

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

February 13, 2019

Nora D. Volkow, M.D., Director



National Institute  
on Drug Abuse



@NIDAnews

# *In Memoriam*



**Dr. Herbert Kleber**  
1934-2018



**Dr. Conan Kornetsky**  
1925-2018



**Nancy J. Soulen, J.D.**  
1930-2018

# NIDA BUDGET

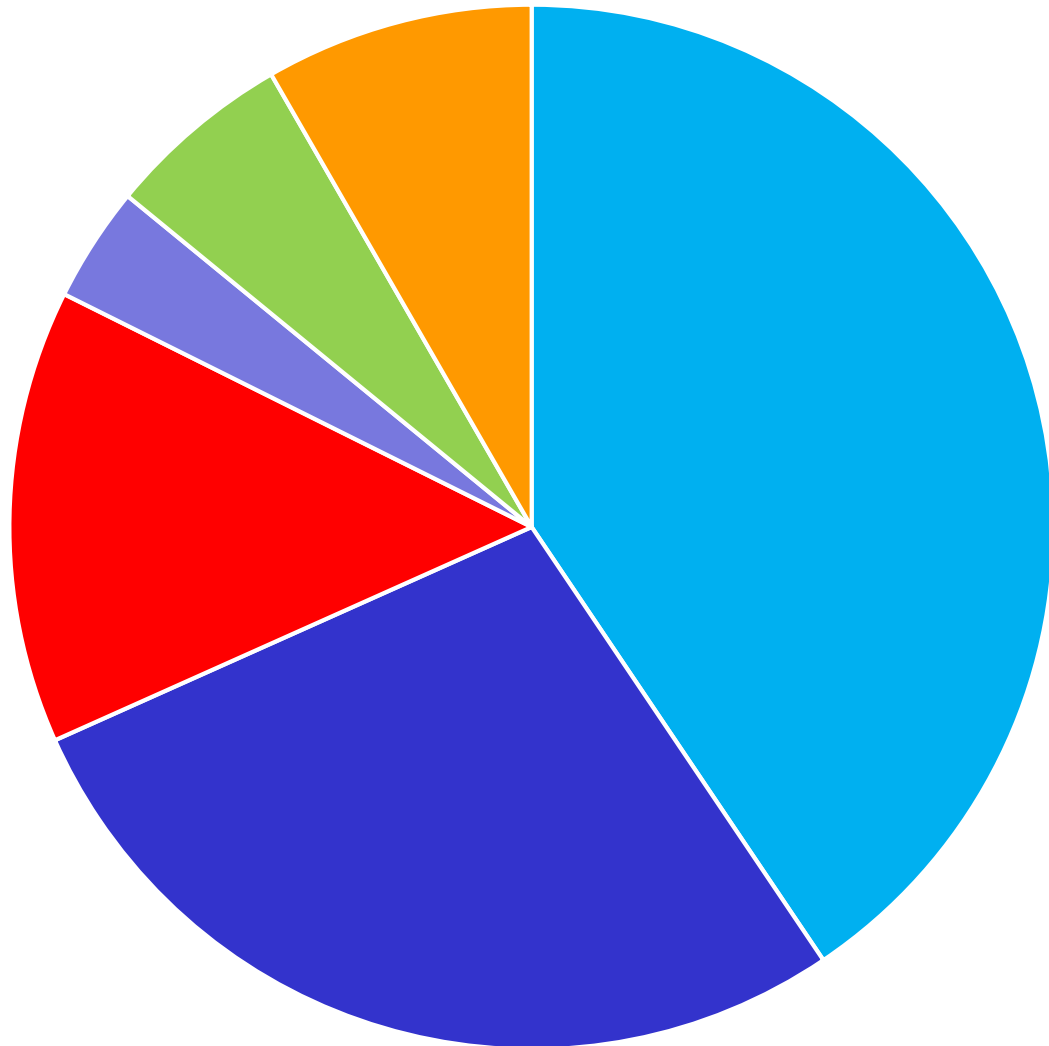
(Thousands)

	<b>FY 2017 Actuals</b>	<b>FY 2018 Budget Authority</b>	<b>FY 2019 Enacted</b>
<b>NonAIDS</b>	\$794,102	\$854,609	
<b>AIDS</b>	\$276,711	\$269,765	
<b>Total</b>	\$1,070,813	\$1,124,374	\$1,169,844
<b>Opioids</b>		\$250,000	\$250,000

# National Institute on Drug Abuse Portfolio

## Annual Appropriation

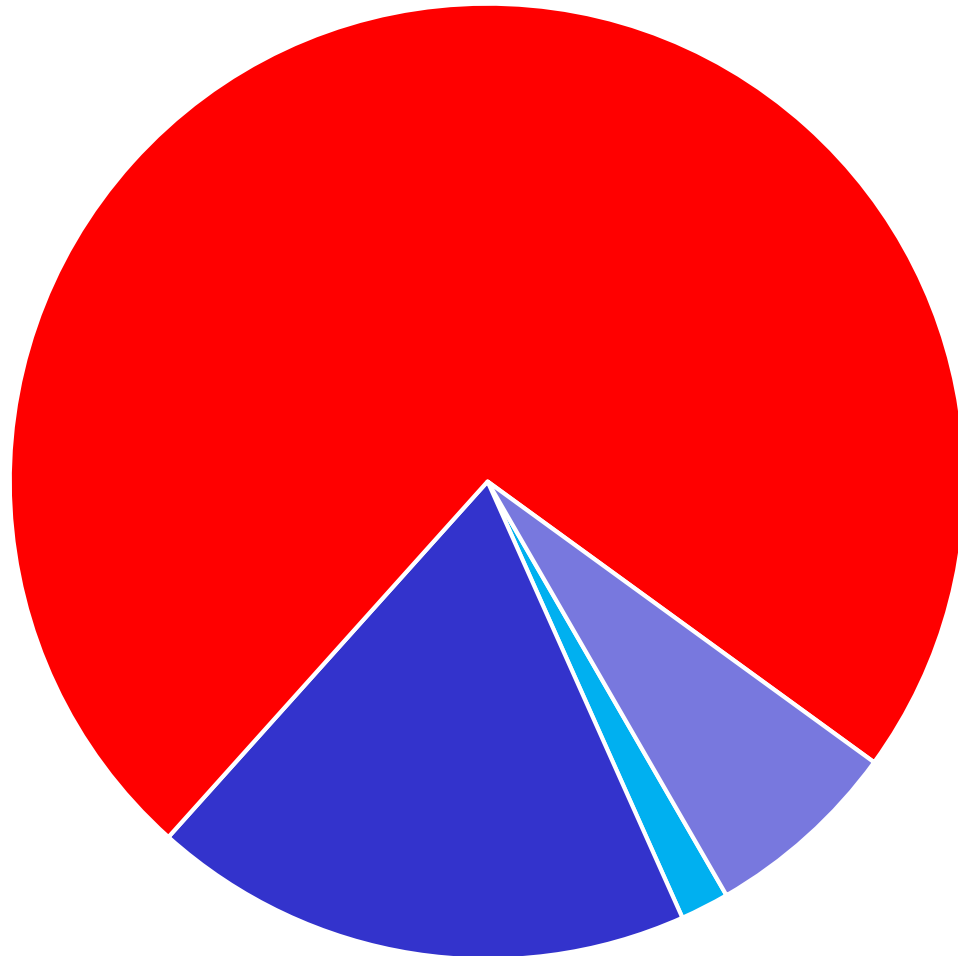
FY 2018 Actual



- Division of Neuroscience & Behavior -- 41%
- Division of Epidemiology, Services & Prevention Research -- 28%
- Division of Therapeutics and Medical Consequences -- 14%
- Center for the Clinical Trials Network -- 4%
- RMS -- 6%
- Intramural Research -- 8%

# NIDA Portfolio HEAL Opioids

(2 Year Average) -- FY 2018 Actual



- **Division of Neuroscience & Behavior**  
-- 2%
- **Division of Epidemiology, Services & Prevention Research** -- 18%
- **Division of Therapeutics and Medical Consequences** -- 73%
- **Center for the Clinical Trials Network** -- 7%



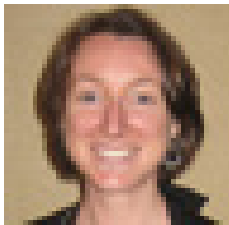
**Dr. Michelle Freund** joined NIDA to Direct the ***HEALthy Baby and Child Development (HBCD) Study***.



