

RADARS[®]
SYSTEM **2019**

13TH ANNUAL SCIENTIFIC MEETING

Thursday, May 16, 2019
13th Annual Scientific Meeting
Transforming Post-Marketing
Surveillance of Prescription Drugs



RADARS System

Scientific Advisory Board

Principal Investigators

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Washington University in St Louis



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Nova Southeastern University



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*American Association for the Treatment of
Drug Dependence*



Richard C. Dart, MD, PhD
*Rocky Mountain Poison
& Drug Center, Denver Health*



Substance Abuse Experts

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Columbia University



Sidney Schnoll, MD, PhD
PinneyAssociates



George Woody, MD
University of Pennsylvania



Epidemiology/Biostatistics

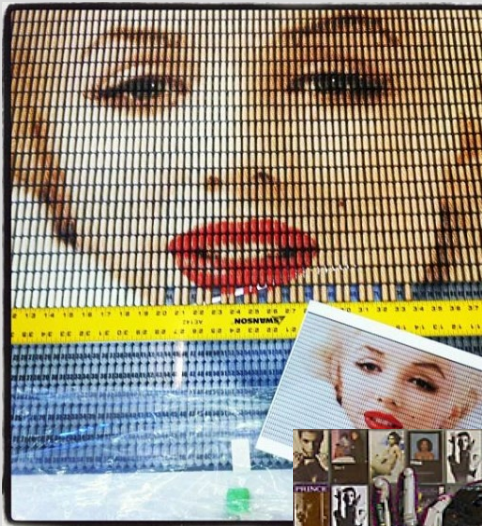
Nabarun Dasgupta, MPH
*Rocky Mountain Poison
& Drug Center, Denver Health*



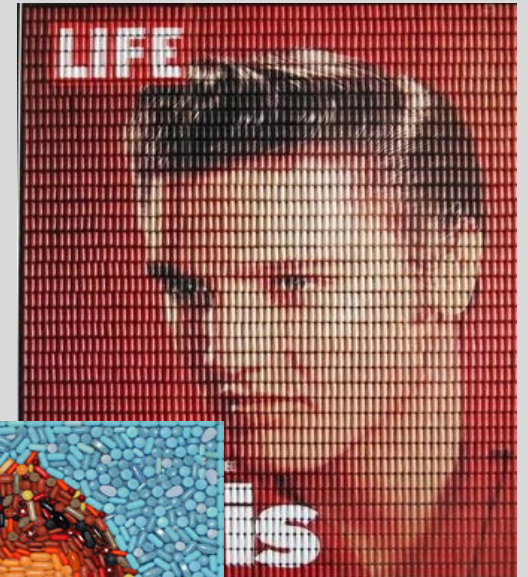
Law Enforcement

John Burke
Pharmaceutical Diversion Education, Inc.;
International Health Facility Diversion
Association





Mac Miller

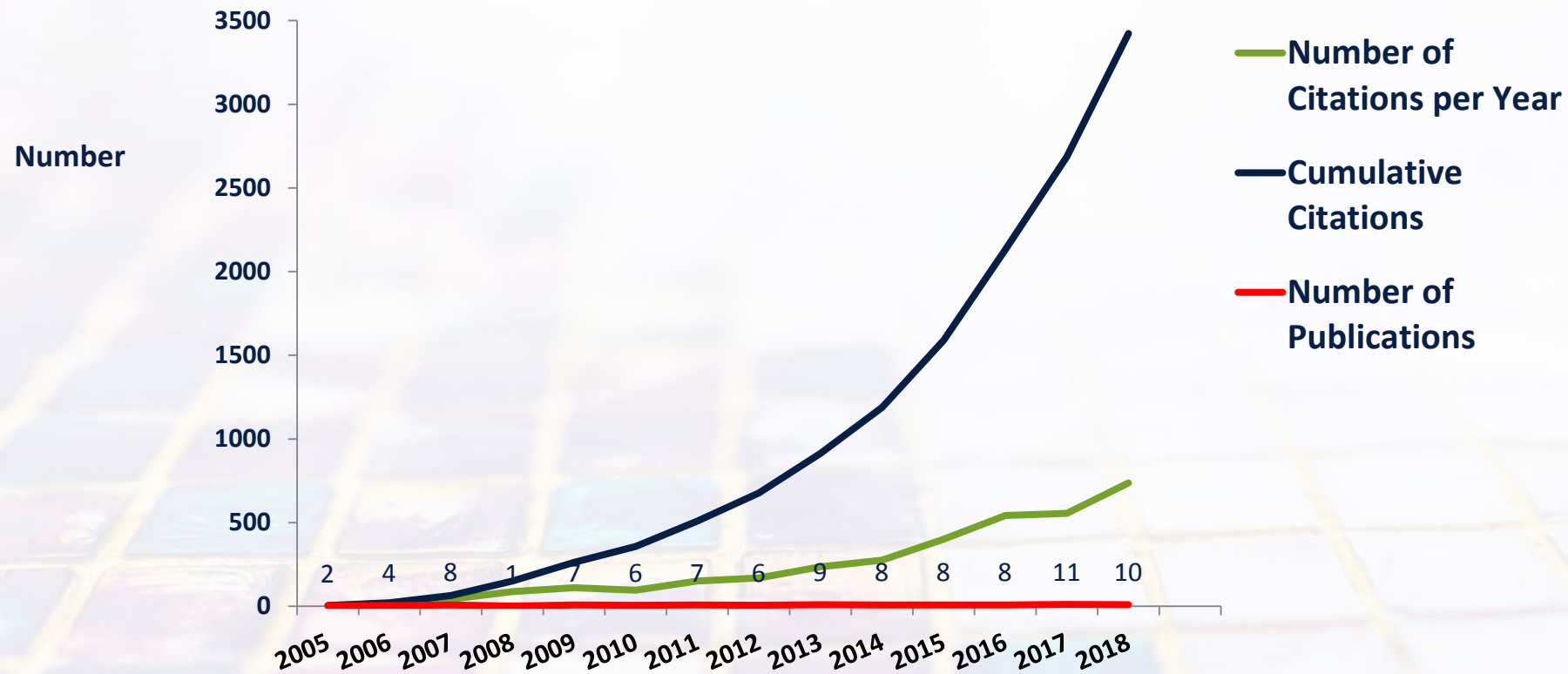


Artist: Jason Mecier

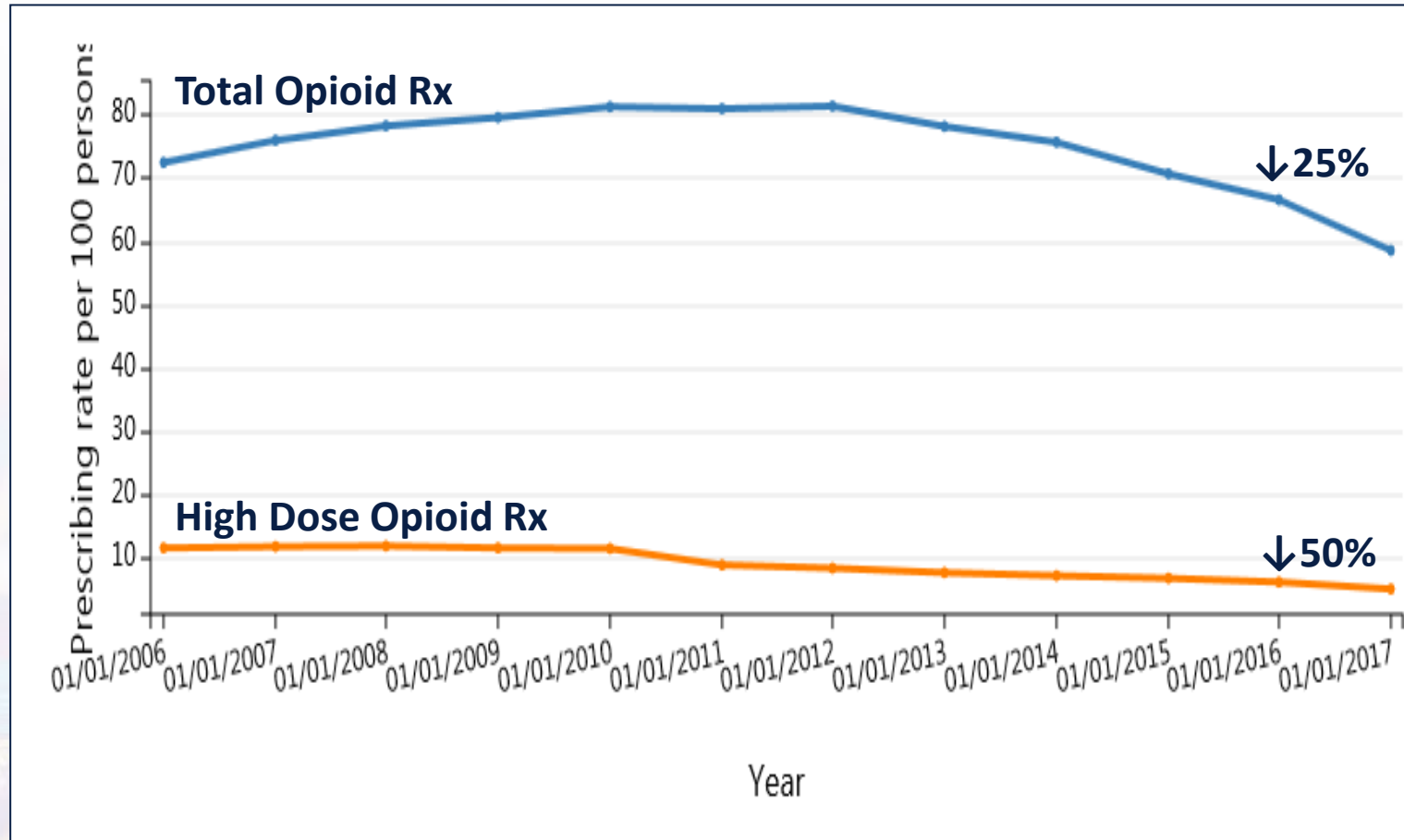
NEWS FROM RADARS SYSTEM

RADARS System – 103 Publications in Scientific Literature

RADARS System Publications Cited over Time



Trends in Annual Opioid Prescribing Rates



Unanticipated Consequences



The NEW ENGLAND
JOURNAL of MEDICINE



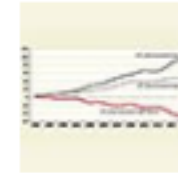
Case Studies in Social Medicine

DISCOVER NOW →



PERSPECTIVE

Pharmaceutical Protections in
U.S. Trade Deals — What Do
Americans Get in Return...



