

Director's Report to the National Advisory Council on Drug Abuse

May 14, 2019

Nora D. Volkow, M.D., Director

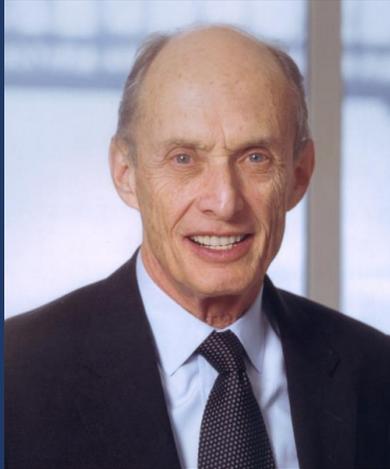


National Institute
on Drug Abuse



@NIDAnews

In Memoriam



Paul Greengard, Ph.D.

1925 -- 2019

Nobel laureate and neurobiologist at Rockefeller University who is best known for his work showing that the brain not only communicates with electrical signals but also with chemicals such as dopamine.



Gavril W. Pasternak, M.D., Ph.D.

1947 -- 2019

Internationally recognized scientist from Memorial Sloan Kettering whose research helped to shape current knowledge of opioid receptors and pharmacology

NIDA



Jack B. Stein, Ph.D.
NIDA Chief of Staff



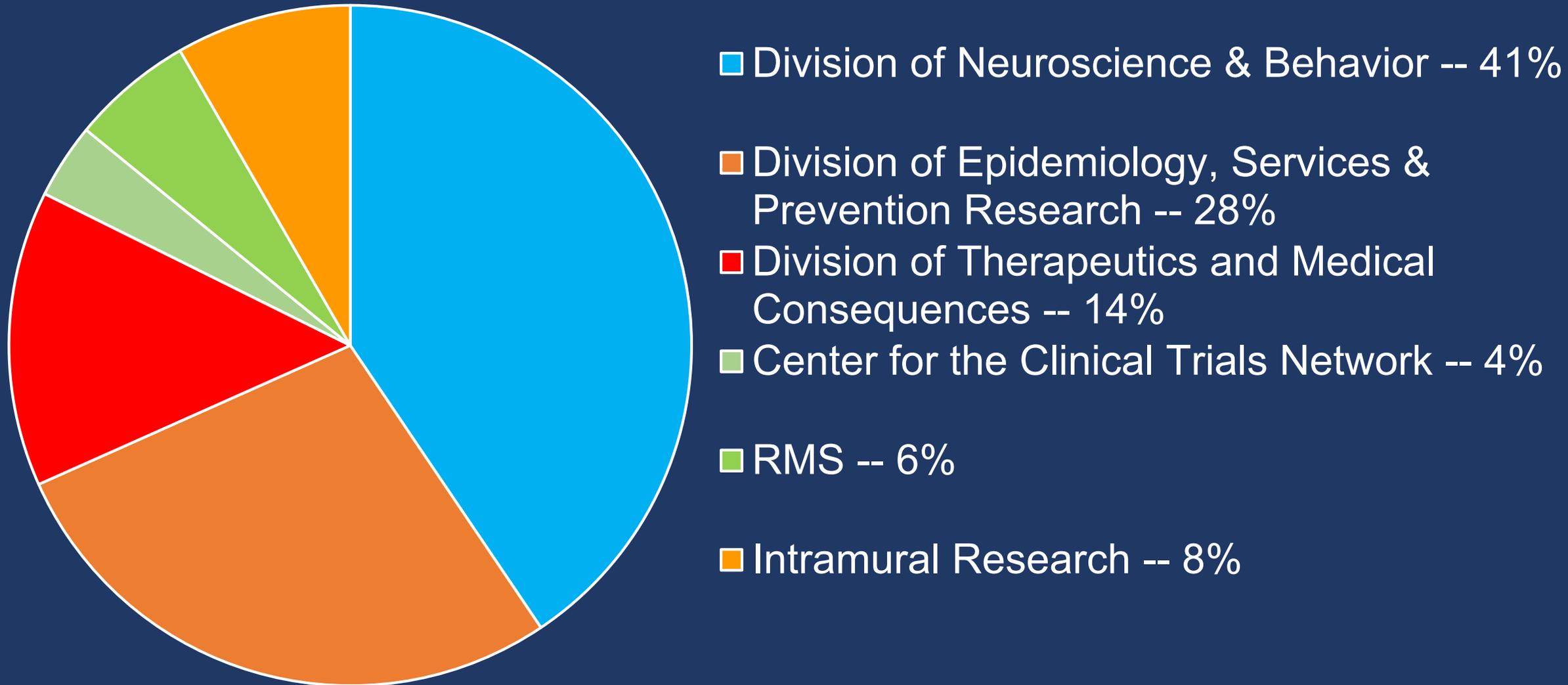
NIDA BUDGET

	FY 2018 Actuals	FY 2019 Enacted	FY 2020 PB
NonAIDS	\$854,609,000	\$893,402,000	
AIDS	\$269,765,000	\$264,814,000	
Total	\$1,124,374,000	\$1,158,216,000	\$796,379,000
Opioids	\$250,000,000	\$250,000,000	\$250,000,000