**Dr. Amy Goldstein** joined the Division of Epidemiology, Services and Prevention Research as ***Prevention Research Branch Chief***.



**Dr. Jennifer Hobin** joined the ***Office of Science Policy and Communications as the Deputy Director*** in October 2018.

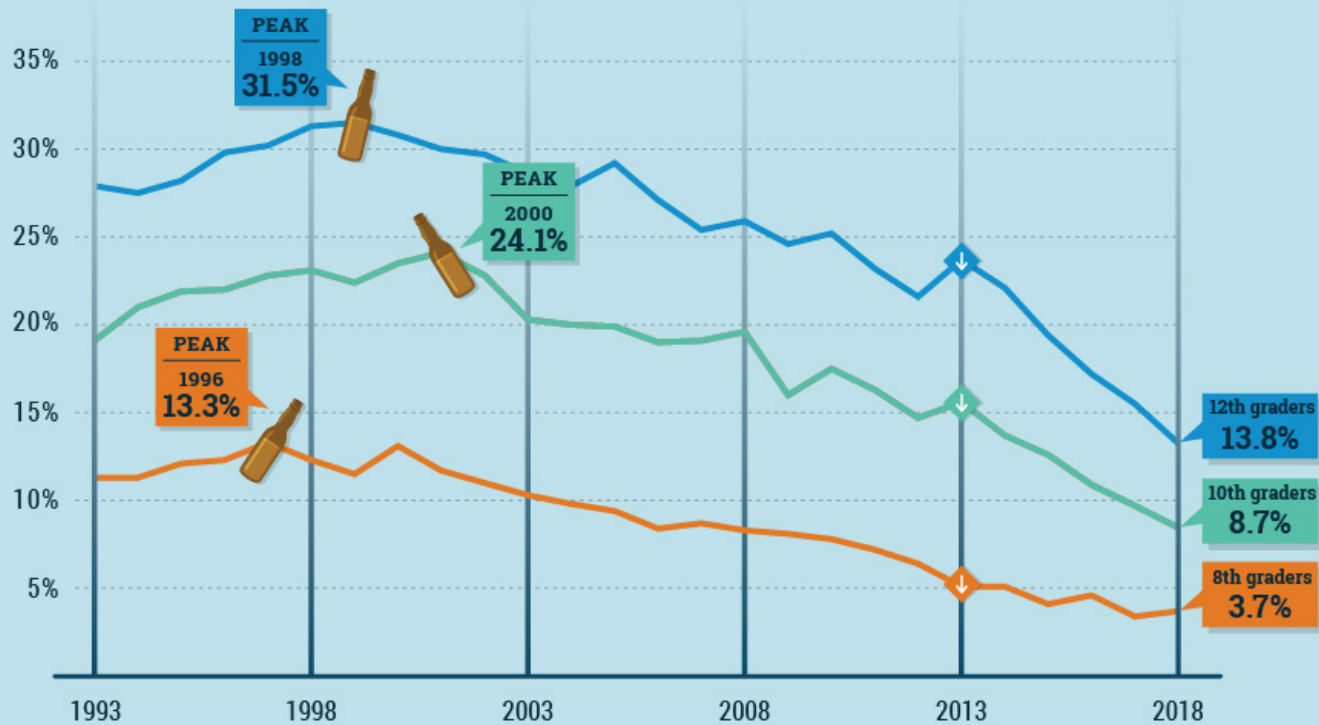


**Dr. Jennifer Villani** joined NIDA to serve as the ***Associate Director for the HEALing Communities Study***.



**Dr. Tisha Wiley** was selected as the SRB Branch Chief in DESPR and will be leading NIDA's ***Justice Community Opioid Innovation Network (JCOIN)***.

# BINGE DRINKING\* RATES CONTINUE DOWNWARD TREND

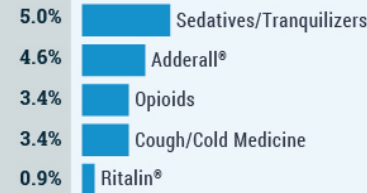


\*Binge drinking is defined as having 5 or more drinks in a row in the last 2 weeks.

**BINGE DRINKING: SIGNIFICANT DROP IN PAST FIVE YEARS ACROSS ALL GRADES.**

# PAST-YEAR MISUSE OF PRESCRIPTION/OVER-THE-COUNTER VS. ILLICIT DRUGS

## PRESCRIPTION/OTC

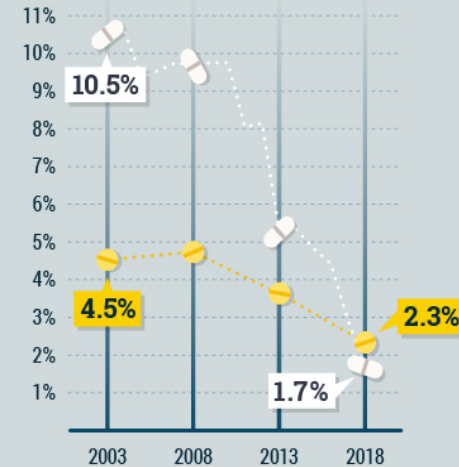


## ILLICIT DRUGS



Past-year use among 12th graders

## VICODIN® VS. OXYCONTIN®



Past-year misuse of Vicodin® and OxyContin® among 12th graders has dropped dramatically in the past 15 years.

KEY  
 Vicodin®  
 OxyContin®

## STUDENTS REPORT LOWEST RATES SINCE START OF THE SURVEY

Across all grades, past-year use of illicit drugs other than marijuana holding steady at the lowest levels in over 20 years.

\*Synthetic cannabinoids are called "synthetic marijuana" in the survey.



