



**RMPDS 18th Annual  
Scientific Meeting**

# Emerging Surveillance Needs for Psychoactive Drugs

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RMPDS/RADARS® System

Professor of Emergency Medicine  
University of Colorado

**ROCKY MOUNTAIN**  
POISON & DRUG SAFETY  
*Saving lives with answers.™*



**DENVER  
HEALTH**  
— est. 1860 —  
FOR LIFE'S JOURNEY



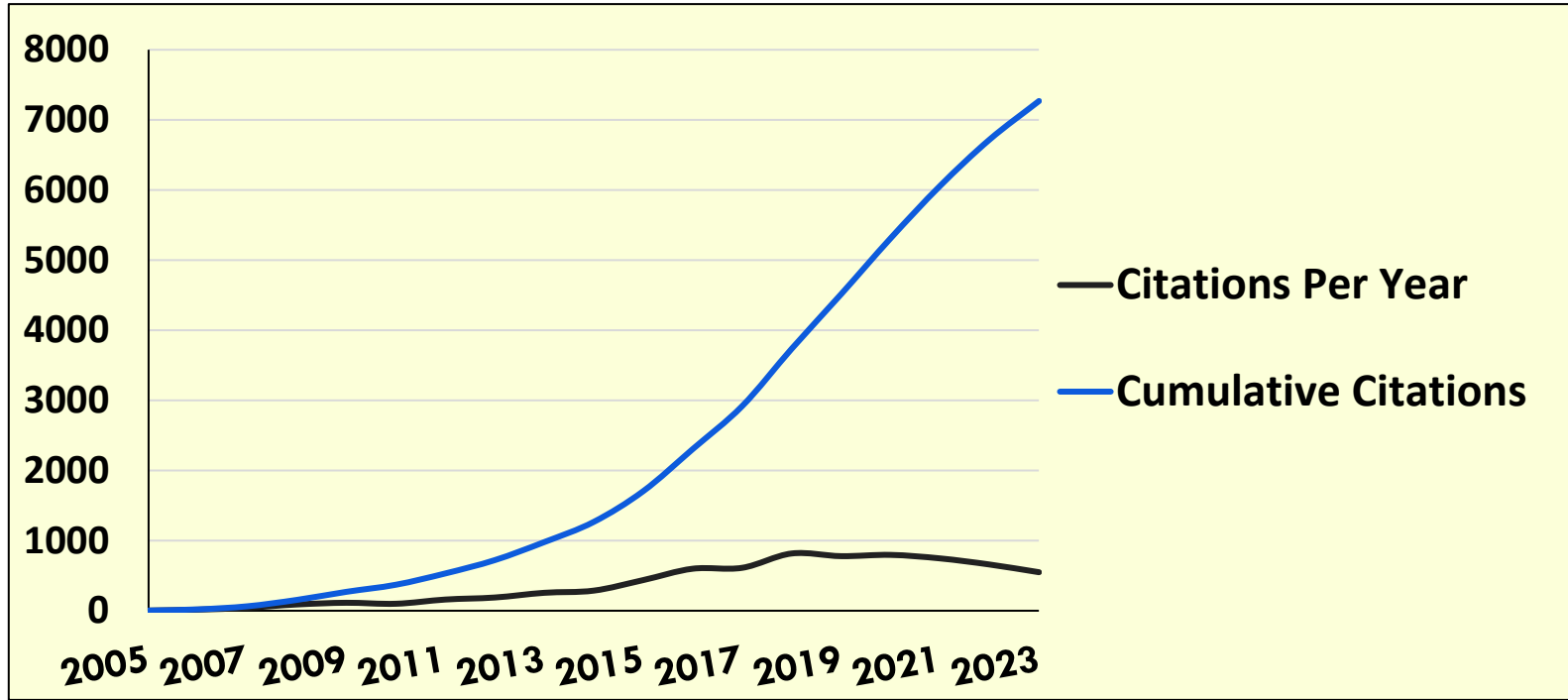
# **RMPDS/RADARS® System 18<sup>th</sup> Annual Scientific Meeting**

<b>Total Registrants</b>	<b>301</b>
<b>Government</b>	<b>82</b>
<b>Academic</b>	<b>153</b>
<b>Industry/Pharma</b>	<b>26</b>
<b>Other</b>	<b>40</b>

**Jess Kryzenske, Senior Product Manager**

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

# RADARS® System Publications Through 2023





**RMPDS 18th Annual  
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# Data Management Team

- Ali Dombek Handel
- Judy Butler
- Dean Garibaldi
- Andrew Schaff

Jenn Jewell, DrPH  
Assistant Research Scientist



# Biostatistics Team

- Heather Olsen
- ellie bau
- Kyle Beekman
- Elizabeth Bemis
- Hannah Burkett
- Kanki Sumbundu
- Annika Czizik
- Michael Ladka
- Eunice Mogusa
- Joe Piccoli
- Nicole Schow
- Becca vogt



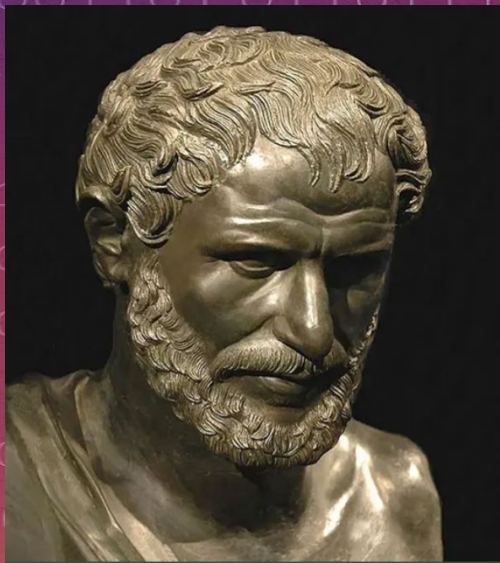
# Project Management Team

- Amanda Rogers
- Crystal Goodiel
- Ana Coggin
- Arsen Ghasabyan
- Micah Copeland
- Alicia Dalton
- Ana Cornell
- Ellie Fox
- Jill Bowman
- Madison Calloway
- Caleb James
- Faith Lyons
- Brooke Kritikos
- Ciara O'Neill