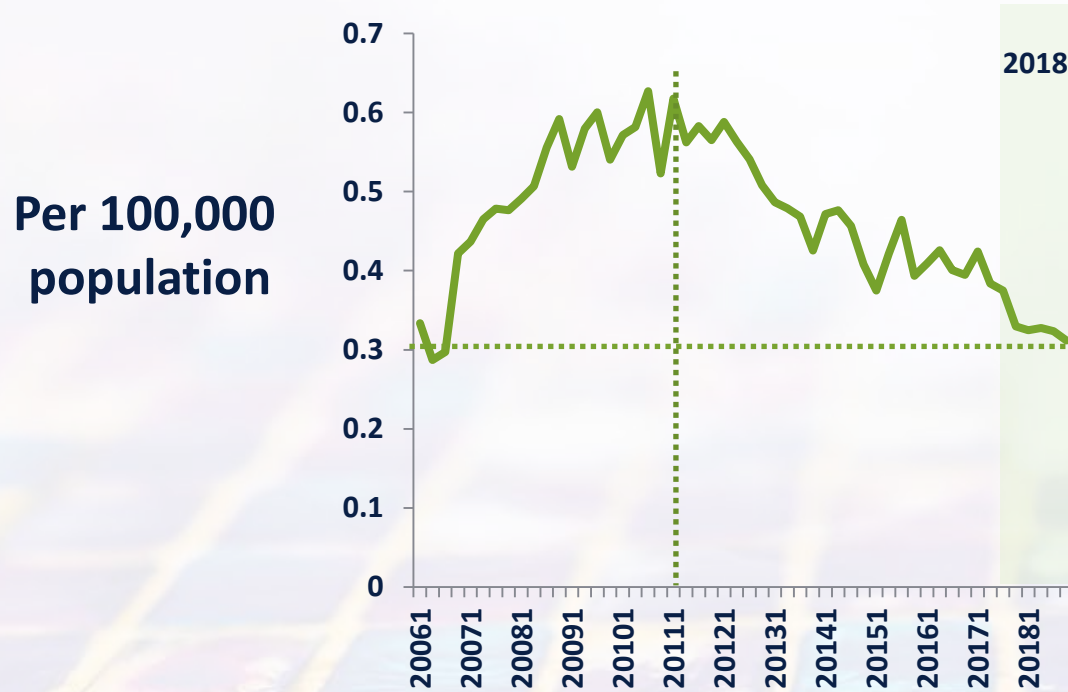
ORIGINAL ARTICLE

Transcatheter Aortic-Valve
Replacement with a Balloon-
Expandable Valve in Low-Ri.

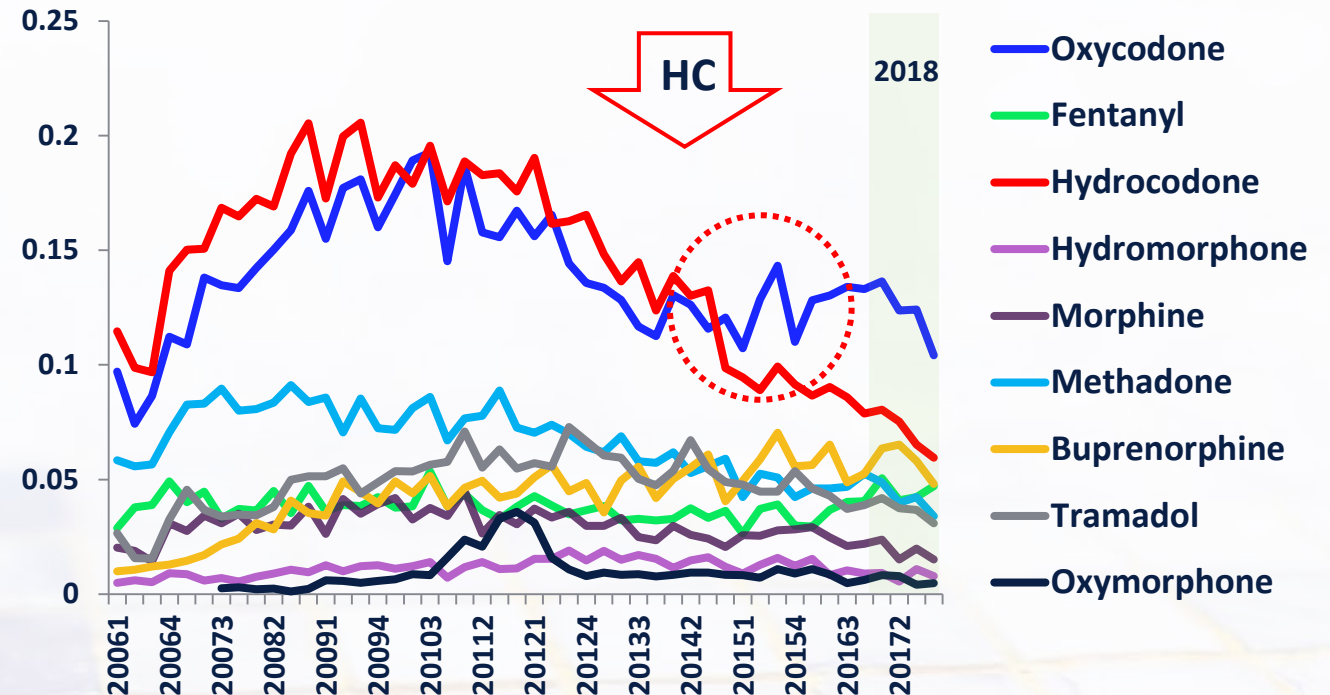
Perspective No Shortcuts to Safer Opioid Prescribing

Deborah Dowell, M.D., M.P.H., Tamara Haegerich, Ph.D., and Roger Chou, M.D.