National Institute on Drug Abuse Portfolio

Annual Appropriation

FY 2018 Actual

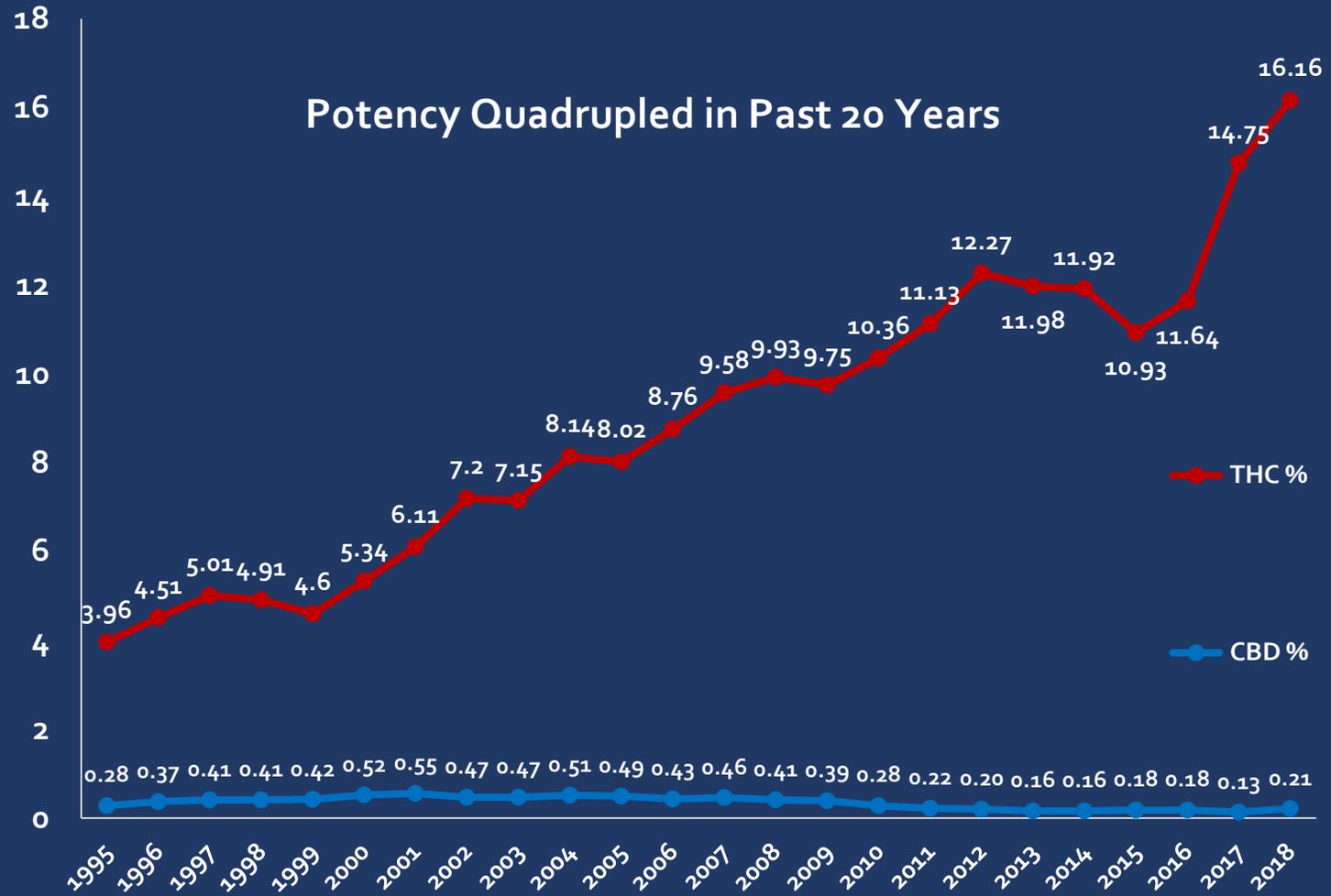


Cannabis Laws in United States



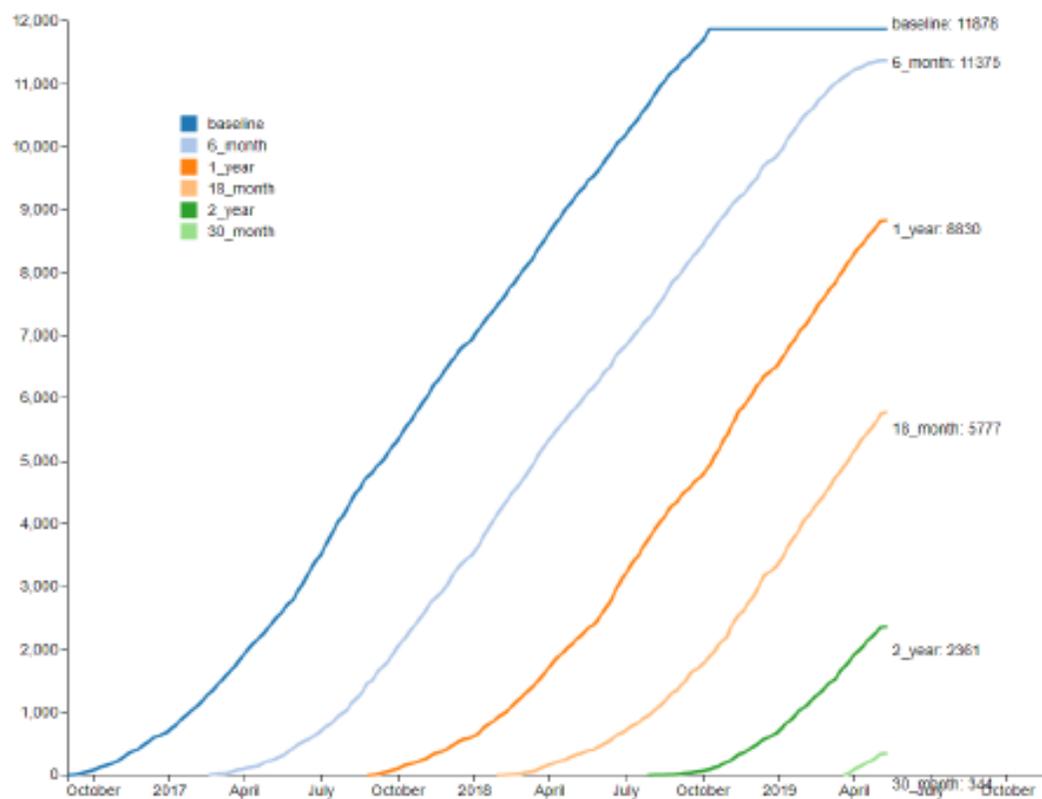
Legal
Legal medical use
Legal medical use, limited THC content
Prohibited

Cannabis Potency (% Δ-9 THC)



Source: Potency Monitoring Program, Quarterly report Number 139, NIDA Contract Number: No1DA-15-7793

Adolescent Brain Cognitive Development (ABCD) Study



ABCD Study Fast Track Neuroimaging Data

<https://data-archive.nimh.nih.gov/abcd>

Full Baseline Curated Data Released

Data on 11,875 participants was released in April 2019, including:

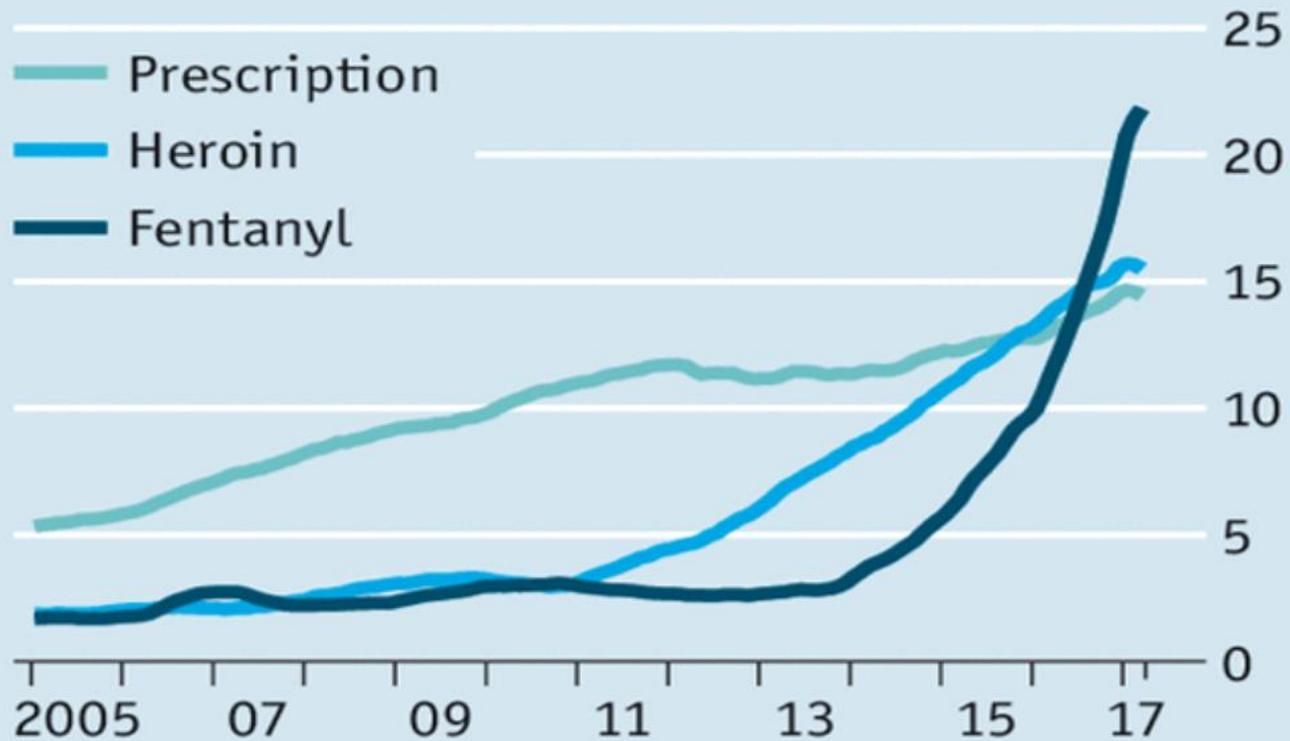
- Basic demographics,
- Assessments of, physical and mental health, substance use, culture and environment, and neurocognition,
- Tabulated structural and functional neuroimaging data,
- Minimally processed brain images,
- Biological data (e.g., pubertal hormone analyses),
- Genotypic data from the Smokescreen array
- Residential history derived data (e.g., crime, area deprivation index, walkability, population density, pollution)

Data Exploration and Analysis Portal (DEAP)

DEAP provides the means to find measures of interest from more than 40,000 shared observations available for each ABCD participant, to test hypotheses using a multi-level regression model suitable for the ABCD study design, and to run novel multi-level statistical analysis directly from the DEAP interface.



OVERDOSE FATALITIES



Source: Centres for Disease Control and Prevention

EVOLUTION OF THE OPIOID CRISIS

Trajectories to Opioid Misuse, Addiction and Overdoses

Opioid Addiction and Overdoses



1. Opioid Prescription for **Pain**
2. Misuse of Opioid Prescription

1. Pain patient who transitions to heroin
2. Px Opioid misuser who transitions to heroin
3. Initiates with Heroin
4. Transitions from heroin to fentanyl and other synthetic drugs

HELPING END
ADDICTION LONG
TERMSM (HEAL)



1. Prevent Chronic **Pain**
2. Improve Treatment of Chronic **Pain**
3. Prevent Opioid **Addiction**
4. Prevent Opioid **Overdoses**
5. Treatment of Opioid Addiction to Achieve **Recovery**

EXPAND THERAPEUTICS FOR OUD AND OD

RFA DA-19-002: Development of Medications to Prevent and Treat OUD and Overdose

Actions to Date:

- 5 cycles of reviews (since May, 2018)
- Rolling acceptance of applications
- Length of time between receipt to approval shortened from 9 months to < 2 months

Recent Actions:

February 21, 2019 – 4th cycle applications reviewed

April 1, 2019 – 5th cycle applications received

Future Plans:

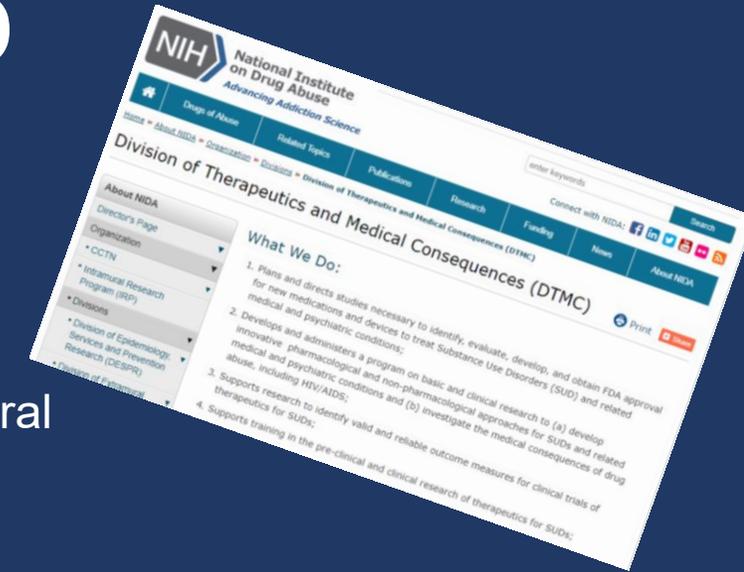
July 1, 2019 -- Next due date



NIDA will launch a new Council Workgroup Therapeutic Development for SUD

Charge:

- To provide scientific input on the current and future research portfolio for NIDA's Division of Therapeutics and Medical Consequences.
- To provide input on the development of medications and devices to treat SUD and review concepts and recommend emerging pharmacotherapies, behavioral therapies and devices to treat SUD.



Chair: Kalpana M. Merchant, Ph.D.
Chief Scientific Officer
Vincere Biosciences, Inc.

David McKinzie, Ph.D.

Professor

Pharmacology & Toxicology

Director

Behavioral Phenotyping Core

Indiana University School of Medicine

Lisa Gold, Ph.D. (invited)

Consultant

Global Director (retired)

Scientific Affairs-Neuroscience

Merck

Chris Schmidt, Ph.D.

Research Fellow (retired)

