

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

January 30, 2020

Nora D. Volkow, M.D., Director

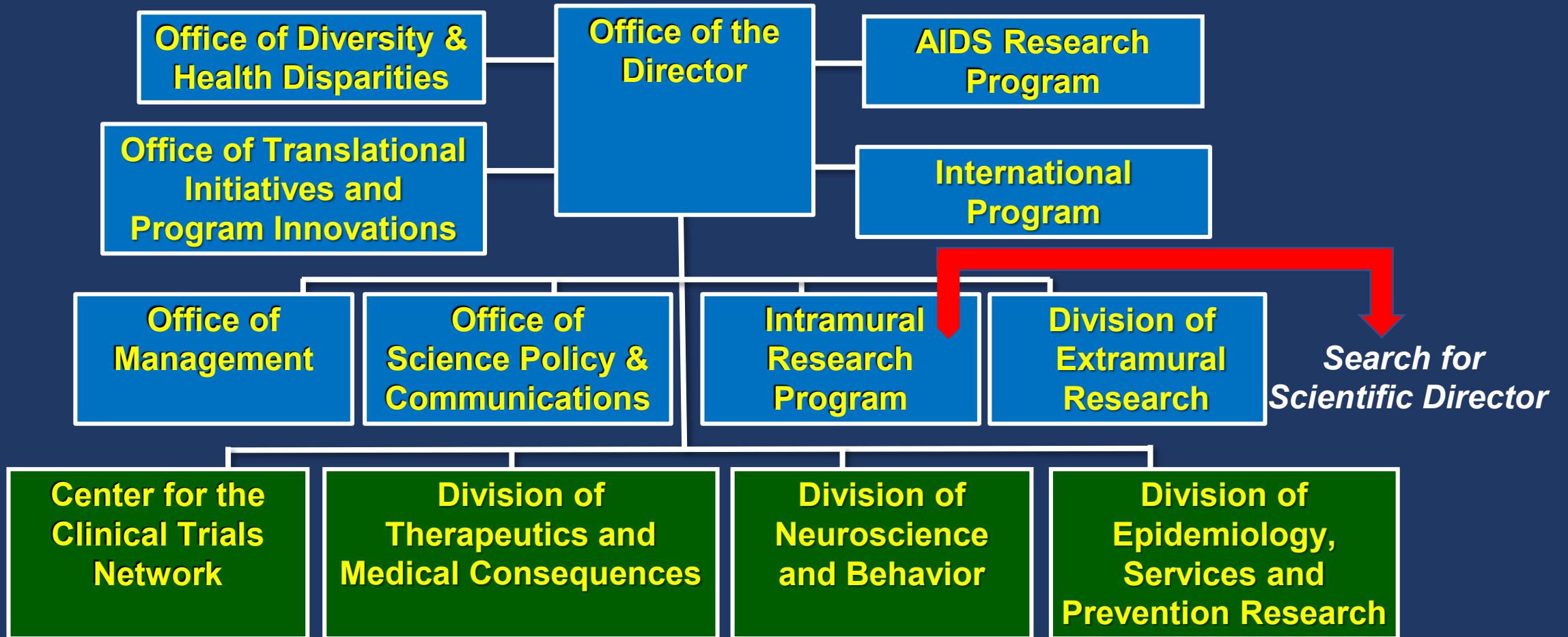


National Institute  
on Drug Abuse



@NIDAnews

# NIDA



## **Donna M. Jones**

NIDA Budget Officer and Chief,  
Financial Management Branch,  
retired on January 2, 2020, after 46  
years of Federal service (all at NIDA)



# NIDA BUDGET

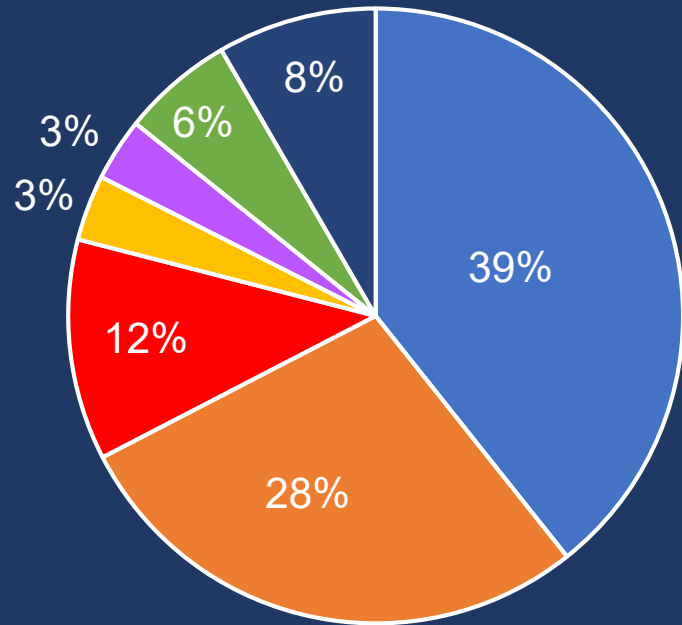
	FY 2018 Actuals	FY 2019 Actuals	FY 2020 PB
<b>NonAIDS</b>	\$854,507,995	\$885,553,022	\$810,682,000
<b>AIDS</b>	\$269,765,000	\$264,813,995	\$235,697,000
<b>Total</b>	\$1,124,272,995	\$1,150,367,017	\$1,046,379,000
<b>HEAL</b>	\$36,876,450*	\$470,966,550**	\$250,000,000

\*Reflects FY 18 usage of funding that was made available for both FY 18 and FY 19 spending. Total funding provided was \$250m.

\*\*Reflects total HEAL funding obligated in FY 19, regardless of source. Includes 1-year funds provided in FY 19 and balance of 2-year funds provided in FY 18.

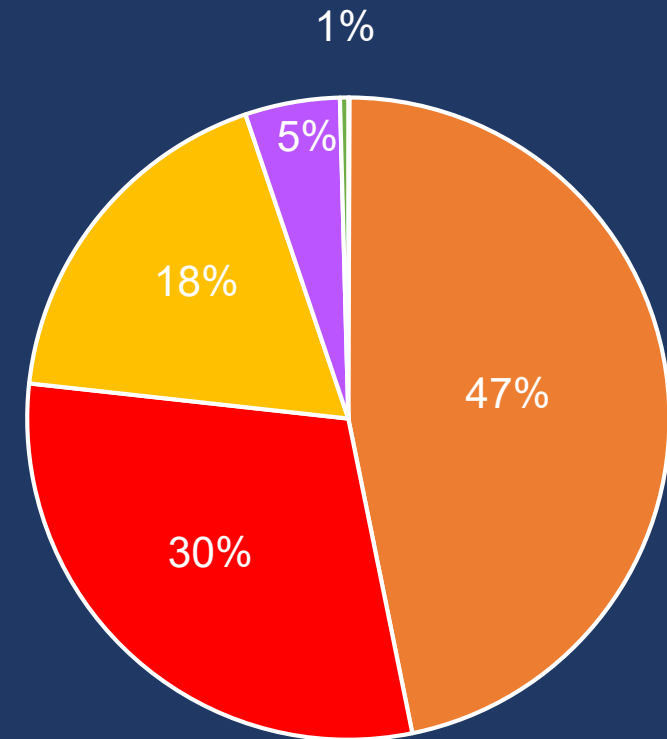
# National Institute on Drug Abuse Portfolio Annual Appropriation FY 2019 Actual

## Excludes HEAL

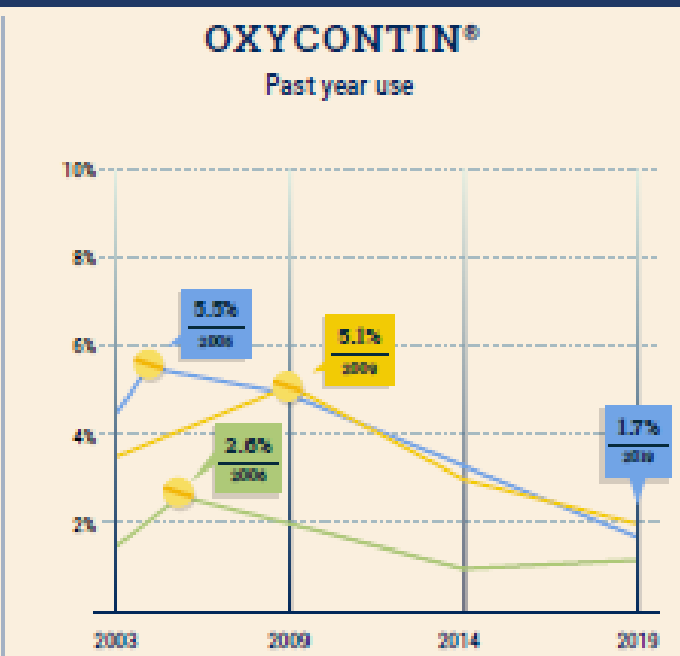
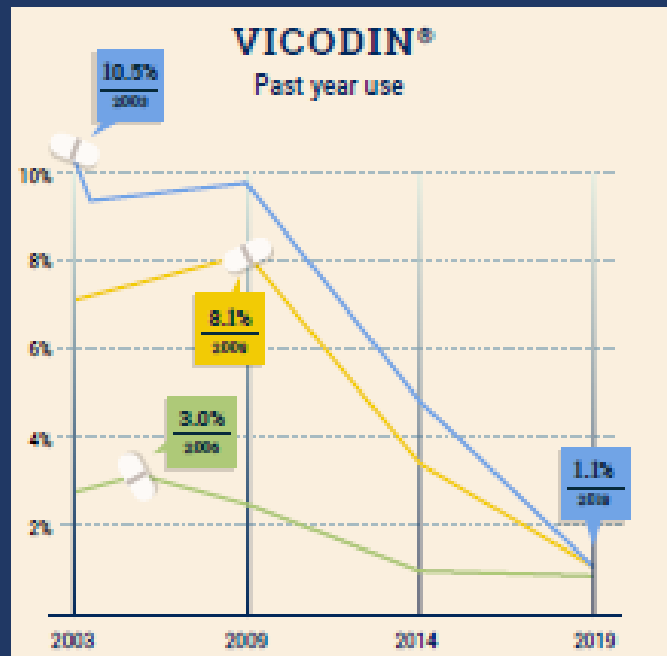