Poison Center Program Intentional Abuse, 2006 - 2018

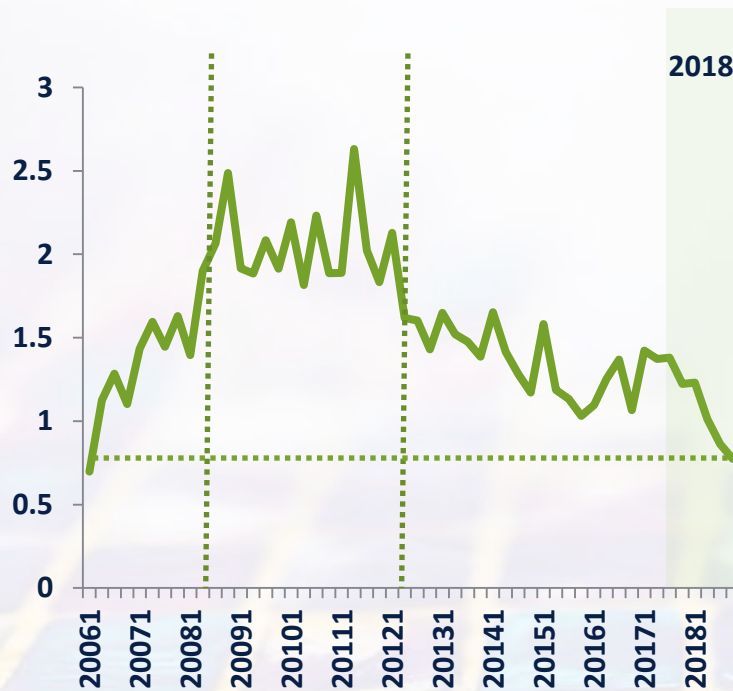


oxycodone, hydrocodone,
hydromorphone, fentanyl,
morphine, tramadol

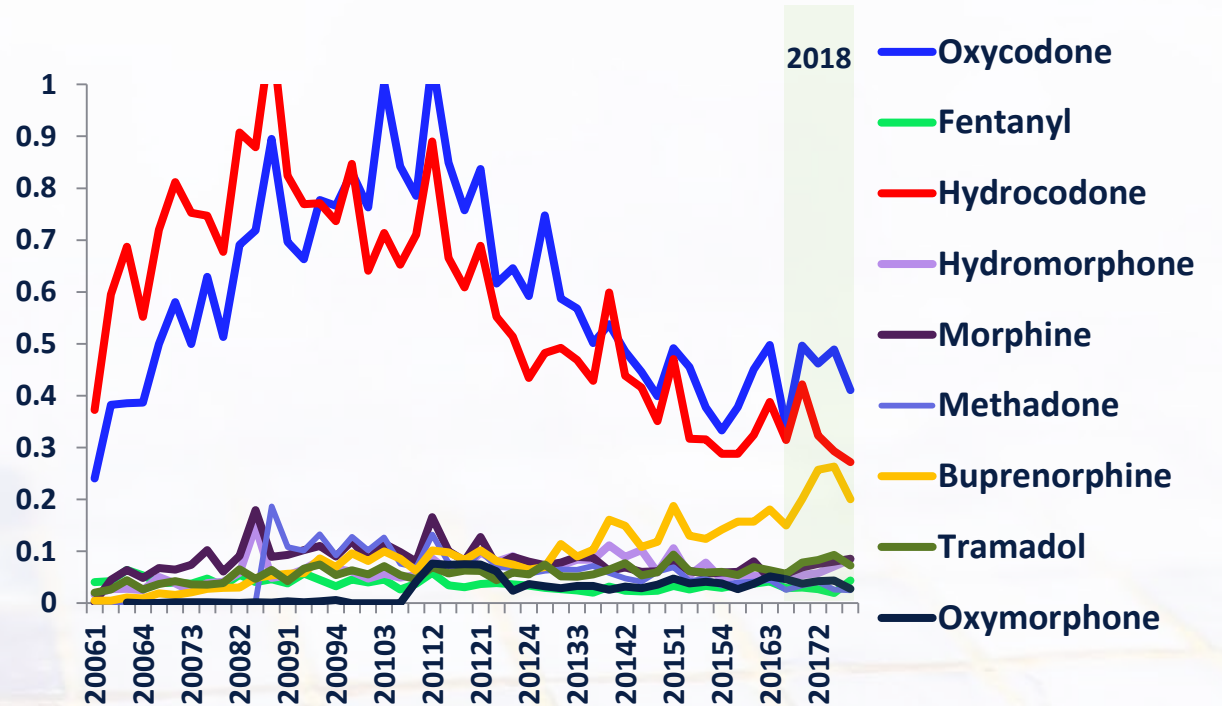


Drug Diversion Program, 2006 - 2018

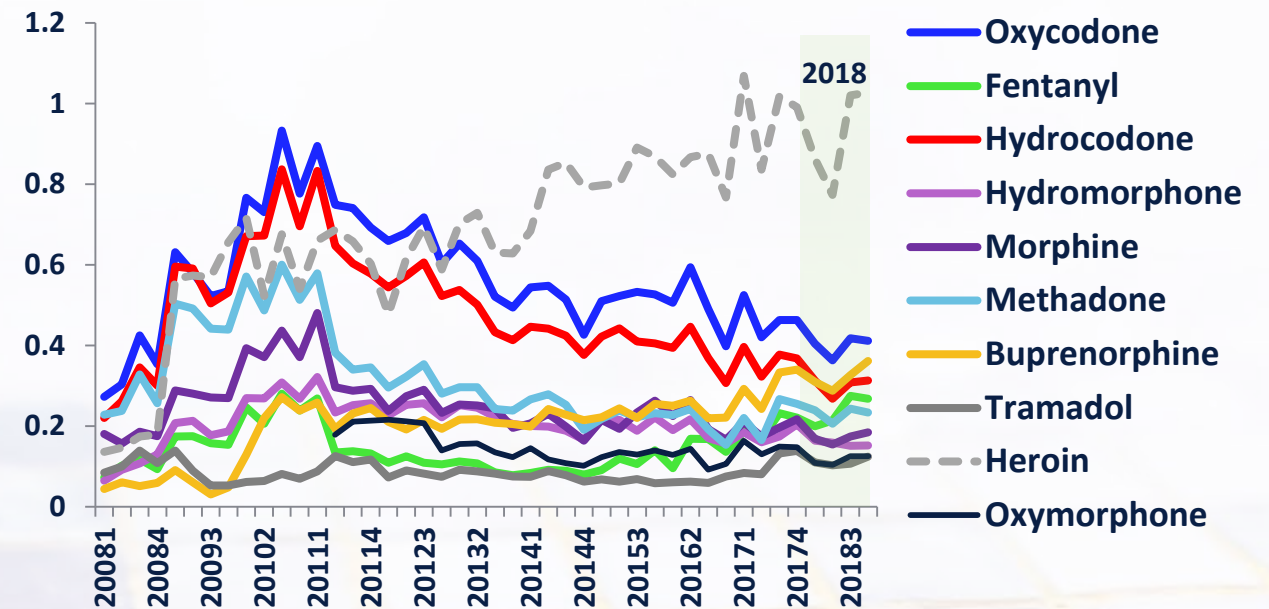
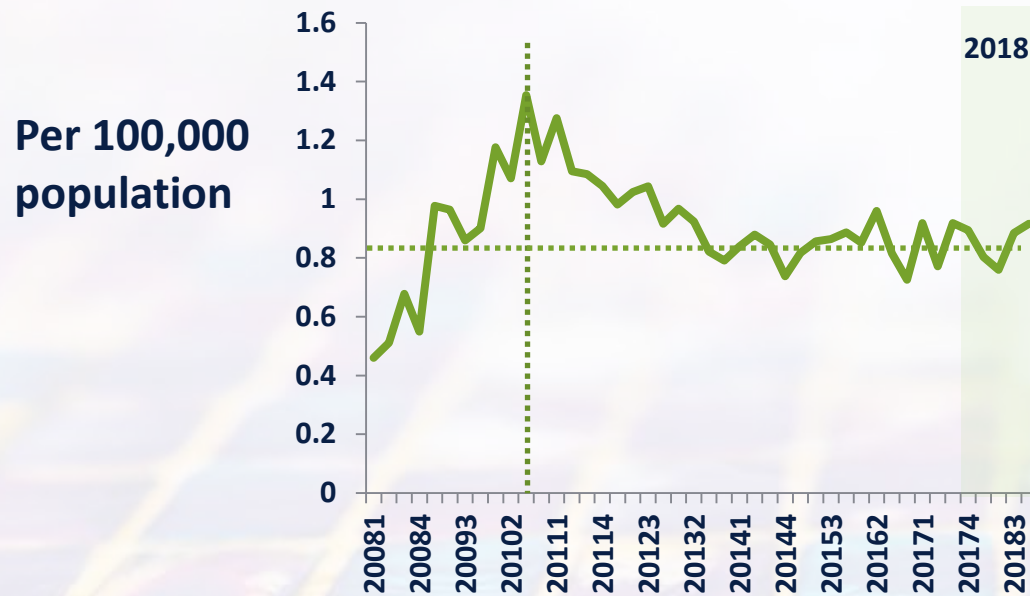
Per 100,000
population



oxycodone, hydrocodone,
hydromorphone, fentanyl,
morphine, tramadol



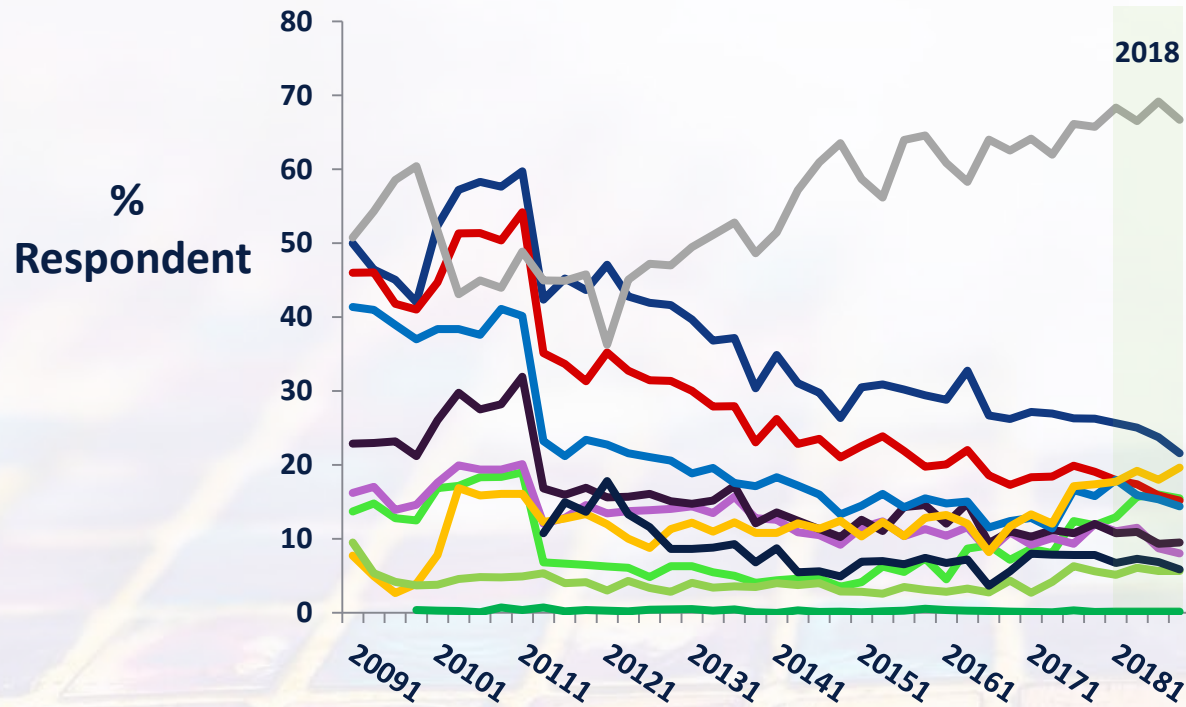
Treatment Center Programs Combined, 2008 - 2018



