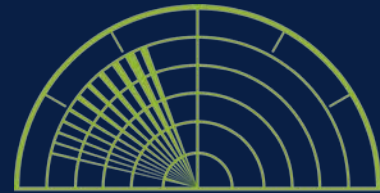


RADARS[®] **2023**
SYSTEM

17TH ANNUAL SCIENTIFIC VIRTUAL MEETING

WELCOME



RADARS[®] **2023**
S Y S T E M

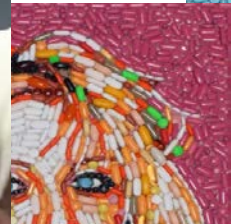
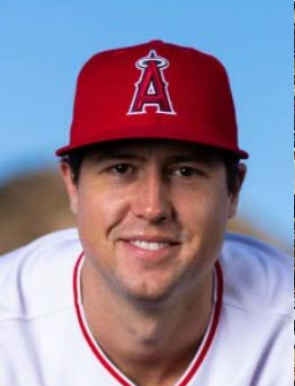
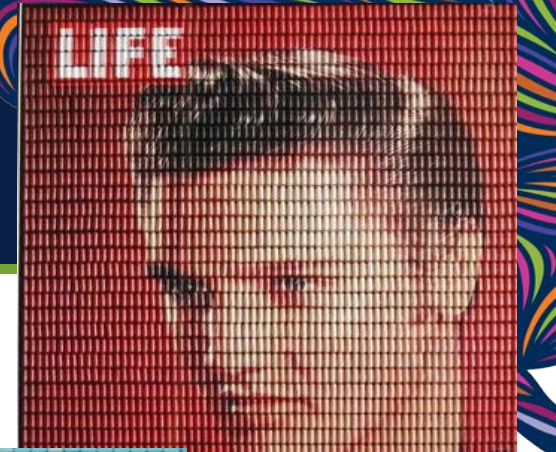
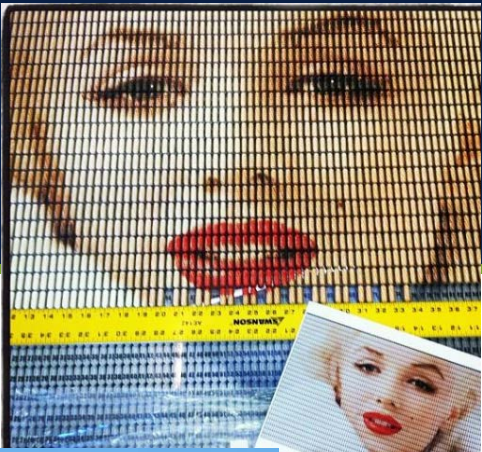
17TH ANNUAL SCIENTIFIC VIRTUAL MEETING

Surveillance of Psychoactive Drugs
Opioids, Psychedelics, and Cannabinoids

Wednesday, May 10, 2023

Surveillance of Psychoactive Drugs

- 2022 Annual RADARS® System review
 - Data
 - Methods and Changes
- New Challenges for PM surveillance of Prescription Drugs
 - Counterfeit or Falsified medications
 - Emergence of the psychedelic medications

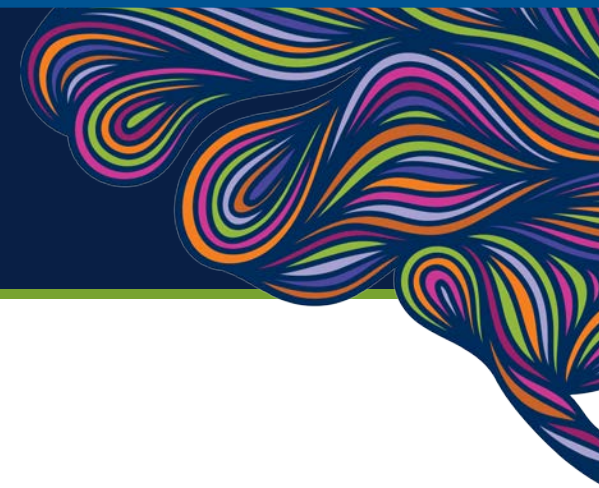


17th ANNUAL SCIENTIFIC VIRTUAL MEETING



RADARS[®] System Update 2006 through 2022

RADARS[®] System 16th Annual Scientific Meeting

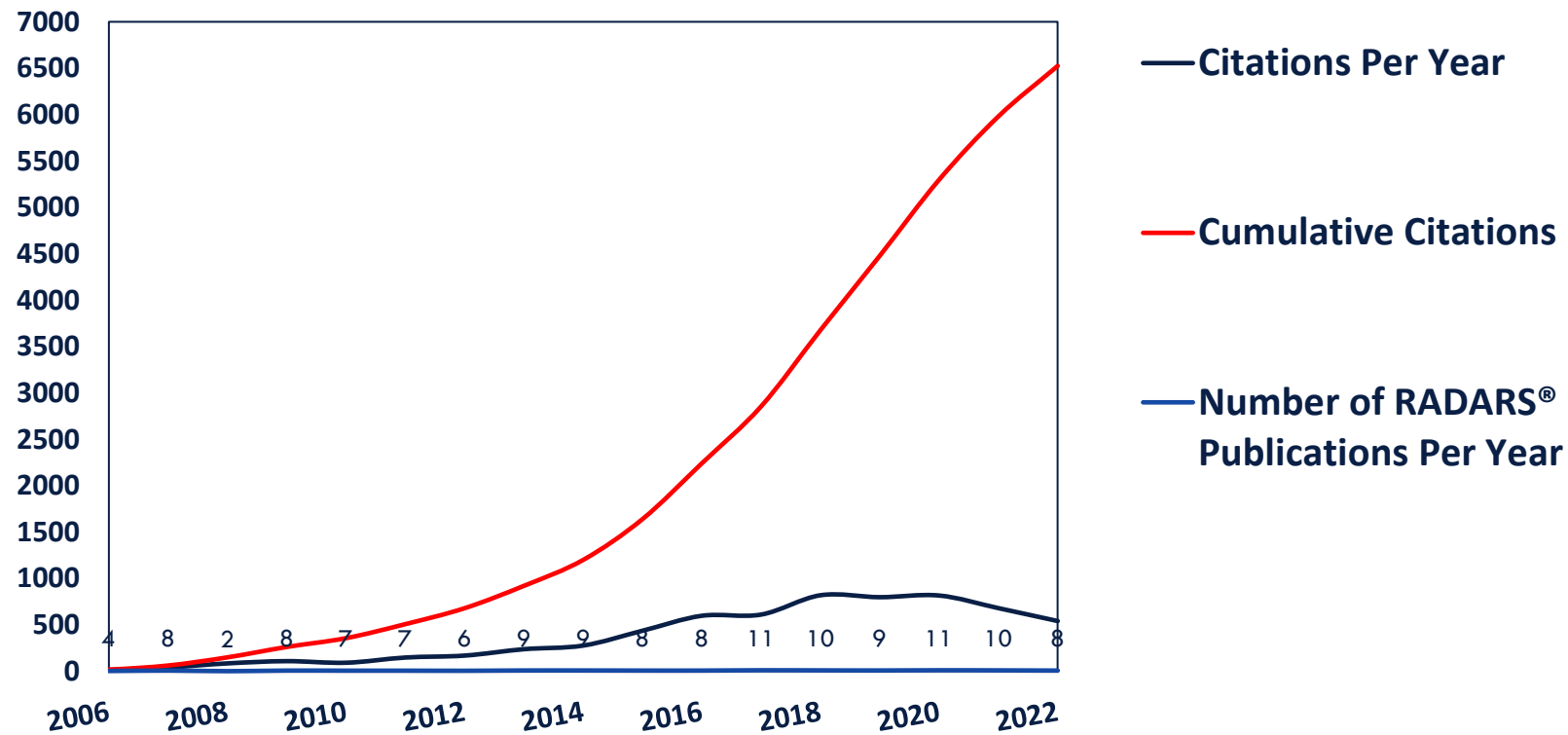


Registrants n=228

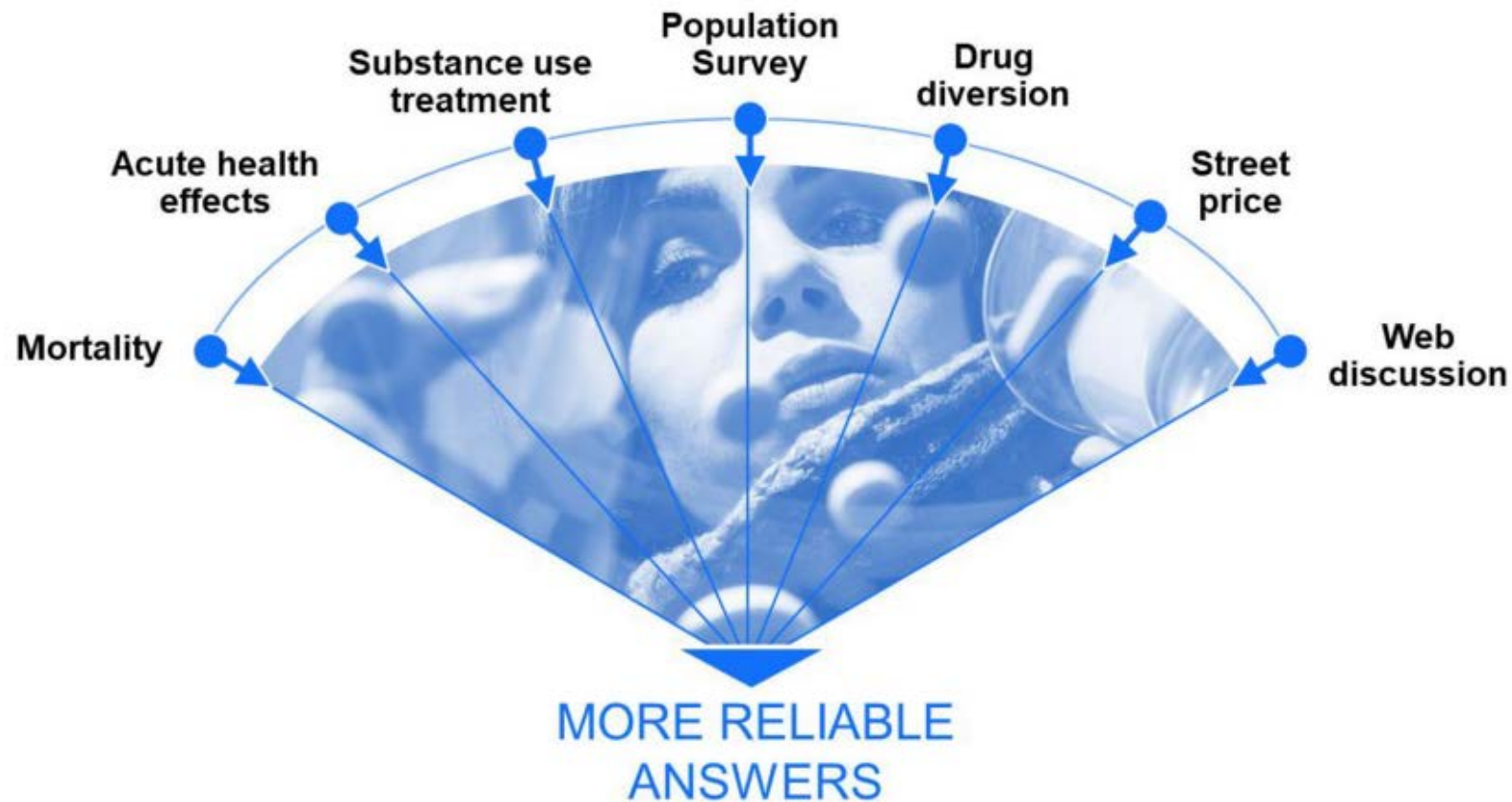
Government	51
Academic	128
Industry/Pharma	31
Other	18