Pfizer

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

CONSENSUS STUDY REPORT

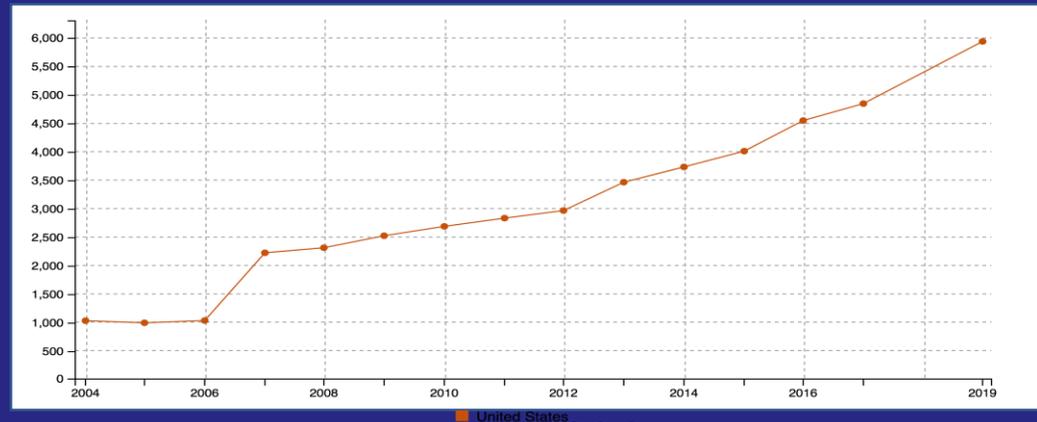
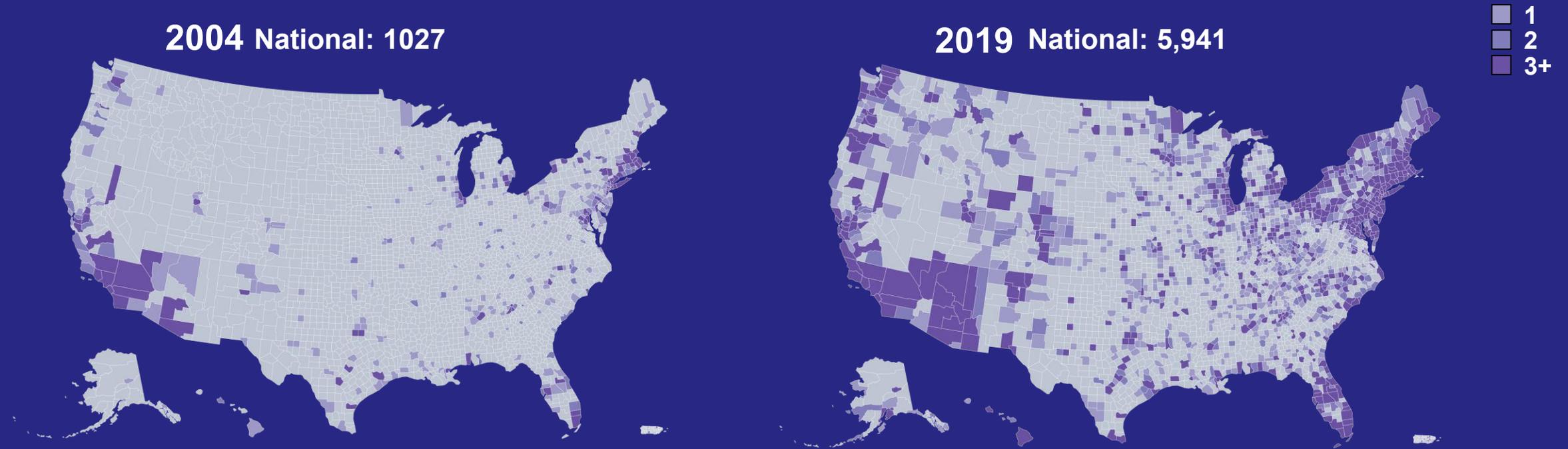
MEDICATIONS FOR OPIOID USE DISORDER SAVE LIVES

- ✓ OUD is a treatable chronic brain disease
- ✓ FDA-approved medications to treat OUD are effective and save lives
- ✓ Long-term retention on MOUD is associated with improved outcomes
- ✓ A lack of availability of behavioral interventions is not justification to withhold MOUD
- ✓ Most people who could benefit from MOUD do not receive it, and access is inequitable
- ✓ Withholding or failing to have available all classes of FDA-approved MOUD in any care or justice setting is denying appropriate medical treatment
- ✓ Confronting the major barriers to use of MOUD is critical to addressing the opioid crisis

Sponsors: National Institute on Drug Abuse (NIDA)
Substance Abuse and Mental Health Services Administration (SAMHSA)

Number Of Substance Abuse Treatment Facilities Offering Any MAT

Data Source: Substance Abuse and Mental Health Services Administration.



Historical Trends (2004 - 2019)

OPTIMIZE EFFECTIVE TREATMENT STRATEGIES: CLINICAL TRIALS NETWORK EXPANSION PROJECT



- Management Of Subsyndromal OUD (12 Million Americans Misuse Opioids; How Do We Treat Them?)
- Improving MOUD Retention (Personalizing Interventions)
- Optimal Length Of MOUD?
- Rural interventions
- Opioid registry in diverse healthcare delivery system



CTN Council Workgroup



Charge:

- Provide scientific input and recommendations for current and future research projects of NIDA's Clinical Trials Network (CTN)

Chair: Carlos del Rio, M.D.

Professor and Chair

Hubert Department of Global Health Rollins

School of Public Health

Emory University

Co-Chair: Hillary Kunins, M.D. Ph.D.

Assistant Commissioner

NYC Department of Health and Mental Hygiene

Clinical Professor

Albert Einstein College of Medicine

Barbara Cimaglio, BA

Project Director

Access to Medication-Assisted Treatment

Division of Substance Use Prevention and Recovery

Illinois Department of Human Services

Dennis McCarty, Ph.D.

Professor

Department of Public Health and Preventive Medicine

Oregon Health & Science University



OPTIMIZE EFFECTIVE TREATMENT STRATEGIES: JUSTICE AND COMMUNITY OPIOID NETWORK (JCOIN)

Reviewed

- Clinical Research Centers,
- Methodology Centers and
- Coordinating Centers

Future Plans:

- MOU with BJA to finalize **June/July 2019**
- Anticipated award dates:
 - June 15, 2019** -- MAARC/CTC
 - July 1, 2019** -- Clinical Research Centers
- Kickoff Meeting: **September 25 -27, 2019**

The HEALing Communities Study: Integrating Evidence Based interventions across Settings

Healthcare

- Primary care
- Emergency departments
- Inpatient hospital care
- Behavioral health

Criminal Justice

- Jails
- Prisons
- Parole/Probation
- Drug courts

Community

- Families
- Schools
- Police and fire departments
- Faith-based organizations
- Local industry

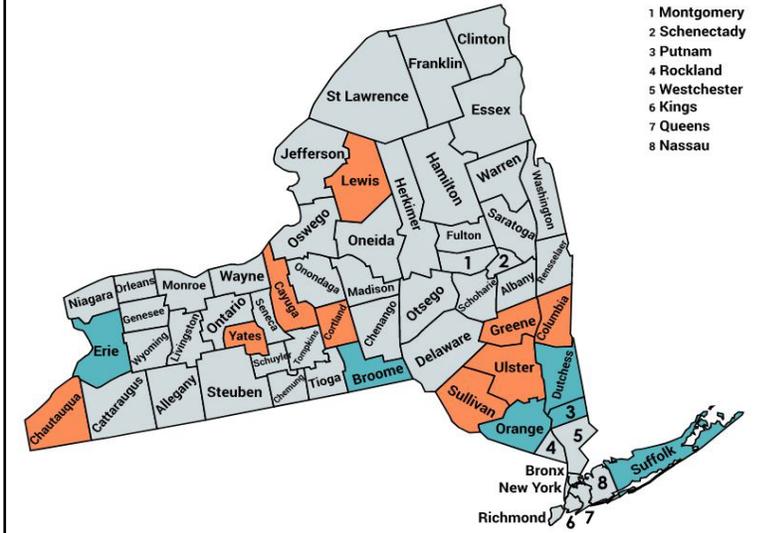


The HEALing Communities Study (HCS): Research Sites

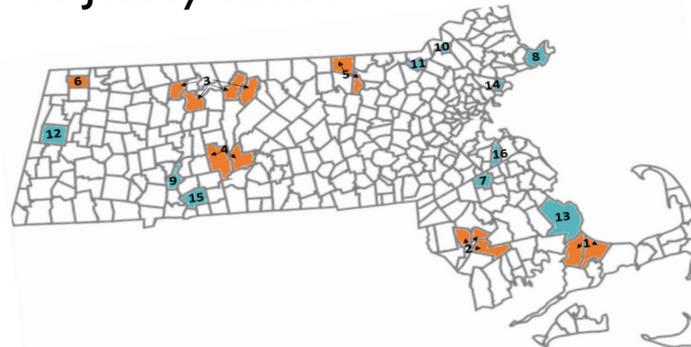
Ohio State University
PI: Rebecca Jackson