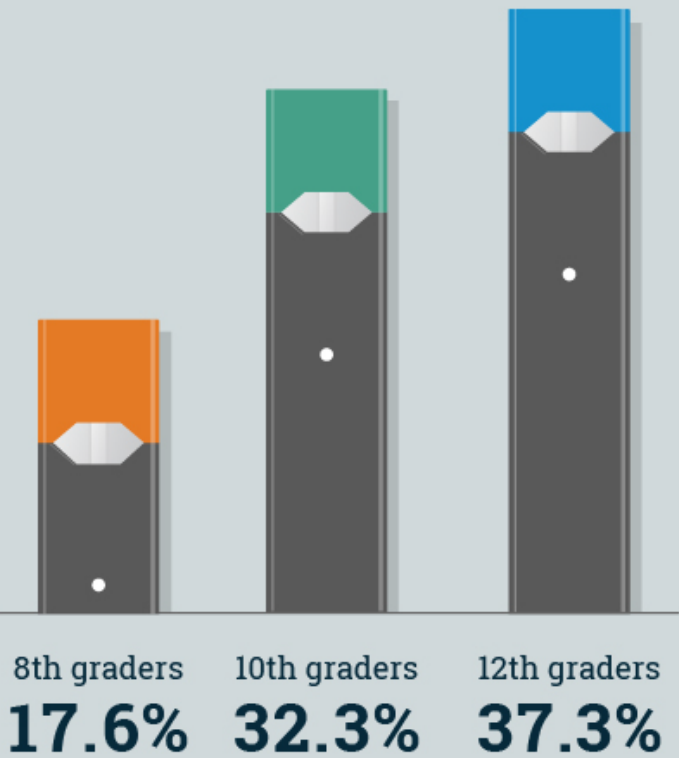
DRUGABUSE.GOV



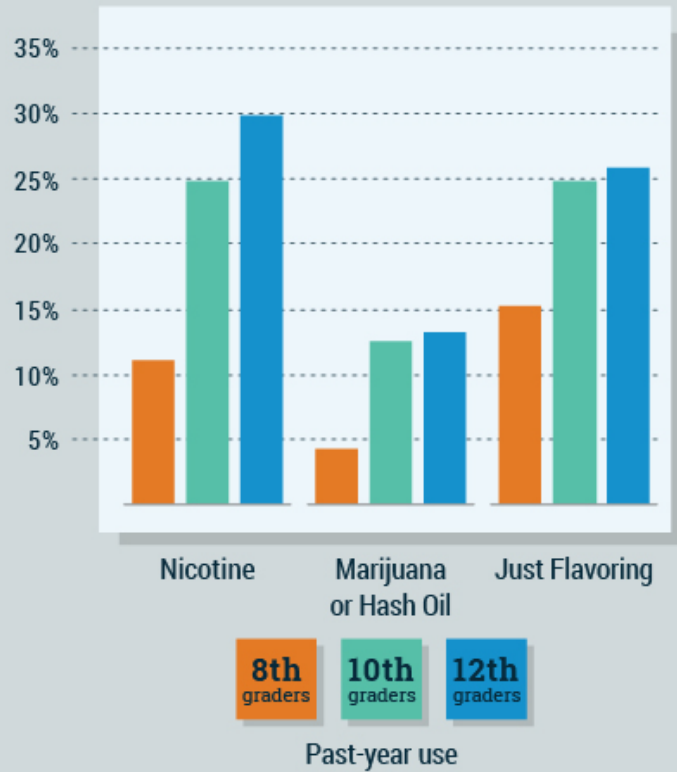
DRUGABUSE.GOV

# TEENS USING VAPING DEVICES IN RECORD NUMBERS

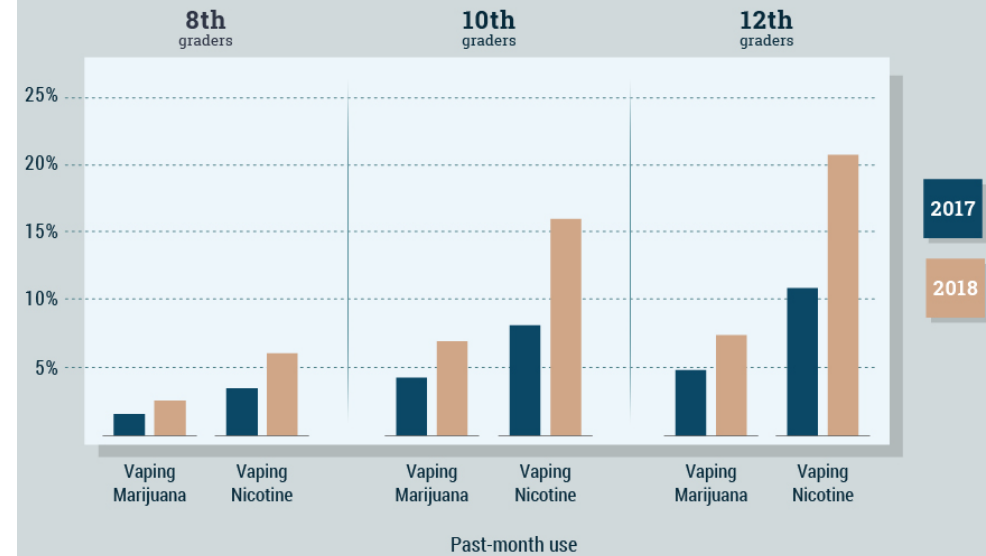
## PAST-YEAR VAPING



## WHAT DO TEENS SAY THEY ARE VAPING?



## TEENS VAPING NICOTINE OR MARIJUANA INCREASED ACROSS ALL GRADES



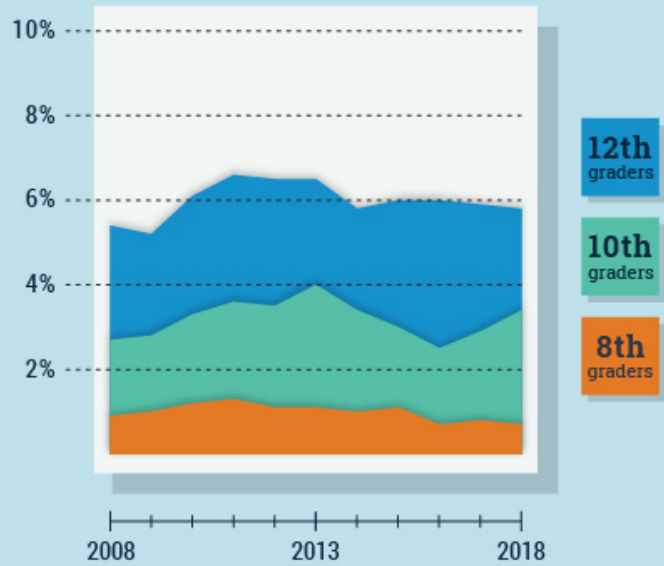
PAST-MONTH VAPING OF NICOTINE OR MARIJUANA JUMPED ACROSS ALL GRADES. PAST-MONTH USE OF MARIJUANA IS STEADY AS CIGARETTE USE DECLINES.

NEARLY 2 IN 5 STUDENTS IN 12TH GRADE REPORT PAST-YEAR VAPING, RAISING CONCERNS ABOUT THE IMPACT ON BRAIN HEALTH AND POTENTIAL FOR ADDICTION.