- Division of Neuroscience & Behavior
- Division of Epidemiology, Services, & Prevention Research
- Division of Therapeutics & Medical Consequences
- Center for the Clinical Trials Network
- Office of Translational Initiatives & Program Innovations
- RMS
- Intramural Research

## HEAL\*



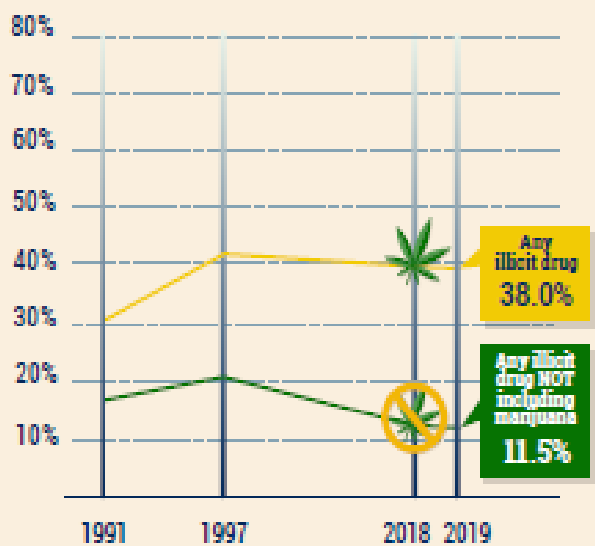
\*Reflects total HEAL funding obligated in FY 19, regardless of source. Includes 1-year funds provided in FY 19 and balance of 2-year funds provided in FY 18.



8th graders  
10th graders  
12th graders

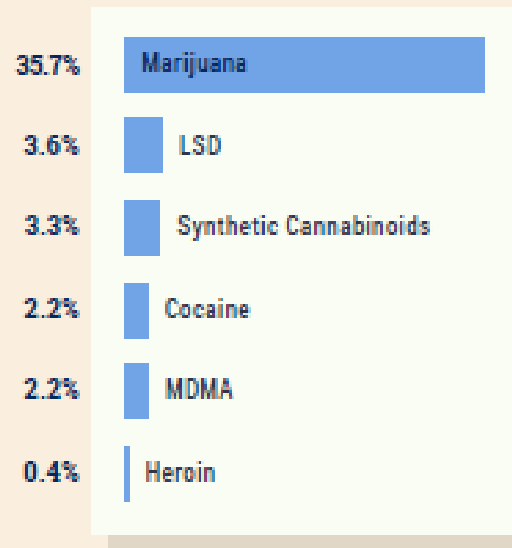
### ILLICIT DRUG USE STEADY

Past year use among 12th graders



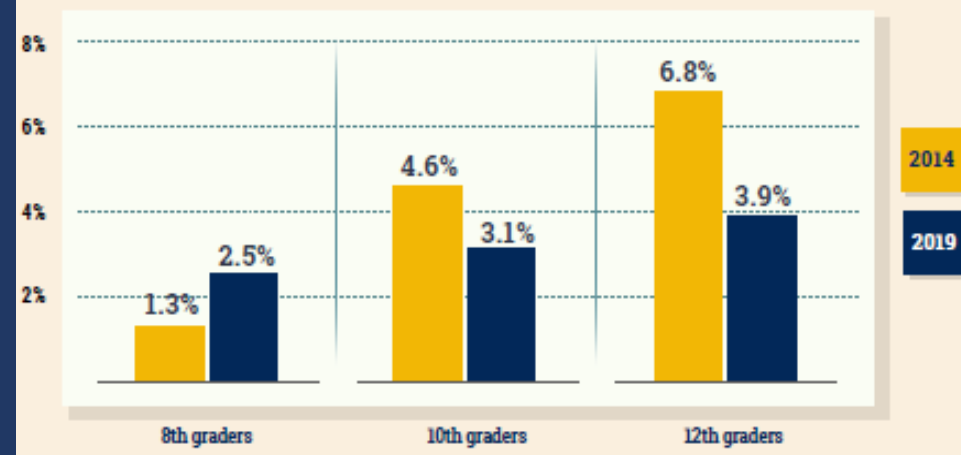
### PAST YEAR ILLICIT DRUG USE

Past year use among 12th graders

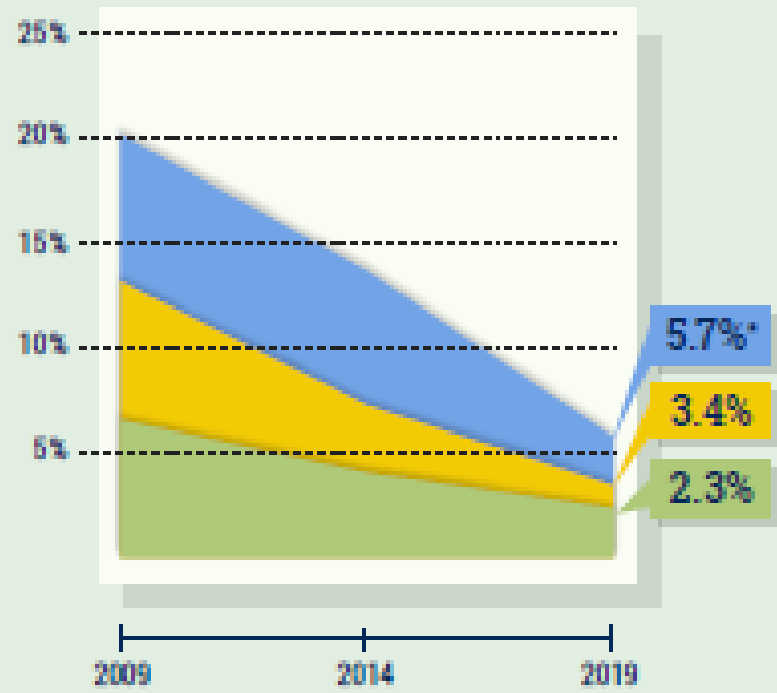


### ADDERALL MISUSE SEES SIGNIFICANT CHANGES IN PAST 5 YEARS

a decrease in 10th and 12th grades, but an increase in 8th grade



## CIGARETTE SMOKING (PAST MONTH) DECLINES OVER PAST TEN YEARS



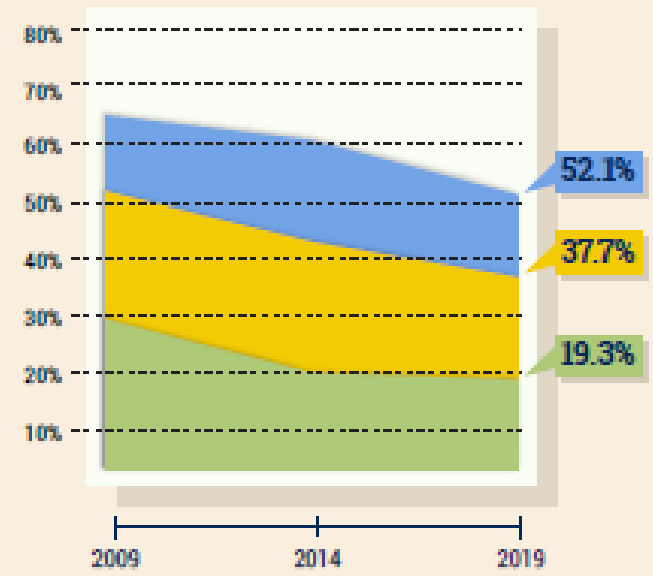
8th graders  
10th graders  
12th graders

\*Significant decline from 2018 (7.6%)

## ALCOHOL USE CONTINUES ITS DECLINE

### PAST YEAR ALCOHOL USE

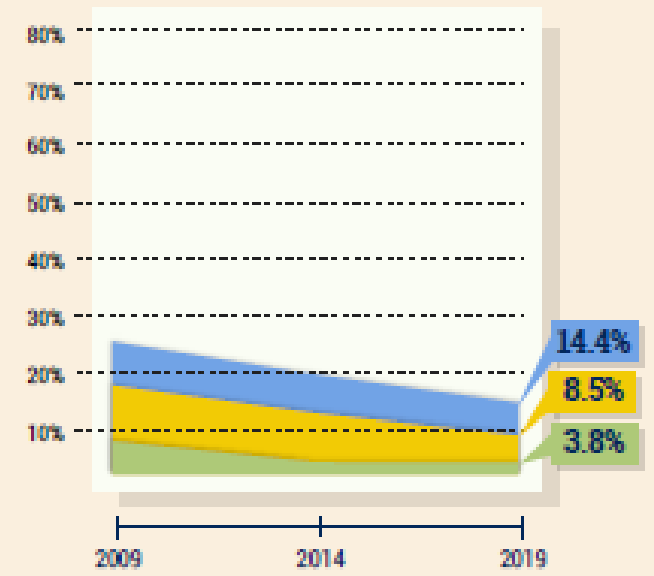
Significant long-term decrease in all grades



8th graders  
10th graders  
12th graders

### BINGE DRINKING\*

Significant long-term decrease in all grades



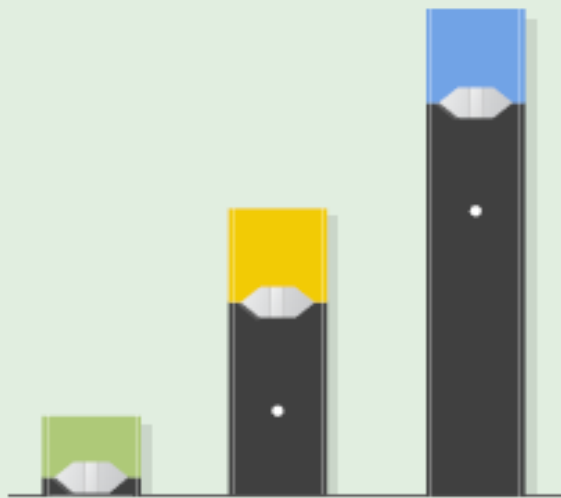
\*5 or more drinks in a row in the past two weeks