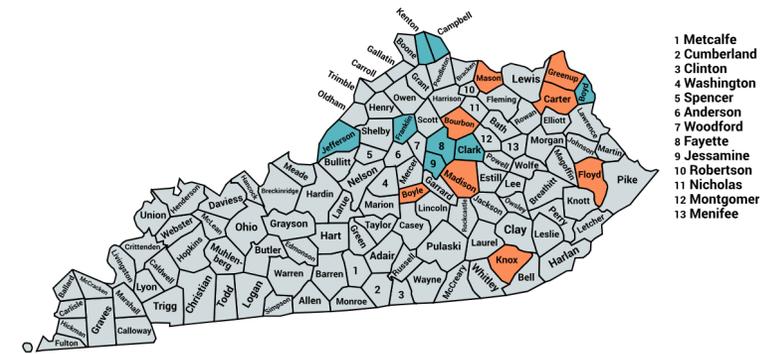
Columbia University
PI: Nabila El-Bassel



Boston Medical Center
PI: Jeffrey Samet



University of Kentucky
PI: Sharon Walsh



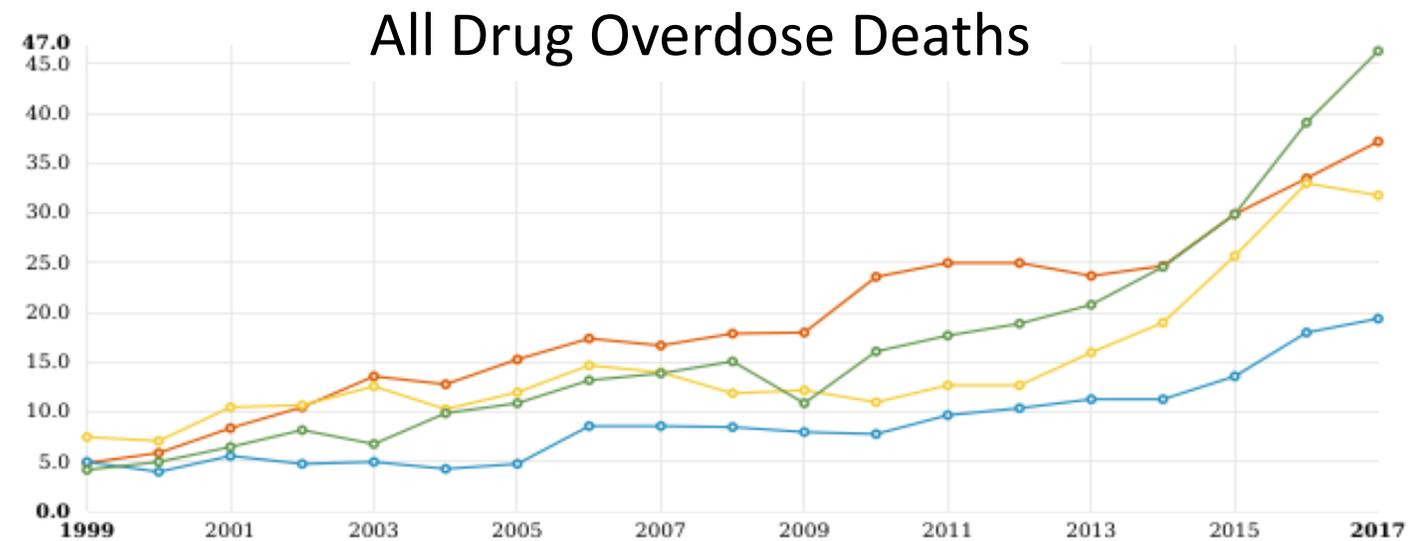
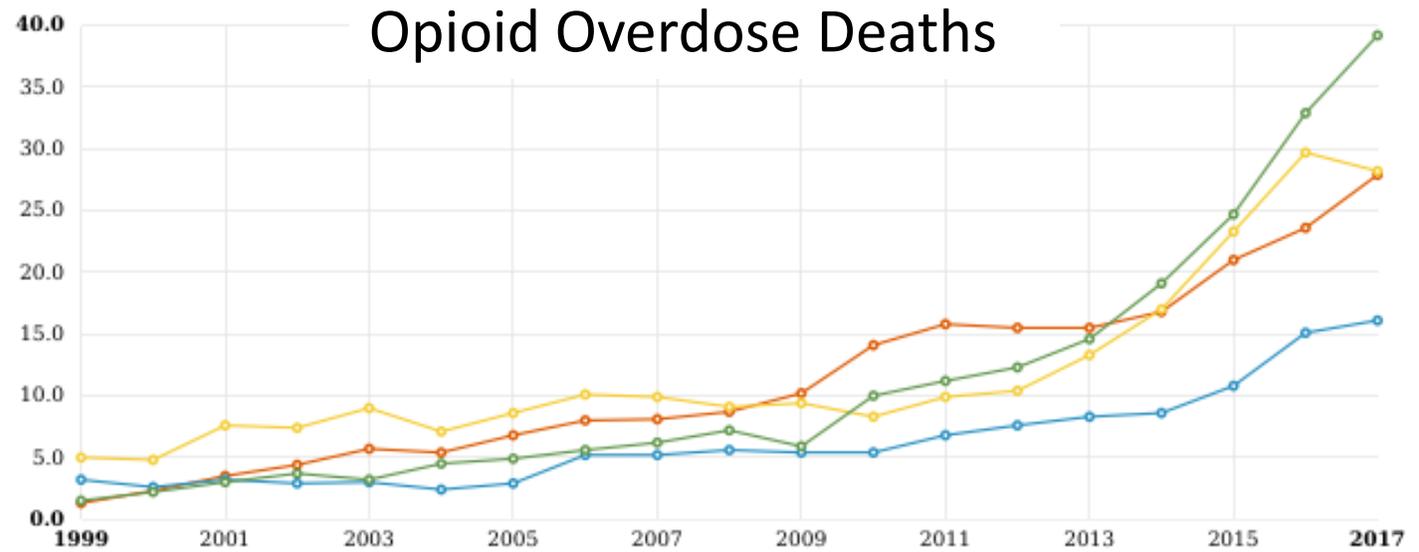
Data Coordination Center:
RTI International