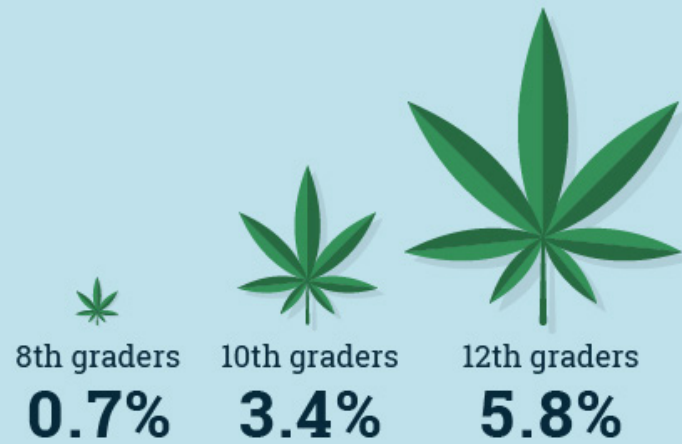


## DAILY MARIJUANA USE MOSTLY STEADY

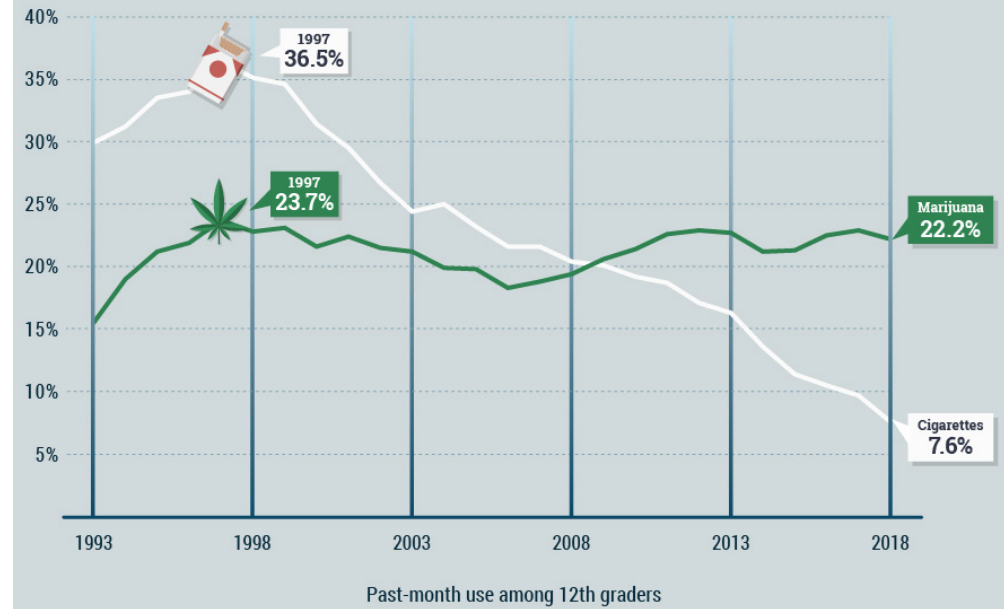
2008 – 2018



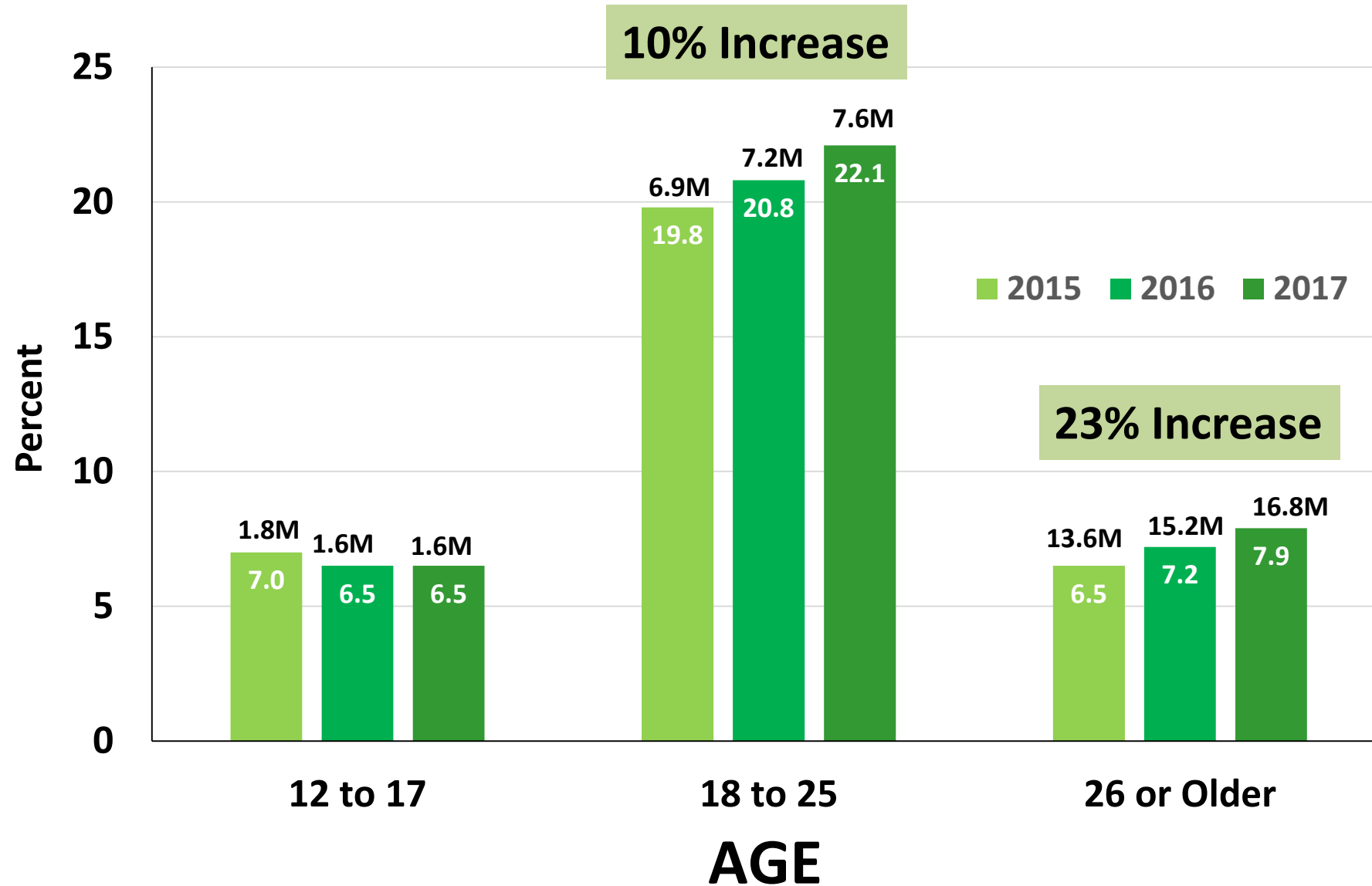
2018



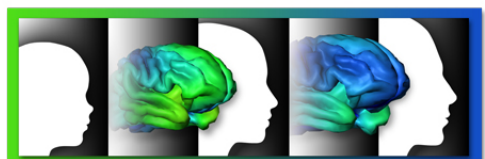
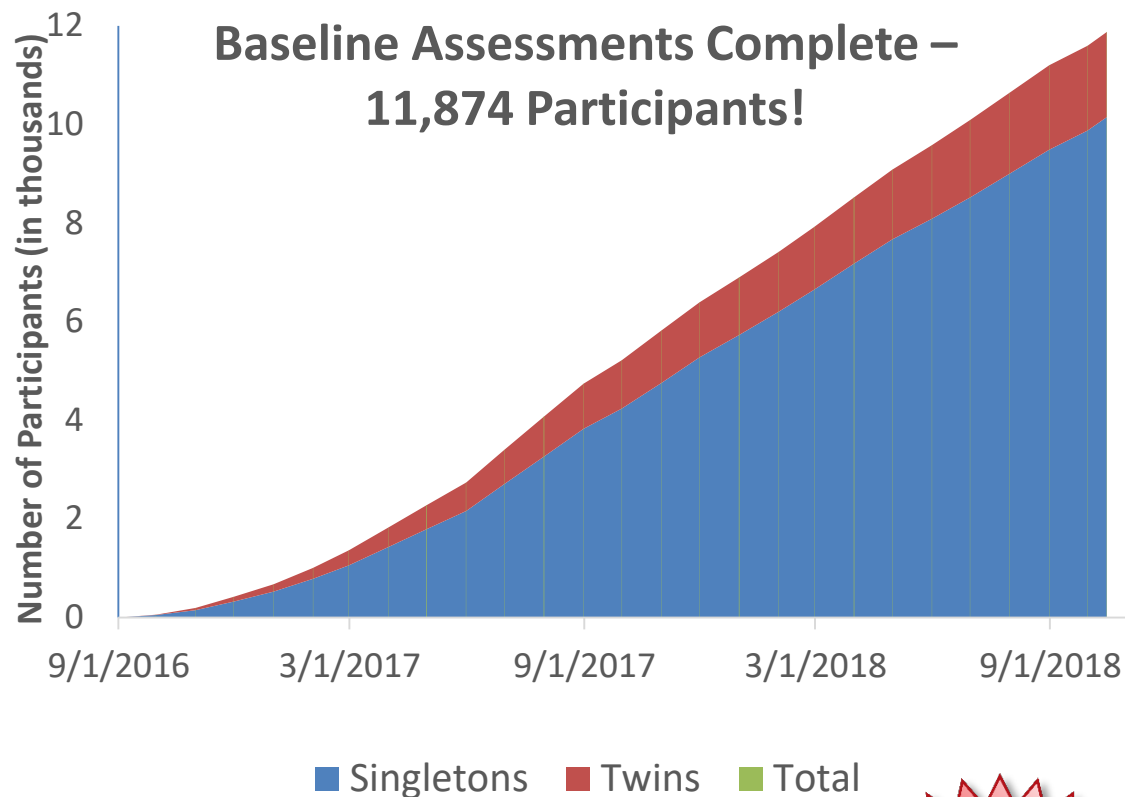
## TEENS MORE LIKELY TO USE MARIJUANA THAN CIGARETTES



# Past Month Marijuana Use in 2015, 2016 and 2017



# Adolescent Brain Cognitive Development (ABCD) Study



Adolescent Brain Cognitive Development®  
Teen Brains. Today's Science. Brighter Future.



## ABCD Study Fast Track Neuroimaging Data

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

DICOM images from ~9,000 participants currently available.

