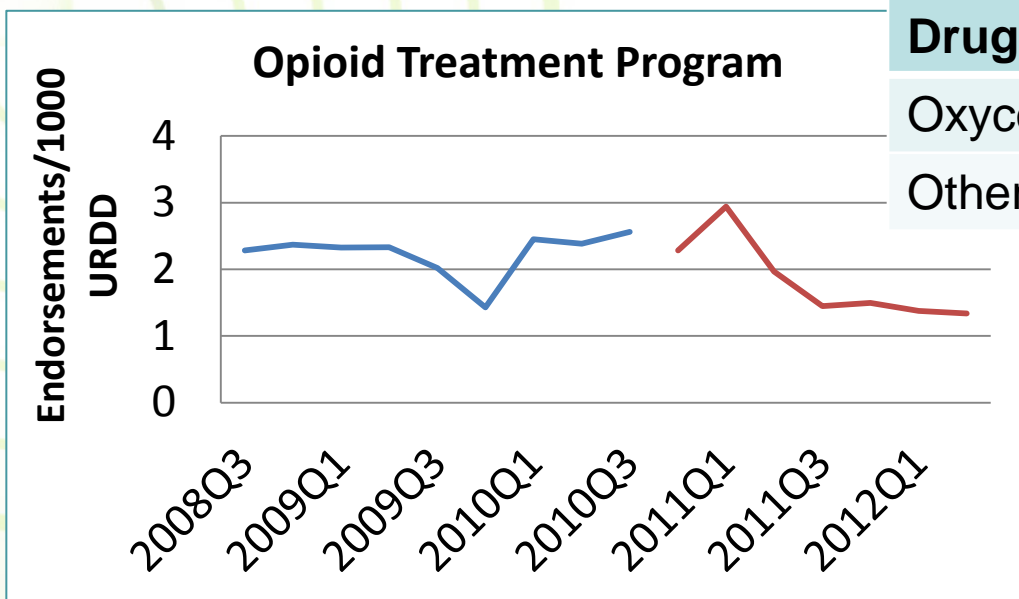
| Drug          | Δ(%)   |
|---------------|--------|
| Oxycontin     | -31.3% |
| Other Opioids | -10.0% |



| Drug          | Δ(%)   |
|---------------|--------|
| Oxycontin     | -52.9% |
| Other Opioids | -16.8% |

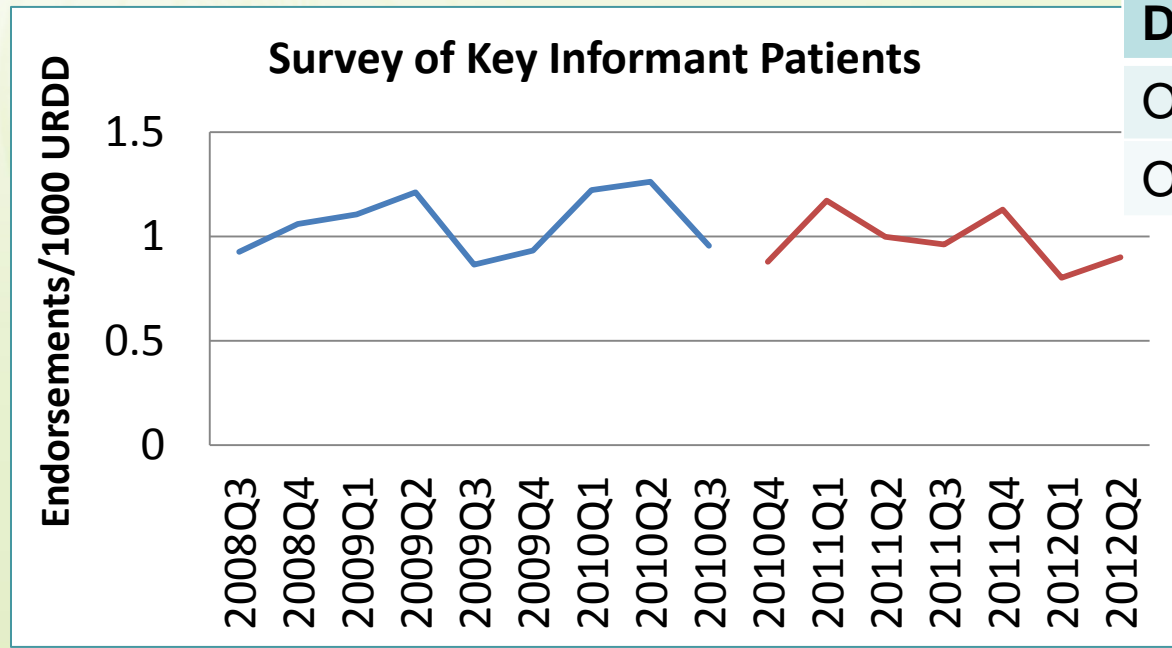


# OxyContin® URDD Rates per 1,000



| Drug          | Δ(%)   |
|---------------|--------|
| Oxycontin     | -14.8% |
| Other Opioids | -11.6% |

— Before Reformulation  
— After Reformulation



| Drug          | Δ(%)  |
|---------------|-------|
| Oxycontin     | -9.4% |
| Other Opioids | 7.6%  |





# Abuse Deterrent Formulations Summary

- FDA is engaged in the evaluation and labeling of abuse deterrent opioids
- These activities are impacting the approval of new opioids without abuse deterrent mechanisms
- Data from several sources associate abuse deterrent formulations with reduction of abuse, misuse and diversion
- Not sure yet of the “squeezing of the balloon” phenomenon, do abuse deterrent formulations prevent abuse or just abuse of that product?

# Conclusion

- **RADARS<sup>®</sup>** System monitors multiple sources using a “mosaic” approach to surveillance of prescription drug abuse, misuse and diversion.
- Colorado data trends for Poison Centers are similar to that of the United States, although the state Drug Diversion activity appears higher than the national average.
- Prescription drug abuse is a complicated issue for which no single intervention will solve. Abuse deterrent formulations appear to be at least part of the solution.