# Significant Increases in Teens VAPING

## NICOTINE

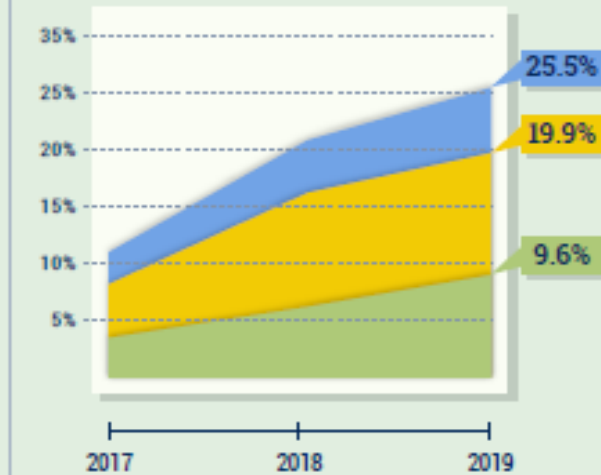
### DAILY NICOTINE VAPING<sup>1</sup>

Measured for the first time in 2019



### NICOTINE VAPING

Past month use



8th graders 1.9%  
10th graders 6.9%  
12th graders 11.7%

8th graders 10th graders 12th graders

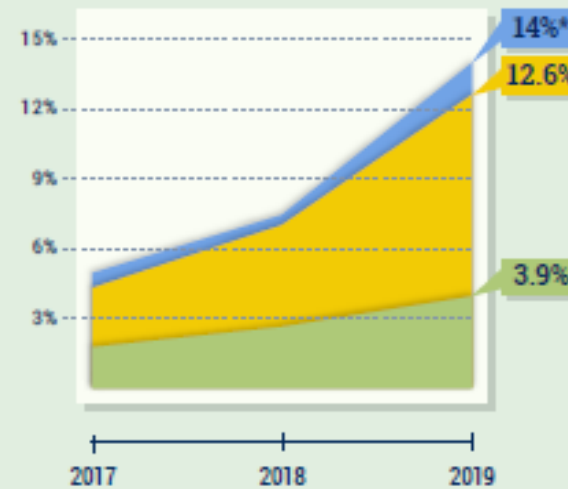
1. Miech R, Johnston L, O'Malley PM, Bachman JG, Patrick ME. Trends in adolescent vaping, 2017–2019. *N Engl J Med* 2019; 381:1490-1491

2019 Past Month Nicotine Vaping Equates to:  
1 IN 4 – 12TH GRADERS • 1 IN 5 – 10TH GRADERS • 1 IN 10 – 8TH GRADERS

## THC

### THC VAPING

Past month use



8th graders 10th graders 12th graders

### DAILY THC VAPING

Measured for the first time in 2019

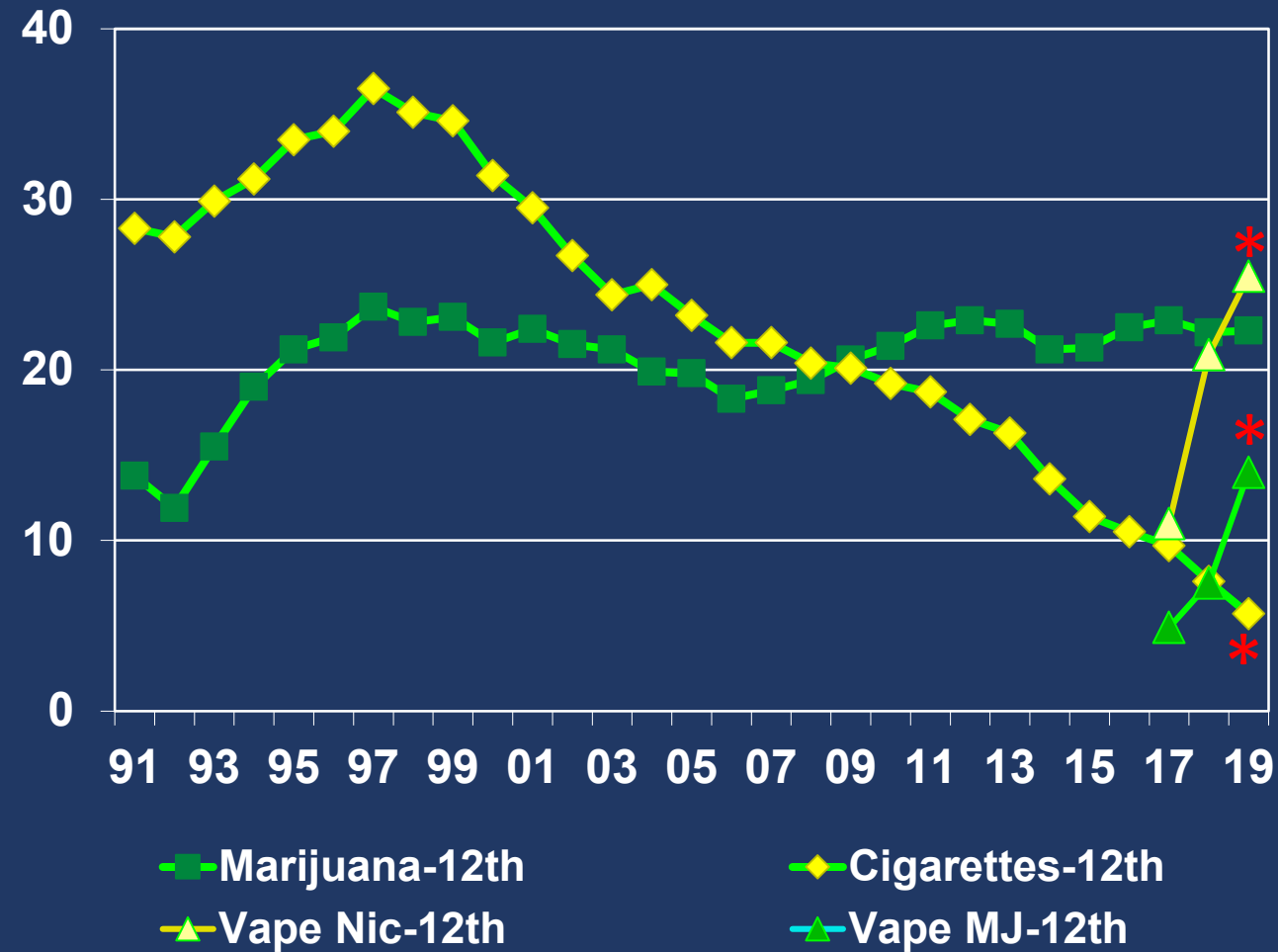


8th graders 0.8%  
10th graders 3.0%  
12th graders 3.5%

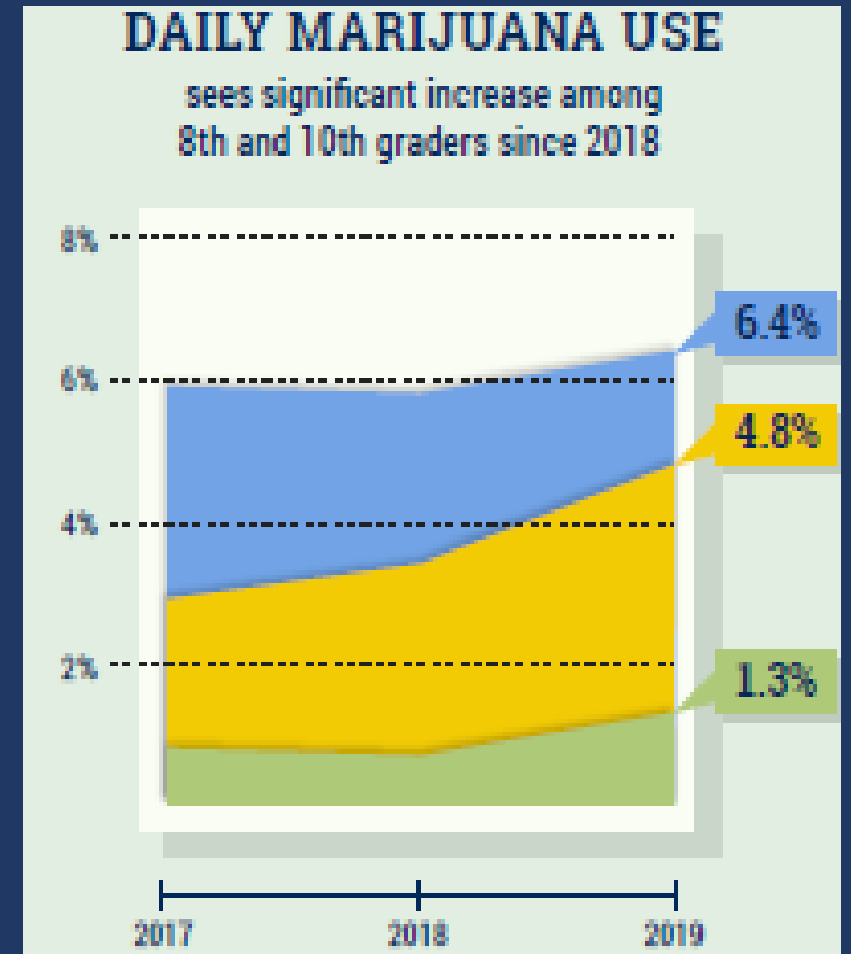
\*2018 – 2019 INCREASE IS THE SECOND LARGEST ONE-YEAR JUMP EVER TRACKED FOR ANY SUBSTANCE IN THE 45-YEAR SURVEY HISTORY (NICOTINE VAPING WAS THE LARGEST FROM 2017 – 2018)