## Interim Curated Data Release

Data on the first 4,500 participants was released in February 2018, 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),
- Residential history derived data (e.g., crime, area deprivation index, walkability, population density, pollution)

## Full Baseline Curated Data Release

Expected Spring 2019

## 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.

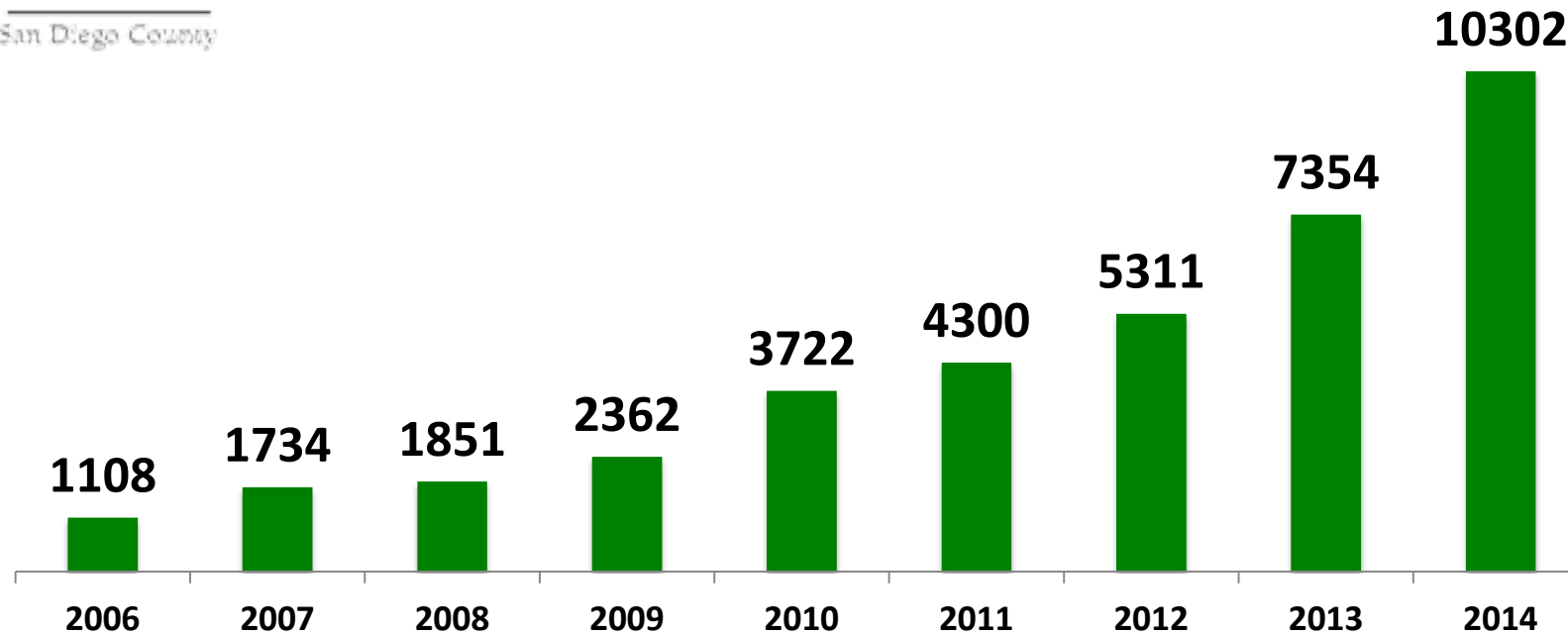
# ED Visits for Cannabis



**MPI**  
Marijuana  
Prevention  
Initiative  
San Diego County

Emergency Department Visits with  
Cannabis Related Diagnosis  
San Diego County

**Up 830%**



The Center for Community Research prepared this analysis for the San Diego County Marijuana Prevention Initiative with data from the California Department of Public Health, March 2016. [mpisdcounty.net](http://mpisdcounty.net)

# Efficacy and safety of fatty acid amide hydrolase inhibitor (PF-04457845) for treatment of cannabis withdrawal and dependence: phase 2a RCT

Self-reported [cannabis](#) use week 4

Urinary THC-COOH levels week 4

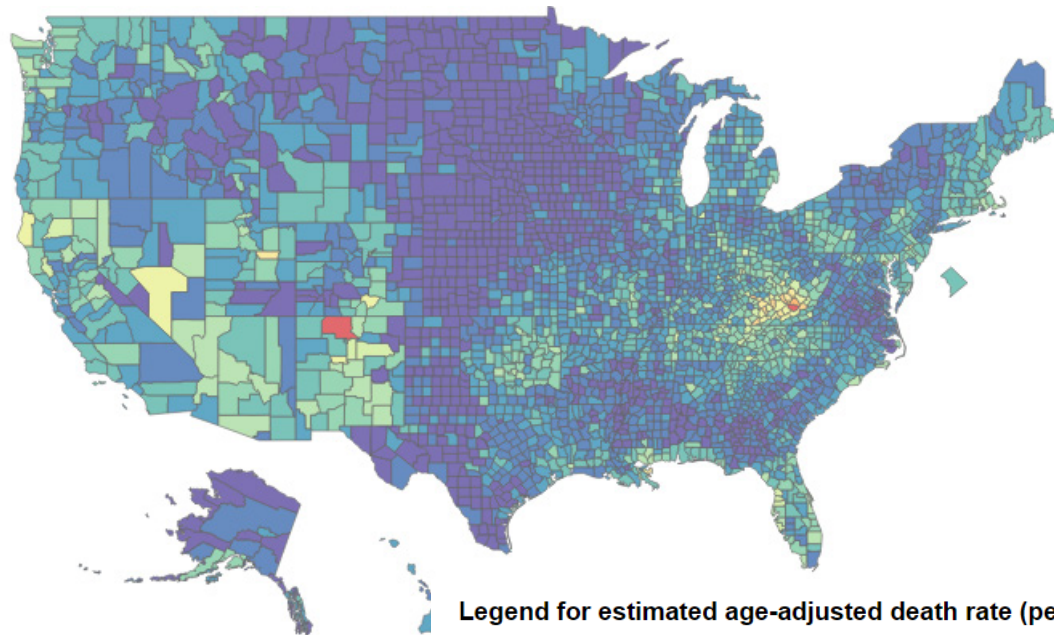
	<b>Cannabis use (joints day)</b>	<b>Difference (95% CI)</b>	<b>p value</b>	<b>Urine levels THC-COOH (ng/mL)</b>	<b>Difference (95% CI)</b>	<b>p value</b>
Placebo (n=19)	1.27 (0.82 to 1.97)	0.88 (0.29 to 1.46)	0.0003	657.9 (381.6 to 1134.30)	392.37 (17.5 to 767.18)	0.009
PF-04457845 (n=32)	0.40 (0.25 to 0.62)	..	..	265.5 (175.6 to 401.5)	..	..

This 4-week RCT showed that treatment with the FAAH inhibitor (PF-04457845 4 mg q/d) reduced cannabis withdrawal symptoms, self-reported cannabis use, urinary THC-COOH concentrations, and deficits in stage N3 sleep and was well tolerated.

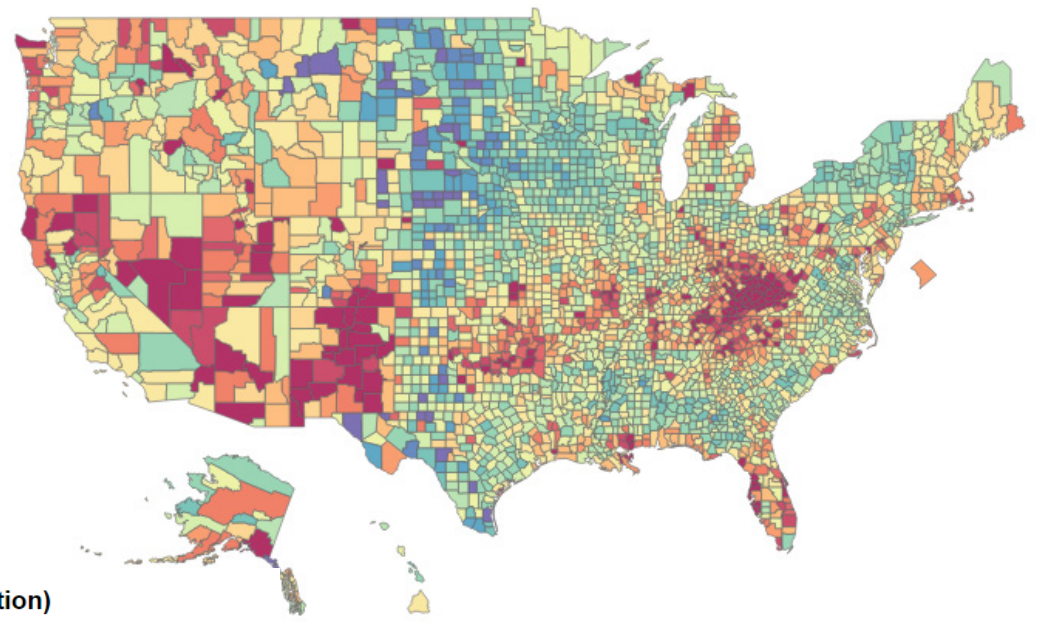
# The Crisis: National Overdose Death Rates

In **2017**, there were **70,237** overdose deaths (9.6% higher than 2016)