**Thanks everyone for you interest (and your questions/comments)
as we go through the meeting!**

RADARS[®] System Publications - 2022



RADARS[®] System: Real World Evidence and Triangulation

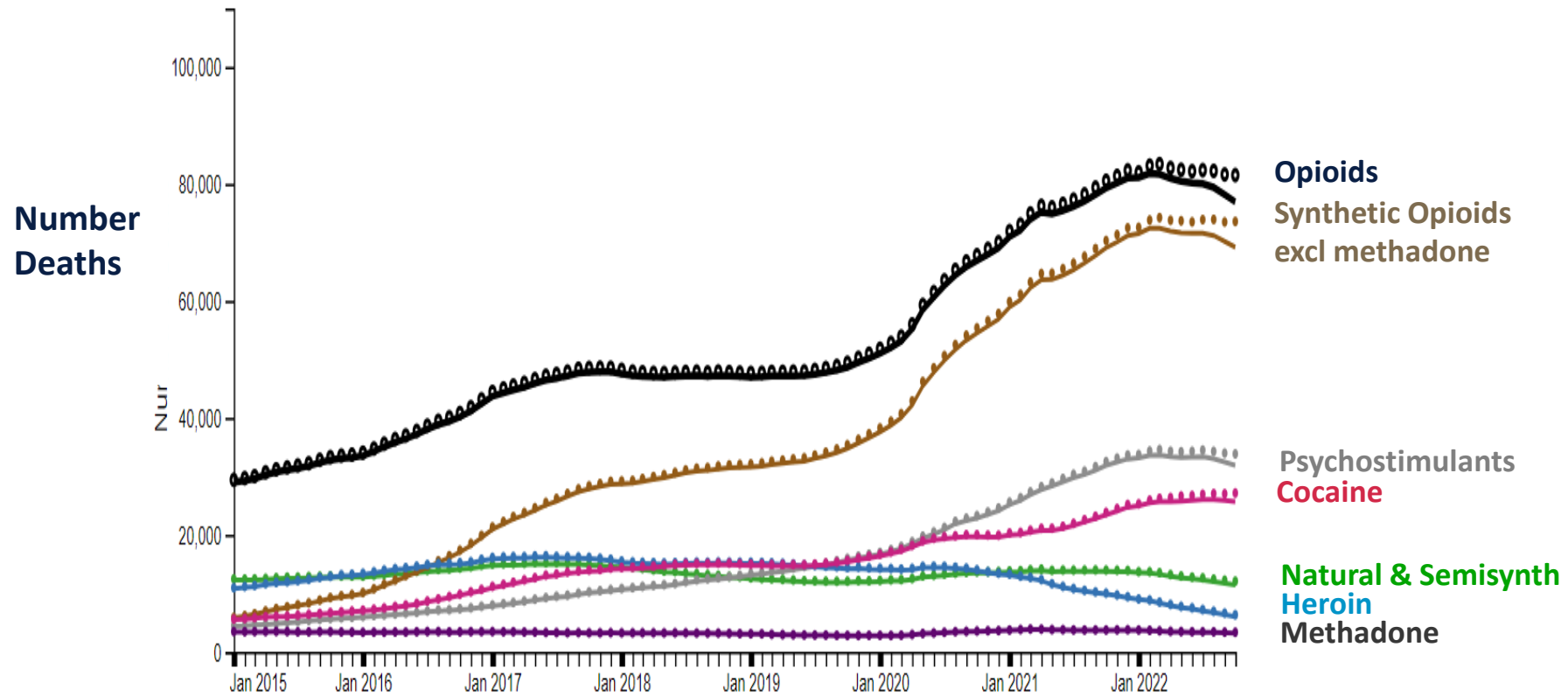
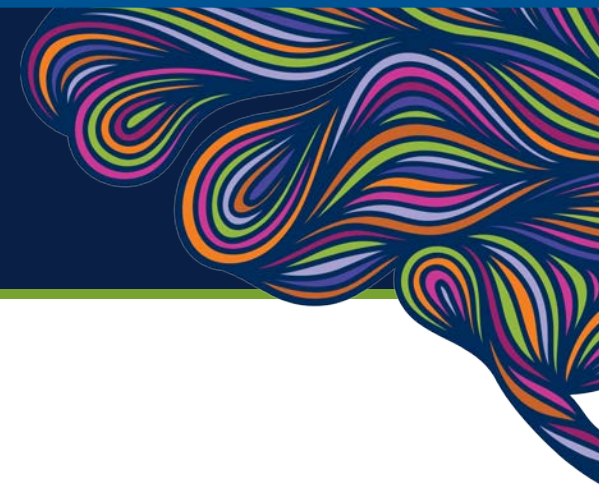


Highlights - RADARS System Improvement 2020-2022



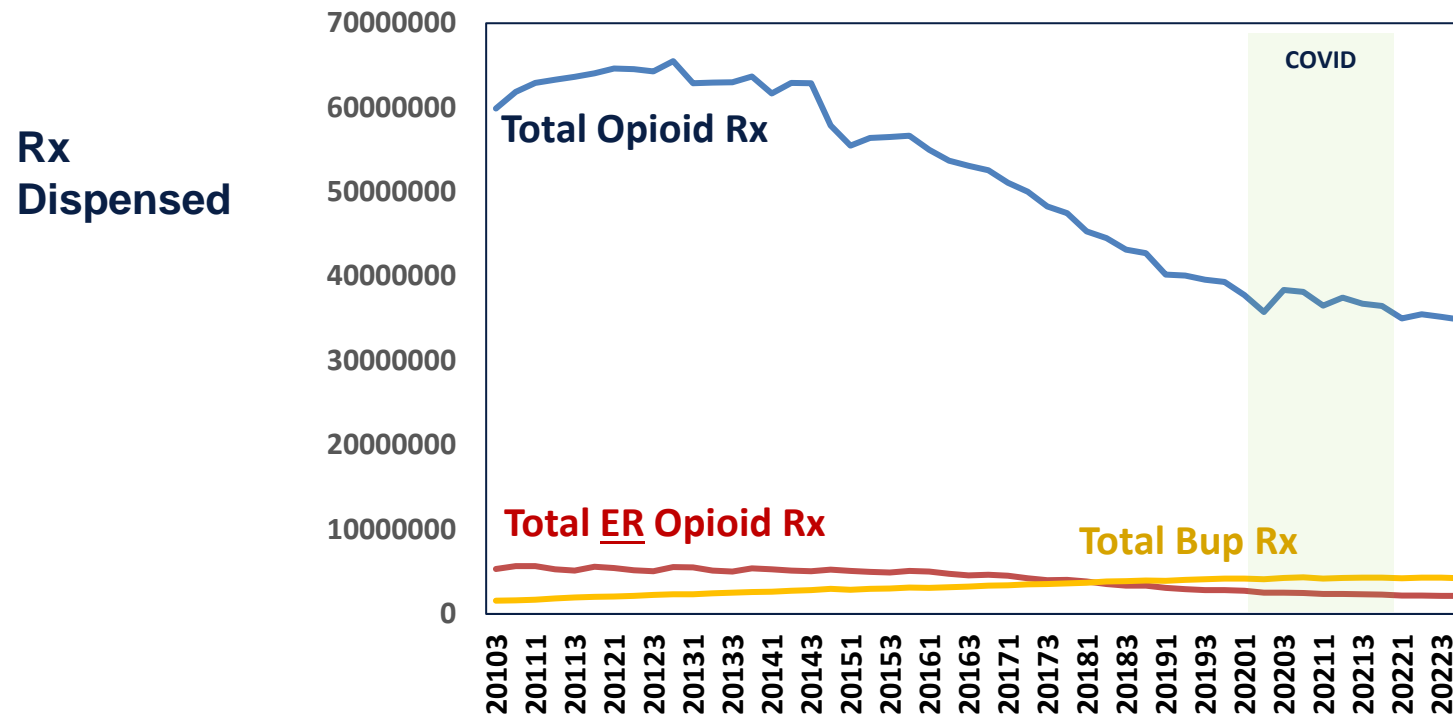
Update	Description	Year
PC Program	Improved quality review with industry best practices	2022
Treatment Centers	Created, validated and applied careless response process to exclude obvious fraudulent responses	2018
NMURx	Refined drug list to focus responses and control length of questionnaire	Every year
	Created methods to <i>follow-up</i> with hard-to-reach populations	2020
Drug Diversion	Improved DBQA process, streamlined process for reporting	2022
StreetRx	Reorganized and categorized datasets to improve accuracy of analysis	2021
Web Monitoring	Implemented machine learning to identify invalid posts	2022
	Implemented Dark Web tracking	2021
	Created methodology for tampering “recipe-tracker”	2020

Drug-related Overdose Deaths in US, 2015-2022



Products - Vital Statistics Rapid Release - Provisional Drug Overdose Data (cdc.gov)