# Percent of Students Reporting Marijuana, Cigarette, Vape Use in Past Month, 12<sup>th</sup> Grade



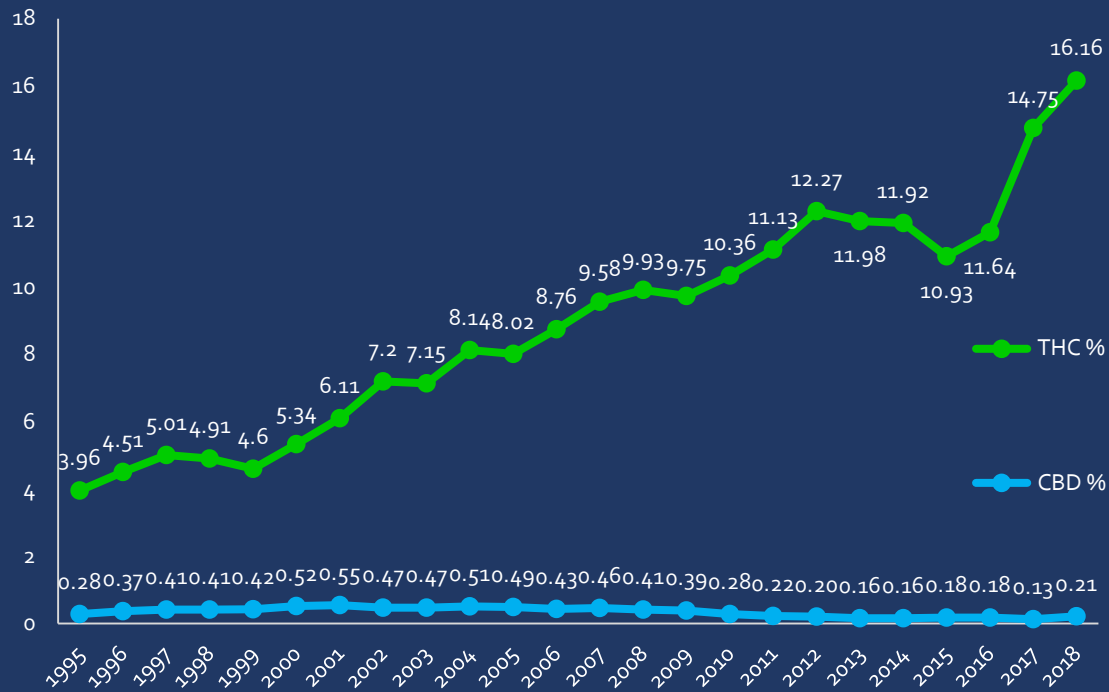
\* Denotes significant difference between 2018 and 2019



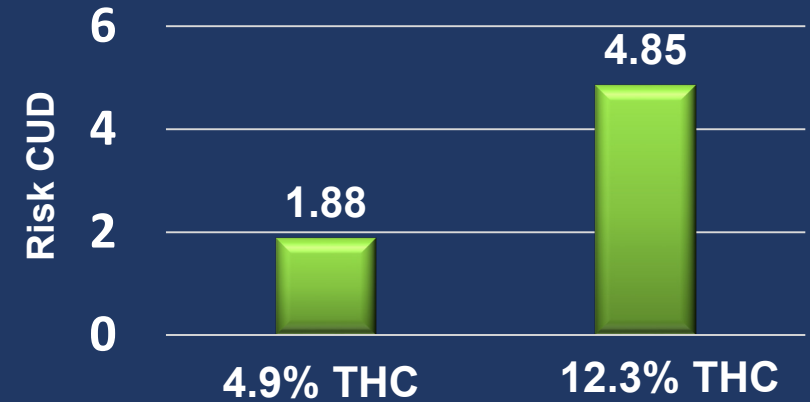
SOURCE: University of Michigan, 2019 Monitoring the Future Study

# Role of Cannabis Potency (%THC) on Adverse Effects

## Cannabis Potency Tripled in Past 20 Years

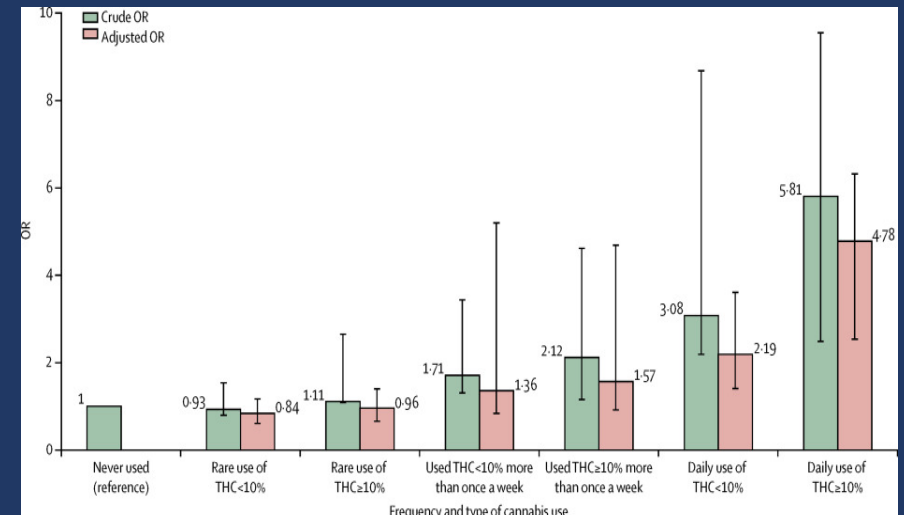


## Increased Risk Cannabis Use Disorder



*Arterberry, et al., Drug Alcohol Dependence (2019)*

## Increased Risk Psychotic Disorders



*Di Forti et al., Lancet Psychiatry (2019)*

# Congressional Hearing “Cannabis Policies for the New Decade”

## Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives

Wednesday, January 15, 2020

### Witnesses

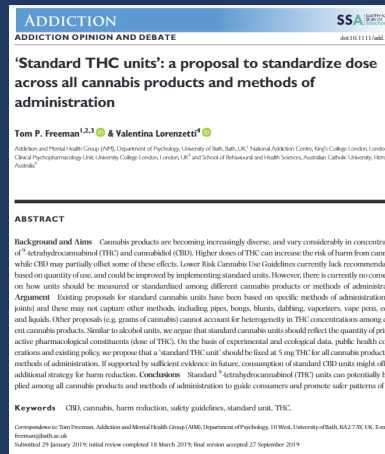
- *Nora D. Volkow, M.D.*  
Director, NIDA
- *Douglas Throckmorton, M.D.*  
Deputy Director for Regulatory Programs,  
Center for Drug Evaluation and Research  
FDA
- *Matthew J. Strait*  
Senior Policy Advisor, Diversion Control Division  
DEA



# Standardized THC dose



*“Explore the possibility of constructing a standardized dose.”*



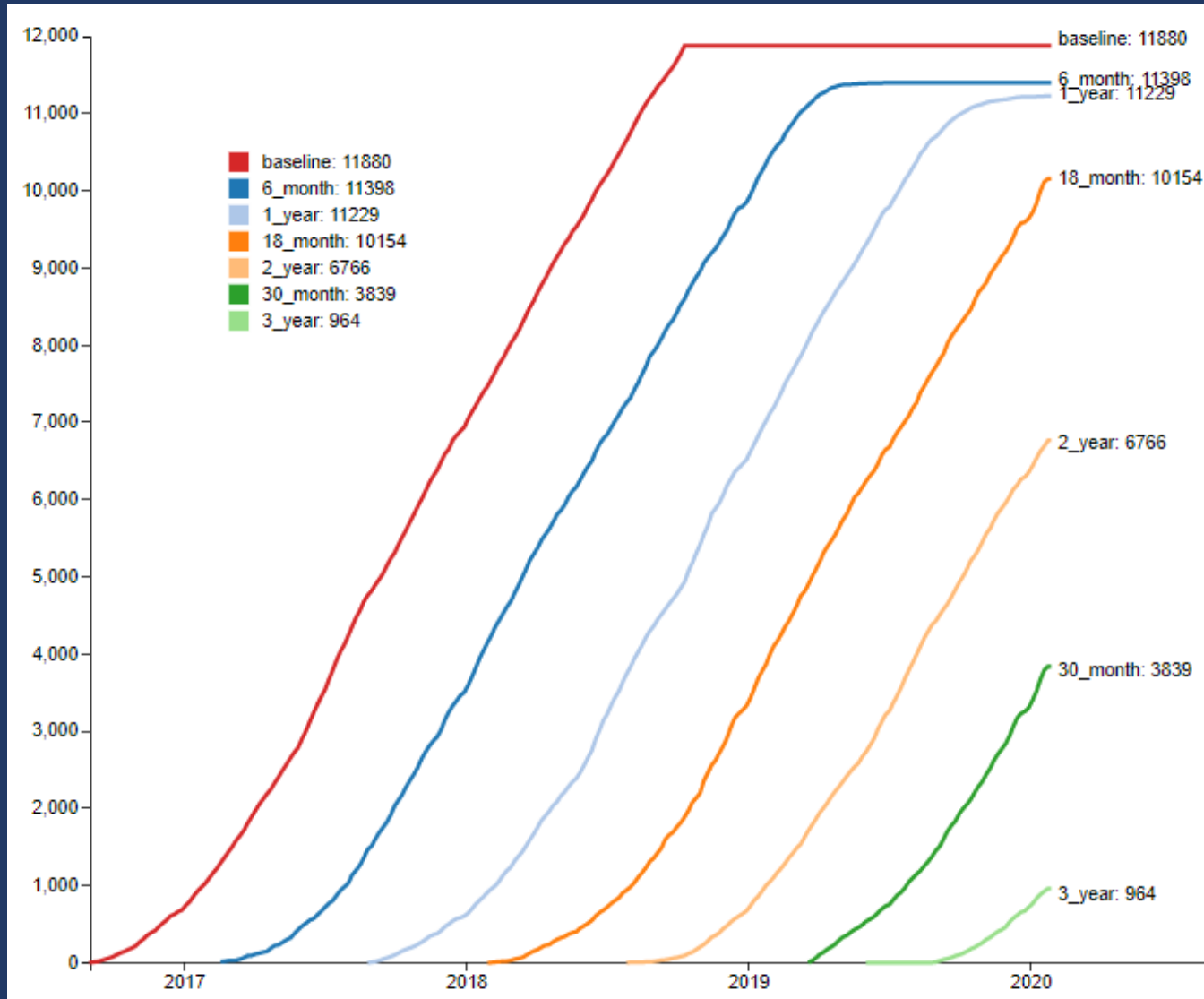
*“...propose a standard THC unit should be fixed at 5 mg THC for all cannabis products and methods of administration.”*

### Next Steps:

- Public Request for Information
- Convene Meeting of Experts
- Implement Use for NIDA-funded Research