1999



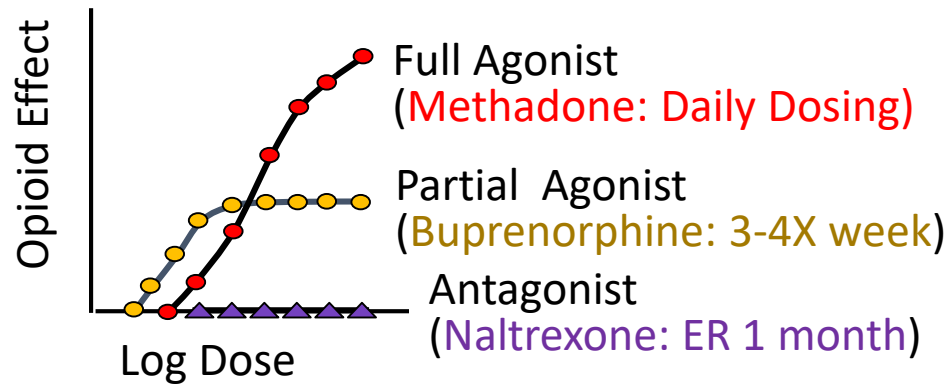
2016



Legend for estimated age-adjusted death rate (per 100,000 population)



# Medication Assisted Treatment (MAT)



## DECREASES:

- Opioid use
- Opioid-related overdose deaths
- Criminal activity
- Infectious disease transmission

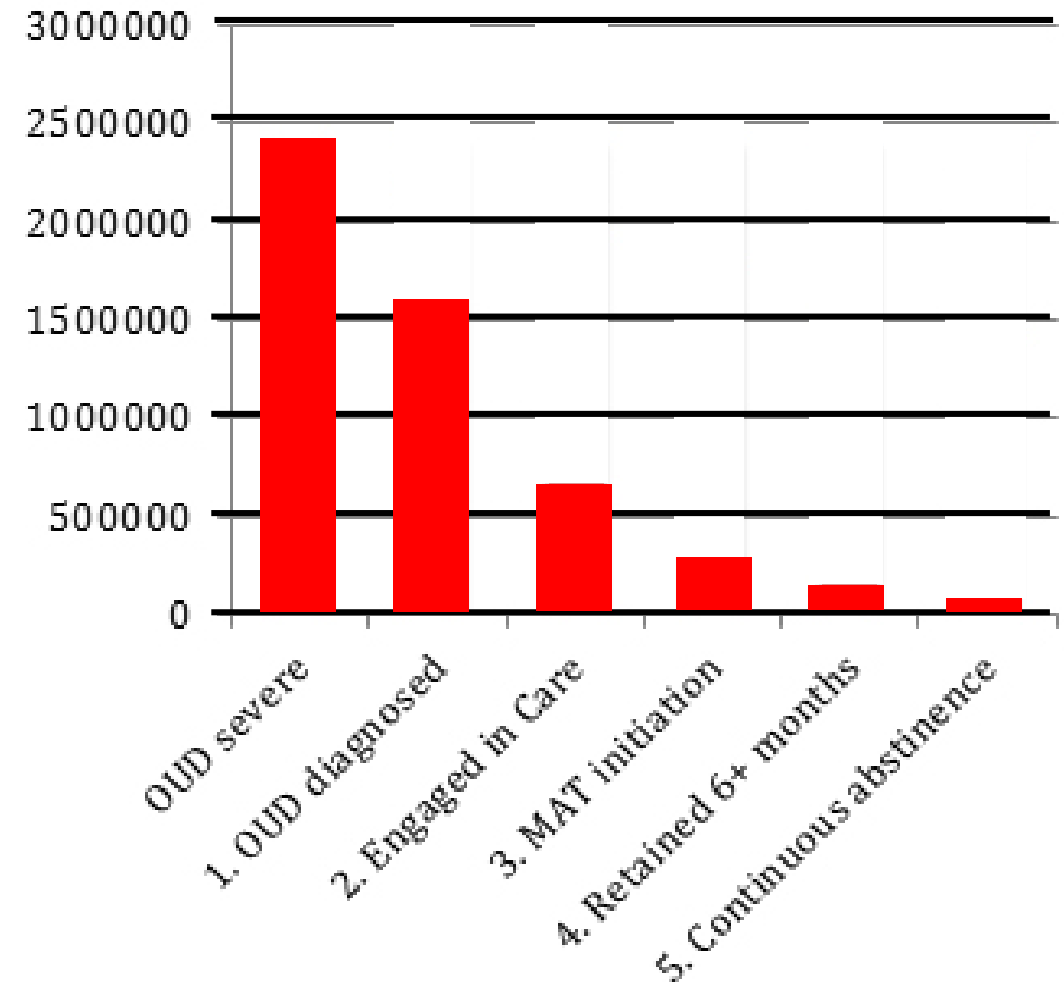
## INCREASES

- Social functioning
- Retention in treatment

**MAT is highly underutilized!**

**Relapse rates are very high (50% in 6 months)**

## OUD Cascade of Care in USA



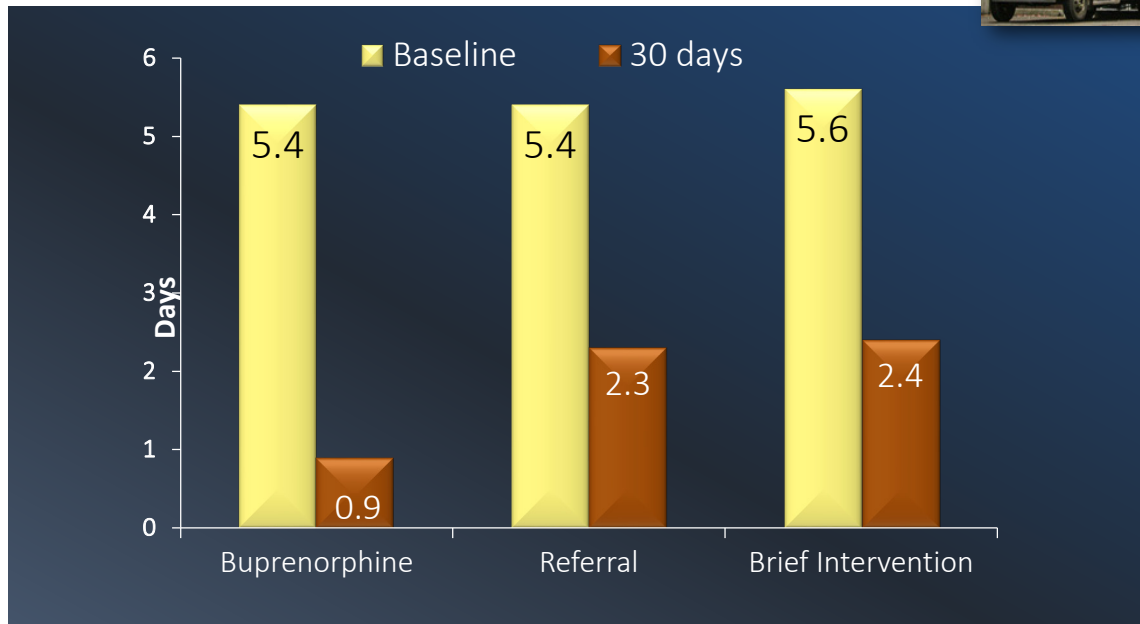
# Implementing Medications for OUD in Healthcare



- ED-initiated buprenorphine
  - Reduced illicit opioid use
  - Increased treatment retention
  - Decreased inpatient treatment