Trends in Opioid Prescribing Rates, 2010 - 2022

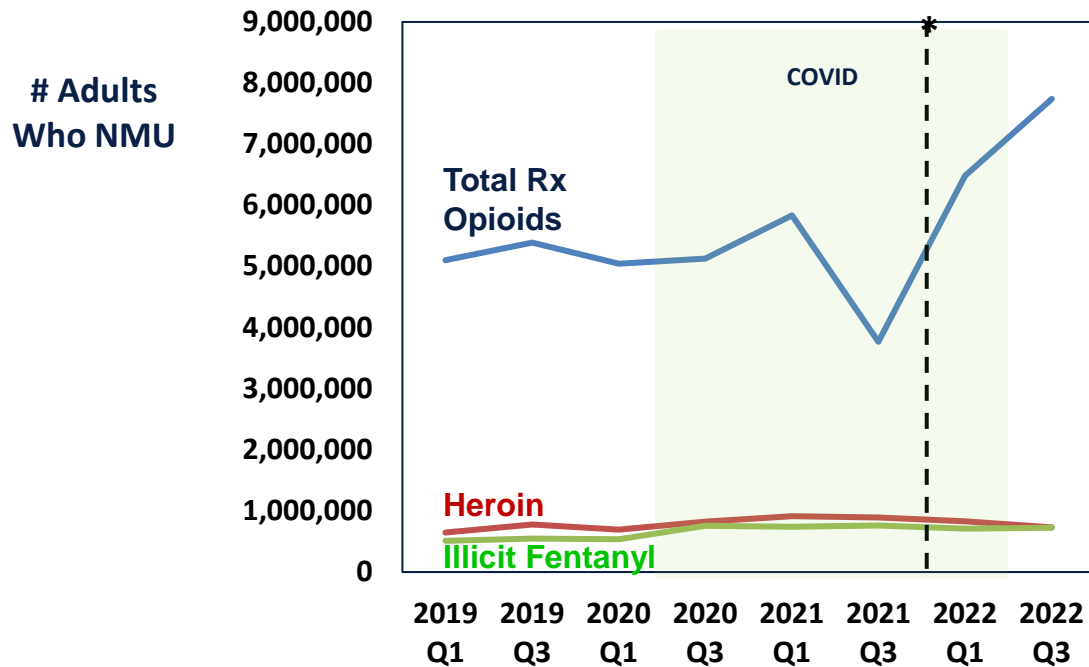


Source: IQVIA™ US-Based Longitudinal Prescription Data

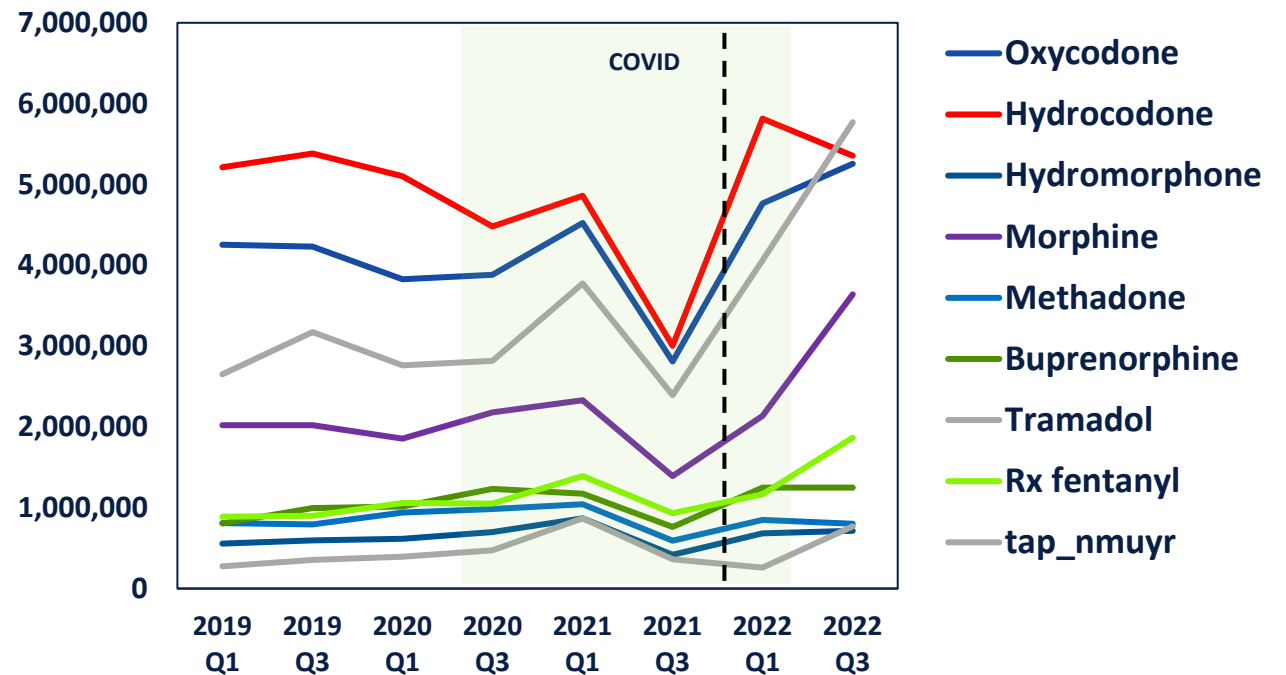
NMURx, Non-Medical Use of Opioids, 2019 - 2022



Major Opioids Combined



Individual API Opioids

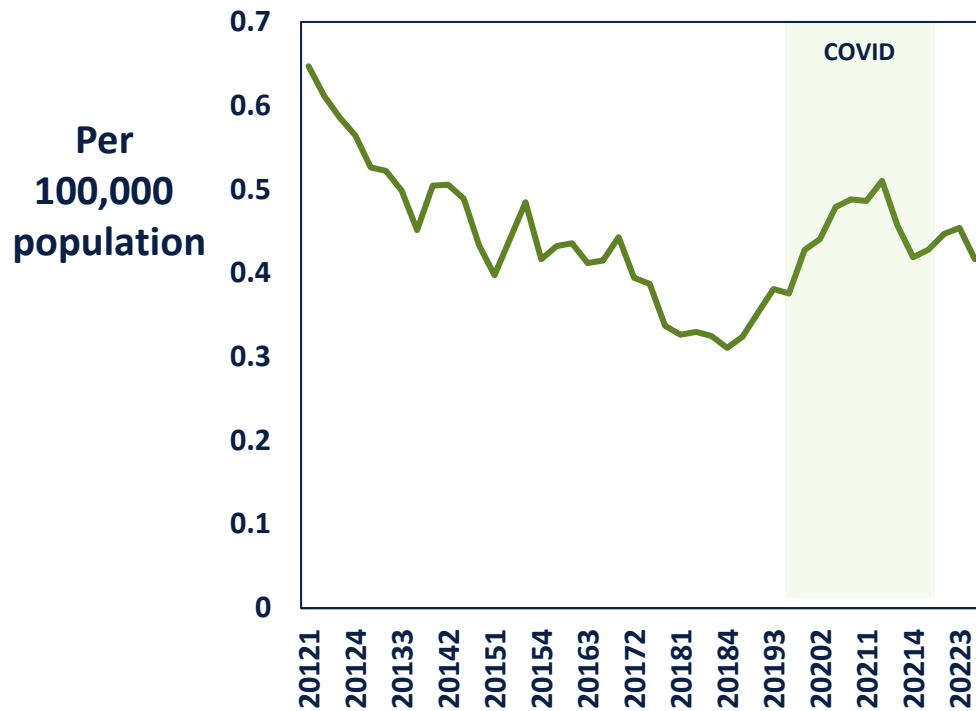


*Drug NMU questions were redesigned for 2022 Q1 and Q3 surveys for better assessment of unknown formulations