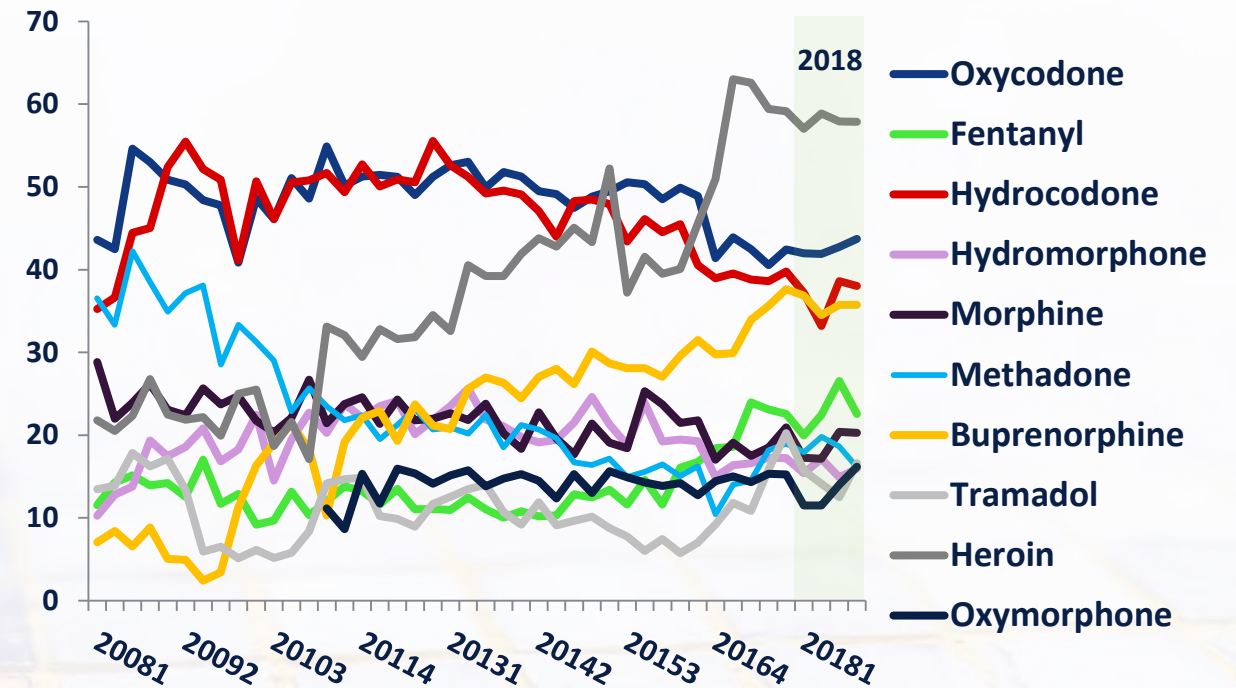
oxycodone, hydrocodone,
hydromorphone, fentanyl,
morphine, tramadol

Treatment Center Programs, 2008 - 2018

Opioid Treatment Program

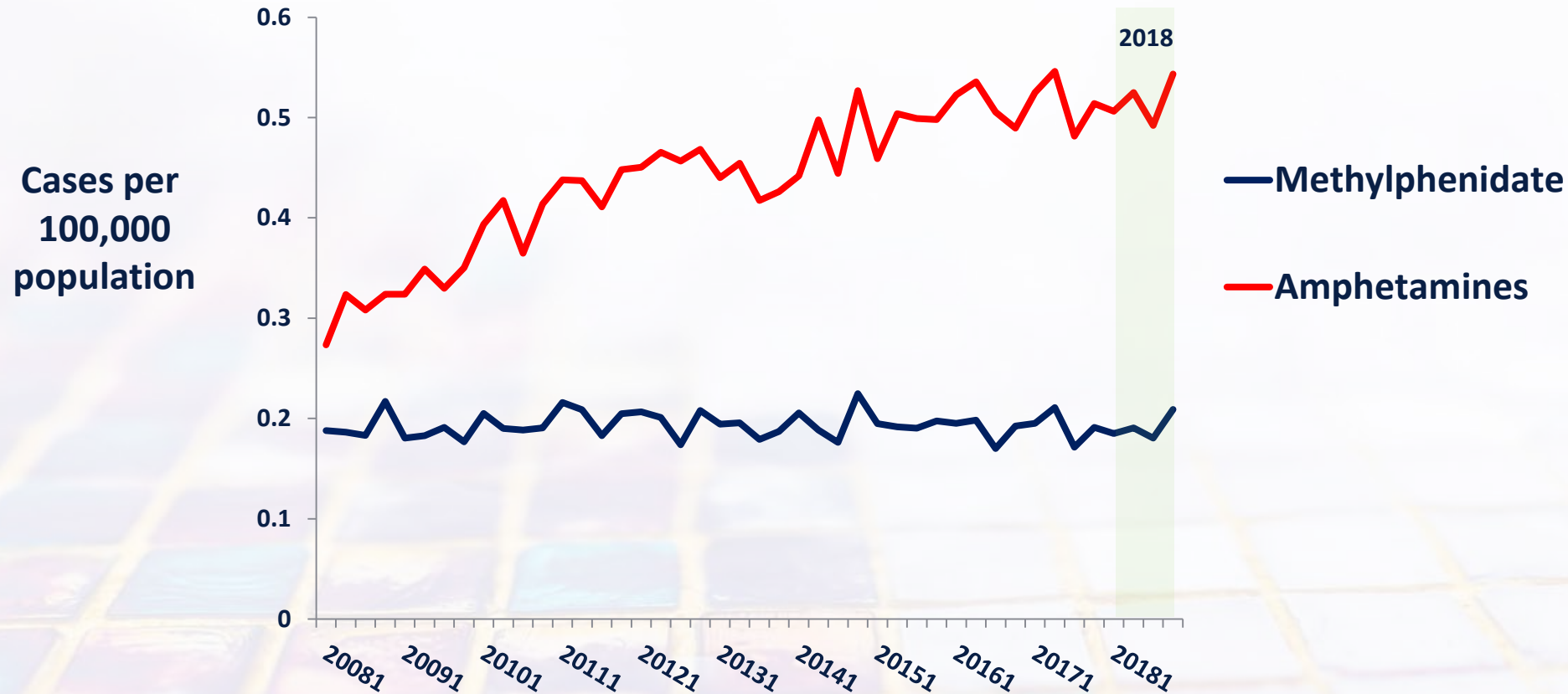


Survey of Key Informants' Patients Program



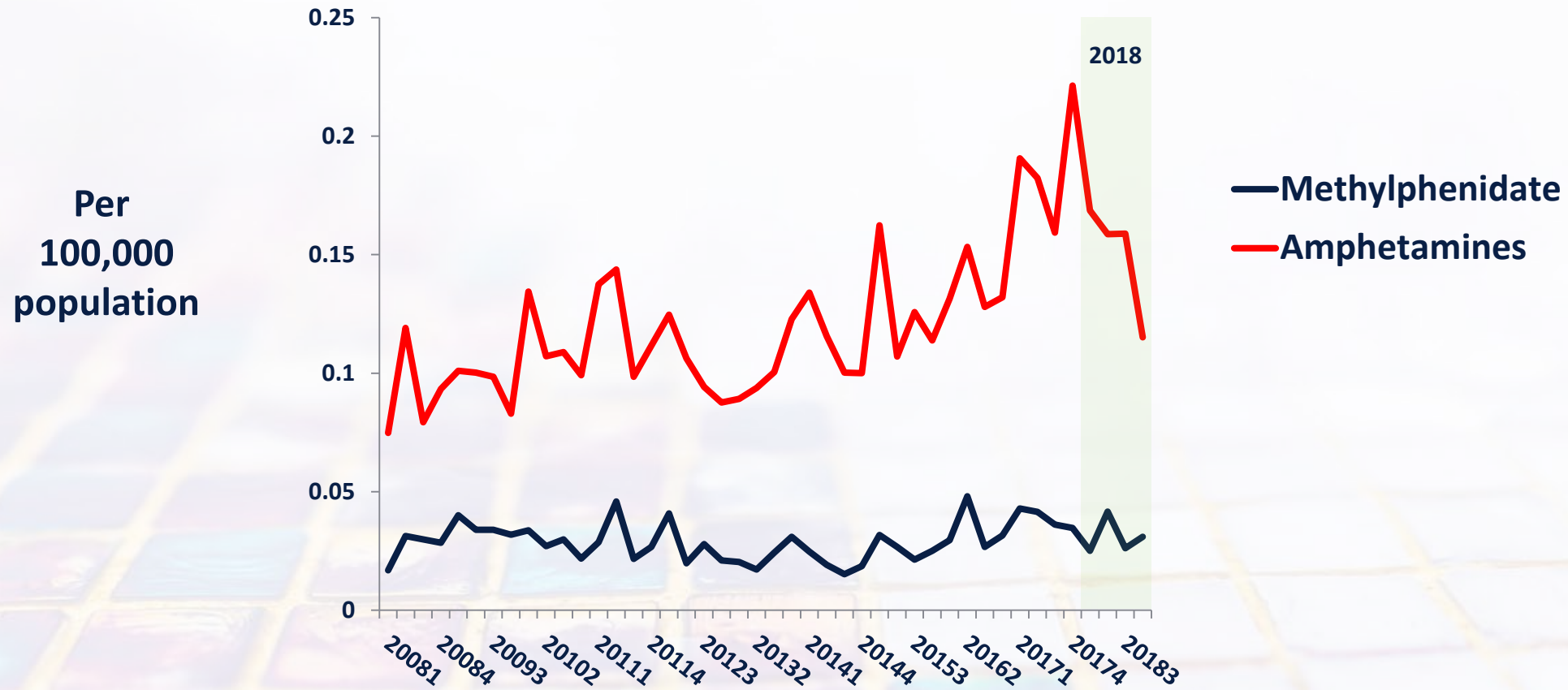
Poison Center Program

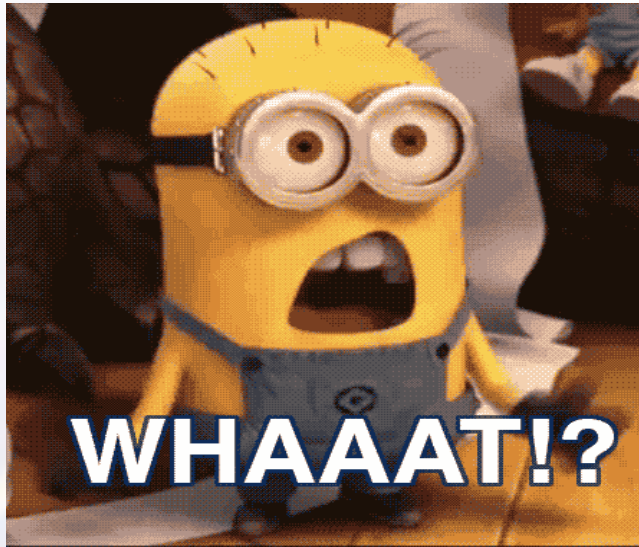
Prescription Stimulant Rates, 2008 - 2018