# Adolescent Brain Cognitive Development (ABCD) Study

99.1 Percent Retained



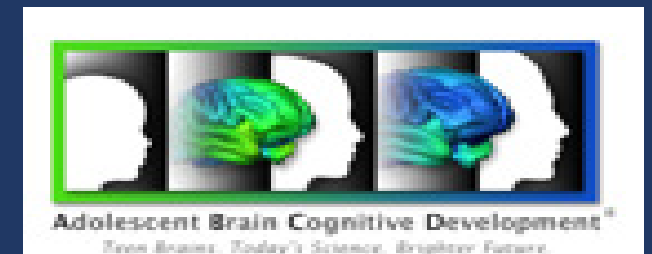
## Data Releases

- ABCD Study Fast Track Neuroimaging Data Ongoing
- Full Baseline Curated Data 2.0 and 2.0.1 releases available now
- ABCD Data Release 3.0 **expected** Summer 2020
  - Full cohort 6-month follow-up
  - Full cohort 1-year follow-up
  - Interim data:
    - 18-month
    - 2-year (imaging)
    - 30-month

+ New ABCD Science Newsletter

To subscribe: email [abcd-data-releases-l-join@mailman.ucsd.edu](mailto:abcd-data-releases-l-join@mailman.ucsd.edu)

**Accelerating the Pace of Child Health Research Using Existing Data from the ABCD Study (PAR-19-162/163)**

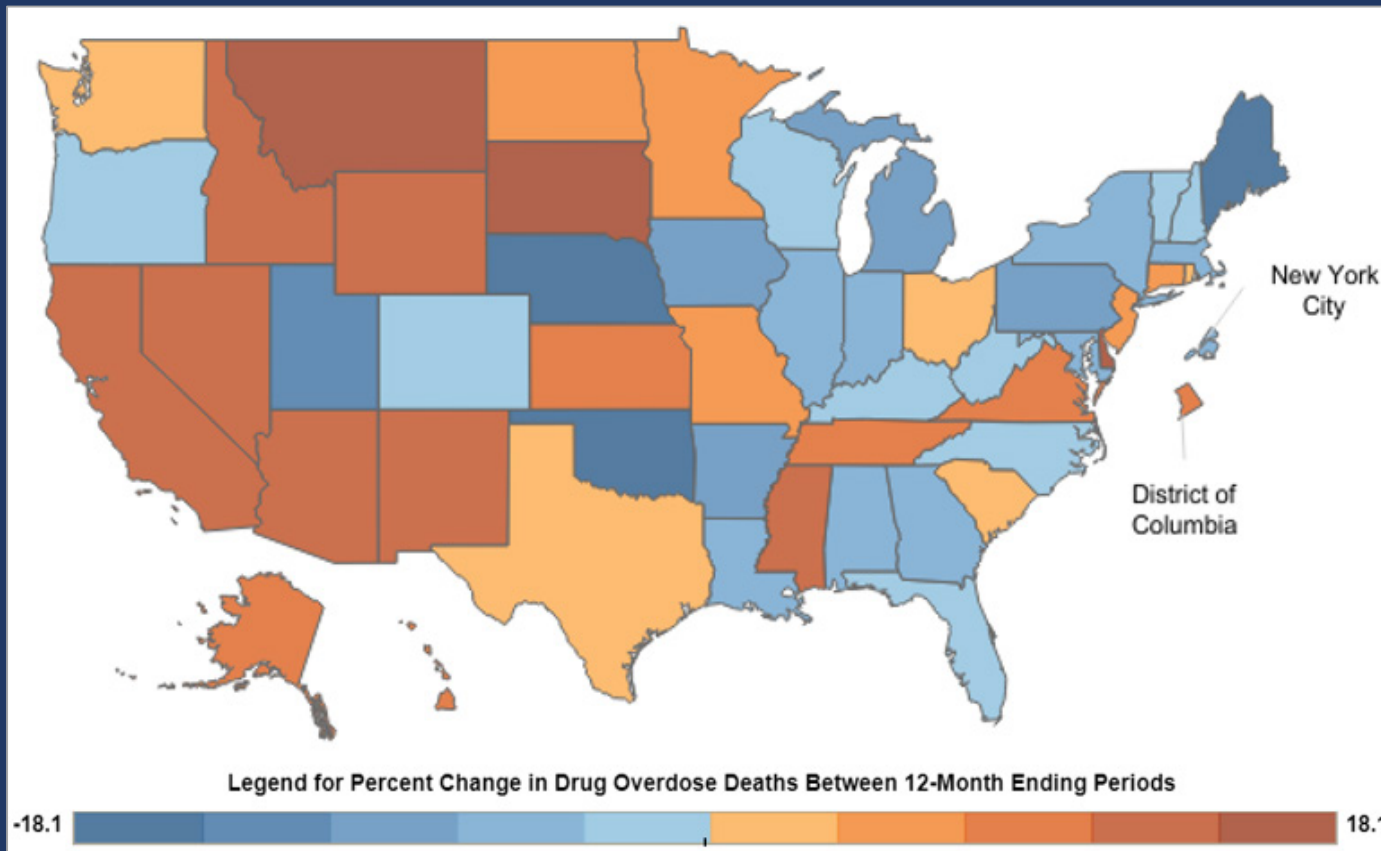


# OPIOID CRISIS: OVERDOSE DEATHS

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

**% CHANGE IN 12 MONTH OVERDOSE DEATHS: CDC, JUNE 2019**

- **California,**  
up 13.6%
- **Ohio,**  
up 1.3%
- **New Jersey,**  
up 3.7%
- **Tennessee,**  
up 10.3%
- **Arizona,**  
up 12.3%



- **New Hampshire,**  
down 2.4%
- **Kentucky,**  
down 1.8%
- **Iowa,**  
down 8.1%
- **Pennsylvania,**  
down 10.4%
- **Oklahoma,**  
down 14.8%

# NIH HEAL Initiative

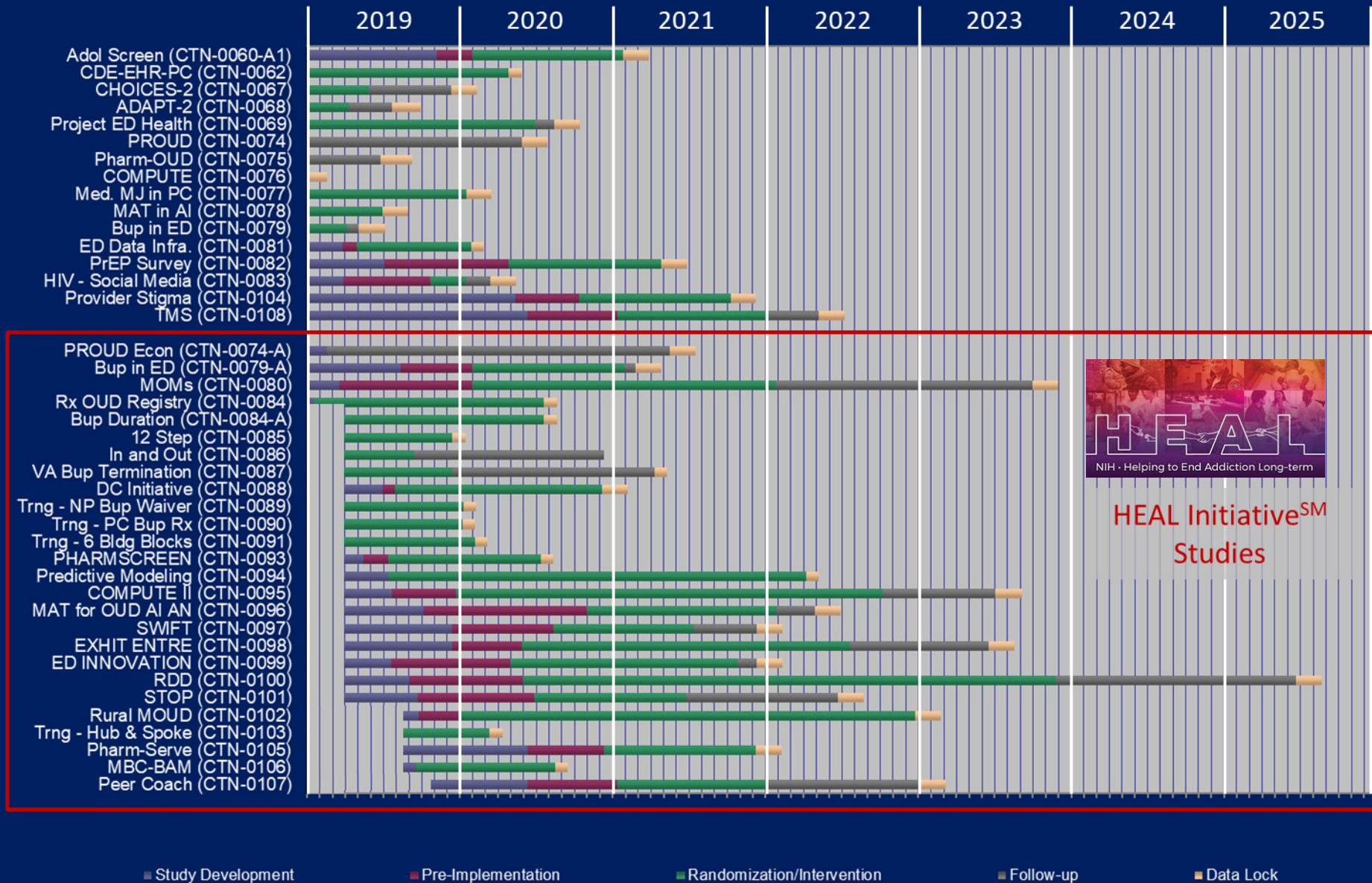


- \$500 million/year aggressive trans-agency effort to speed scientific solutions to stem the national opioid public health crisis
- Research to enhance pain management, curb OUD and overdose, and achieve long-term recovery
- 12 NIH Institute and Centers leading over 375 research projects
- Approximately \$945 million issued in FY 2019 across 41 states