Poison Center Program, Intentional Abuse 2012 - 2021

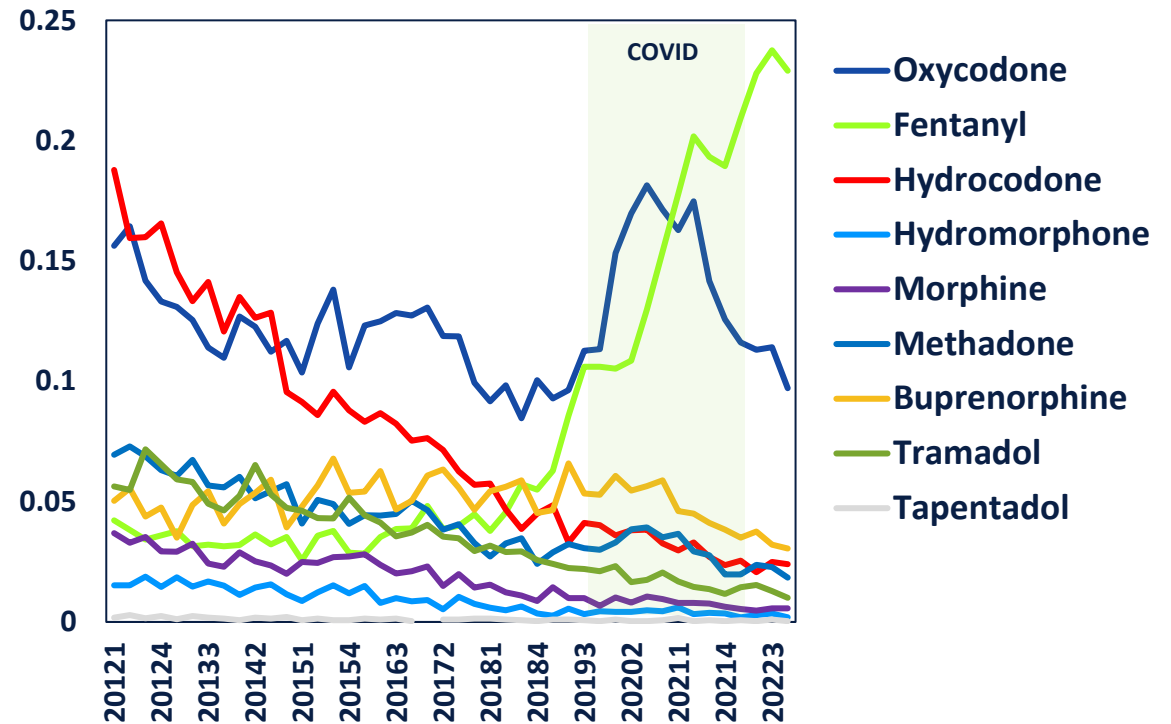


Major Opioids Combined

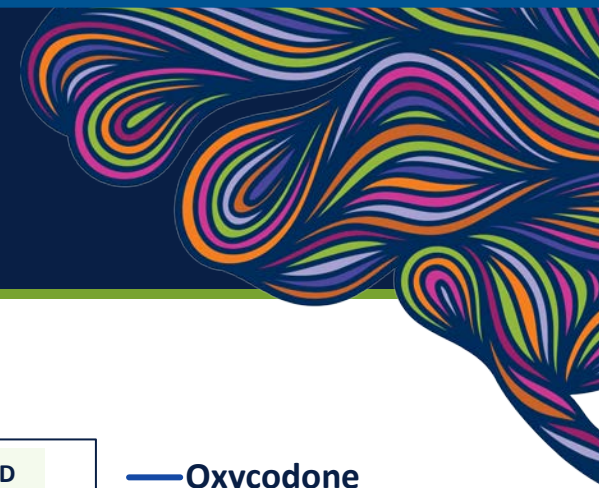


Includes oxycodone, hydrocodone, hydromorphone, morphine, tramadol

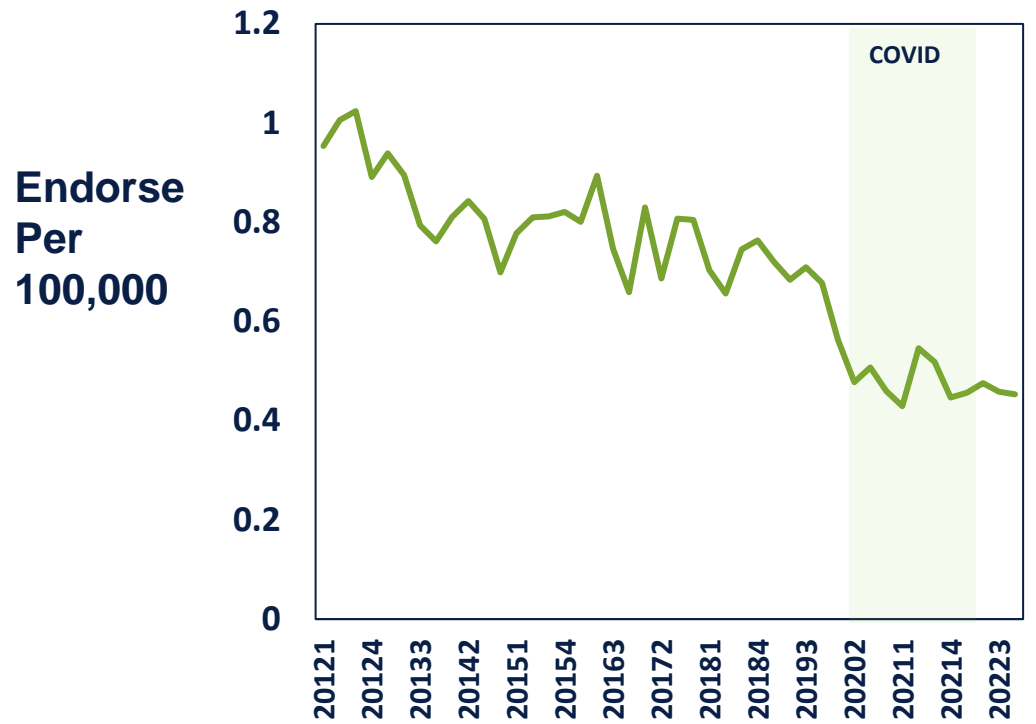
Individual API Opioids



Treatment Center Programs Combined 2012 - 2022

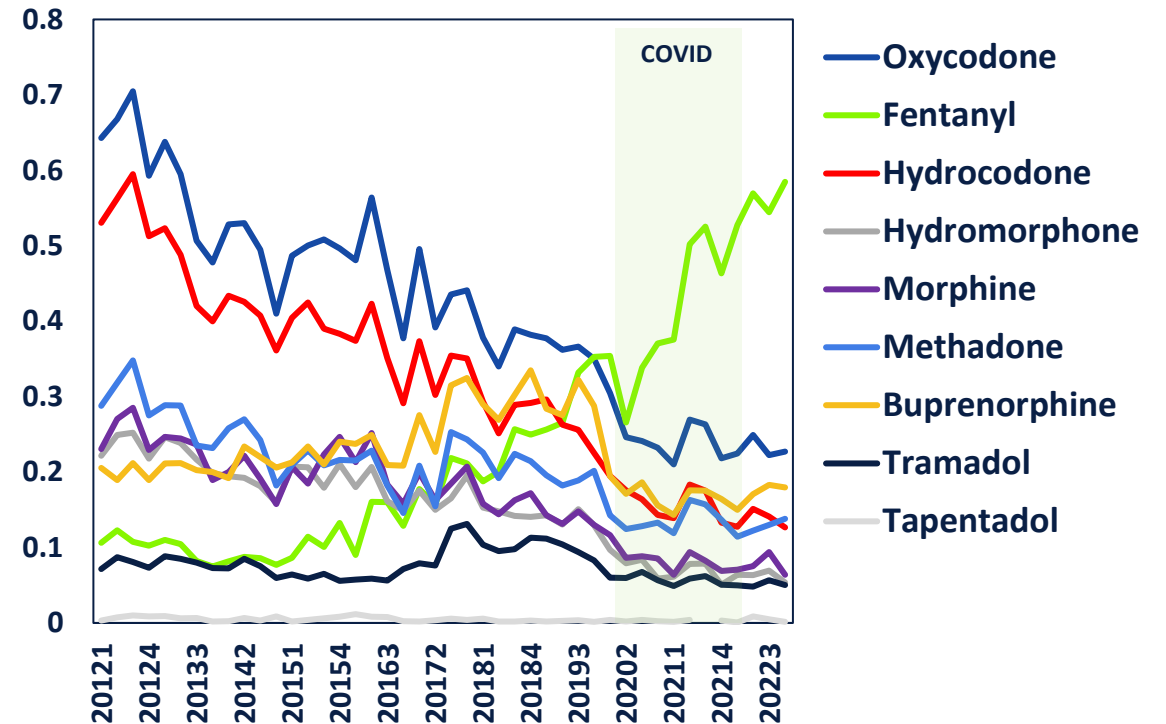


Major Opioids Combined



Oxycodone, hydrocodone,
hydromorphone, morphine, tramadol

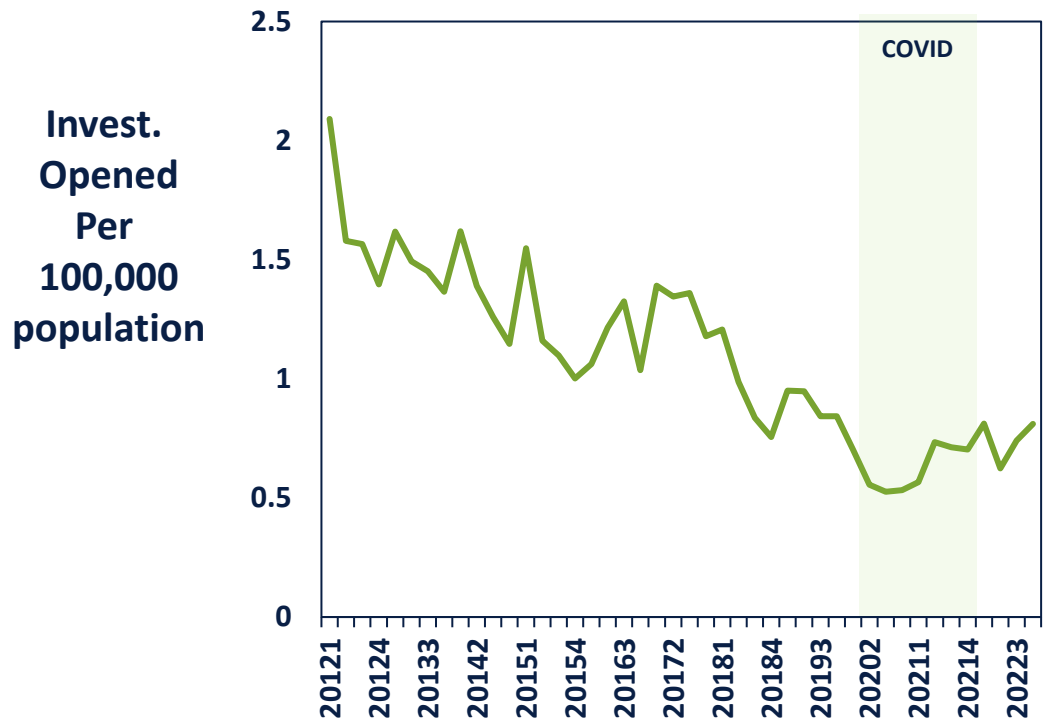
Individual API Opioids



Drug Diversion Program 2012 - 2022

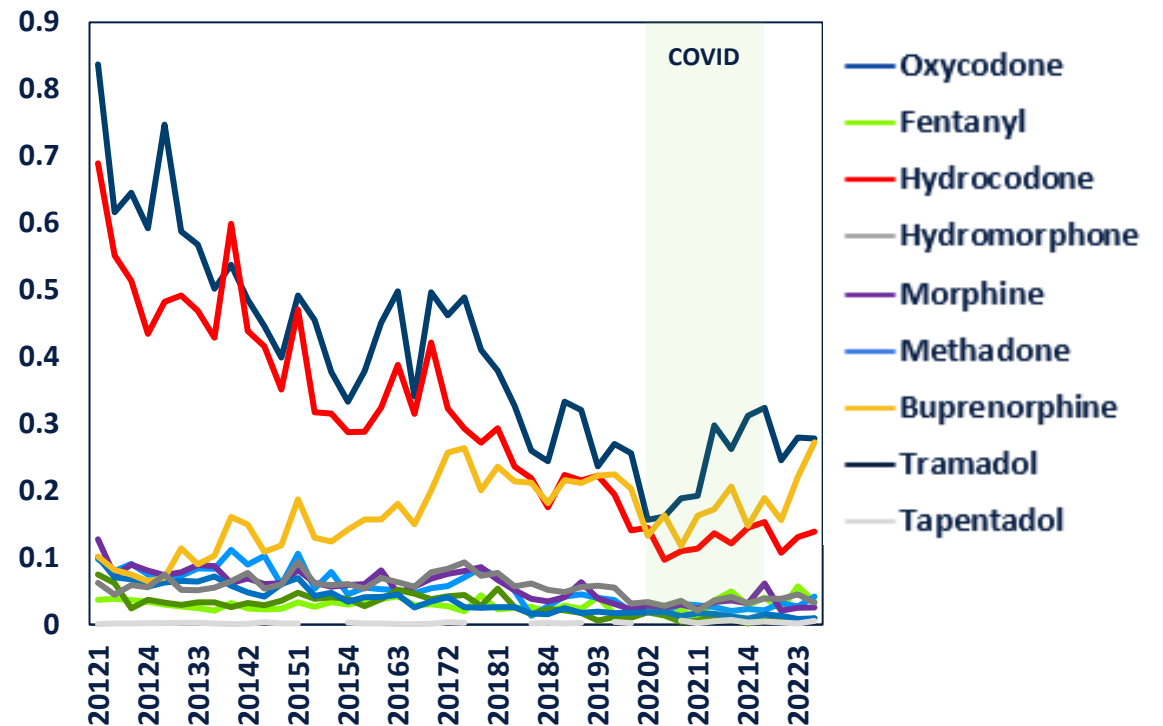


Major Opioids Combined

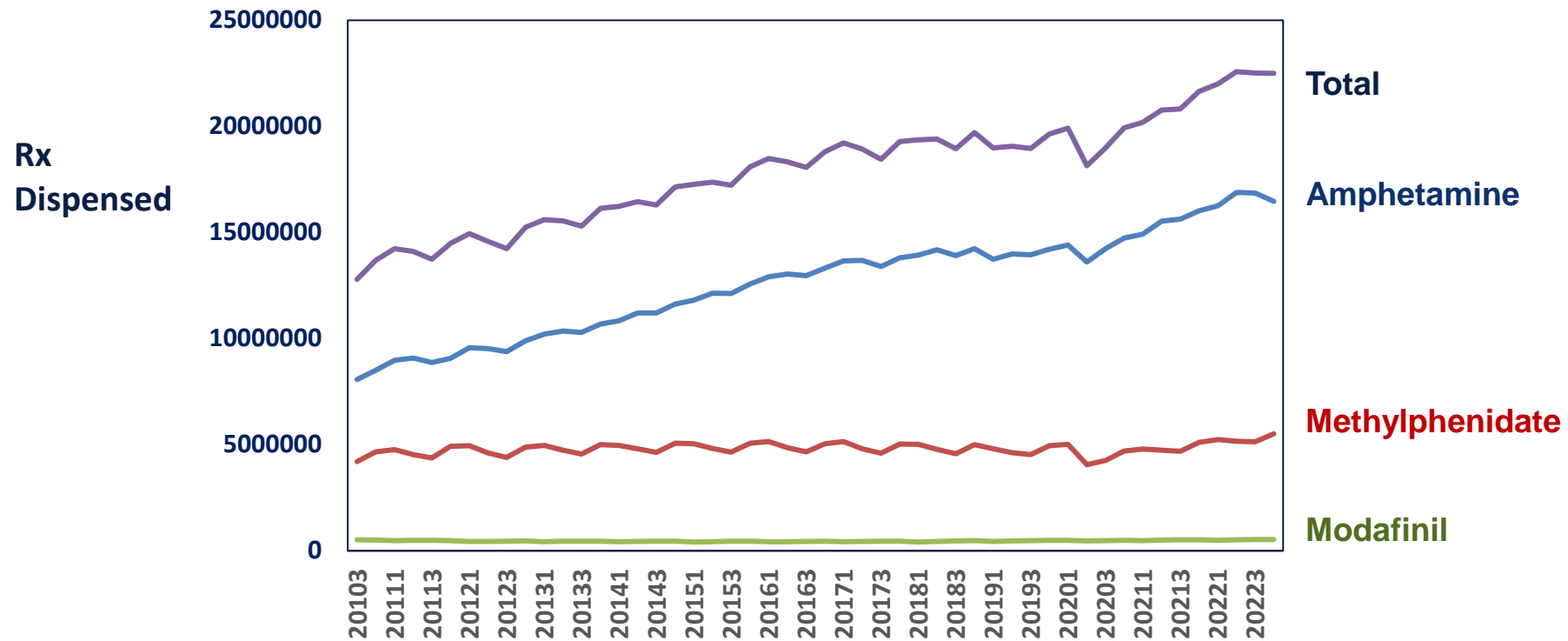
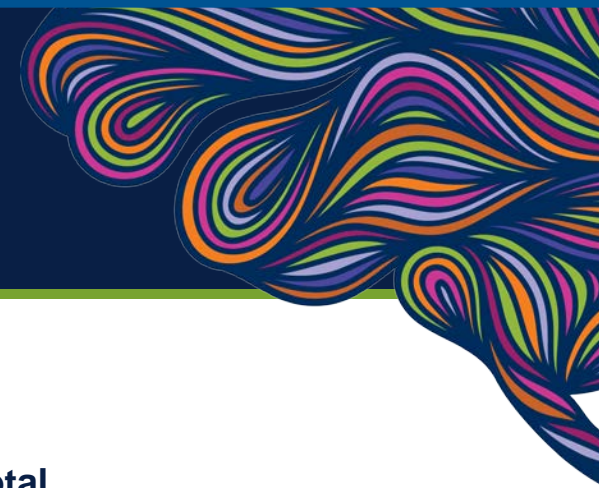