Rural Communities 

Urban Communities 

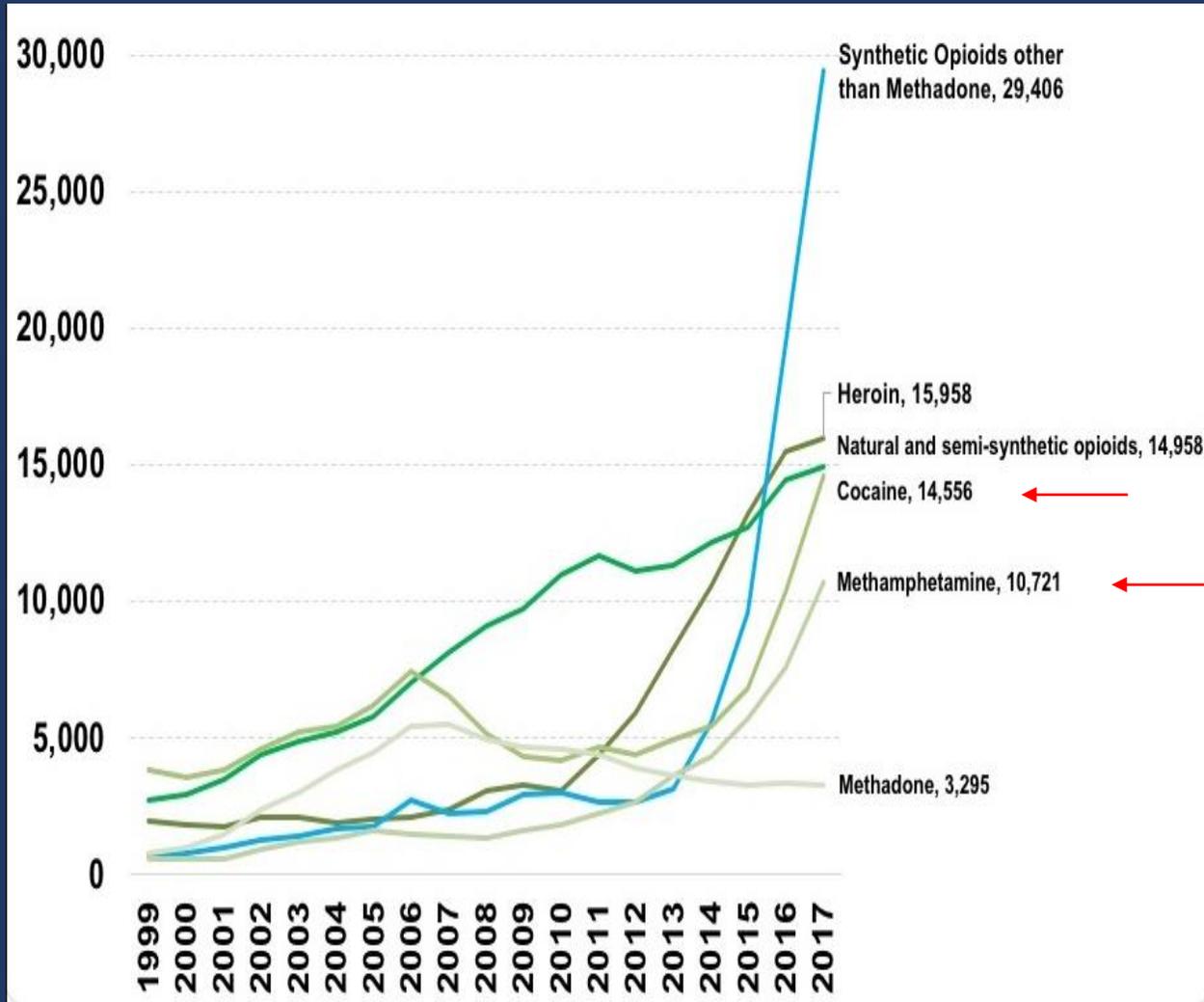
Overdose Rates per 100,000 Population (age-adjusted) in Research Site States

Source: Kaiser Family Foundation

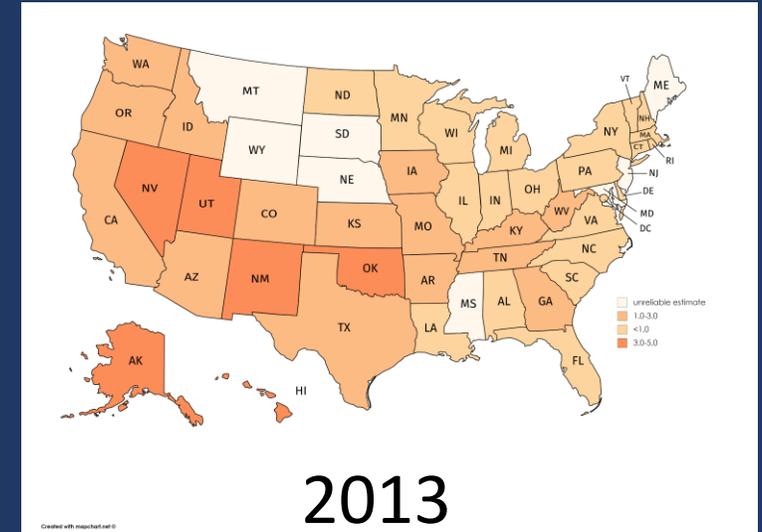


Kentucky Massachusetts New York Ohio

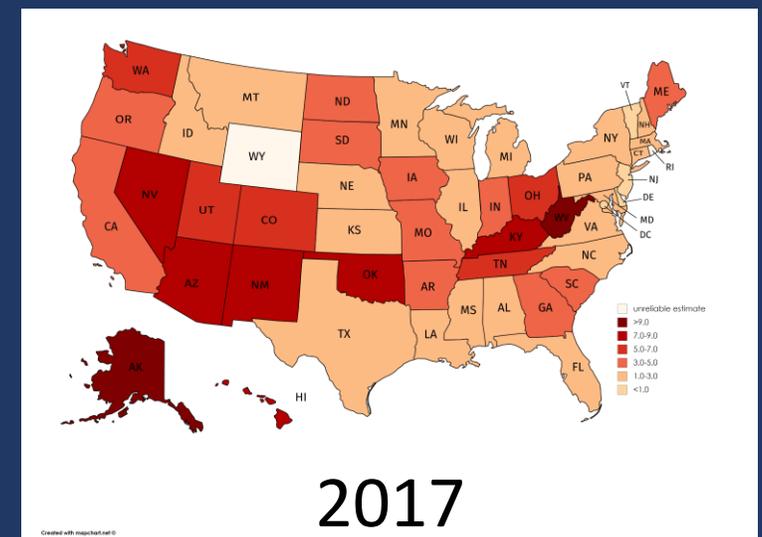
Overdose Death Rates: Psychostimulants (Including Methamphetamine)