Drug Diversion Program

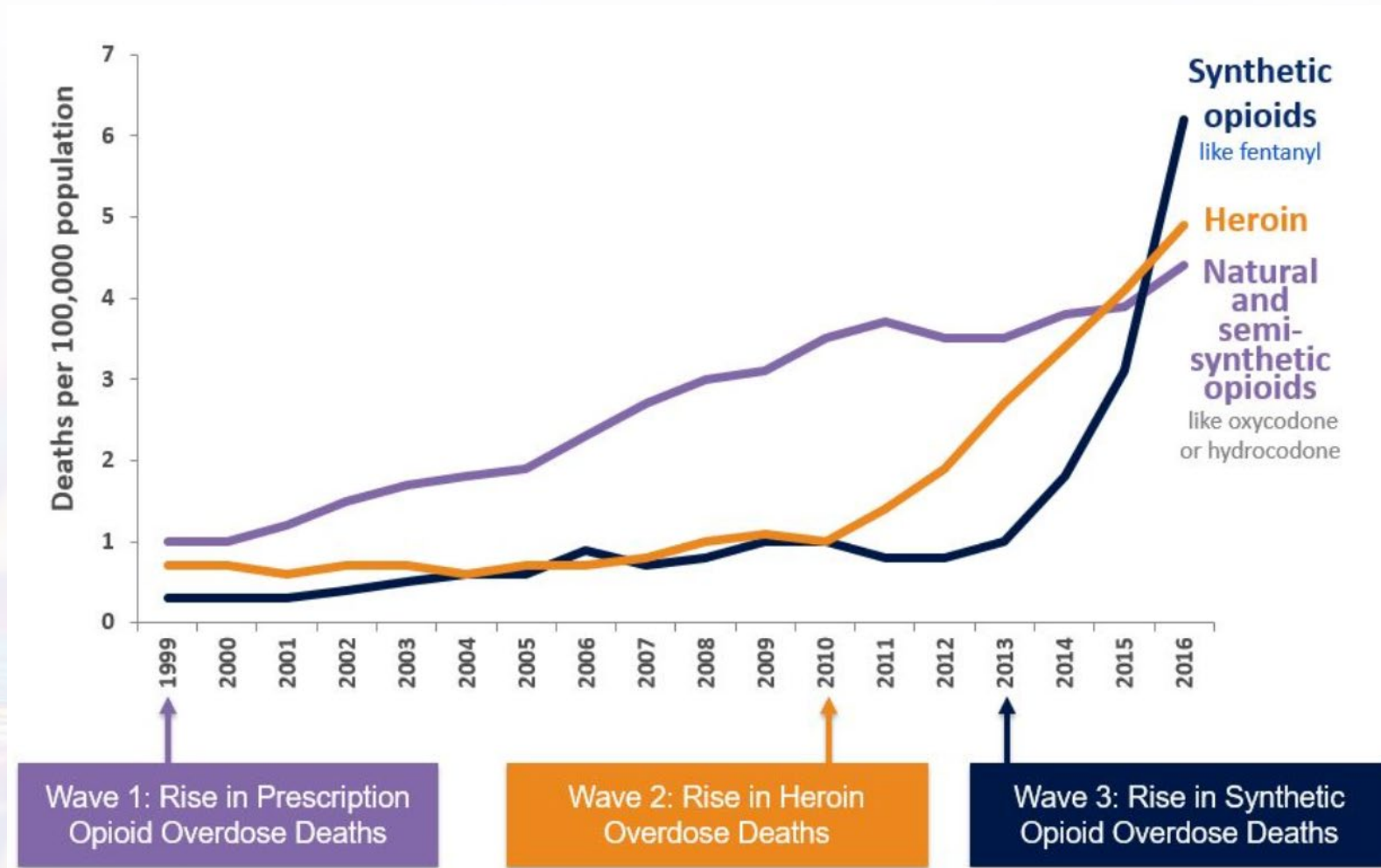
Prescription Stimulant Rates, 2008 - 2018



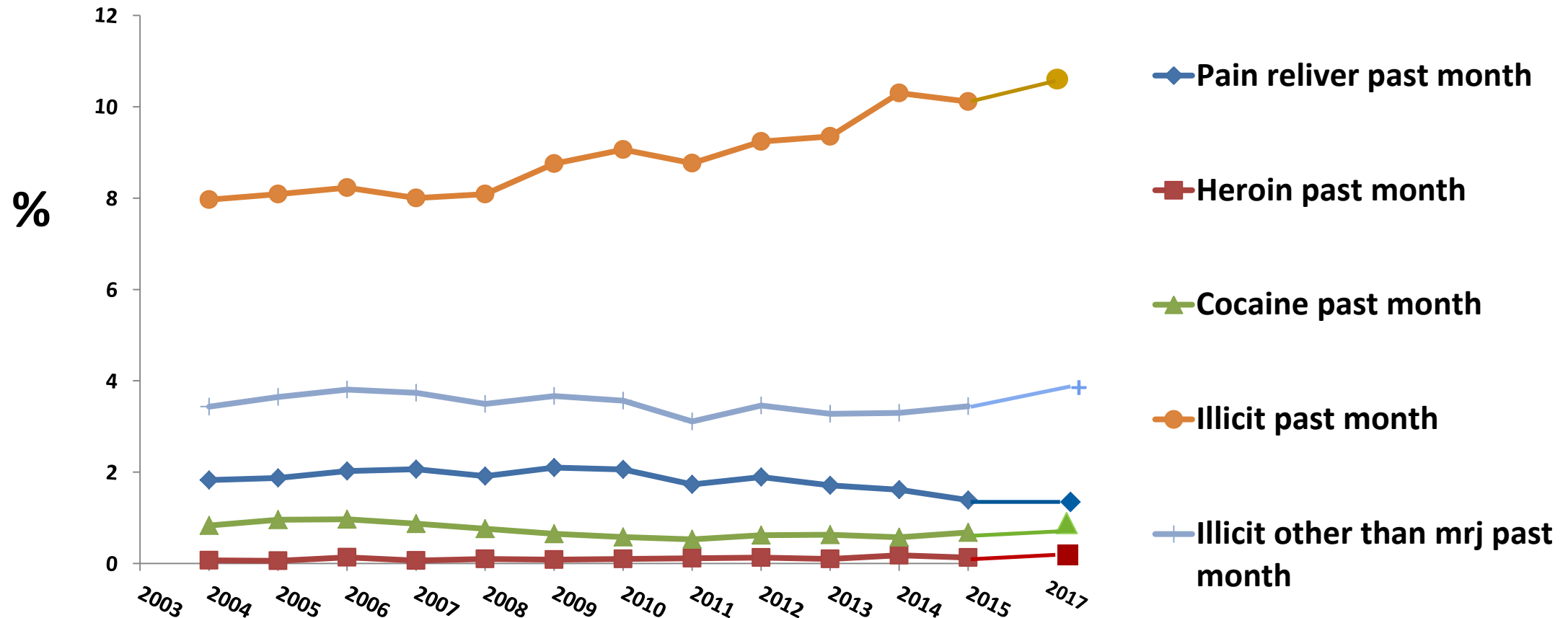


DECREASING
RX OPIOID ABUSE,
BUT **INCREASING**
DEATHS?