oxycodone, hydrocodone, hydromorphone, fentanyl, morphine, tramadol

Individual API Opioids

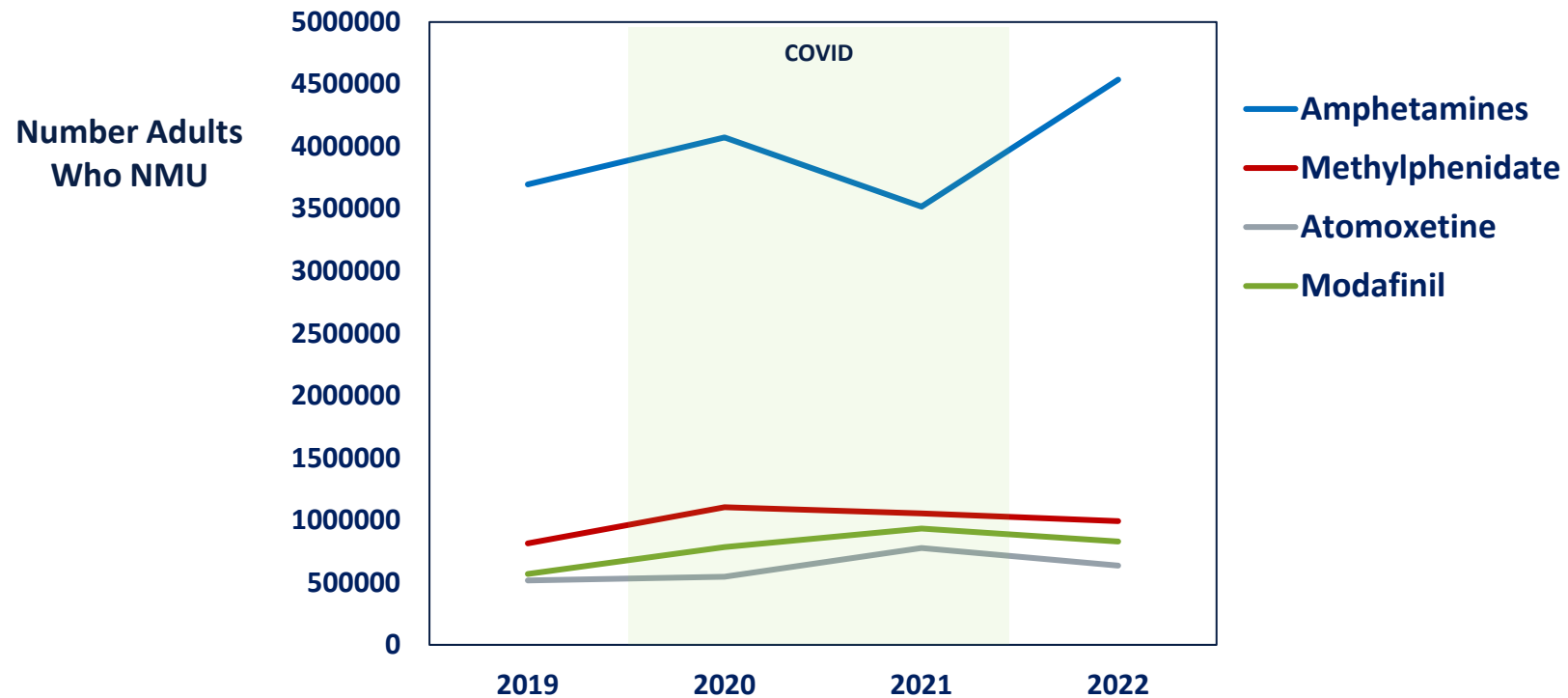
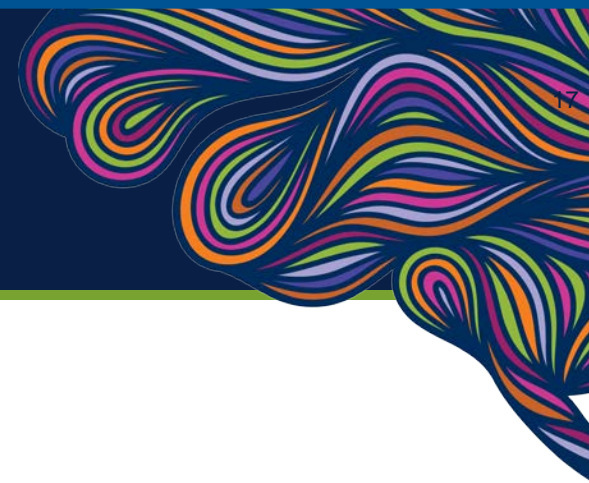


Prescribing of Stimulants 2010 - 2022

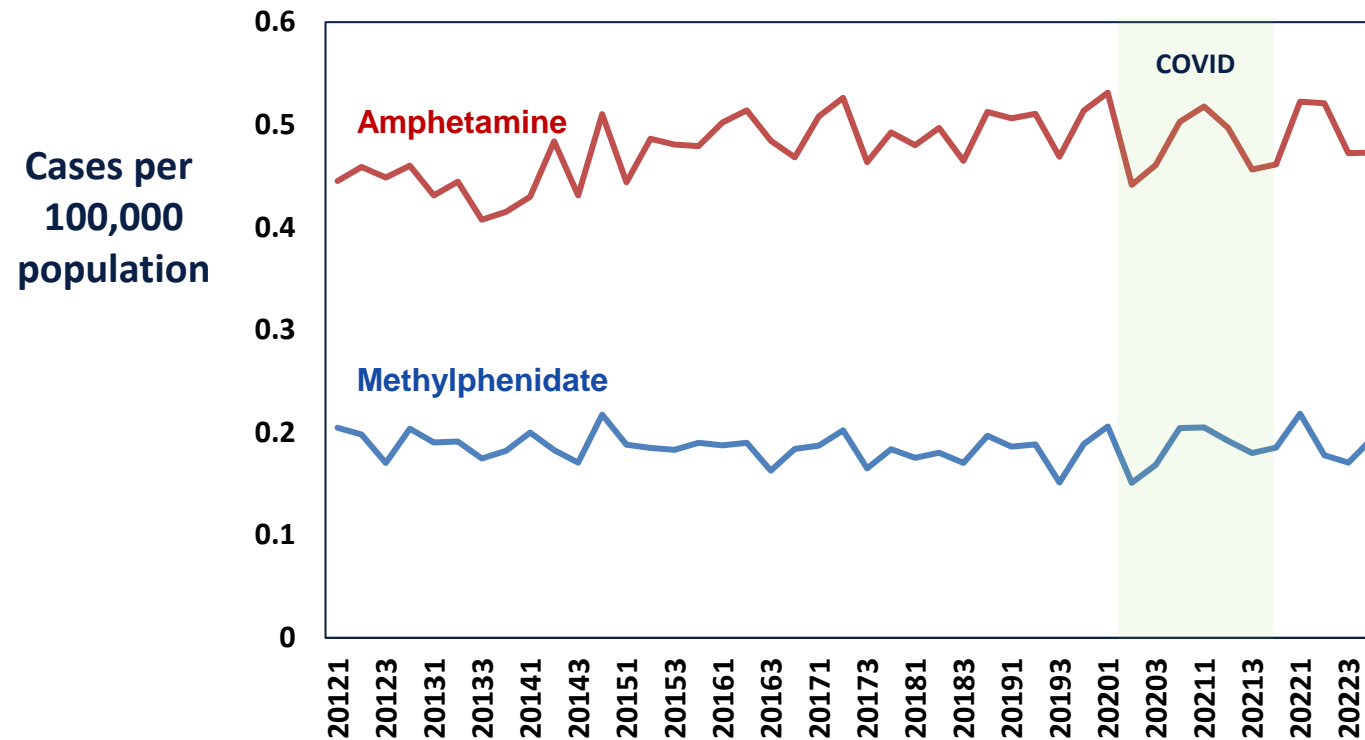
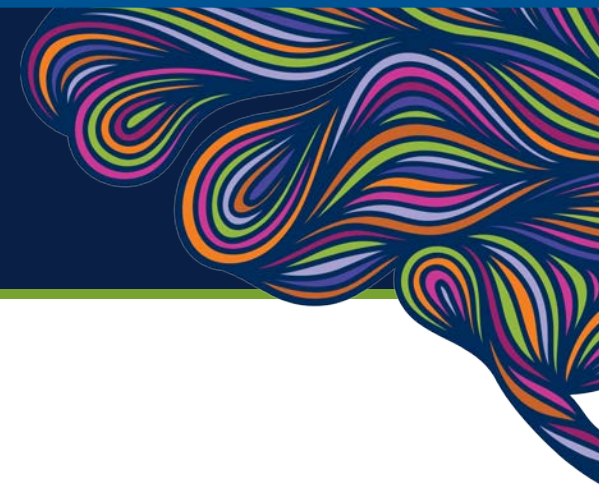