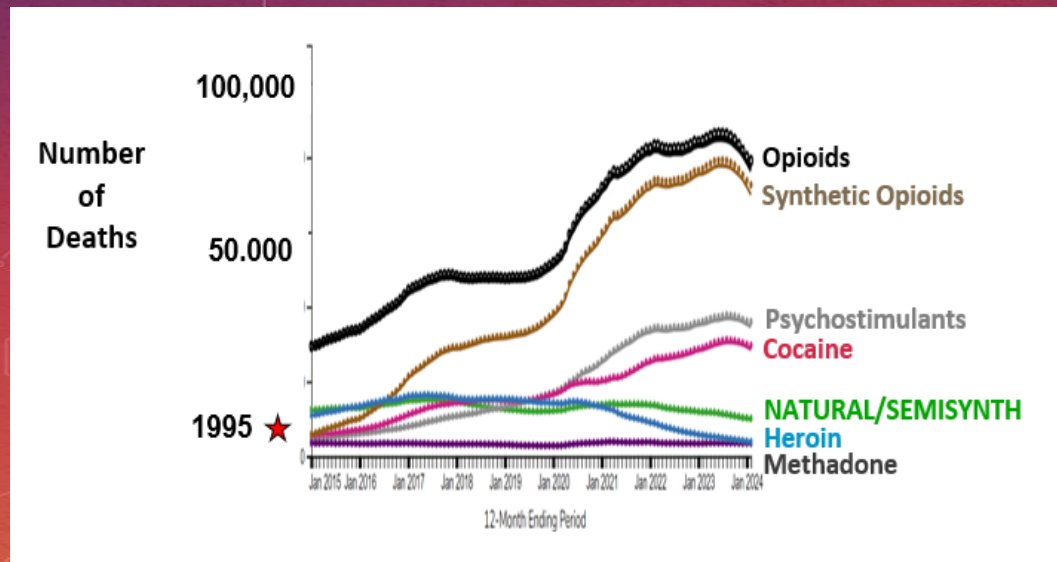


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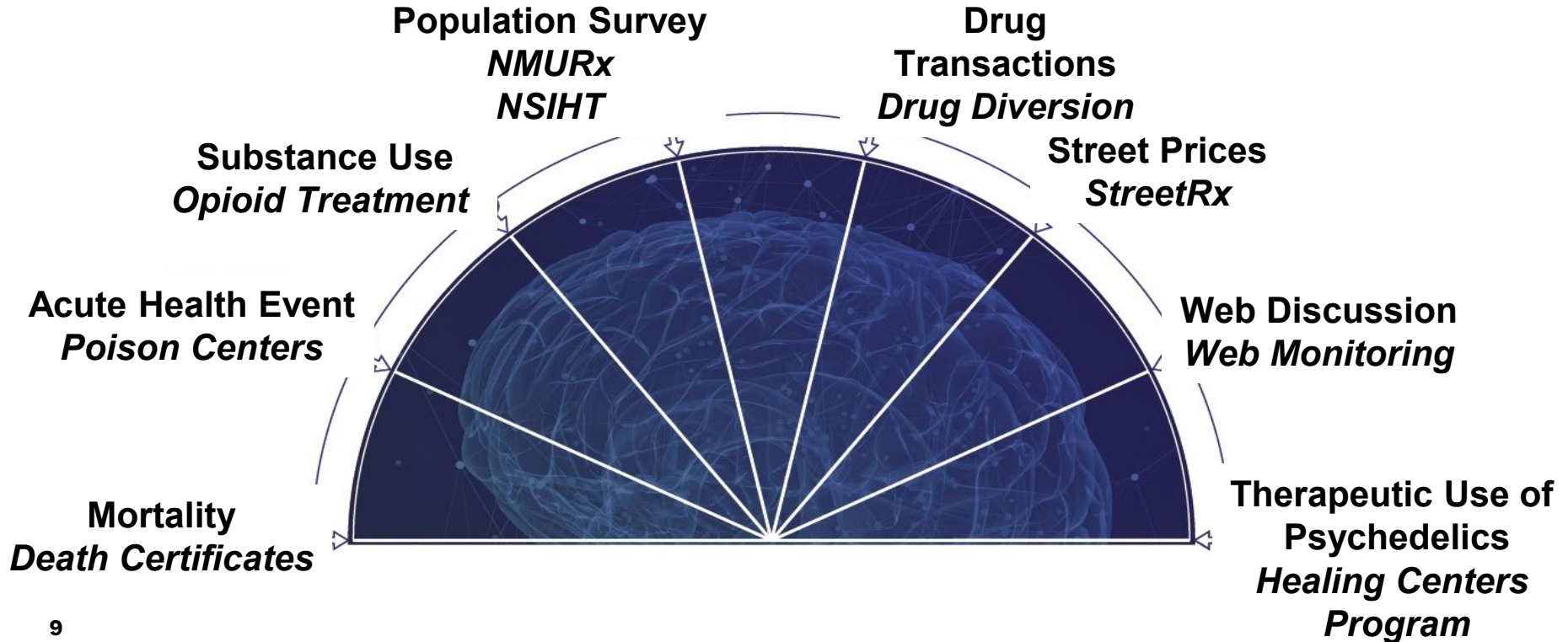
# *The Only Constant in Life is Change*