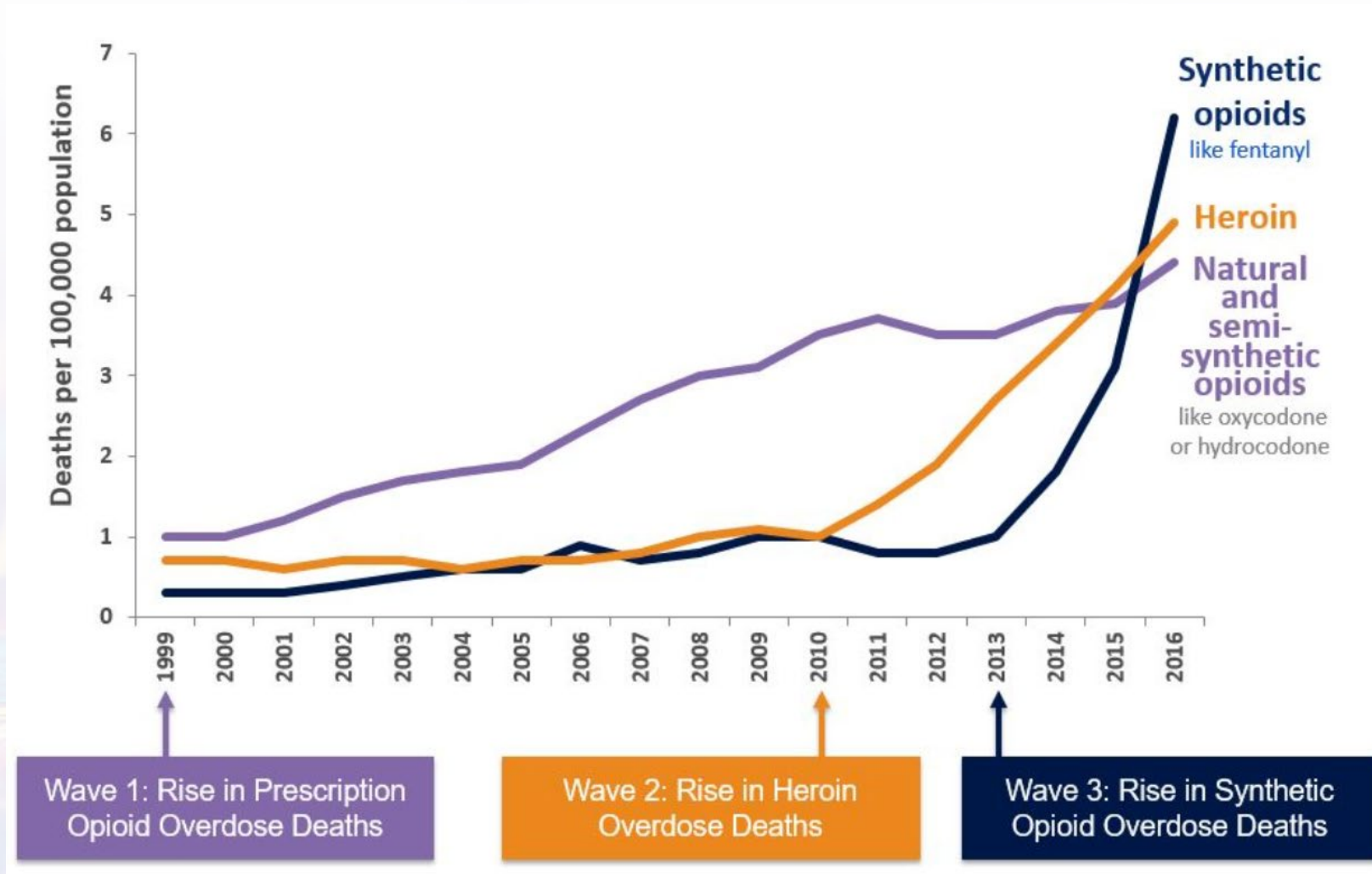
The Opioid Epidemic



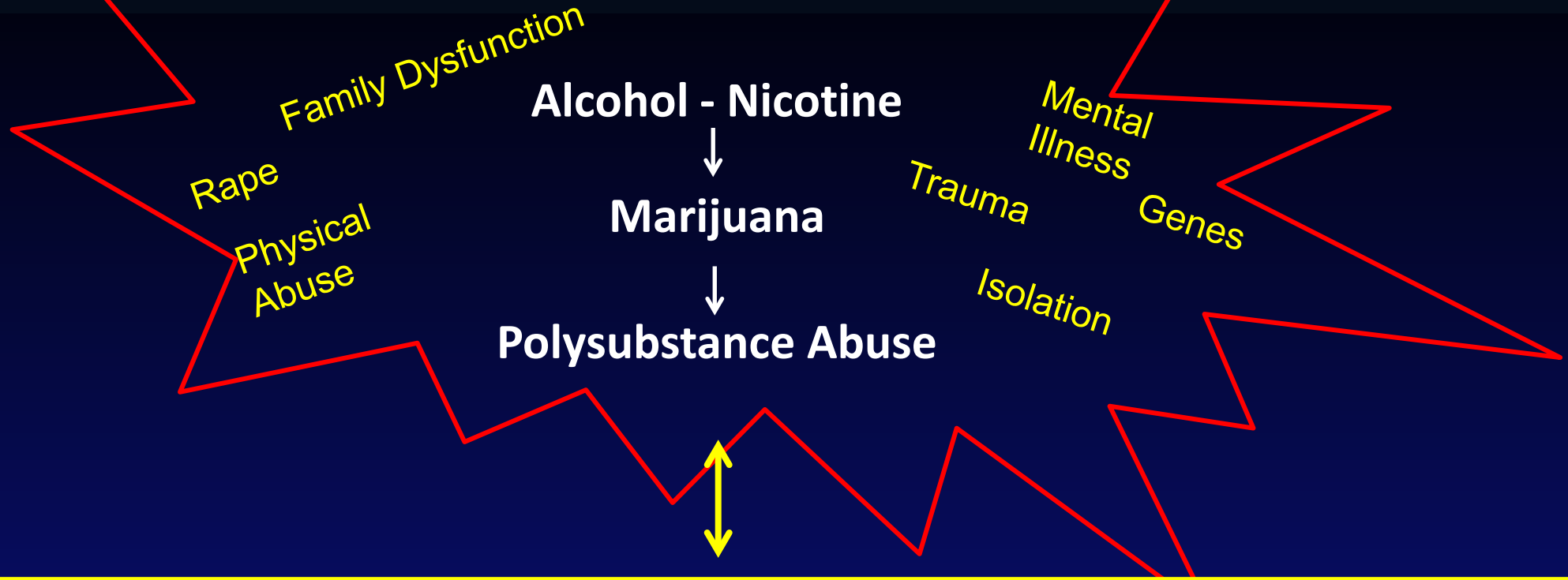
Is Total Substance Abuse Increasing?



~~Opioid Epidemic~~ Epidemic of Opioid *Deaths*



Anything that Reduces Opioid Drug Supply will Increase Use of Heroin



| Opioids | Benzodiazepines | Antipsychotics | AEDs |
|---|---|---|--|
| <ul style="list-style-type: none">• Heroin• Fentanyl• Rx analgesics• Loperamide | <ul style="list-style-type: none">• Alprazolam• Diazepam | <ul style="list-style-type: none">• Quetiapine• Olanzapine | <ul style="list-style-type: none">• Pregabalin• Gabapentin |
| | Stimulants | Hallucinogens | NPS/synthetics |
| | <ul style="list-style-type: none">• Cocaine• Amphetamine• Methylphenidate | <ul style="list-style-type: none">• Ketamine• LSD | <ul style="list-style-type: none">• Mephedrone• Cathinones• Synthetic cannabinoids |



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OPIOID CRISIS · Published 1 day ago

Former US drug czar says national focus on opioid epidemic is overlooking real culprit

Bill Bennett



Needed: Better Data on Prescription Drug Abuse

Needs: A Dataset for the Evaluation of **Rx** Drug Abuse

- To assess safety
 - **Product / API specificity**
 - Dosage form, formulation
 - Respondent behaviors, motivation
 - Longitudinal data
 - Large numbers?
- Characteristics
 - Accuracy
 - Fast
 - General population + special populations
 - Power for subpopulation assessment
 - Cost effective
 - Understanding of strengths and weaknesses

Survey of Non-Medical Use of Prescription Drugs Program (NMURx), United States



Study Design

- Online, Cross-sectional
- Self-administered, Anonymous
- Semi-annual - 60,000 responses
 - 30,000 twice annually
- Acknowledgement

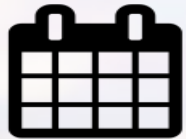
Lori Crane, PhD
University of Colorado

NMURx Key Design Features



- **Revised NMU definition**

- Simpler definition
- Better orientation (examples included)
- Similar to NSDUH



- **12 Month Focus**

- Enhanced recall
- Better estimates of current state



- **Ease of use**

- Fewer questions per screen
- Simplified language
- Easy navigation
- Clear instructions



- **Device Compatibility**

- Better representation
- Sustainable sample pool
- Redesign: 30% smartphone
7% tablet
64% desktop



- **Randomization**

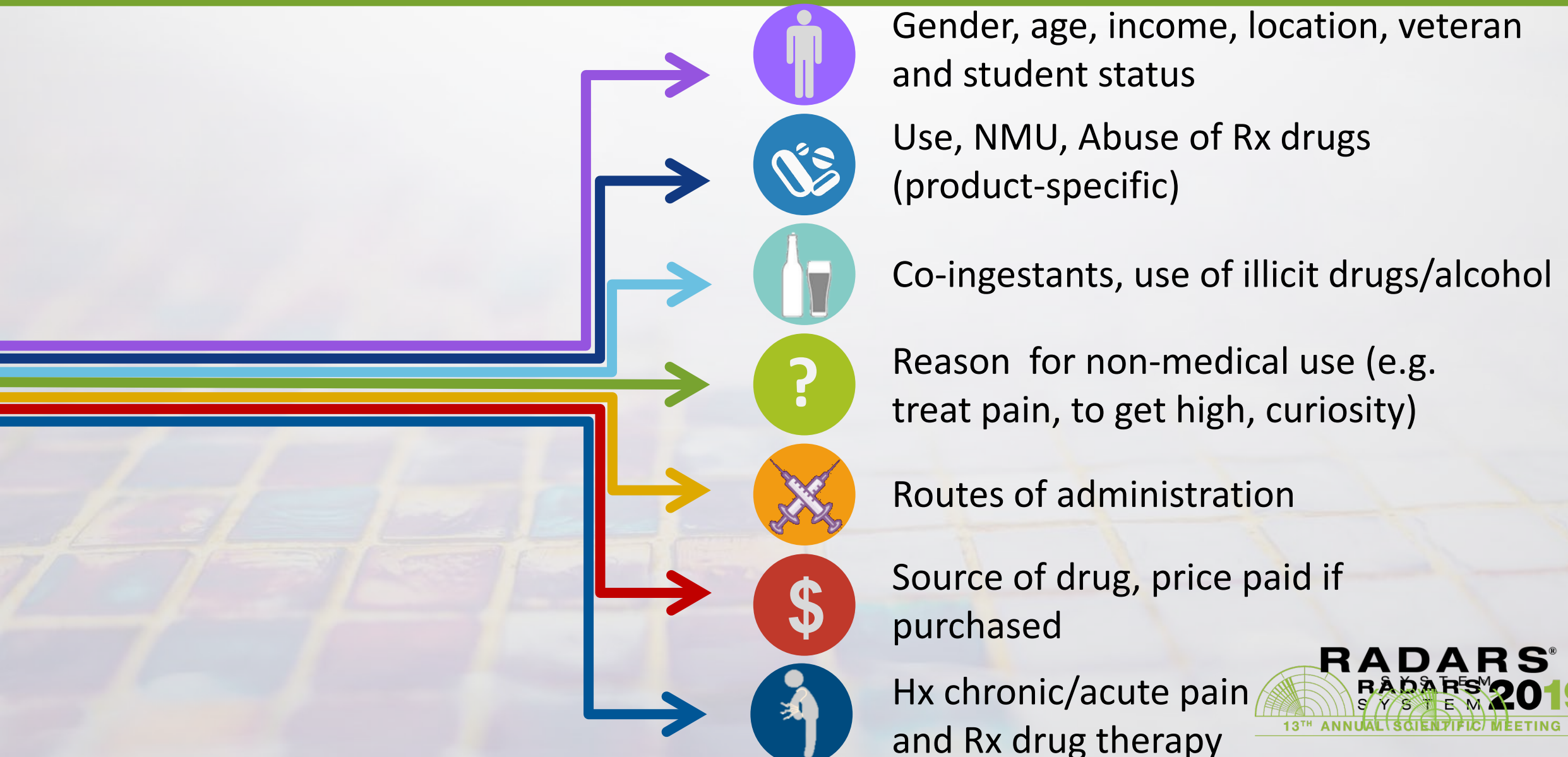
- Drug classes, API
- Reason, route, source
- Illicit drugs