Source: IQVIA™ US-Based Longitudinal Prescription Data

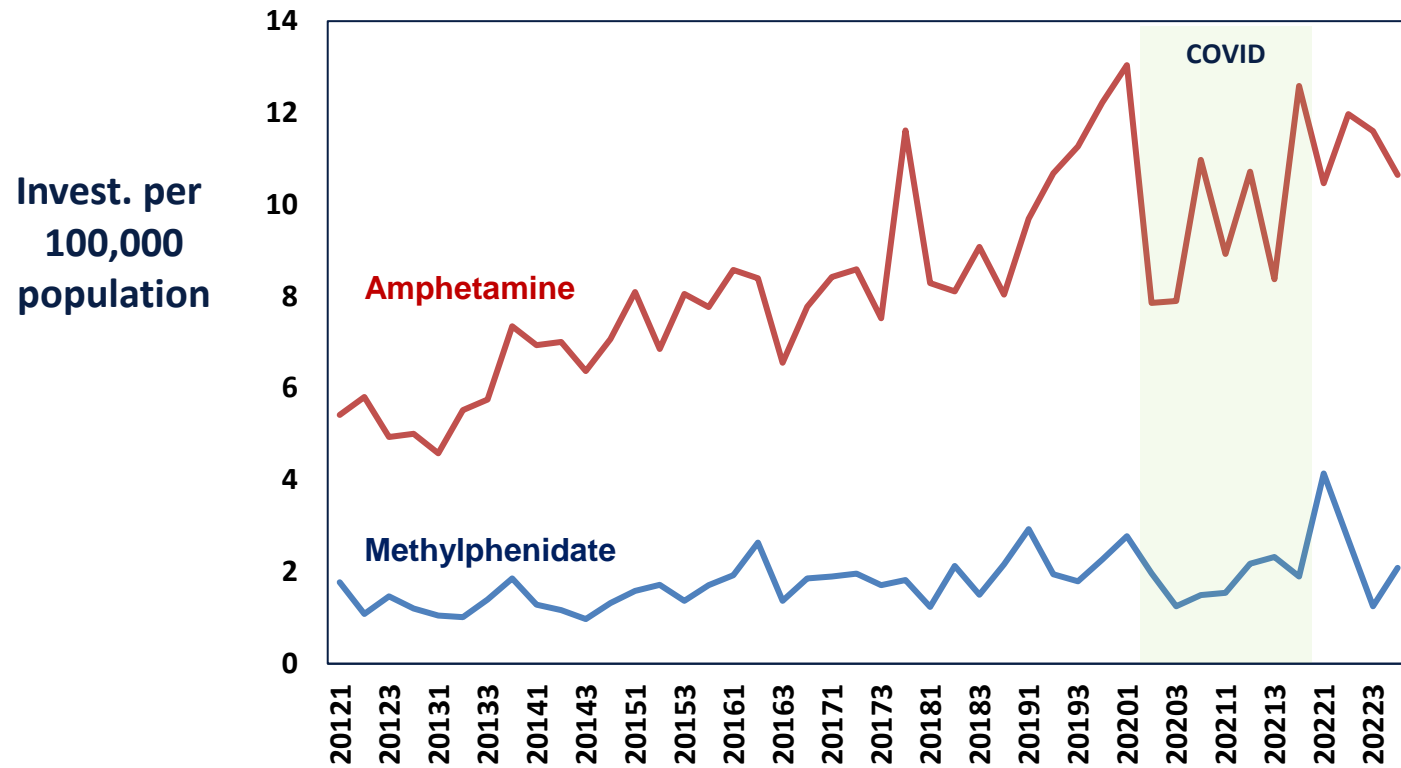
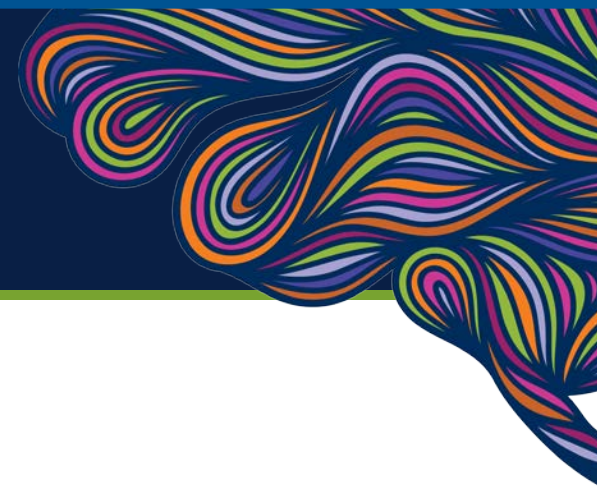
NMURx, Non-Medical Use of Rx Stimulants 2019 - 2022



Poison Center Program, Rx Stimulants 2012 - 2021



Drug Diversion Program, Rx Stimulants 2012 - 2022



Summary of Trends through 2022

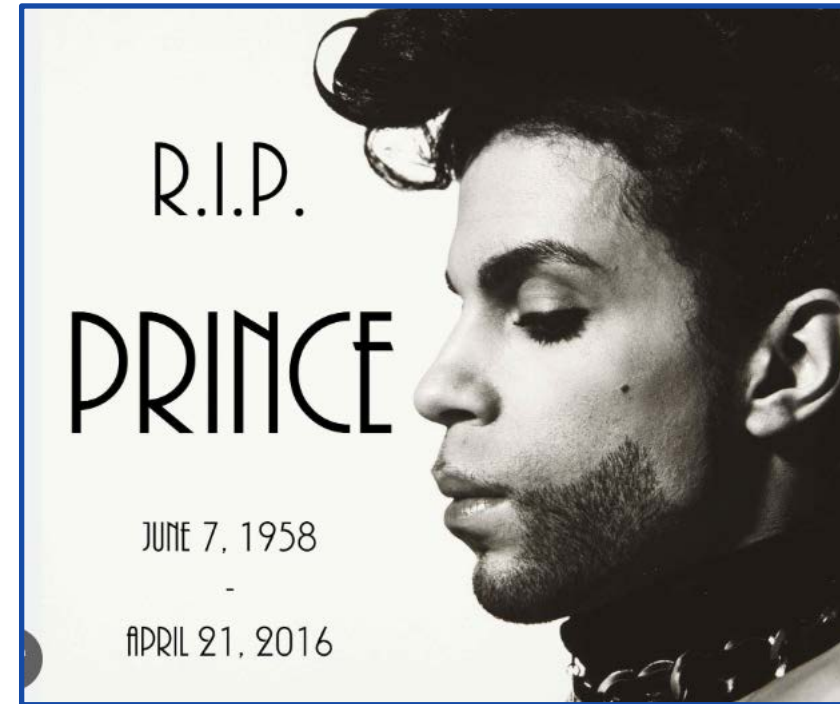
- Prescribing, use and misuse of prescription opioids
 - Improved, but still a substantial source of drug that is misused/abused.
- Prescribing, use and misuse of prescription stimulants are similar although amphetamine is still gradually rising.
- Illicit opioids and stimulants remain dominant in terms of abuse and mortality.
- If we take our eye off the ball, Rx medications will worsen.



Challenges Ahead

Challenges Ahead

- Counterfeit/Falsified Drugs
- Psychedelic medications

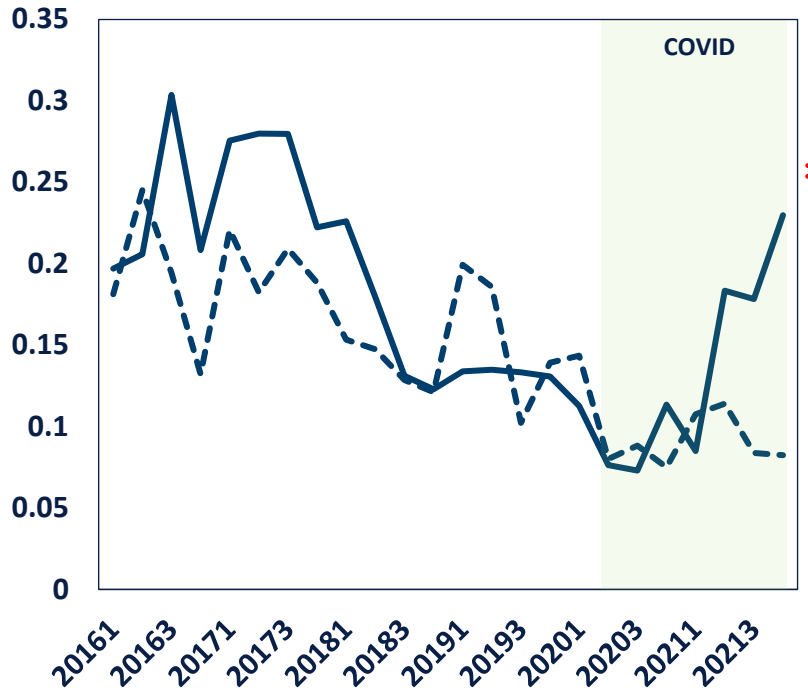


Falsified Drugs in RADARS Drug Diversion Program



RADARS System Drug Diversion Program

Invest.
Opened
Per
100,000
population



- Other oxycodone
- Other known IR oxycodone



Use of Falsified Drugs in the US Among People Who Endorse Drug Diversion



Characteristic	Falsified Products		NMU of Rx Opioids/Stimulants	
	%	(95%)	%	(95%)
National Prevalence	1.8	(1.7, 1.9)	6.7	(6.4, 6.9)
Male	62.8	(59.4, 66.2)	52.4	(50.5, 54.2)
18-24 yrs of age	22.7	(18.9, 26.5)	12.3	(10.7, 14.0)
Bachelor/higher	48.1	(44.6, 51.7)	44.7	(42.8, 46.5)
Current HCP	20.8	(18.3, 23.3)	6.2	(5.3, 7.1)
DAST Score 3+	36.5	(33.2, 39.8)	10.3	(9.1, 11.4)

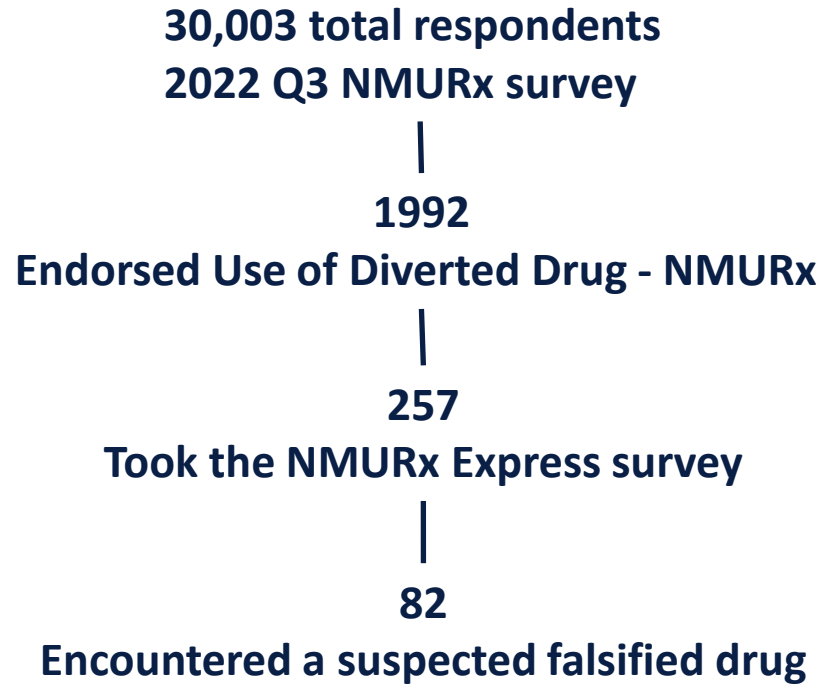
Users of Falsified Products

- Lower prevalence
- Male
- Younger
- + Current HCP
- Higher DAST

Research supported by *the US Food and Drug Administration (FDA)* award 75F40120C00151

Perceptions and Identification of Counterfeit Medications by Adults Using Diverted Drugs

- Goal
 - Describe how counterfeit drugs are identified and used in people who endorse diverted drugs
- Methods
 - Mixed method design using the RADARS[®] System NMURx methodology to identify a cohort of users of diverted drugs.