Heraclitus, 540 BCE

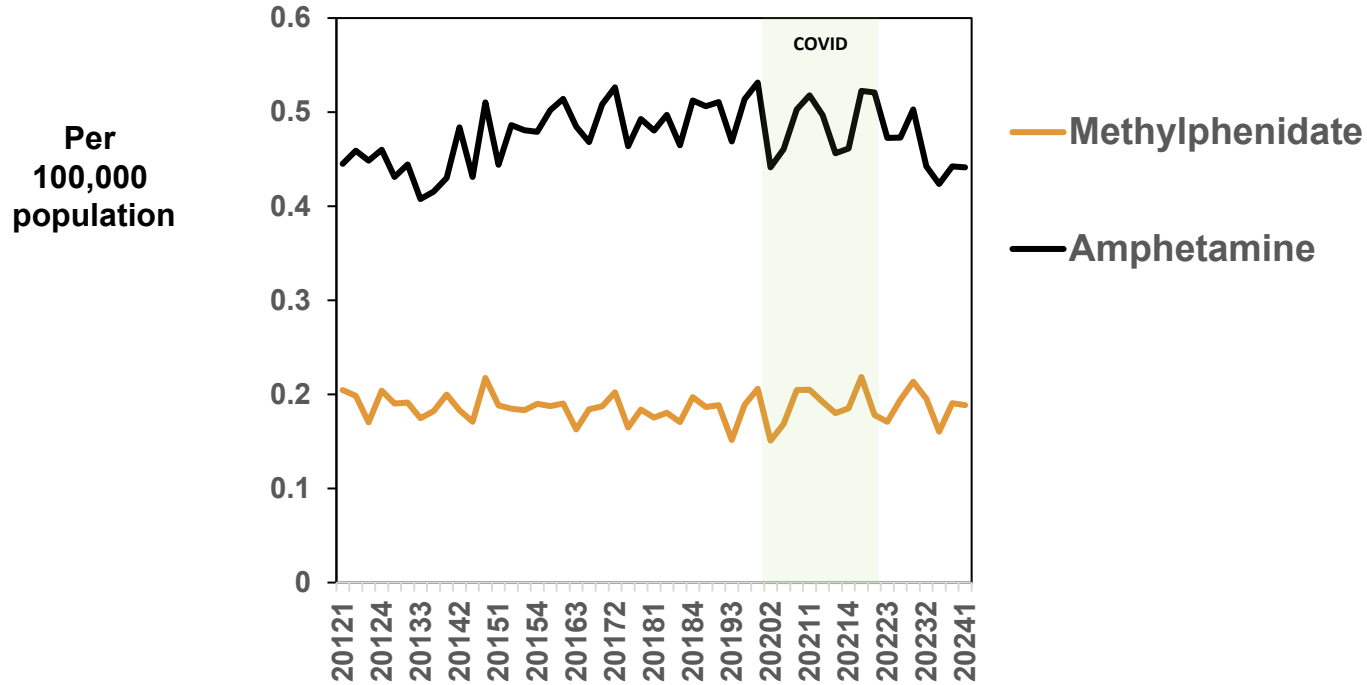




# Mosaic Surveillance

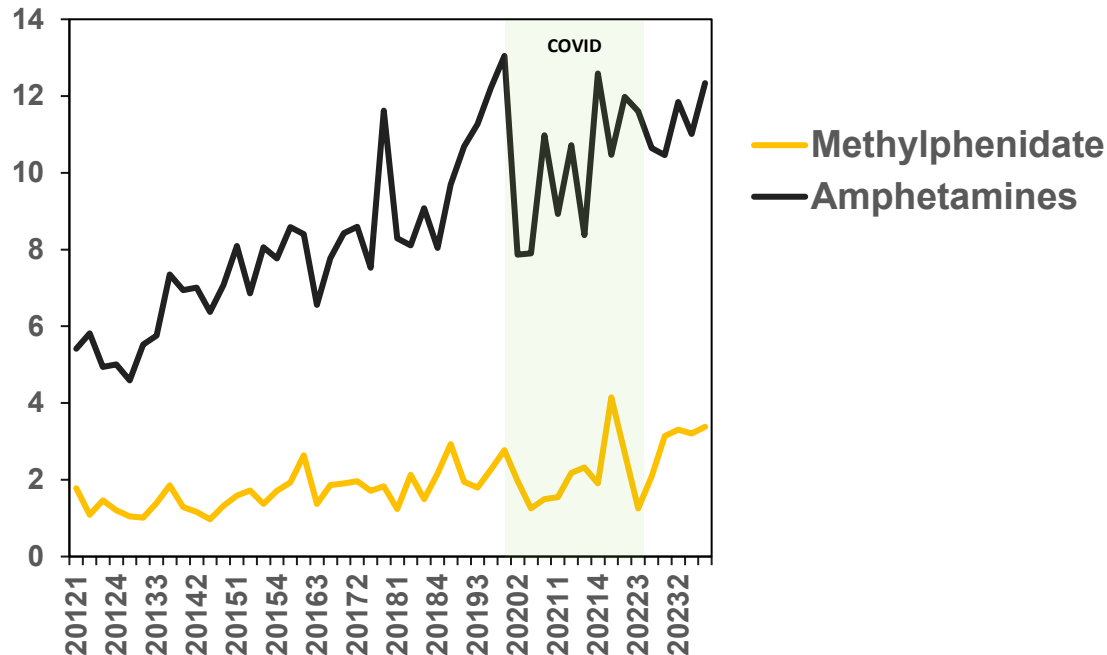


# Rx Stimulants, Poison Center Program 2012-2023

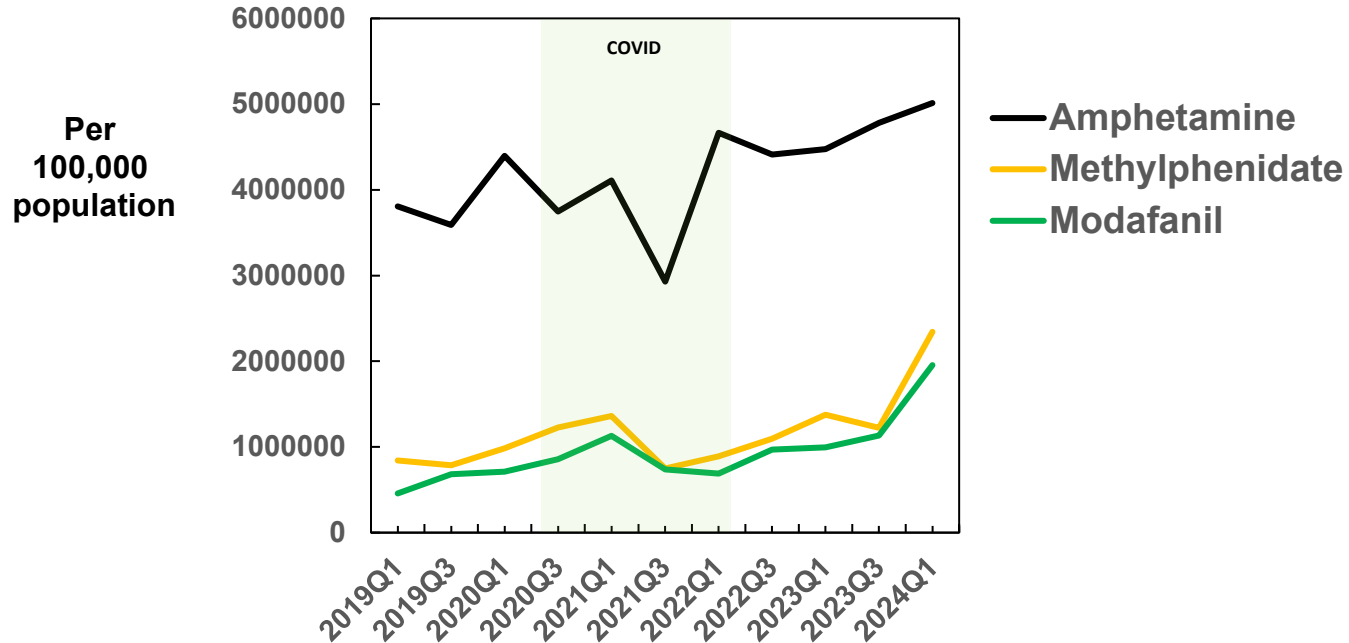


# Rx Stimulants, Drug Diversion 2012 - 2023

Proportion (%)  
Rx Diversion  
Cases



# Nonmedical Use of Prescription Drugs (NMURx) Prescription Stimulants, 2019 - 2024



# Summary of Rx Stimulants

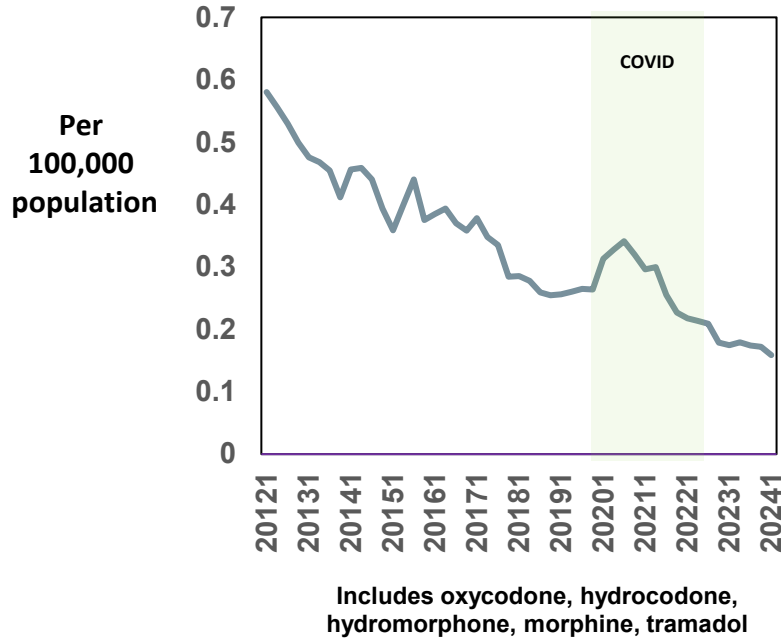
- **Poison Centers: No increase**
- **Drug Diversion: Increasing illicit trafficking of Rx stimulants**
- **Nonmedical Use of Rx Drugs (NMURx)**
  - **NMU increasing**
- **Primary forms involved are the immediate-release preparations**