Early Preclinical Time to Launch: >12 yrs		Late Preclinical 10-12 yrs		Phase I 6-10 yrs	Phase Ib 5-9 yrs	Phase II 4-6 yrs	Phase III 3-5 yrs	New Formulation <3 yrs	
<b>DM24</b> MOR/DOR het antagonist	<b>SBI-553</b> NT-1 biased PAM	<b>ITI-333</b> MOR PA/5HT2a antagonist	<b>KLS13019</b> CBD analogue	<b>ANS6637</b> ALDH2 inhibitor	<b>Guanfacine</b> α2 adren agonist	<b>Pregab + Lofex</b> VDCC inh/α2 agonist		<b>Olani</b> 6 mo naltr implant	<b>LAAM</b> Oral, re-intro
<b>PZM21</b> MOR biased agonist	<b>NAN/NAQ</b> MOR modulator	<b>Nalmefene implant</b> MOR antag	<b>PF5190457</b> GHS1αR antag	<b>C4X3256</b> OX-1 antagonist	<b>Ketamine</b> NMDA antagonist			<b>BICX102</b> 3 mo naltr implant	<b>Naltrexone</b> 1 yr implant
<b>MOR biased agonist</b>	<b>GPR151 antagonist</b>	<b>NORS-033</b> Nalmefene prodrug	<b>Mor, Her, Oxy, Hydro vaccine</b>	<b>Semiglutide</b> GLP-1R agonist	<b>Suvorexant</b> OX-1/2 antagonist			<b>OPNT003</b> Nasal nalmefene	<b>Brixadi</b> Bupr 1 wk/1 mo inj
<b>Oxy/Fentanyl nano-vaccine</b>	<b>AT-121</b> NOP/MOR partial agonist	<b>LYN-014</b> Long acting methadone	<b>NYX-783</b> NMDA modulator	<b>Cannabidiol</b>	<b>Lorcaserin</b> 5HT2c agonist			<b>Bupren/Nalox</b> Oral, long acting	<b>AP003</b> Mlt-dose nlx nasal spray
<b>Fentanyl vaccine</b>	<b>PTPRD inhibitor</b>	<b>KNX100</b> Unknown mechanism	<b>Heroin Vaccine</b>	<b>Tradipitant</b> NK-1 antagonist	<b>Gabapentin</b> VDCC blocker			<b>Naltrexone</b> 2 mo injection	<b>AP004</b> Nlx prefilled syringe
<b>Heroin/Fent vaccine</b>	<b>R-methadone prodrug</b>	<b>AP007</b> Extd-release nalmefene	<b>NP10697</b> GluN2B antagonist	<b>AZD4041</b> OX-1 antagonist				<b>Naltrexone</b> 6 mo implant	<b>Naloxone</b> Hi-dose nasal spray
<b>Fentanyl mAb</b>	<b>Muscarinic M5 NAM</b>							<b>Nalmefene</b> Transmucosal	
<b>Metho-cinnamox</b> MOR antag									

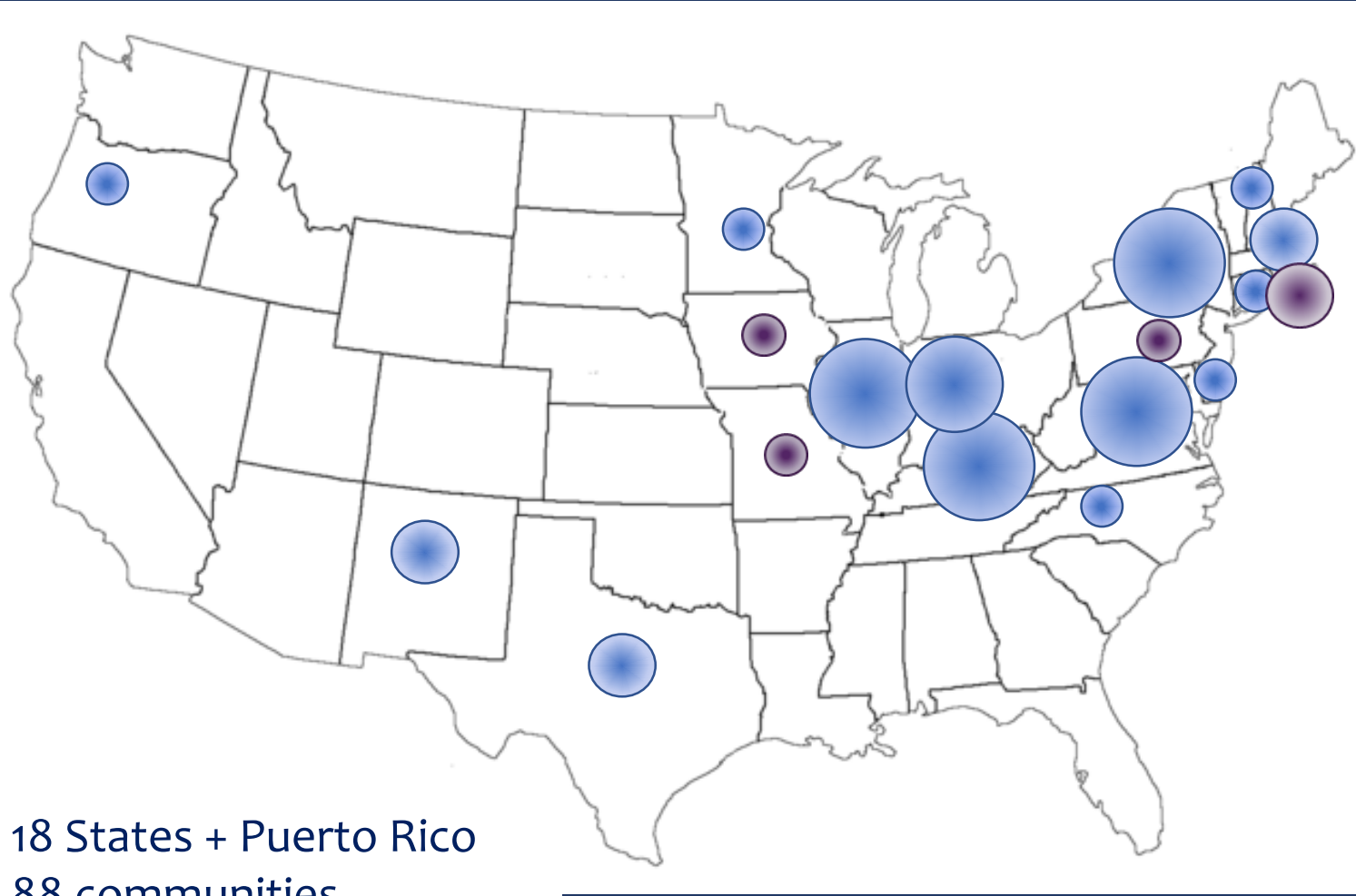


# CTN Study Timeline





# Justice Community Opioid Innovation Network (JCOIN)



18 States + Puerto Rico  
88 communities  
>25,000 justice-involved  
individuals

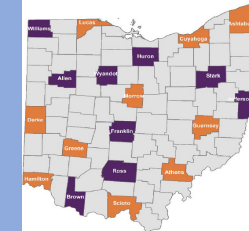
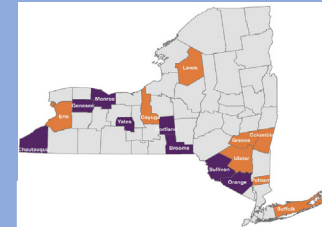
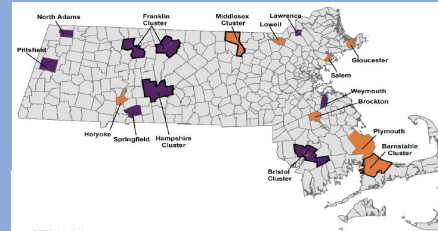
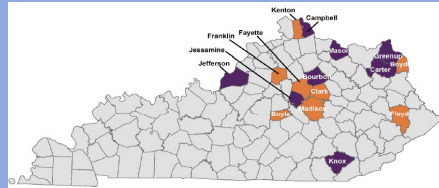
- 13 multisite effectiveness and implementation trials
- National surveys jails, prisons & drug courts nearing completion
- Convened meetings with Practitioner and Stakeholder Boards (leaders 74 key justice and health organizations)
- Received 56 applications for Year 1 training program on conducting research in justice settings



# HEALing Communities' Study

4 States: KY, MA, NY, OH; 67 Communities; 10,144,261 Covered Lives

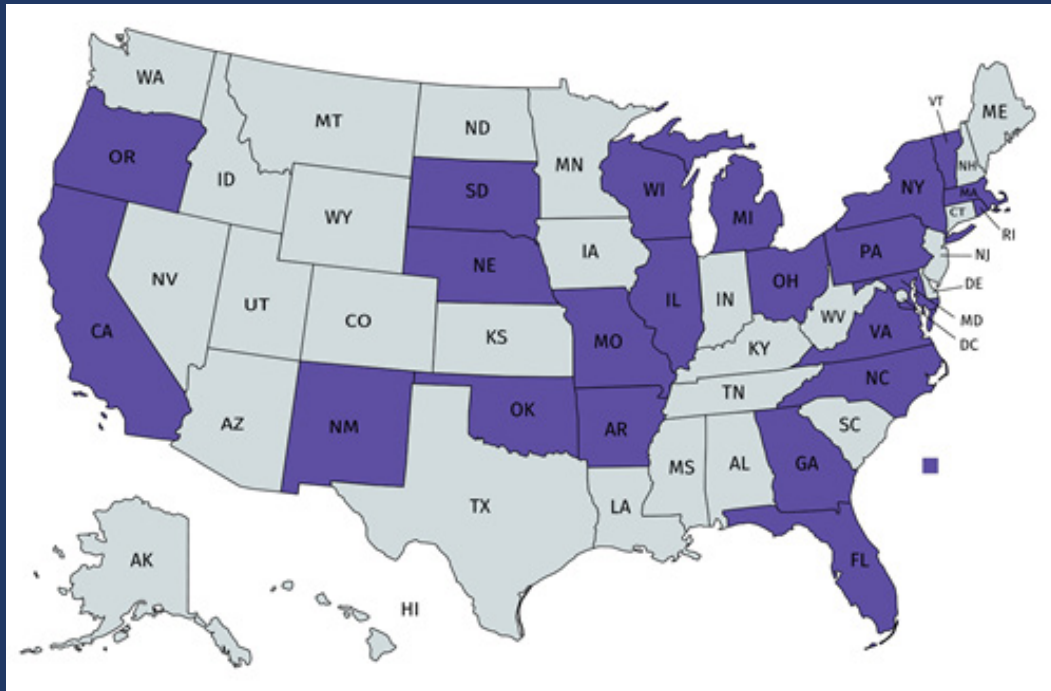
Month	Activity
April, 2019	Grants Funded
May, 2019	Decision to Develop Single Protocol
May – July, 2019	Development of Intervention & Protocol
July – December, 2019	s-IRB Approvals
October, 2019	Randomization of Communities
November, 2019 – January, 2020	Baseline Data Collection
December, 2019	Phase 0 Meetings with all Communities
January, 2020	Phase 1 Meetings with Wave 1 Communities