◆ WSJ NEWS EXCLUSIVE

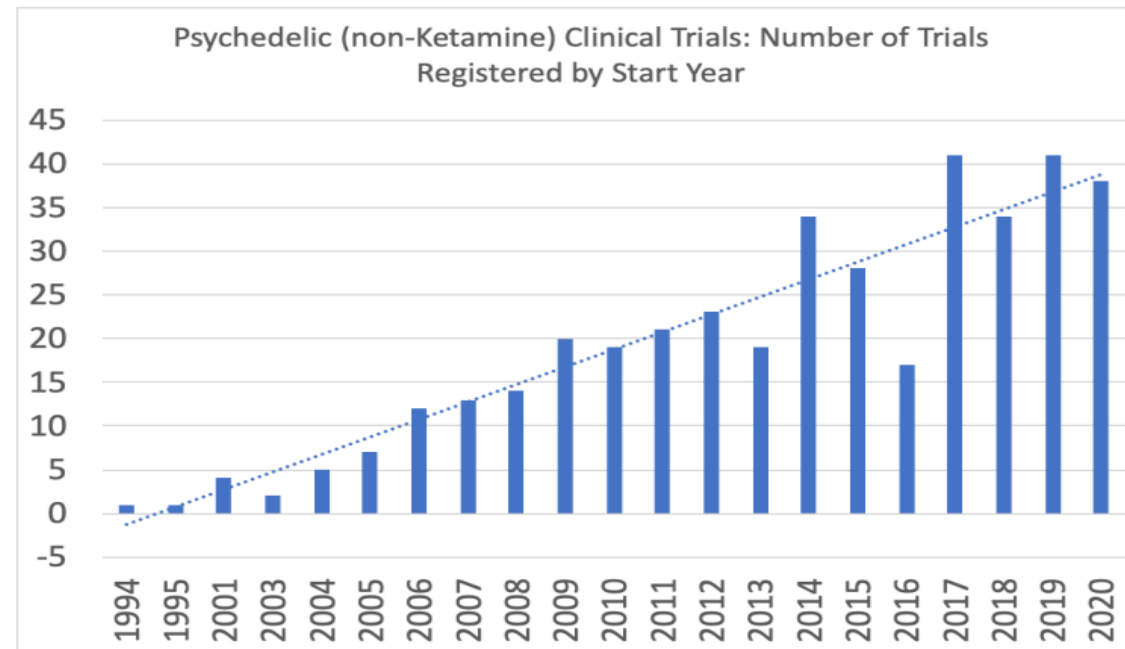
Wall Street Backs New Class of Psychedelic Drugs

Psychedelic-therapy industry gets a reality trip as investors focus on
treatments costing less time and money

By Matt Wirz
Feb. 23, 2023

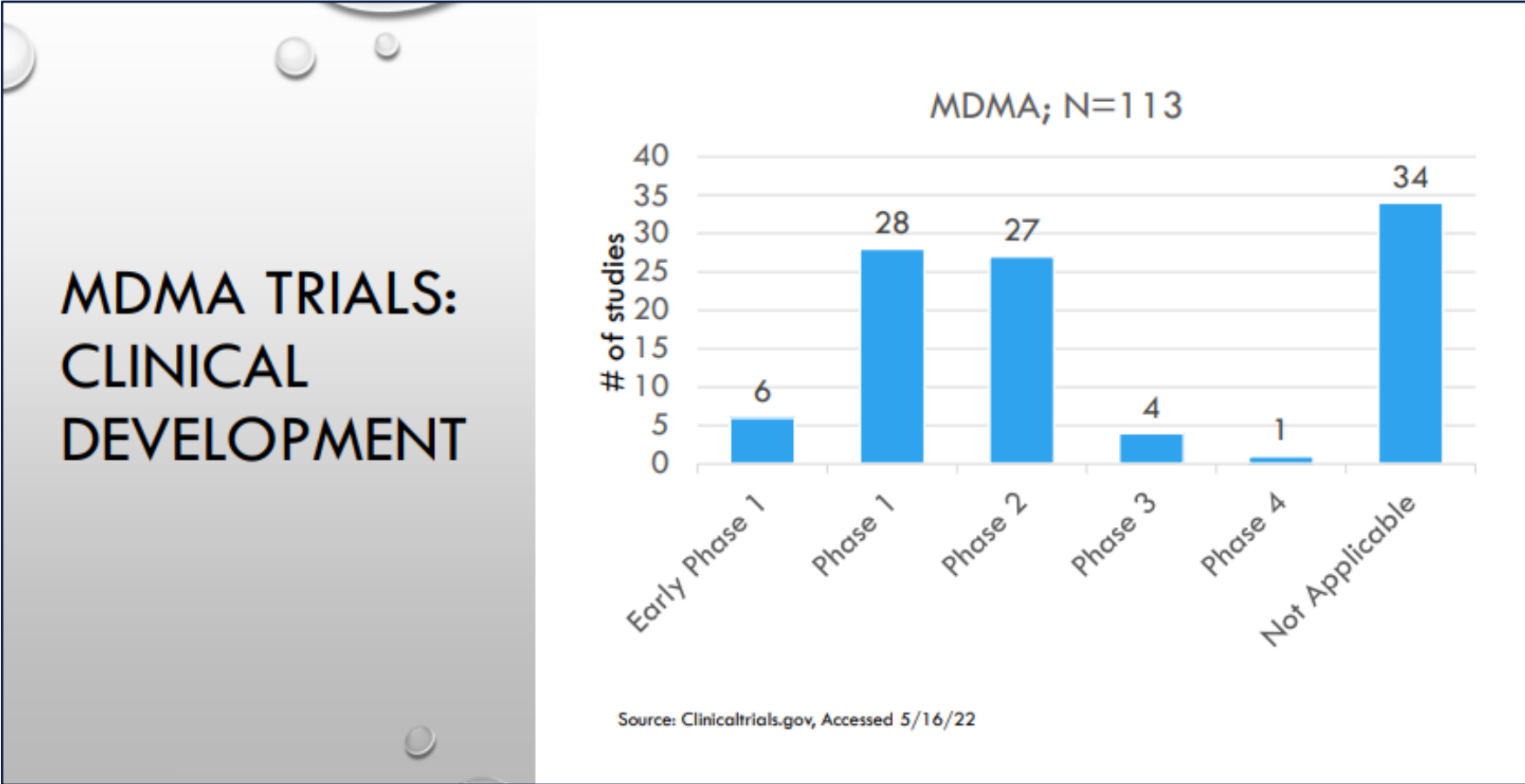
Psychedelics

Psychedelic Clinical Trials: Count 1994-2020 (excludes ketamine)



Alex Belser, Yale University Founding President, Nautilus Sanctuary Chief Clinical Officer, Adelia Therapeutics Chief Clinical Advisor, Cybin https://isctm.org/public_access/17th_Annual/Presentation/Belser_Session2.pdf

Ecstasy Trials



The Rise of the Psychedelic Medications

- Smoking cessation
- Alzheimer's
- Anorexia nervosa
- Depression and AUD
- Lyme disease
- Obsessive-Compulsive disorder
- Anxiety, depression, PTSD
- Romantic relationships




<https://www.hopkinsmedicine.org/psychiatry/research/psychedelics-research.html>

Many Addictive Medications Started Out as “Safer”

- Heroin
- Methadone
- Cocaine
- Amphetamine
- Traditional postmarketing surveillance takes years to detect adverse effects.

From the makers of Aspirin.
Introducing...

HEROIN

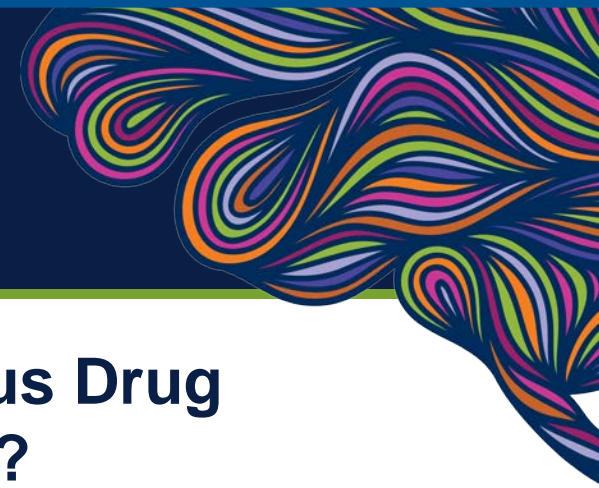


For non-addictive relief from the coughs, since 1898

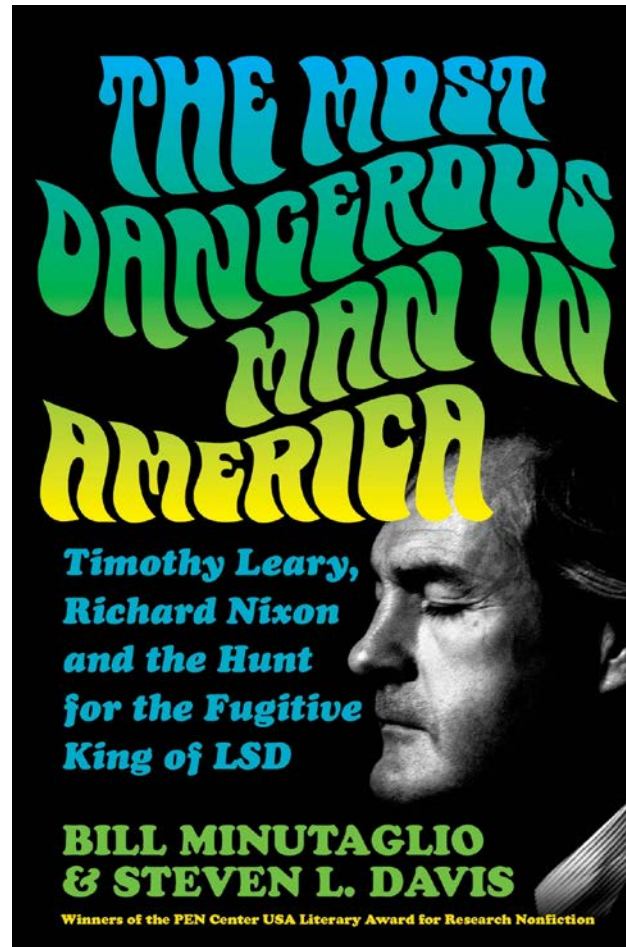
Also recommended as a safe and non-addicting cure for morphine addiction.

"BAYER PHARMACEUTICAL PRODUCTS"
Farbenfabriken of Elberfeld Co. 40 Stone Street, New York.

Turn on, Tune in, Drop Out



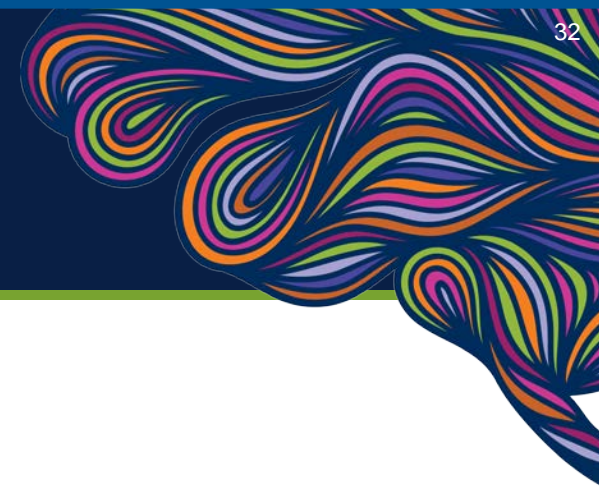
Respected
Therapeutic
Intervention?