- **Advanced flow / skip logic**

- Fewer questions; 10.5 minutes
- Avoid adapting to question flow

NMURx Key Measures

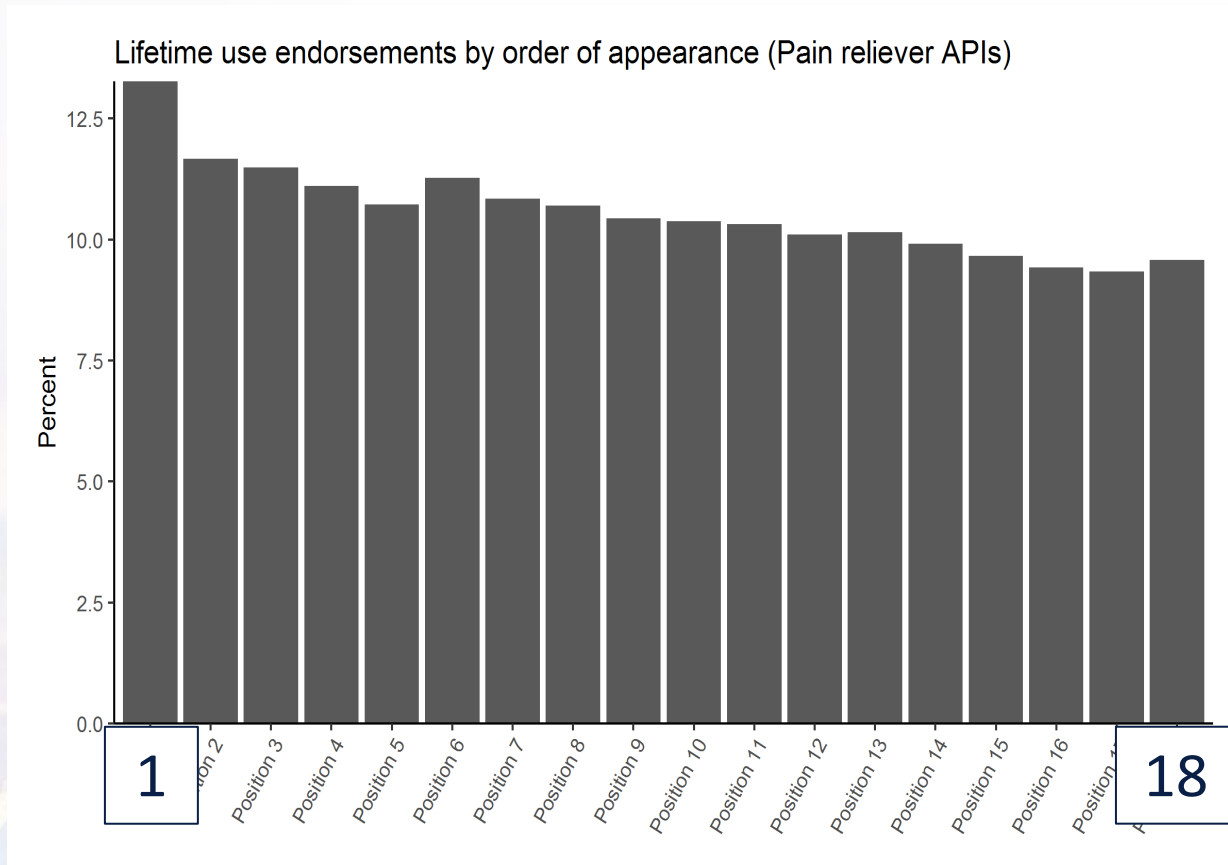


NMURx Program Coverage

- North America
 - US
 - Canada
- Europe
 - UK
 - France, Italy
 - Germany, Spain
- Singapore



Order Effect is a Large Source of Inaccuracy in Web-based Surveys

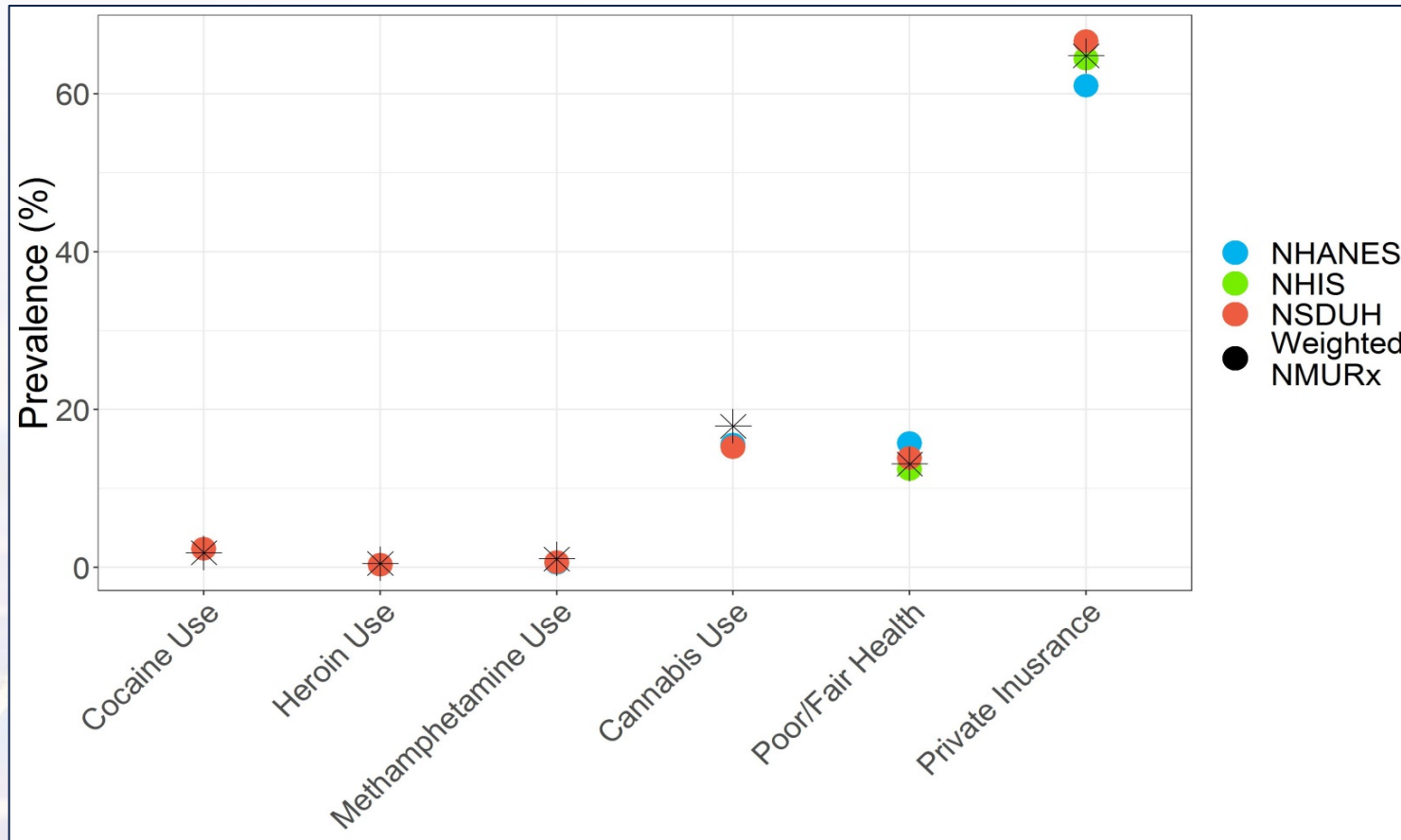


Without randomization, the survey would underestimate as position decreased

- 7.7% of respondents endorsed lifetime use of any product in position 1.
- For position 42, it was 4.3%
- Opioids: effects are about the same.
 - Fentanyl, 8.0% of respondents in 1st position; 4.6% in last position
 - Oxycodone, 39.7% in first position; 29.5% in last position