# HEALthy Brain and Child Development Study (HBCD)

## Progress Update for Phase I

29 planning grants awarded in September 2019



PI meeting May 4-5<sup>th</sup>, Alexandria, VA

## HBCD Working Groups

5 working groups formed, with 18 subgroups

### Study Design

- Recruitment & Retention
- Sampling strategy
- Biostatistics

### Imaging Assessments

- MRI
- EEG
- NIRS

### Biospecimens

- Biomarkers of substance exposure
- Biomarkers of biological responses
- Pre and post-natal co-exposures

### Ethics & Legal

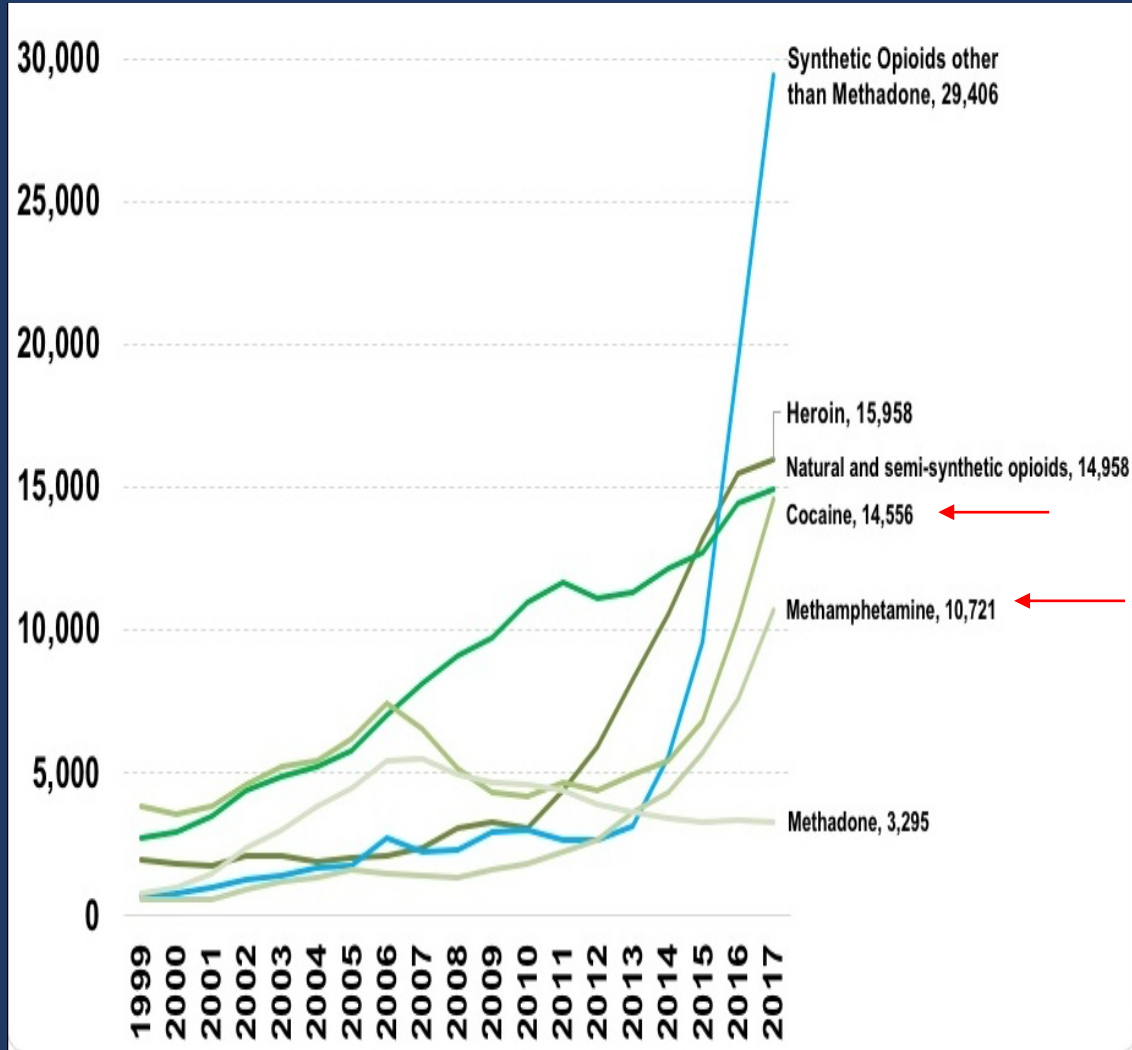
- Ethics in research
- Protecting vulnerable subjects
- Privacy & confidentiality
- Consent, permission & assent

### Non-Imaging Assessments

- Maternal & pre/perinatal
- Infant development
- Toddler/early childhood development
- Family & environment

Will provide input for Phase II design

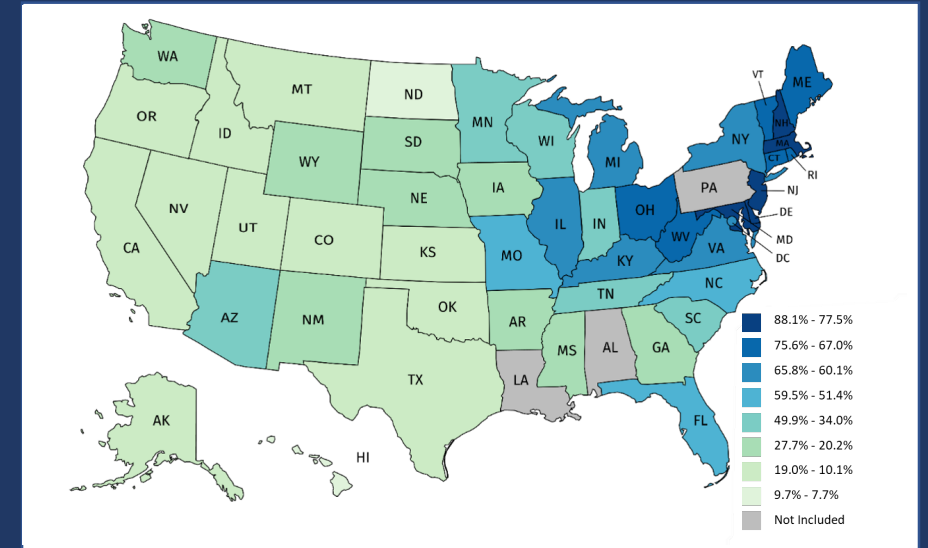
# Percentage Overdose Deaths by Drug Class: Provisional Data March 2018 - February 2019



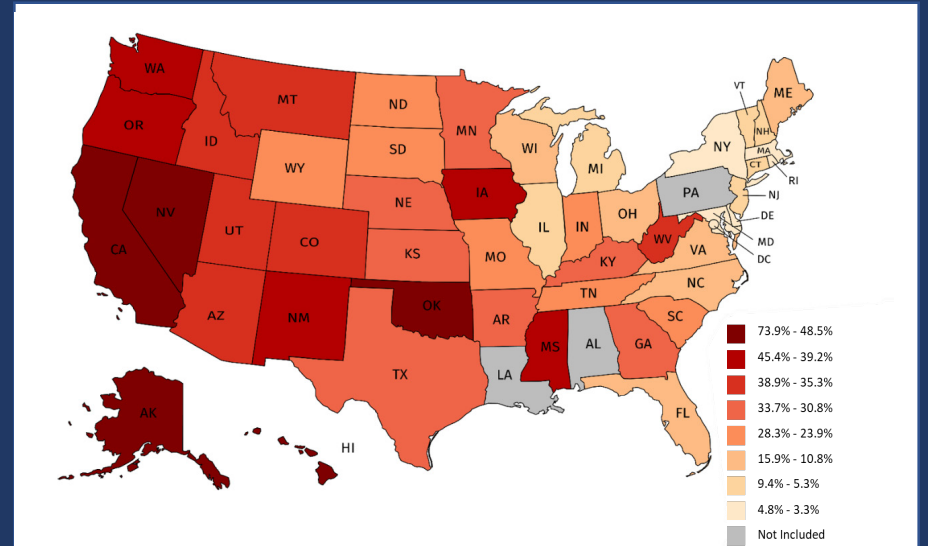
Centers for Disease Control and Prevention

Source: CDC National Vital Statistics System, retrieved September 12, 2019

## SYNTHETIC OPIOIDS



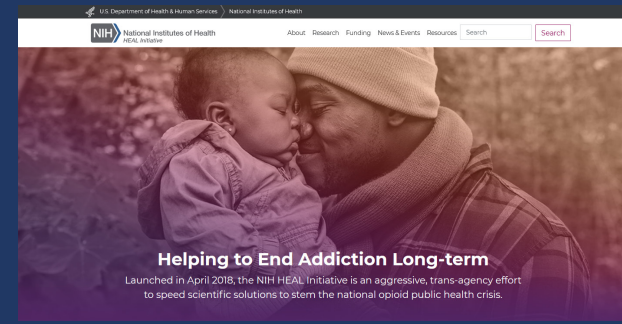
## PSYCHOSTIMULANTS



# Ongoing HEAL Funding Opportunities

New funding opportunities planned for 2020:

[www.heal.nih.gov](http://www.heal.nih.gov)