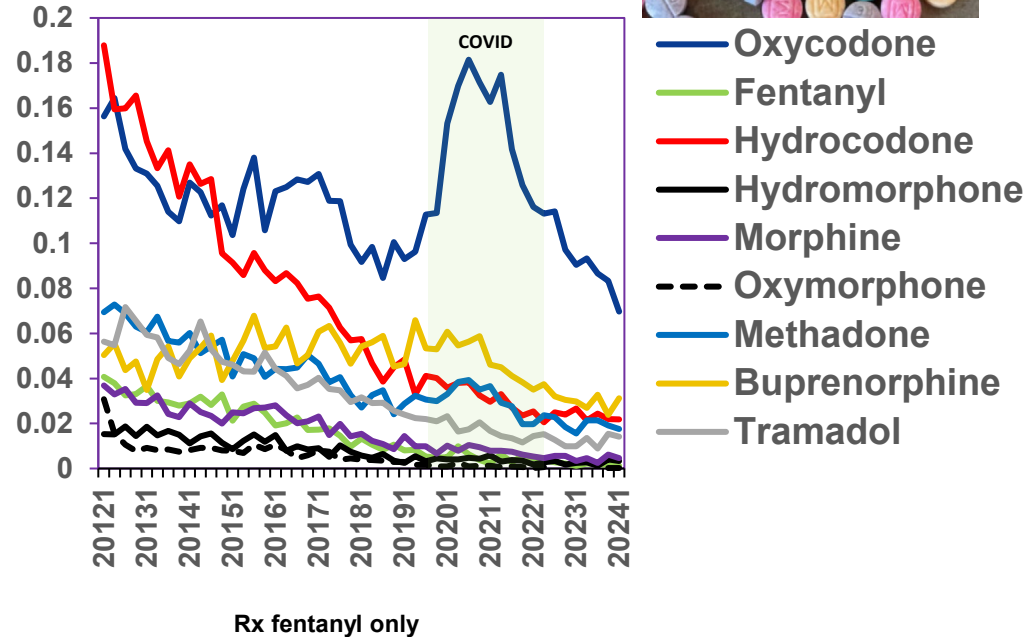
# Rx Opioids, Poison Center Program Intentional Abuse, 2012 - 2024



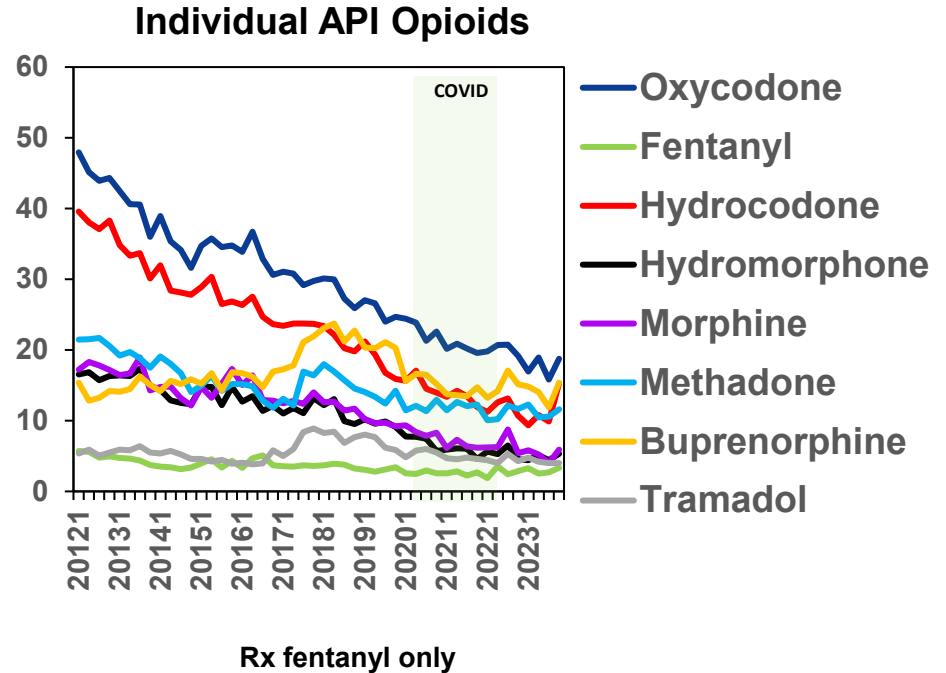
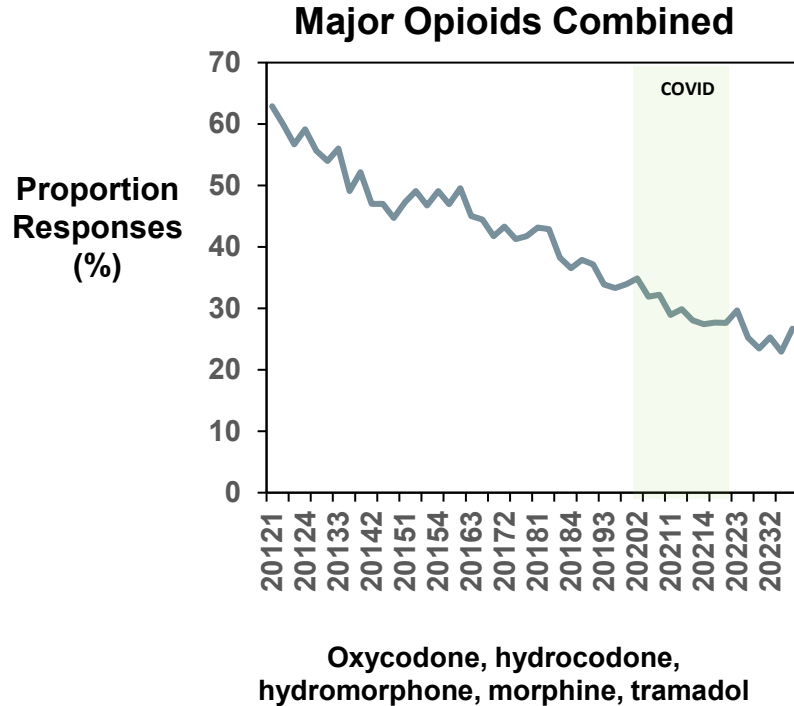
Major Opioids Combined