NMURx Estimates vs National Probability Surveys

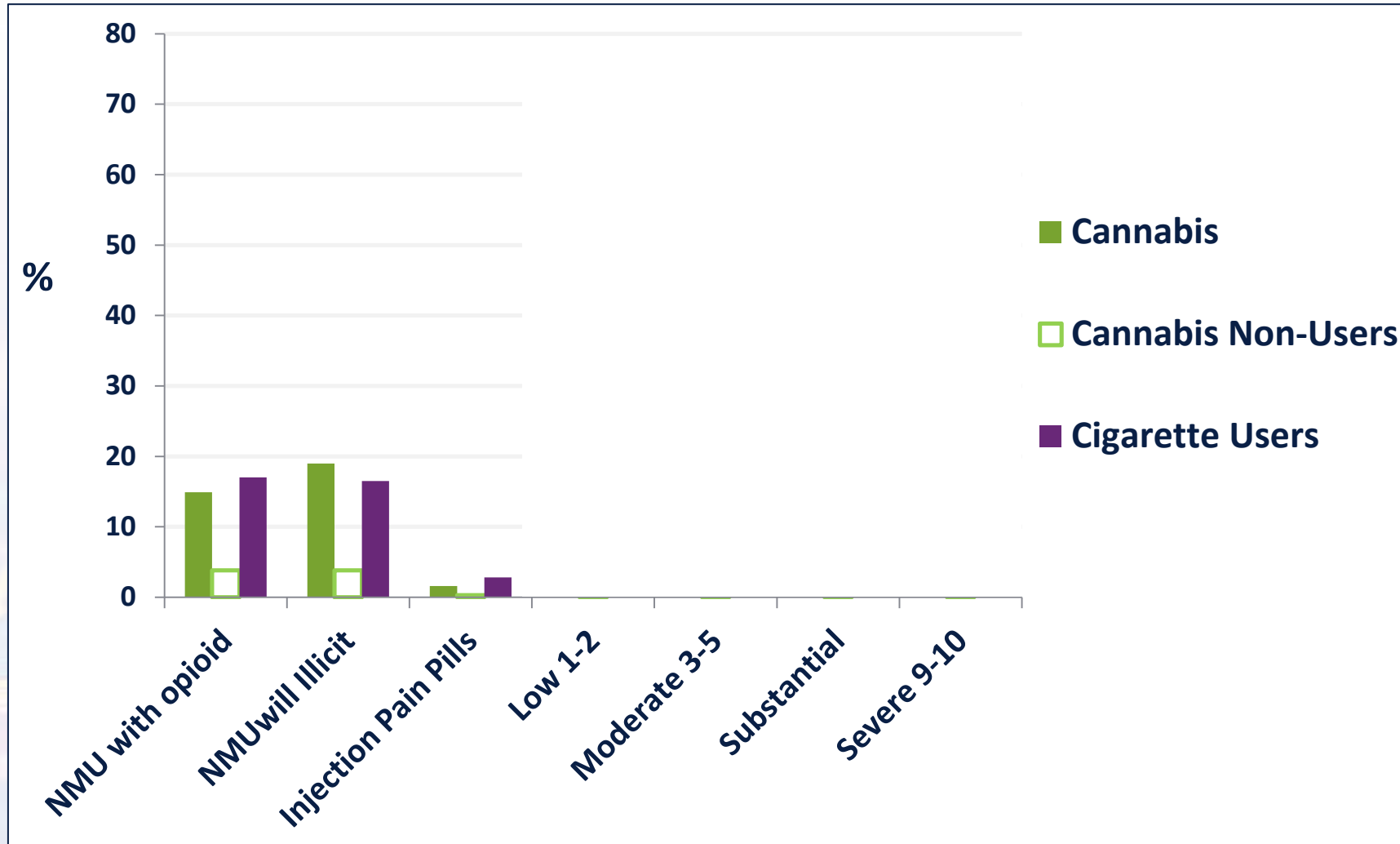
Calibration Weighting for Representative Estimates



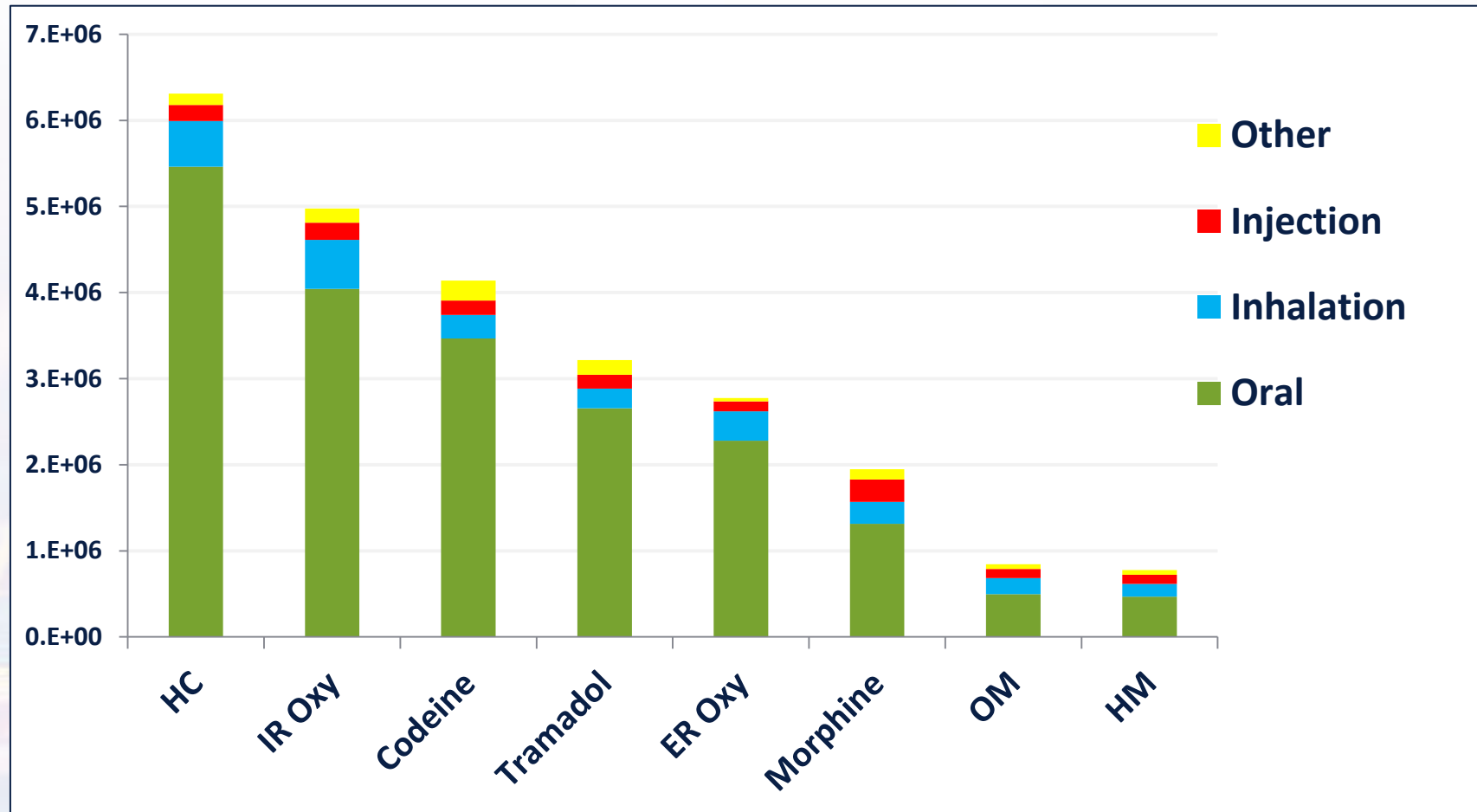
NHIS - National Health Interview Survey
NHANES - National Health and Nutrition Examination Survey
NSDUH - National Survey of Drug Use and Health

Cannabis Users Non-Medical Use and DAST-10

NMURx, United States, 3Q 2018



Route of Opioid Analgesic Abuse, NMURx, Q3 2018



Drug Use in Pregnancy

NMURx, Q3 2018

- 228,291 (9.4% of pregnant women ages 18-49 years) used an illicit drug or non-medically used a prescription drug in the past month
 - Men 18.6%
 - Non-pregnant women ages are 16.5%.
 - Largely driven by illicit drug use (8.9%) specifically cannabis with past month use prevalence of 7.5%
- **Prescription** drug classes examined
 - 2.1% prevalence for stimulant NMU
 - 1.6% pain relievers
 - 1.5% sedatives

Summary

- Prescription drug abuse continues to decrease even as opioid deaths increase
- Methadone decreasing and buprenorphine increasing
- Abuse of prescription stimulants and other non-opioid drugs are increasing
- Anything that restricts the opioid drug supply will increase heroin abuse
- Illicit fentanyl is our biggest challenge

2019 Program

Transforming Post-Marketing Surveillance of Prescription Drugs

Richard C. Dart, MD, PhD

*Executive Director, RADARS® System, Denver Health and Hospital Authority
President, Canadian Consumer Product and Pharmaceutical Safety Inc.*

Project Lazarus: Local Solutions to National Opioid Crisis; What They Need to Know

Fred Wells Brason II, Chaplain

*President and CEO, Project Lazarus
Speaker, U.S. Department of State U.S. Speaker Program,
The Bureau of International Information Programs*

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The Epidemiology of Prescription Opioid Abuse: A Regulatory Perspective

Gerald J. Dal Pan, MD, MHS

Director, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, US Food and Drug Administration

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The Dead Speak: How Can Mortality Data Improve Drug Safety?

The Evolution of Mortality Data in the United States

Richard C. Dart, MD, PhD

*Executive Director, RADARS® System, Denver Health and Hospital Authority
President, Canadian Consumer Product and Pharmaceutical Safety Inc.*

Mortality Involving Prescription Drugs

Joshua C. Black, PhD

*Associate Research Scientist, Rocky Mountain Poison & Drug Center, Denver
Health and Hospital Authority*

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Lessons from Opana® ER: Policy, Behavior, and Reality

Janetta L. Iwanicki, MD

Scientific Director of Research and Surveillance, Rocky Mountain Poison & Drug Center, Denver Health and Hospital Authority

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The Route to Utilization of Trend-in-Trend

Introduction: Remember Quinoa?

John Schwarz, PhD

Director of Biostatistics, Rocky Mountain Poison & Drug Center, Denver Health and Hospital Authority

Comment: Using Trend-in-Trend to Evaluate Drug Abuse

Rose Radin, PhD, MPH

Epidemiologist, Division of Epidemiology, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, United States Food and Drug Administration

Next Steps: Evaluating Routes and Comparators

John Schwarz, PhD

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Drug Diversion in Healthcare Facilities: Our Nation's Little Secret

John J. Burke

President, Pharmaceutical Diversion Education Inc.

President and Co-Founder, International Health Facility Diversion Association

Panel Discussion and Summary

Richard C. Dart, MD, PhD (Moderator)

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

President, Canadian Consumer Product and Pharmaceutical Safety Inc.

End