U.S. Department of Health & Human Services National Institutes of Health

NIH National Institutes of Health  
HEAL Initiative

About Research Funding News & Events Resources Search

## Open Funding Opportunities

Enter Keywords Search

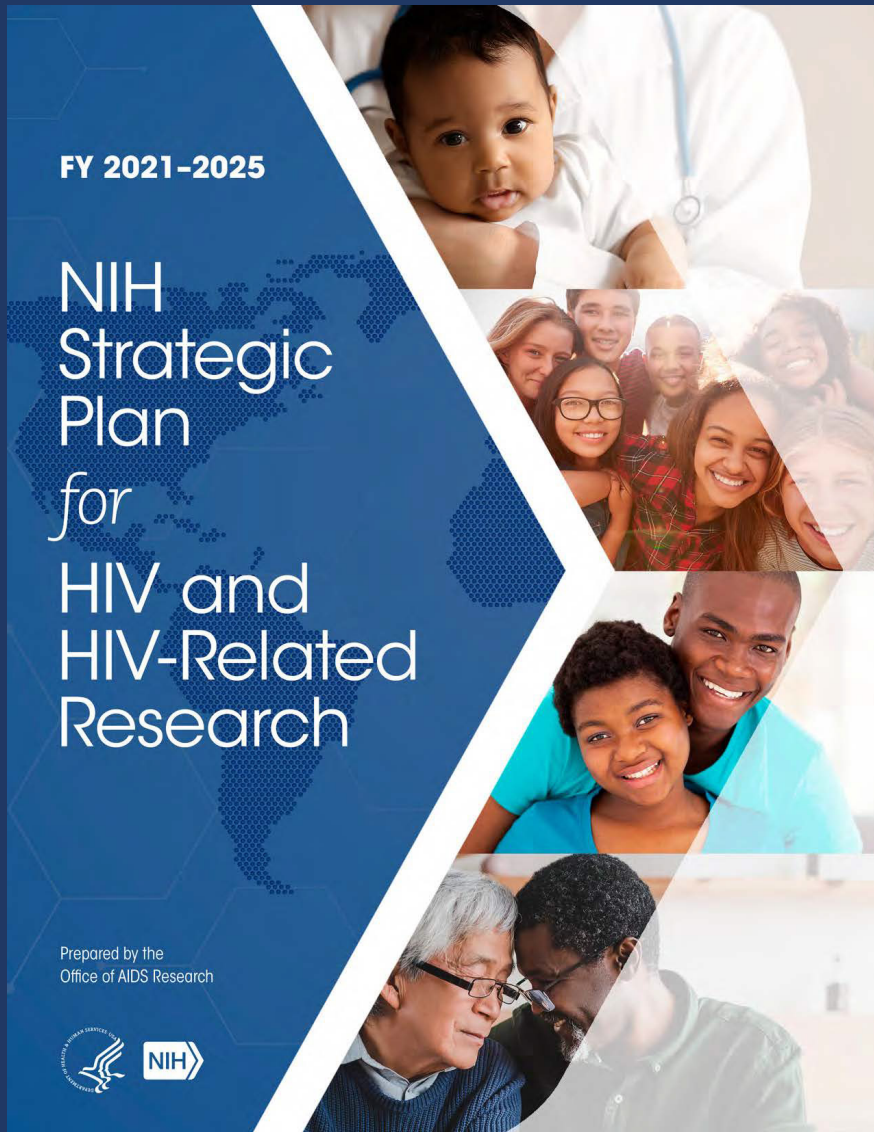
Grant Mechanism Research Focus Area Research Program Improve treatments for o Show 5 per page

Apply Filters CSV Email me

FOA #	FOA Title	Research Focus Area	Research Program	Earliest Submission Date	Expiration Date
<a href="#">RFA-DA-19-019</a>	HEAL Initiative: America's Startups and Small Businesses Build Technologies to Stop the Opioid Crisis (R43/R44 - Clinical Trial Optional)	New Strategies to Prevent and Treat Opioid Addiction		Sun, 12/09/2018 - 12:00pm	Thu, 09/09/2021 - 12:00pm
<a href="#">RFA-DA-19-002</a>	Development of Medications to Prevent and Treat Opioid Use Disorders and Overdose (UG3/UH3) (Clinical Trial Optional)	Novel Medication Options for Opioid Use Disorder and Overdose	Focusing Medication Development to Prevent and Treat Opioid Use Disorder and Overdose	Thu, 01/25/2018 - 12:00pm	Thu, 01/02/2020 - 12:00pm



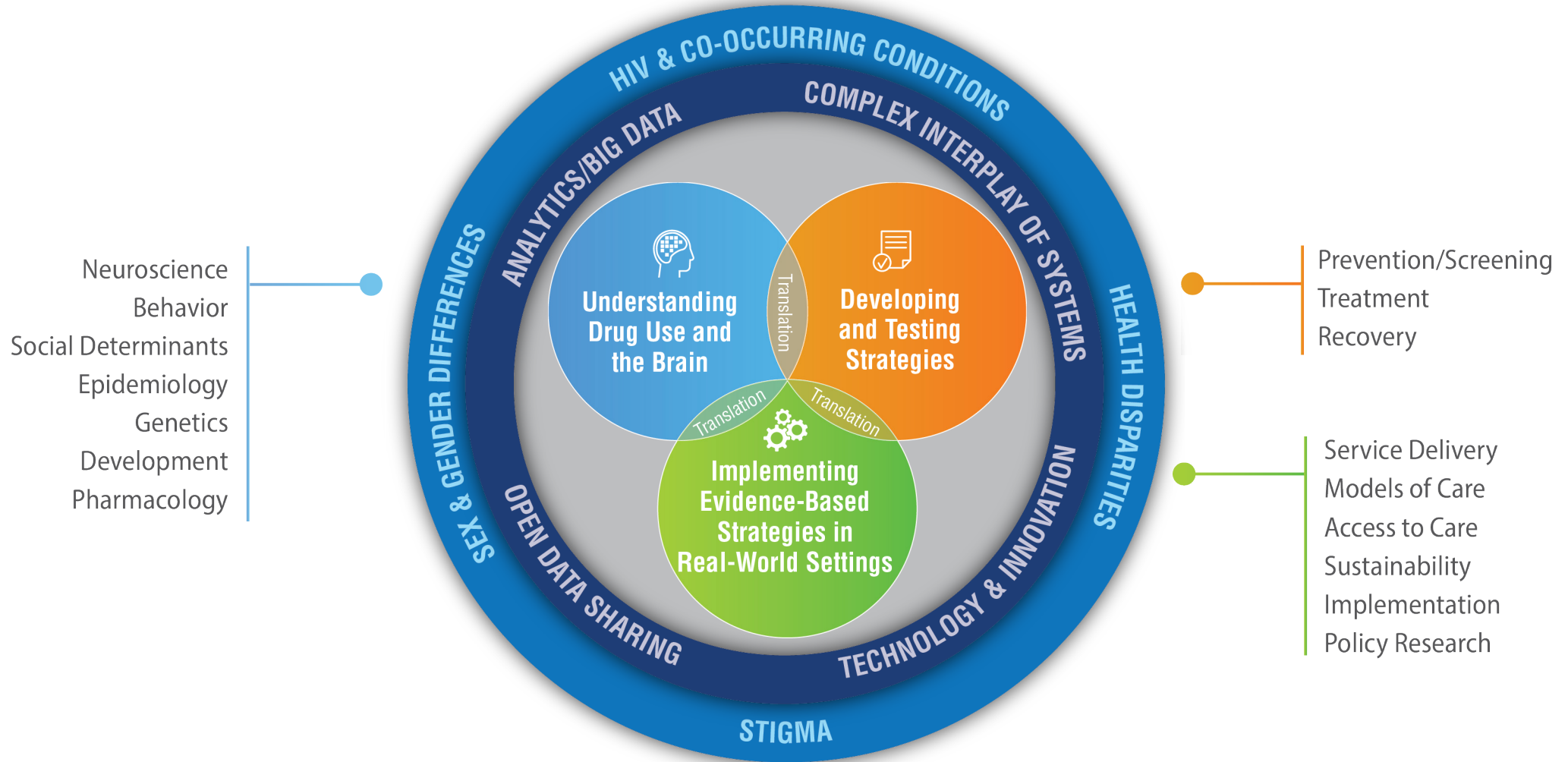
# NIH Strategic Plan for HIV and HIV-Related Research



## NIDA Funding Opportunity Announcement

- RFA-DA-20-022: Assessing the Effects of Cannabinoids on HIV-Induced Inflammation (R01 Clinical Trial Optional)

# NIDA Strategic Plan 2021-2025



Neuroscience  
 Behavior  
 Social Determinants  
 Epidemiology  
 Genetics  
 Development  
 Pharmacology

Prevention/Screening  
 Treatment  
 Recovery

Service Delivery  
 Models of Care  
 Access to Care  
 Sustainability  
 Implementation  
 Policy Research

STEWARDSHIP	
• Research Training	• Collaboration
• Workforce Diversity	• Infrastructure Development
• Dissemination	• Rigor and Reproducibility

# Welcome NIH BRAIN Initiative Director



**John Ngai, Ph.D.**

- Coates Family Professor of Neuroscience, University of California, Berkeley
- Professor of Neurobiology, University of California, Berkeley
- Director, QB3 Functional Genomic Laboratory
- Co-Chair, BRAIN Initiative Cell Census Consortium Steering Group
- B.A. Chemistry and Zoology, Pomona College; Ph.D. Biology, California Institute of Technology



# Major Conclusions

## Smoking Cessation

A Report of the Surgeon General



*Released January 23, 2020*

U.S. Department of Health and Human Services

1. Smoking cessation benefits persons at any age and can add as much as a decade to life expectancy.
2. Smoking places a substantial financial burden on smokers, healthcare systems, and society.
3. More than 3 out of 5 U.S. adults who have ever smoked cigarettes quit; however, less than 1/3 use medications or counseling.
4. Disparities in smoking cessation exist among subgroups—quit attempts, receiving advice from a health professional, and using cessation therapies.
5. Smoking cessation reduces risk of negative health effects, including reproductive health, cardiovascular diseases, COPD, and cancers.
6. Cessation medications approved by FDA and behavioral counseling increase successfully quitting, particularly when combined.
7. Insurance coverage for smoking cessation that is comprehensive, barrier-free, and widely promoted increases their use, leads to higher rates of successful quitting, and is cost-effective.
8. E-cigarettes, are continually changing diverse products used in a various ways. Thus, it is difficult to generalize about efficacy for cessation. There is inadequate evidence regarding benefits.
9. Smoking cessation can be increased by raising price, smoke-free policies, mass media campaigns, pictorial health warnings, and comprehensive statewide tobacco control programs.