Centers for Disease Control and Prevention

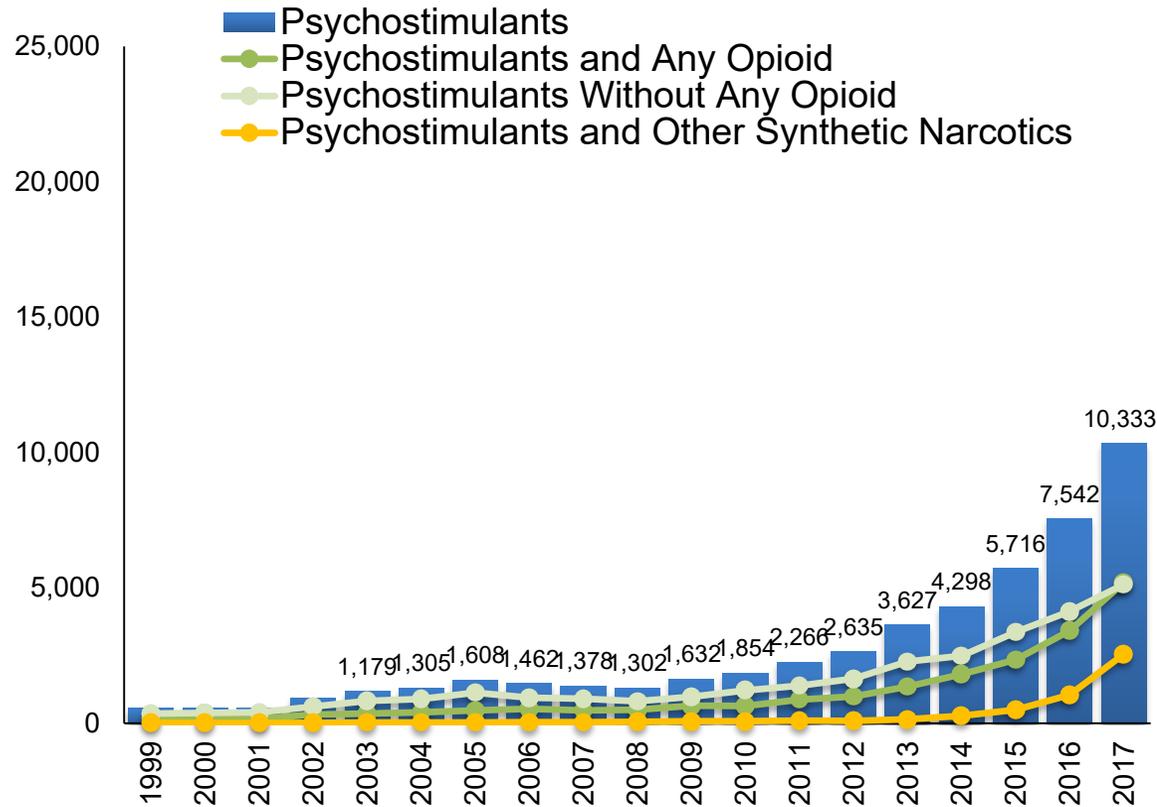


2013



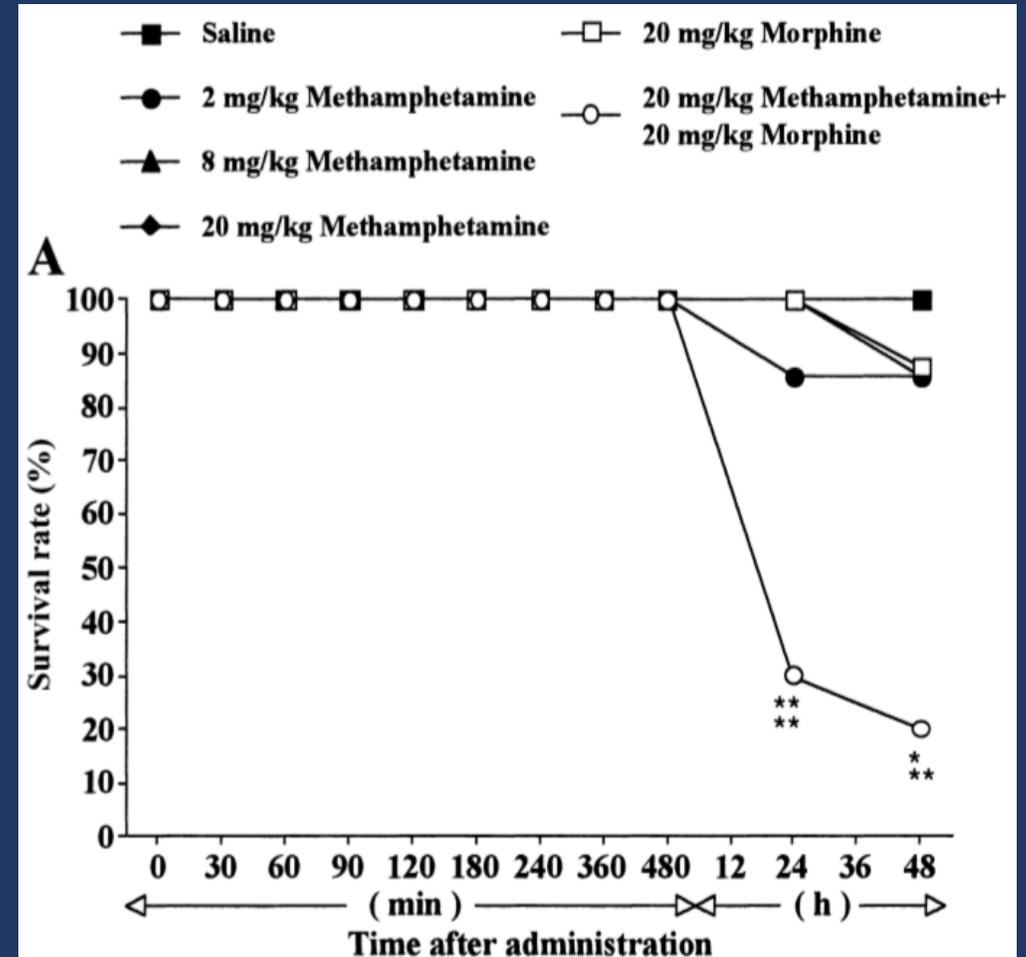
2017

Drug Overdose Deaths Involving Psychostimulants (Mainly Methamphetamine), by Opioid Involvement



Centers for Disease Control and Prevention, December, 2018.

Methamphetamine and Morphine Combination Increase Lethality >70% in Mice



Namiki et al., J Pharmacol Sci. 2005.