Individual API Opioids

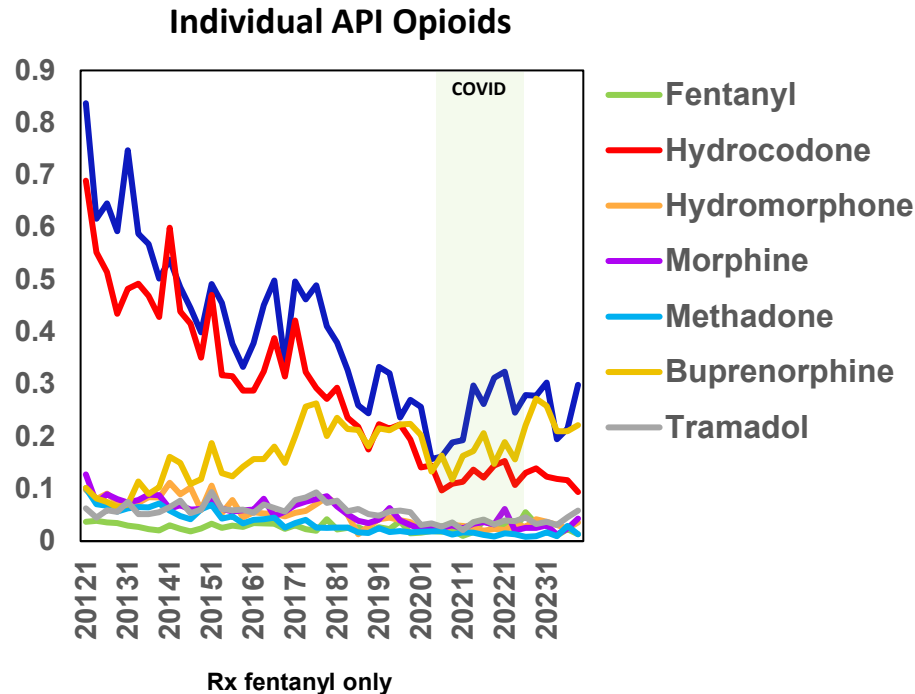
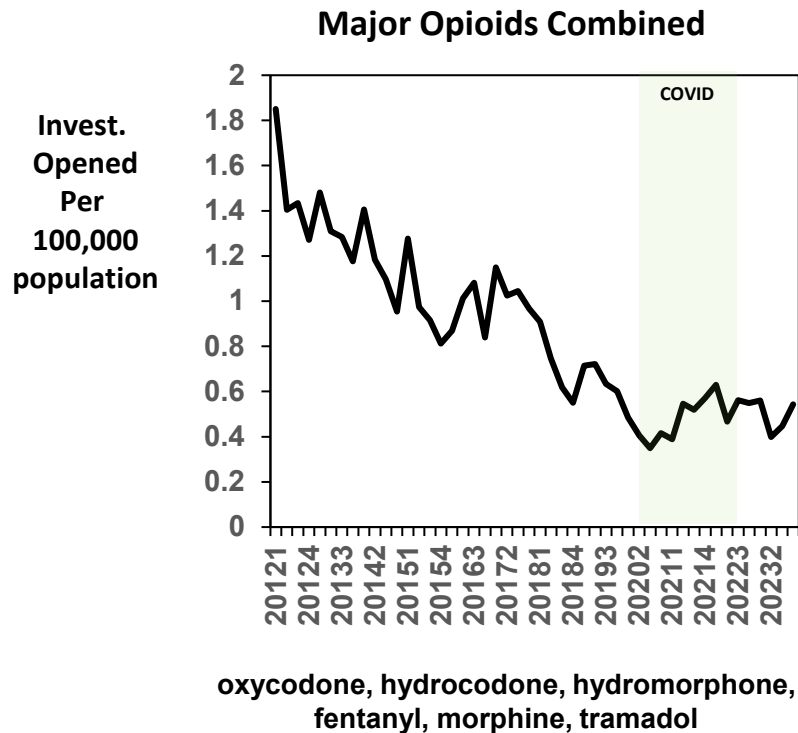