Self-Reported Illicit Opioid Use in the Past 7 Days

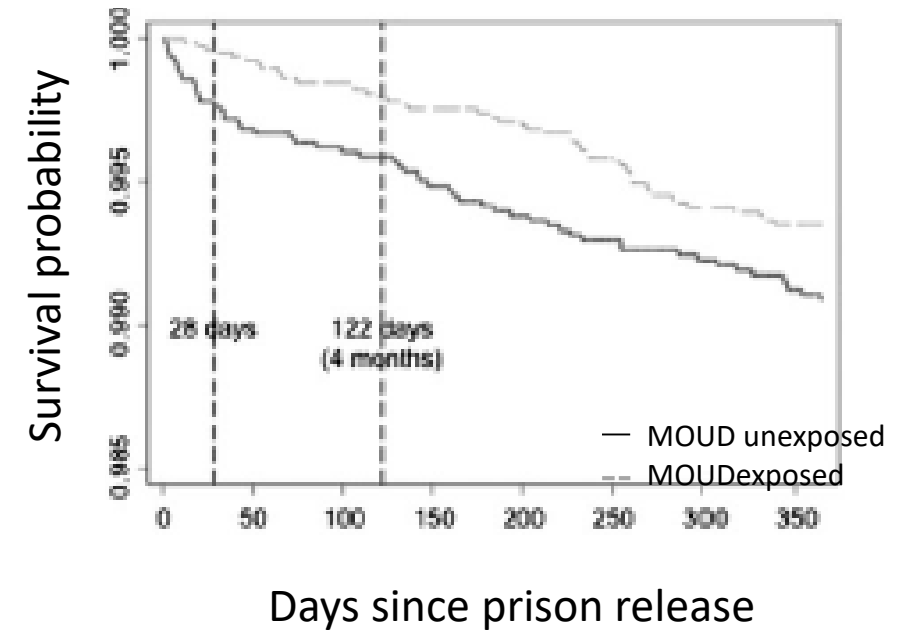


*D'Onofrio G et al., JAMA April 28, 2015.*

# Implementing Medications for OUD in Justice Settings



Survival Curve During the Year Following Release (Drug-Poisoning Mortality)



MOUD reduced mortality by 75% in the first month post release

*Marsden J et al., Addiction 2017; 112:1408-1418.*

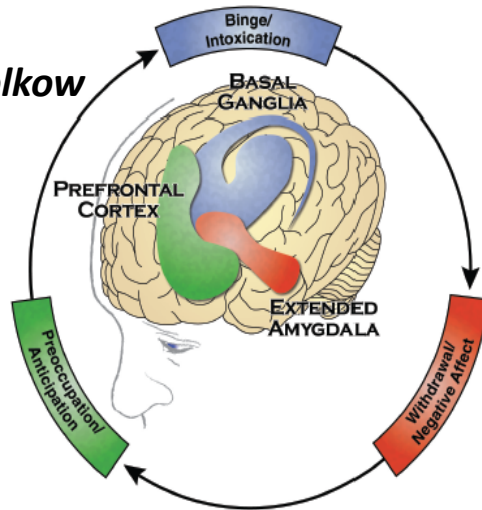


# Expand Therapeutic Options: Novel Treatments

## Neuromodulation

### Addiction Cycle and Relevant Brain Regions

Koob and Volkow  
2017



Transcranial  
Magnetic  
Stimulation  
(TMS)



Transcranial Direct  
Current Stimulation  
tDCS)

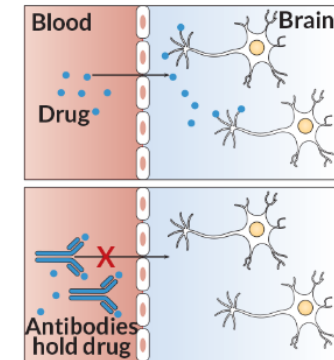
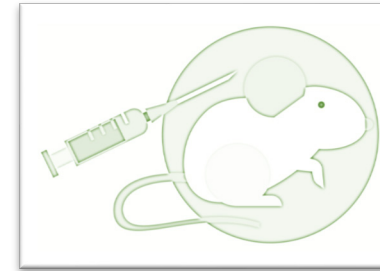


Deep Brain  
Stimulation (DBS)

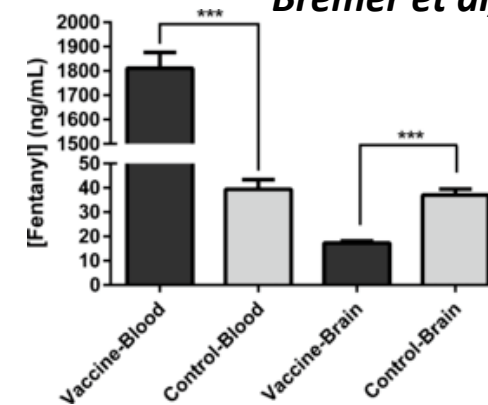


## Vaccines and Immunotherapies

- Vaccines (fentanyl (and analogues), heroin/morphine)
- Reduced drug reaching brain
- Protection against overdose



Bremer et al, 2016; Janda and Treweek, 2012



# Improving Prevention and Treatment for Opioid Misuse, Addiction and Overdoses

## *Priority Research Areas:*

*Expand Therapeutic Options*

*Optimize Effective Treatment Strategies*

*Develop New/Improved Prevention & Treatment Strategies*

*Enhance Treatments for Infants with NAS/NOWS*

## *Research Opportunities:*

- New formulations
- Longer duration
- Respiratory depression
- Immunotherapy
- New targets and approaches

- Clinical trials expansion
- Criminal justice innovation
- Collaborative care
- Behavioral interventions
- Multi-site implementation (HEALing Communities Study)

- Treatment of Early/moderate OUD
- Optimal length of MOUD Treatment
- Prevention in Transition to adulthood

- Brain development of opioid-exposed infants
- ACT NOW

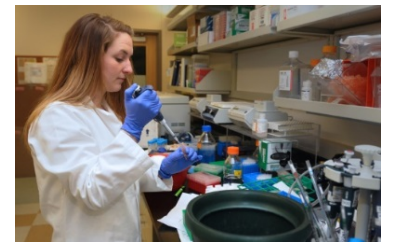
# Expand Therapeutic Options: OUD and Overdose Reversal

- New Targets for OUD
- Drug combinations to improve retention (lofexidine + Bup)
- Stronger, longer acting formulations and new targets for OD from synthetic opioids (e.g. fentanyl) and drug combinations (bdz + opioids)
- Stimulation devices to prevent respiratory depression
- OD, alert technologies and naloxone autoinjectors
- *Post-overdose interventions to ensure engagement in treatment*



## New Medication Outcomes

- Craving,
- Insomnia,
- Depression



# Medications Development Research Project

- ***RFA DA-19-002: Development of Medications to Prevent and Treat Opioid Use Disorders and Overdose*** (Contact PO: Ivan Montoya)
  - 4 cycles of reviews (since May, 2018)
  - 103 applications reviewed
  - 22 applications approved for funding
  - Rolling acceptance of applications
  - Length of time between application receipt to approval for funding has been shortened from 9 months to < 2 months

# CTN OUD Expansion Project

## RFA-DA-19-008 – The National Drug Abuse Treatment Clinical Trials Network (UG1 Clinical Trial Optional) – Review March 18, 2019

Expand CTN to 1) increase scientific and clinical research capabilities, and 2) better cover geographic regions most impacted by epidemic

- Optimizing Retention, Duration and Discontinuation Strategies for OUD medications (MOUD) in healthcare
- Strategies for *inducting* MOUD in hospitalized patients and *enhancing* post-discharge care
  - More effective linkage models (Bridge clinics)
- *Implement ED-initiated BUP* in multiple EDs and compare BUP-SL and BUP-XR
- *Rural expansion* of MOUD treatment using *telemedicine* and *mHealth approaches*.
- *Opioid registry* in diverse health care delivery systems
- Efficacy of “*Subthreshold OUD Prevention (STOP)*” intervention in primary care
- Compare BUP-XR, BUP-SL on *OUD expecting Mothers* on infant outcomes.
- *Surmounting naltrexone (NTX) induction hurdle*

# NIDA will launch a new **Council Workgroup**

## ***Charge:***

- To provide external scientific input and recommendations for current and future research projects of NIDA's National Drug Abuse Treatment Clinical Trials Network (CTN)
- To provide annual updates to Council on CTN initiatives

***Chair:*** Carlos del Rio, M.D.  
Emory University

***Co-Chair:*** Hillary Kunins, M.D. Ph.D. (*invited*)  
NYC Department of Health  
and Mental Hygiene  
Albert Einstein College of Medicine



# Justice Community Opioid Innovation Network (JCOIN) Update

## *Progress to Date:*

- 11 supplement awards made in September 2018
- Solicitations released December 10, 2018 for Research Centers, Coordination and Translation Center, and Methodology and Analytics Center
- Expected awards total **\$30M**
- Technical Assistance webinar held January 9, 2019
- Applications Due: February 27, 2019
- Review: Summer 2019
- Awards expected: *Late Summer/Early Fall 2019*

# The HEALing Communities Study: *Goals*

- Develop and test strategies to help communities respond rapidly and effectively to opioid crisis with a focus on achieving 40% reduction in 3 years for OD fatalities and improving other outcomes
- Measure impact of integrating evidence-based prevention and treatment for opioid misuse, OUD, OD, and OD fatalities across multiple settings (healthcare, behavioral health, justice, communities.)
- Determine factors (structural, organizational, policy, etc.) that contribute to successful implementation and sustainability of the integrated interventions
- Determine cost-effectiveness of integrated intervention compared to standard of care



# The HEALing Communities Study: *Actions to Date*

- Application receipt date: December 4, 2018
- Research Site application in-person review: January 30-31, 2019
- Data Coordinating Center in-person review: February 20, 2019
- Research Site application site visits: February 25-March 15, 2019
- Earliest estimated award date: April 19, 2019

# HEALthy Brain and Child Development (HBCD) Study

Large multi-site longitudinal study to examine brain, cognitive, behavioral, social, and emotional development beginning *prenatally* and extending through *childhood*.