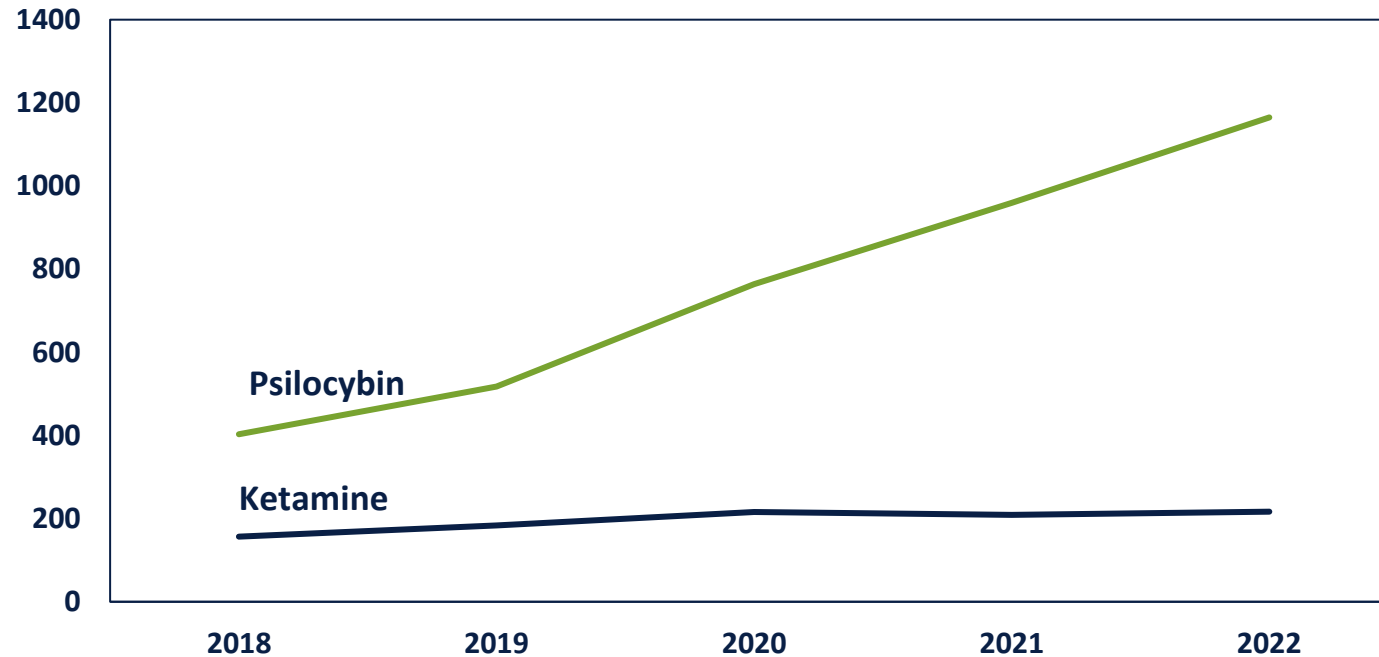
Dangerous Drug
of Abuse?

https://www.washingtonpost.com/outlook/president-richard-nixon-and-ldg-guru-timothy-leary-crazy-in-their-own-ways/2018/01/12/76220fa4-ebf2-11e7-b698-91d4e35920a3_story.html

Intentional Abuse of Psilocybin US National Poison Data System, 2018 - 2022



Psychedelic Drugs





Software



Ketamine

Special K, Green K, Super K, Super acid, Jet, and Cat Valium



The Benefits of Ketamine Therapy:



Relatively safe; while ketamine does have some side effects (most notably, hallucinations), they are usually mild and short-lived.



Few side effects when used in low doses; high doses of ketamine can cause serious side effects, such as coma or death.



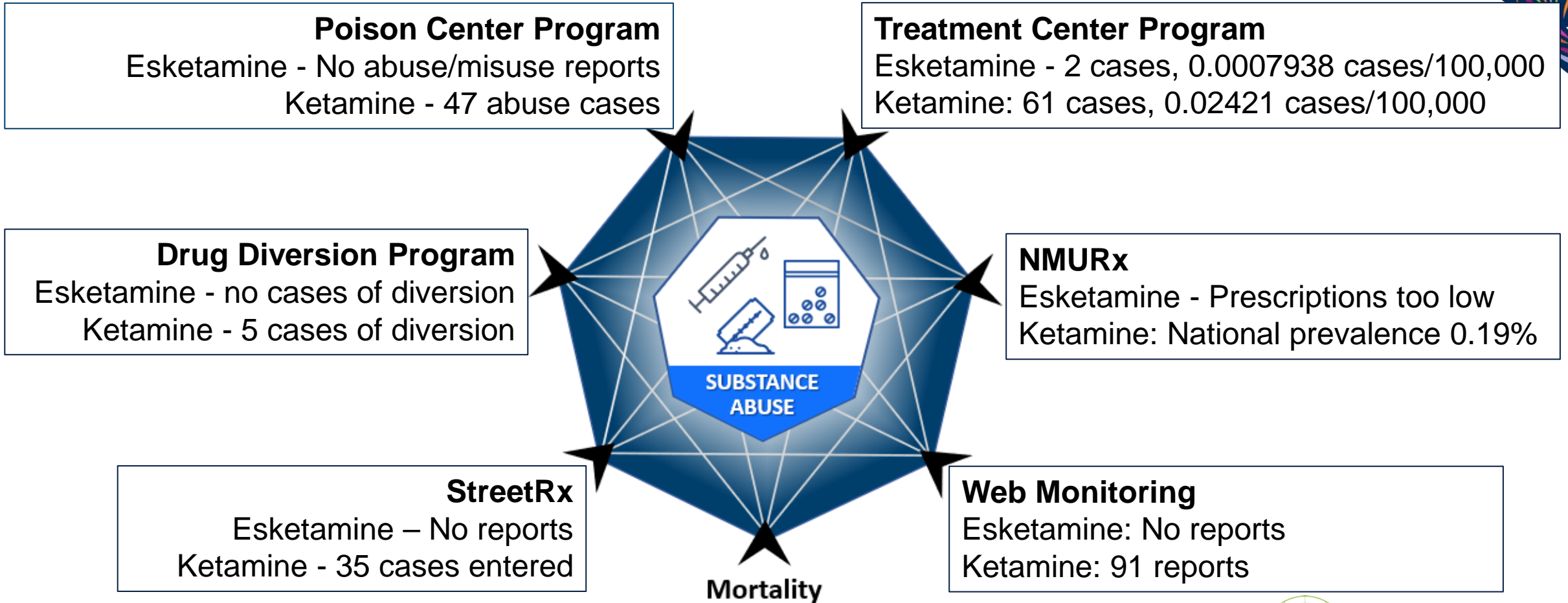
Fast-acting; it takes effect within minutes and lasts up to four hours.

<https://treatmentindiana.com/>

Spravato™
(esketamine) 
nasal spray



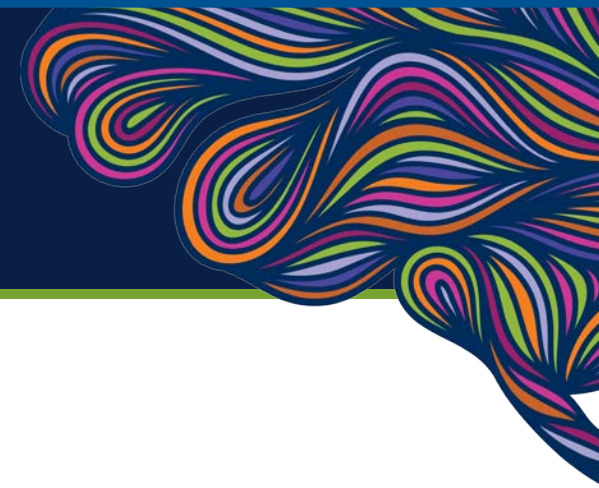
RADARS[®] System: Esketamine in 2022



Postmarket Surveillance of Psychedelics

- Patient
 - Treatment seeking vs. experience seeking
- Drug
 - Approved pharmaceutical product vs. illegal
- Provider
 - High school training vs. experience lay person vs. addiction psychiatrist
- Setting
 - Living room vs. religious setting vs. medical facility

The Heart of the Matter



RADARS® System Evidence Generators

- 51 US Poison Centers
- 150 Treatment Centers
- 197 Drug Diversion Programs
- 60,000 respondents NMURx

The RADARS® System Team Members

- Kate Reynolds, Research Director
- Joshua Black, PhD
- Rick Olson, MA
- Jennifer Jewell, PhD
- Kari Rockhill, PhD
- Numerous chart reviewers, data managers
- Nabarun Dasgupta, PhD
- Andrew Monte, MD, PhD

RADARS[®] System - Scientific Advisory Board



Theodore J. Cicero, PhD

Washington University in St Louis



Steven P. Kurtz, PhD

Nova Southeastern University



Mark W. Parrino, MPA

American Association for the Treatment of Drug Dependence



Richard C. Dart, MD, PhD

Rocky Mountain Poison & Drug Center, Denver Health



Sidney Schnoll, MD, PhD

PinneyAssociates



George Woody, MD

University of Pennsylvania



Nabarun Dasgupta, MPH

Rocky Mountain Poison & Drug Center, Denver Health



John Burke

*Pharmaceutical Diversion Education, Inc.;
International Health Facility Diversion Association*





Surveillance of Psychoactive Drugs Opioids, Psychedelics, and Cannabinoids

Richard C. Dart, MD, PhD

Executive Director – RADARS® System, Rocky Mountain
Poison & Drug Safety, Denver Health and Hospital Authority

President, Canadian Consumer Product and
Pharmaceutical Safety Inc.

Professor of Emergency Medicine, Medical Toxicology and
Pharmacology, University of Colorado



Application of socioecological framework of drug abuse to psychedelic drugs

Mohammad Jalali, PhD

Assistant Professor, Harvard Medical School

Senior Lecturer, MIT Sloan



Policy Needs to Address the Safety of Psychedelic Drugs

Brian Anderson, MD, MSc

Assistant Clinical Professor, UCSF

Principal Investigator, Community Uses of Psychedelics
and Safety Study (FDA)



Assessing Polysubstance Use of Licit (Gabapentin, Xylazine) and Illicit Substances

Sandra Comer, PhD

Professor of Neurobiology, Columbia University

Director the Opioid Laboratory in the Division of
Substance Use Disorders



Cannabis: Lessons Learned from Public Experience in Colorado

Mike Van Dyke, PhD, CIH

Associate Professor, Center for Health, Work & Environment
Department of Environmental and Occupational Health
Colorado School of Public Health, CU Anschutz Medical
Campus



Fireside Chat: The Evidence Generation System in Postmarket Surveillance

Robert M. Califf M.D., MACC

Commissioner of Food and Drugs,
Food and Drug Administration



Defining Polysubstance Use in a National Population-based Survey

Kari Rockhill, MPH, PhD (c)

Biostatistician III

Rocky Mountain Poison & Drug Safety



Satisfying the Craving for Novel Psychoactive Post-Market Surveillance

Andrew Monte, MD, PhD

Scientific Director of Research, RMPDS

Medical Director, Rocky Mountain Drug Center &
Denver Health Nurseline

Professor of Emergency Medicine, Medical Toxicology
and Pharmacology, University of Colorado Health
Sciences Center