# Rx Opioids, Treatment Centers Combined 2012 - 2024



# Rx Opioids, Drug Diversion Program

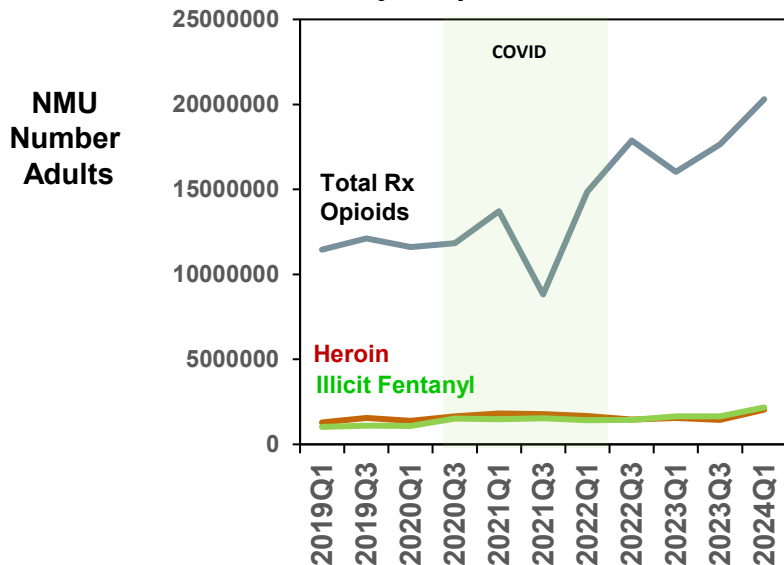
## 2012 - 2024



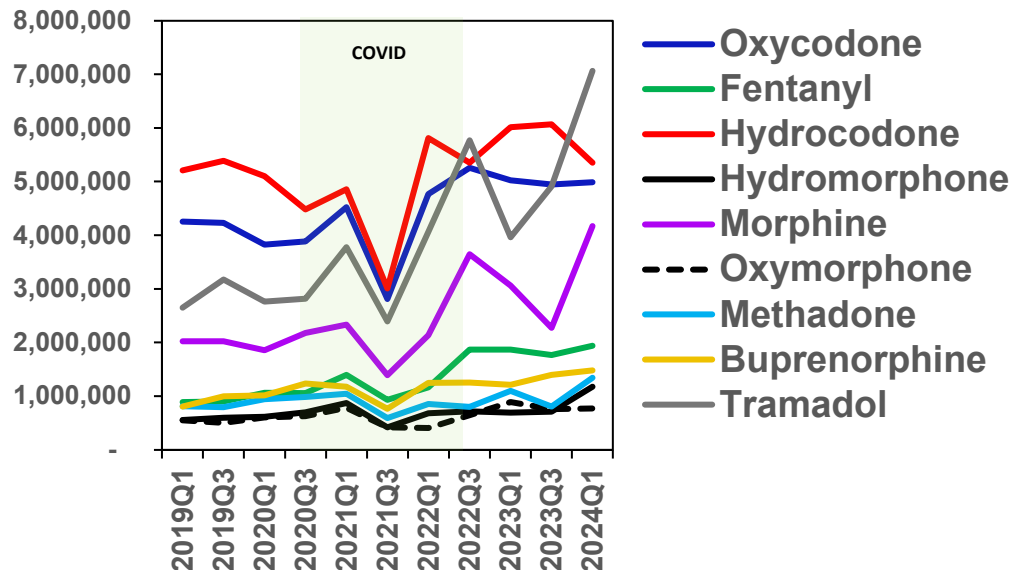
# NMURx, Non-Medical Use of Opioids

## 2019 - 2023

Major Opioids Combined



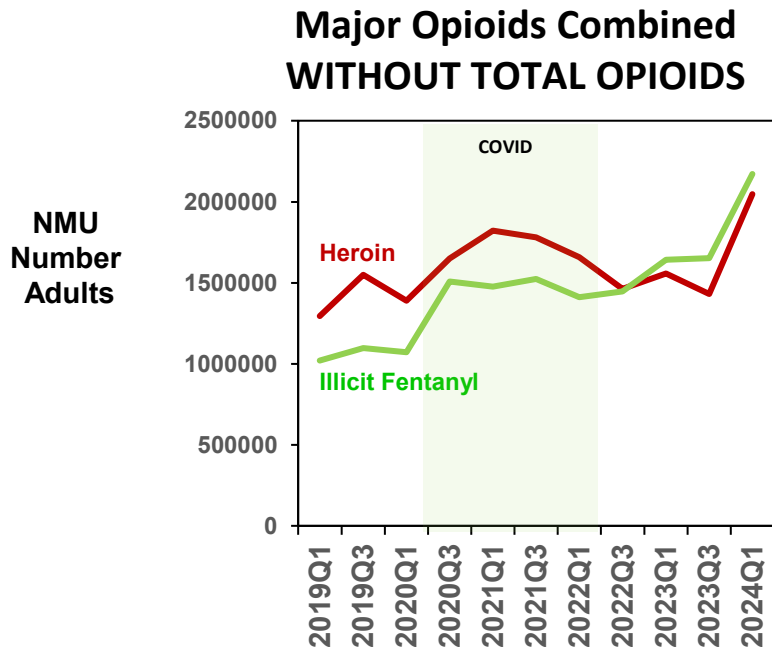
Individual API Opioids



NMU questions were redesigned for 2022 Q1/Q3 surveys for better assessment of unknown formulations

Rx fentanyl only

# NMURx, Non-Medical Use of Opioids 2019-2023

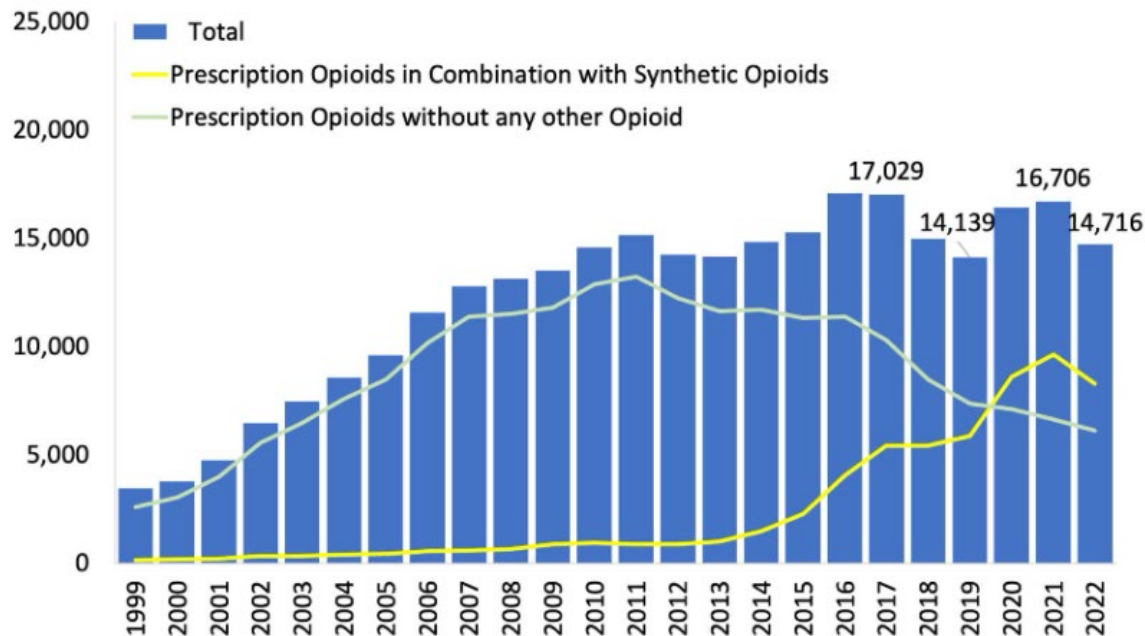


NMU questions were redesigned for 2022 Q1/Q3  
surveys for better assessment of unknown formulations



# National Prescription Opioid-Related Deaths

## CDC, 1999 - 2022



<https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates>

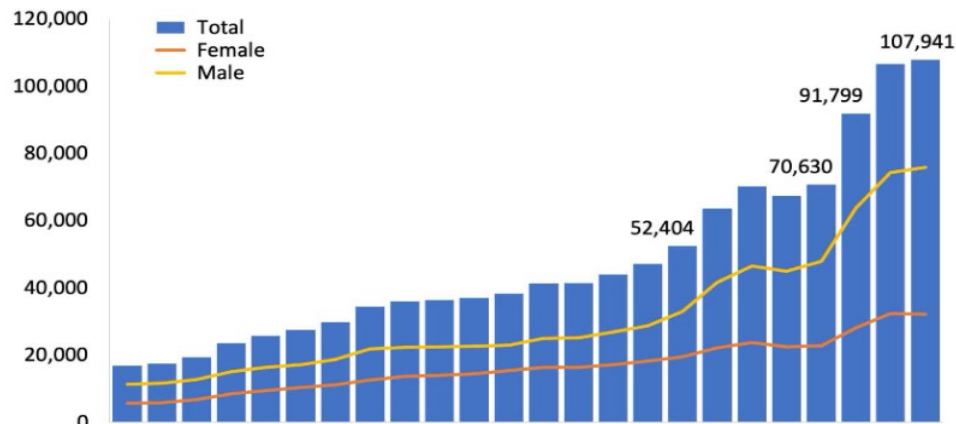
# Summary of Prescription Opioids

- **Overall, measures of prescription opioids misuse/abuse decreasing over the past decade**
  - Particularly in poison center program
  - Increase during COVID
- **Concerning recent recent trends**
  - Increased diversion during COVID persists
  - Oxycodone, buprenorphine
  - Heroin, illicit fentanyl
- **Misuse and abuse data consistent with mortality data**