HIV and HCV: Another Consequence of Opioid Epidemic

 Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People™

Search

Morbidity and Mortality Weekly Report (MMWR)

CDC    

Outbreak of Human Immunodeficiency Virus Infection Among Heterosexual Persons Who Are Living Homeless and Inject Drugs — Seattle, Washington, 2018

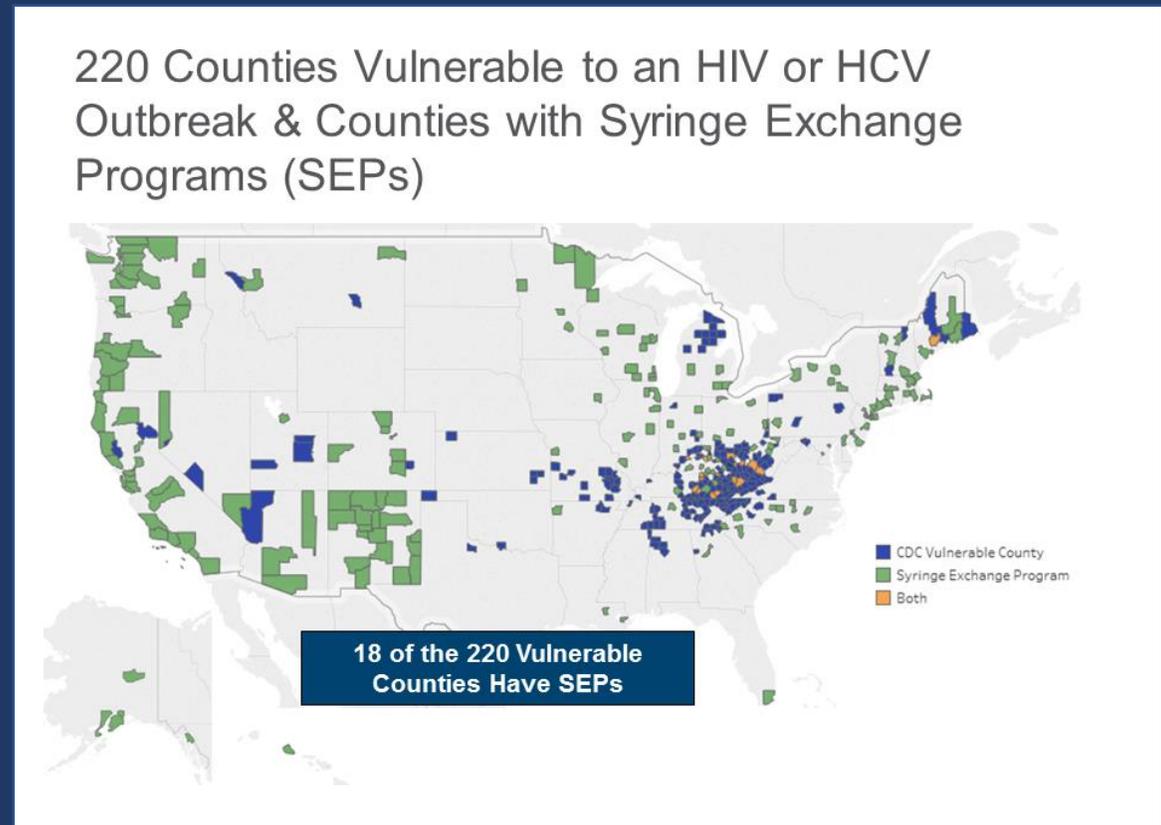
Weekly / April 19, 2019 / 68(15):344–349

Matthew R. Golden, MD^{1,2}; Richard Lechtenberg, MPH¹; Sara N. Glick, PhD^{1,2}; Julie Dombrowski, MD^{1,2}; Jeff Duchin, MD^{1,2}; Jennifer R. Reuer, MPH³; Shireesha Dhanireddy, MD²; Santiago Neme, MD²; Susan E. Buskin, PhD¹ ([View author affiliations](#))

TOP STORY

HIV cluster in Cabell County, WV, totals 44 confirmed cases, mainly among IV drug users

Apr 28, 2019

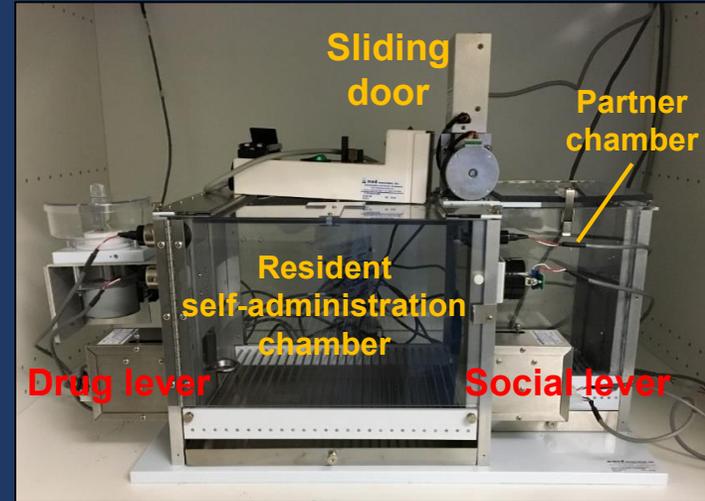


- HIV Prevention Trials Network: Approved protocol, **INTEGRA**: A Vanguard Study of Integrated Strategies for Linking Persons with OUD to Care and Prevention for Addiction, HIV, HCV, and Primary Care
- PrEP for HIV Prevention among Substance Using Populations— Approved concept
- **RFA-DA-19-003**: Molecular Regulation of Persistent HIV in Individuals with SUD

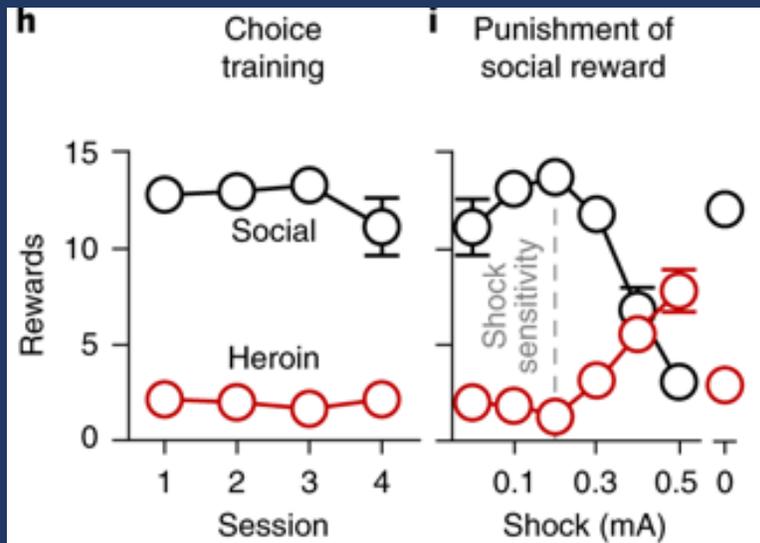
Social Interaction Preferred Over Heroin and Methamphetamine

Venniro et al., 2018

Rats given a choice, choose social interactions over Heroin or Meth but when stressed (shock) then heroin or Meth choices increase



HEROIN



METHAMPHETAMINE