- Oversample for prenatal opioid exposure
- Progress to Date:
  - Expert Panel Meeting on Research Methodologies – September 24, 2018
  - Expert Panel Meeting to Discuss Study Design – October 22, 2018
  - R34 Planning Grant Funding Opportunity Announcements - RFA-DA-19-029; RFA-DA-19-036
    - Published – December 21, 2018
    - Pre-application webinar – February 6, 2019
    - Application deadline – March 25, 2019
    - Review – June/July 2019
    - Earliest start date – September 2019



# HEAL Prevention Initiative: Preventing OUD in Older Adolescents and Young Adults (ages 16 –30)

**Goal:** Develop the evidence base for interventions and strategies to prevent initiation of opioid misuse and development of OUD in at-risk older adolescents and young adults

**Focus on:**

Healthcare, justice and other systems and settings opportune for accessing and engaging at risk adolescents and young adults

**Components:**

**HEAL Prevention Cooperative** – up to 10 research projects and 1 coordinating center.

Two FOAs published:

- UG3/UH3 Research Projects (RFA-DA-19-035)
- U24 Coordinating Center (RFA-DA-19-034)
- Application due – 3/13, 2019;
- Review – Summer 2019
- Earliest start date – 10/2019

**Administrative Supplements**

- Application due date: February 1
- Next steps: **Internal review**

# Priority Areas

## Prevention Research

(Children & Adolescents)  
genetics/epigenetics  
development  
environment  
co-morbidity

## Treatment Interventions

(New Targets & New Strategies)

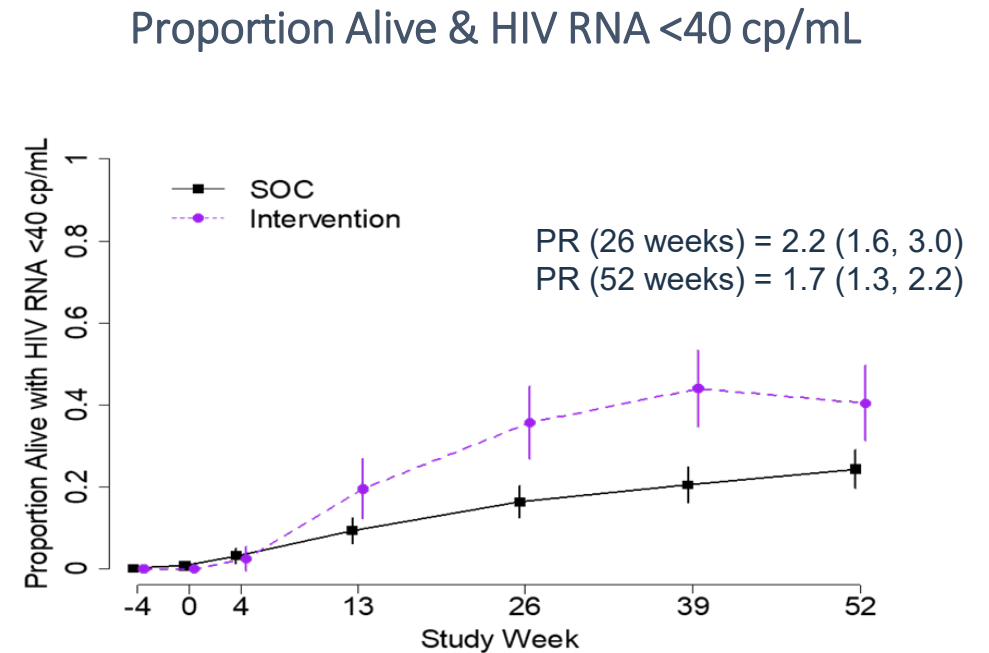
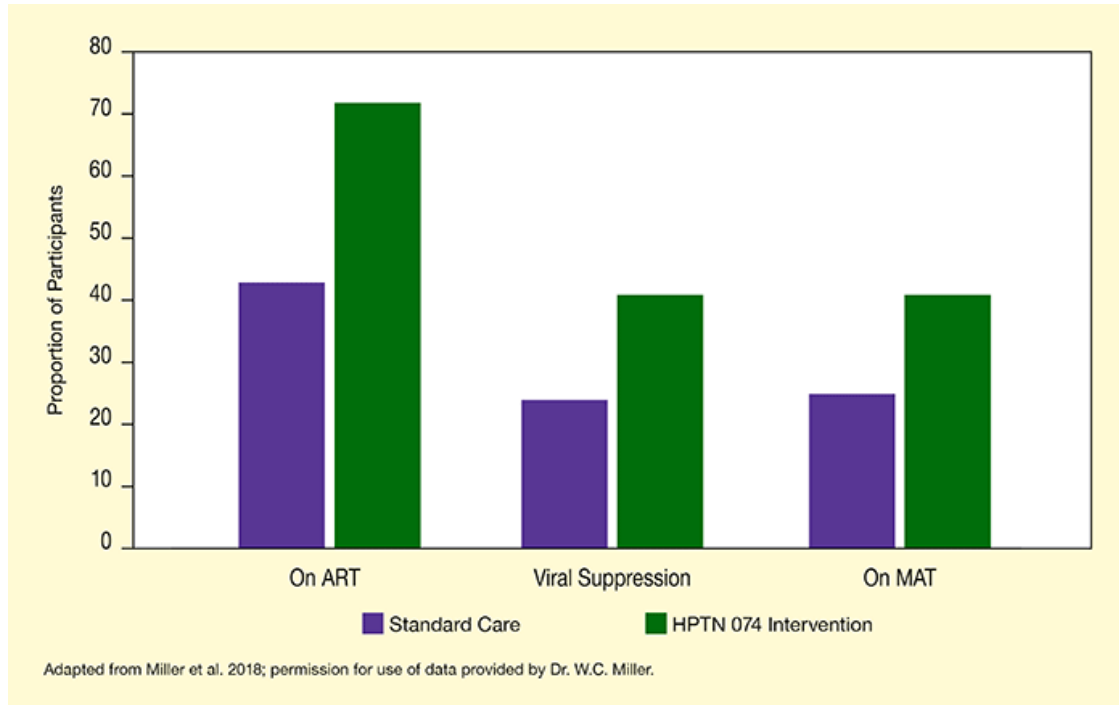
## HIV and Drugs

Prevention  
Treatment



# Scalable, Integrated Intervention To Engage IDU In HIV Care and MOUD (HPTN 074)

*Systems navigators facilitate engagement, retention, adherence in HIV care and MAT Psychosocial counseling, at least 2 sessions ART at any CD4 count*



**All incident HIV infections among partners occurred in the SOC arm:**

*Intervention: (0 cases/215.6 p-y)  
(7 cases/683.6 p-y)*

*IR: 0.0/100 p-y (CI 0.00, 1.7) SOC:  
IR: 1.0/100 p-y (CI 0.41, 2.1)*

**Miller WC et al., Lancet 2018; 392: 747–759.**



# January 22 – 27<sup>th</sup> 2019

There were **1918 events** held in the U.S. and 23 other countries, including Pakistan, Nigeria, Afghanistan, Myanmar, South Africa, India, Mexico and Ukraine



Gibson County High School in Dyer (Tennessee)



Boys & Girls Club Starkville (Mississippi)