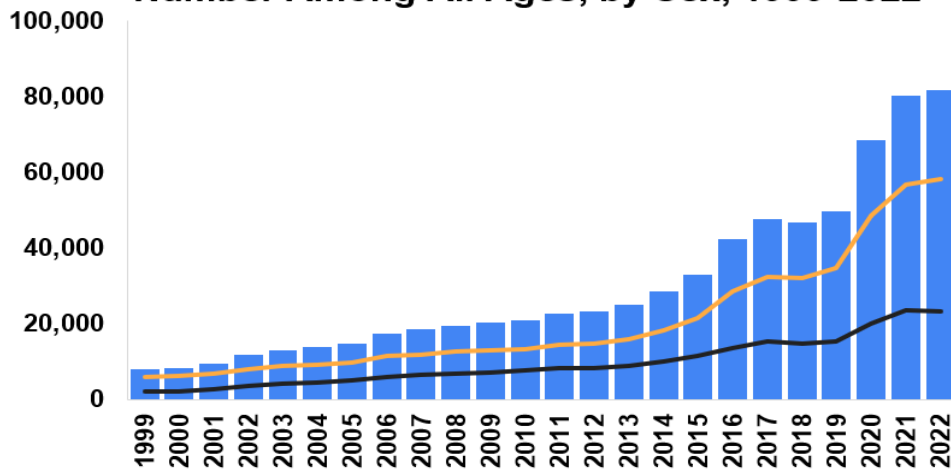
**25,000 Deaths**

**Drug-Related Deaths  
Without  
Opioid Involvement**

**National Drug Deaths, All Ages, CDC, 1999-2022**



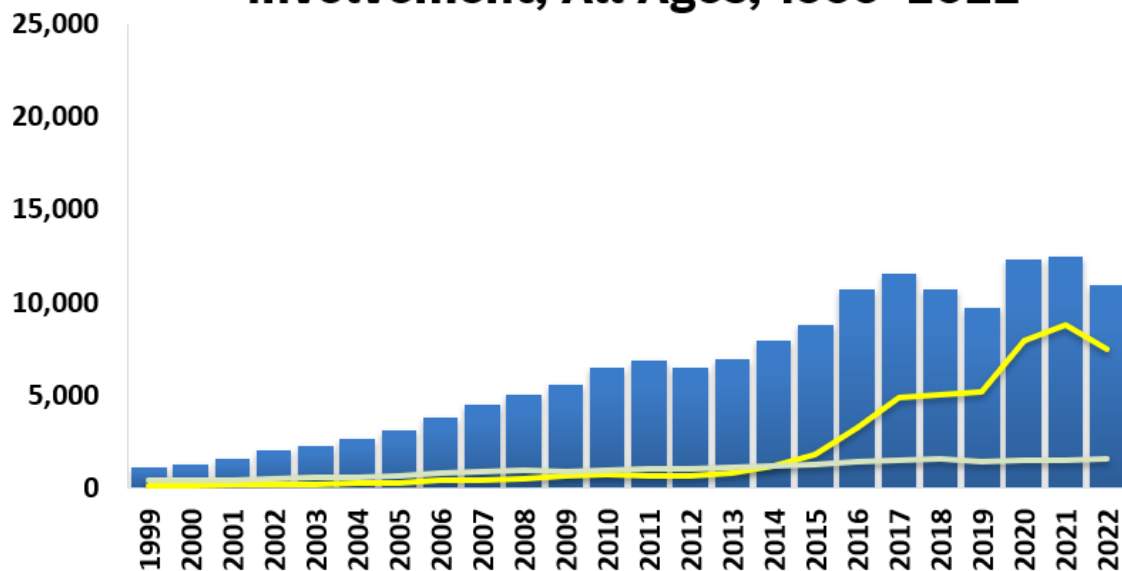
**National Overdose Deaths Involving Any Opioid\*  
Number Among All Ages, by Sex, 1999-2022**



# Benzodiazepines and Antidepressants

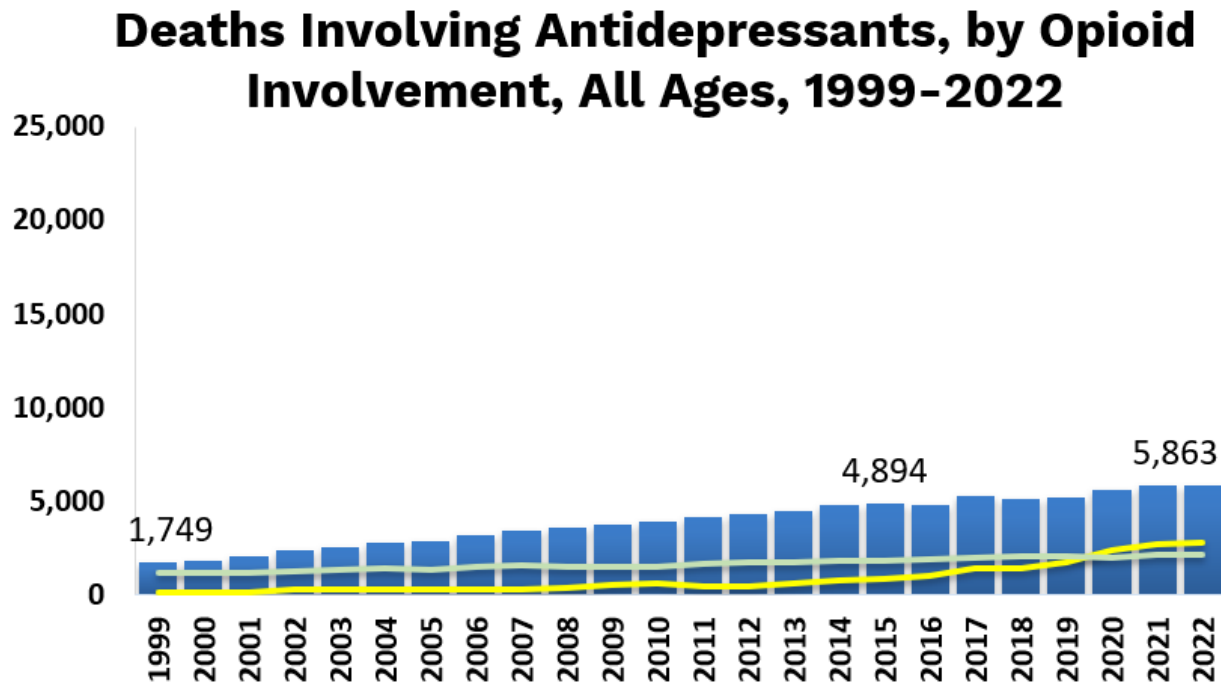
## - Increasing sources of drug related deaths

**Deaths Involving Benzodiazepines, by Opioid Involvement, All Ages, 1999-2022**



# Benzodiazepines and Antidepressants

## - Increasing sources of drug related deaths





# NMURx, Types of Misuse

Type of Use	Opioids	Stimulants	BDZ
Any NMU	↑↑↑	↑↑	↑↑
All ABUSE	↑↑↑	↑	
Medical Misuse	↑↑↑	↑	↑↑
Other	↑	↑	↑
<b>ED/UC Visits</b>			
All ABUSE	↑	↑↑↑	↑↑
Medical Misuse	↑↑	↑↑↑	↑↑
Other	↑	-	↑

# NON-Opioid Drugs - Summary Missing Mortality

- Multiple drug categories
  - Rx and OTC, mostly CNS active medications
- Misuse and mortality increasing
- Can we use drugs with CNS effects safely?



**Temptation of St. Anthony**  
**Salvador Dali, 1946**

# **FDA's Risk Evaluation and Mitigation Strategies (REMS): Effective and Efficient Safety Tools or Process Poltergeist?**

66 Food & Drug L.J. 569 (2011)

FDA's Risk Evaluation and Mitigation Strategies (REMS):  
Effective and Efficient Safety Tools or Process Poltergeist



# What is REMS?

- REMS = Risk Evaluation and Mitigation Strategy
- ETASU = Elements to Assure Safe Use
- FDA requires for certain medications with serious safety concerns
  - Communicating risk information to patients and clinicians
  - Requiring actions that need to be taken before prescribing or dispensing the drug
  - Interventions like packaging or disposal systems
- REMS can help the FDA approve drugs that would otherwise have risks that exceed their benefits (not approvable).

# REMS Example – Esketamine (Spravato®)



Home

Inpatient Healthcare  
Settings

Outpatient Healthcare  
Settings

Pharmacies

Patients

Contact  
Us



## Inpatient Healthcare Setting

Inpatient Healthcare  
Settings must be certified  
in the SPRAVATO® REMS in  
order to treat patients with  
SPRAVATO®



## Outpatient Healthcare Setting

Outpatient Healthcare  
Settings must be certified  
in the SPRAVATO® REMS in  
order to treat patients with  
SPRAVATO®



## Pharmacy

Pharmacies must be  
certified in the SPRAVATO®  
REMS in order to dispense  
SPRAVATO®



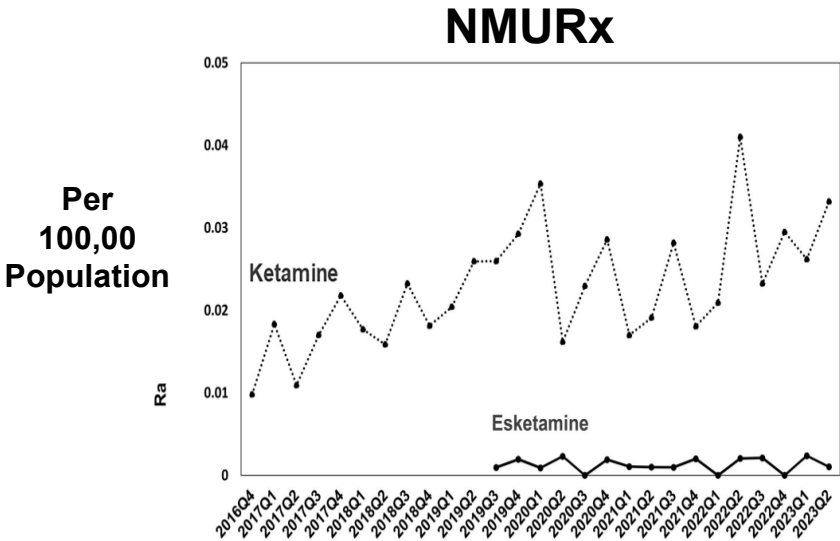
## Patient

Patients must be enrolled  
in the SPRAVATO® REMS in  
order to receive SPRAVATO®  
treatment in an Outpatient  
Healthcare Setting



# RADARS® System Postmarket Surveillance

## Esketamine v. Ketamine, 2019-Q1 through 2023-Q2



Program	Ketamine
Poison Centers, #	102
NMURx, % US Pop	1120
Drug Diversion	47
Treatment Programs	409
StreetRx.com	47
Web monitoring Posts mentioning misuse, abuse	7

# REMS Medication Surveillance, NMURx

Program	Ketamine	Esketamine	Sufentanil	Sodium xybate/Xyrem®
Poison Centers, #	102	0	0	23/1
NMURx, % US Pop	1120	0	0	N/A
Drug Diversion	47	1	0	N/A
Treatment Programs	409	20	0	N/A
StreetRx.com	47	1	0	N/A
Web monitoring Posts mentioning misuse, abuse	7	0	0	N/A

# Characteristics of REMS/ETASU Programs

ETASU	Ketamine	Esketamine	Sufentanil	Sodium oxybate
Controlled Access	CIII	X	X	X
Prescriber Certification	-	X	X	X
Pharmacy Certification	-	X	X	X
Observed Administration	-	X	X	-

**ETASU – Elements to Assure Safe Use**



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**Every system is perfectly designed to  
get the results it gets.**

**W. Edwards Deming**

- **Summary**
  - **Misuse of prescription stimulants is rising**
  - **Misuse of prescription opioids is rising**
  - **Misuse of other medications is rising**
  - **Drugs with considerable abuse potential**
  - **REMS/ETASU has been very effective in specific instances**
    - **Should we modify access to medications?**



## RMPDS 18th Annual Scientific Meeting

# First Session Speakers



### RMPDS 18TH ANNUAL SCIENTIFIC MEETING

#### MARTA SOKOLOWSKA, PHD

Deputy Center Director for Substance Use and Behavioral Health (Center for Drug Evaluation and Research (CDER), Food and Drug Administration)



### RMPDS 18TH ANNUAL SCIENTIFIC MEETING

#### NABARUN DASGUPTA, PHD, MPH

Fellow at University of North Carolina Gillings School of Public Health, Senior Scientist at UNC Chapel Hill, and Co-Founder of Remedy Alliance for the People



### RMPDS 18TH ANNUAL SCIENTIFIC MEETING

#### JOSHUA BLACK, PHD

Senior Research Scientist, Rocky Mountain Poison & Drug Safety



### RMPDS 18TH ANNUAL SCIENTIFIC MEETING

#### RICHARD C. DART, MD, PHD

Director, Rocky Mountain Poison & Drug Safety. President, Canadian Consumer Product and Pharmaceutical Safety Inc. Professor of Emergency Medicine & Medical Toxicology and Pharmacology, University of Colorado







## RMPDS 18th Annual Scientific Meeting

# Afternoon Speakers



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### NEERAJ GANDOTRA, MD

Chief Medical Officer, Substance Abuse and Mental  
Health Services Administration (SAMHSA)



RMPDS 18TH ANNUAL  
SCIENTIFIC MEETING

### ANDREW A. MONTE, MD, PHD

Scientific Director of Research, Rocky Mountain  
Poison & Drug Safety, Medical Director of Rocky  
Mountain Drug Center & Denver Health Nurseline,  
Professor of Emergency Medicine & Medical  
Toxicology and Pharmacology, University of  
Colorado Health Sciences Center



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### ERICA SIEGAL, LCSW

Harm Reduction Advocate and Psychedelic  
Psychotherapist, CEO - NEST Harm Reduction &  
Consulting



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SCIENTIFIC MEETING

### KARI ROCKHILL, PHD

Assistant Statistical Research Scientist, Rocky  
Mountain Poison & Drug Safety





**Judging by the size and frequency of the droppings,  
I'd say we've found the campaign trail.**