

NIDA Director's Report to the CRAN Joint Council

May 16, 2018



Nora D. Volkow, M.D.
Director



National Institute
on Drug Abuse

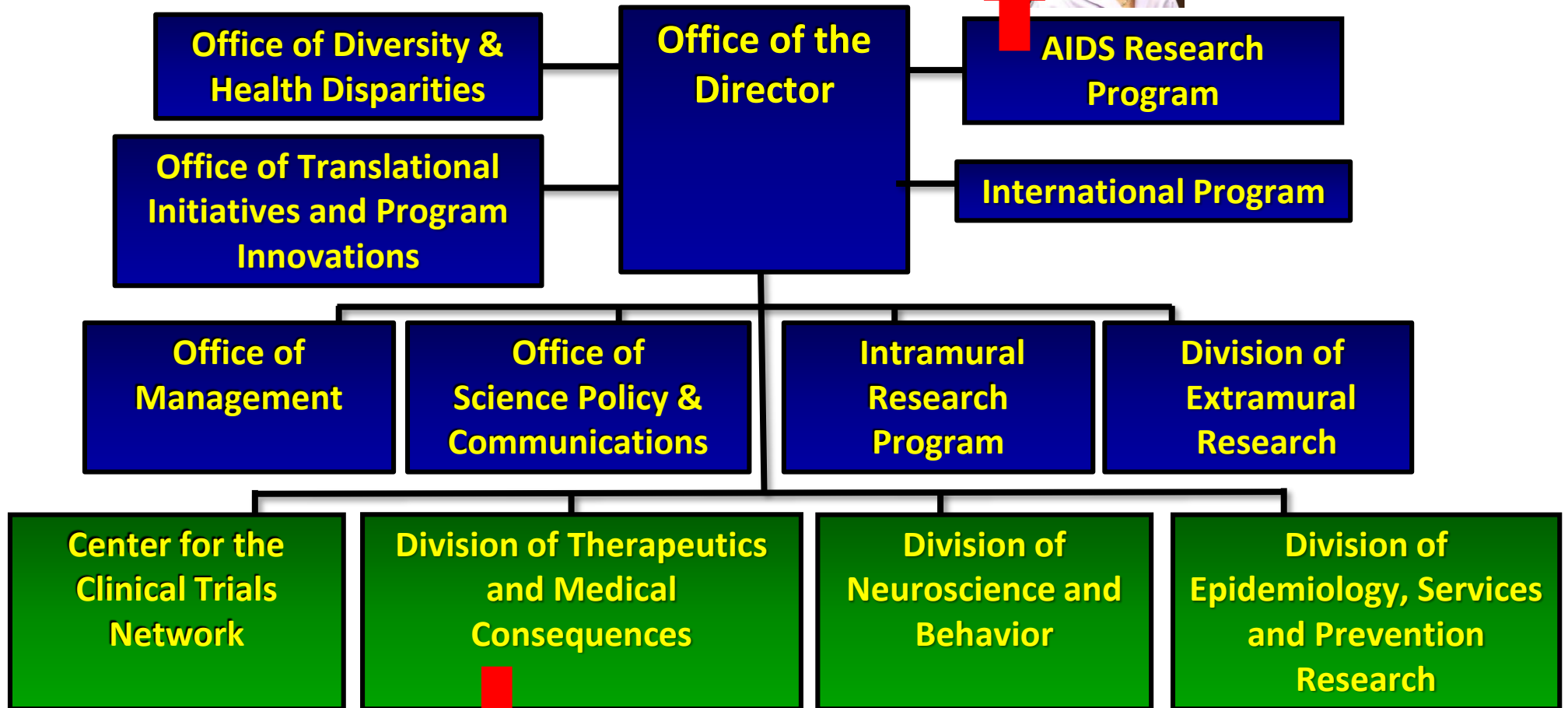


@NIDAnews

NIDA

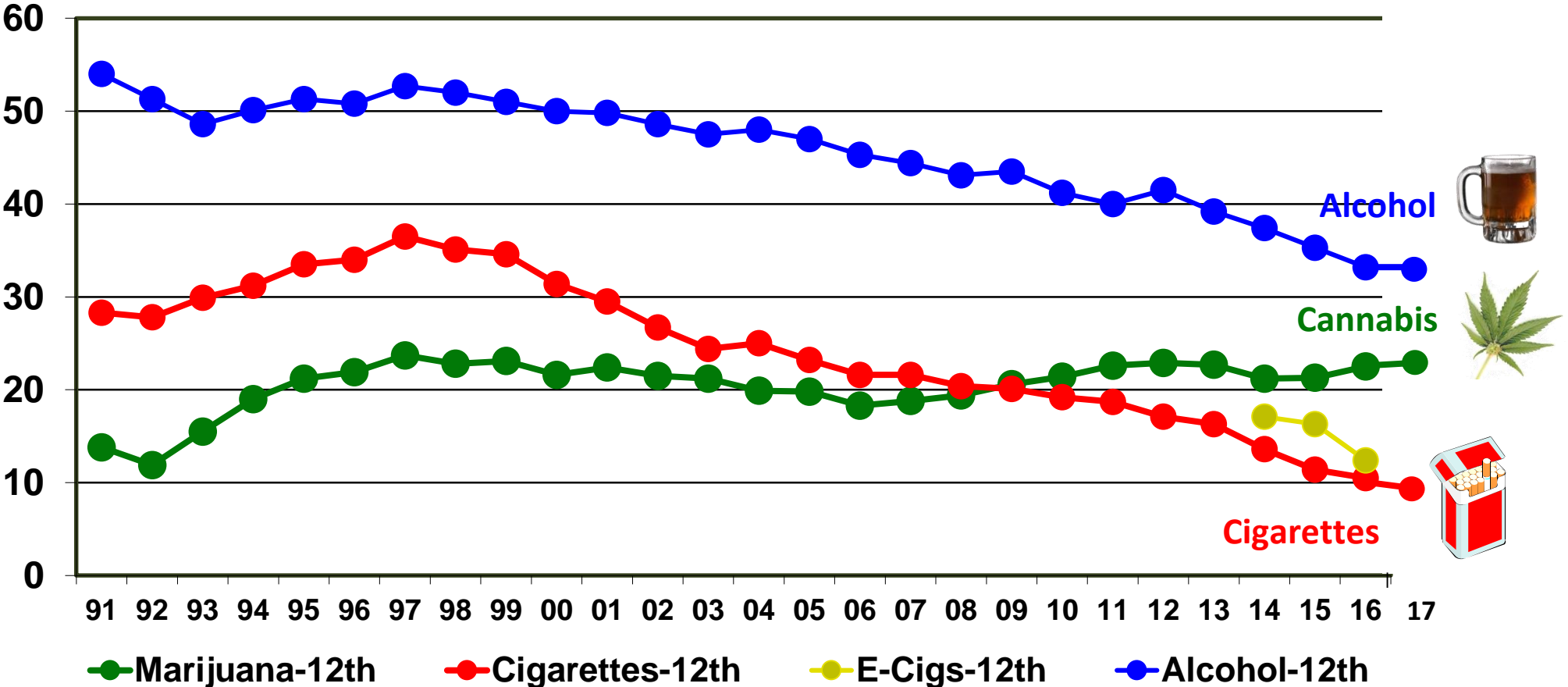


Dr. Redonna Chandler



Kurt Rasmussen, Ph.D., Director, DTMC
Formerly: Senior Research Advisor,
Neuroscience Division, Eli Lilly & Co.

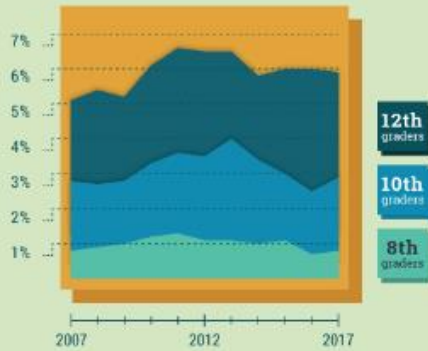
Past Month *Marijuana Use Remains Steady* while Alcohol and Cigarette Use Declining among High School Seniors



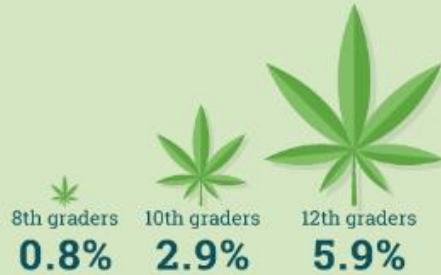
SOURCE: University of Michigan, 2017 Monitoring the Future Study

DAILY MARIJUANA USE MOSTLY STEADY

2007 – 2017



2017



71.0% OF HIGH SCHOOL SENIORS DO NOT VIEW REGULAR MARIJUANA SMOKING AS BEING VERY HARMFUL, BUT 64.7% SAY THEY DISAPPROVE OF REGULAR MARIJUANA SMOKING.

TEENS MORE LIKELY TO USE MARIJUANA THAN CIGARETTES

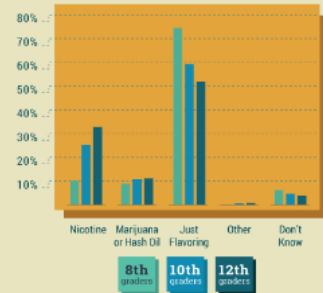
Daily use among 12th graders



PAST-YEAR E-VAPORIZER USE AND WHAT TEENS ARE INHALING



When asked what they thought was in the e-vaporizer mist students inhaled the last time they smoked, these were their responses:



NEARLY 1 IN 3 STUDENTS IN 12TH GRADE REPORT PAST-YEAR USE OF E-VAPORIZERS, RAISING CONCERNS ABOUT THE IMPACT ON THEIR LONG-TERM HEALTH.

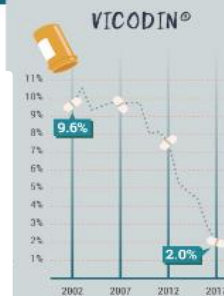
BINGE DRINKING RATES STEADY AFTER DECADES OF DECLINE



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

BINGE DRINKING APPEARS TO HAVE LEVELED OFF THIS YEAR, BUT IS SIGNIFICANTLY LOWER THAN PEAK YEARS.

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

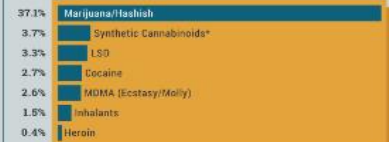


Past-year misuse of Vicodin among 12th graders has dropped dramatically in the past 15 years. Misuse of all Rx opioids among 12th graders has also dropped dramatically, despite high opioid overdose rates among adults.

PRESCRIPTION/OTC



ILLICIT DRUGS



Past-year use among 12th graders

STUDENTS REPORT LOWEST RATES SINCE START OF THE SURVEY

Across all grades, past-year use of heroin, methamphetamine, cigarettes, and synthetic cannabinoids* are at their lowest by many measures.

*Called "synthetic marijuana" in survey

Workshop: Social Media, Mobile Technology and Youth Risk Behaviors

October 17, 2017

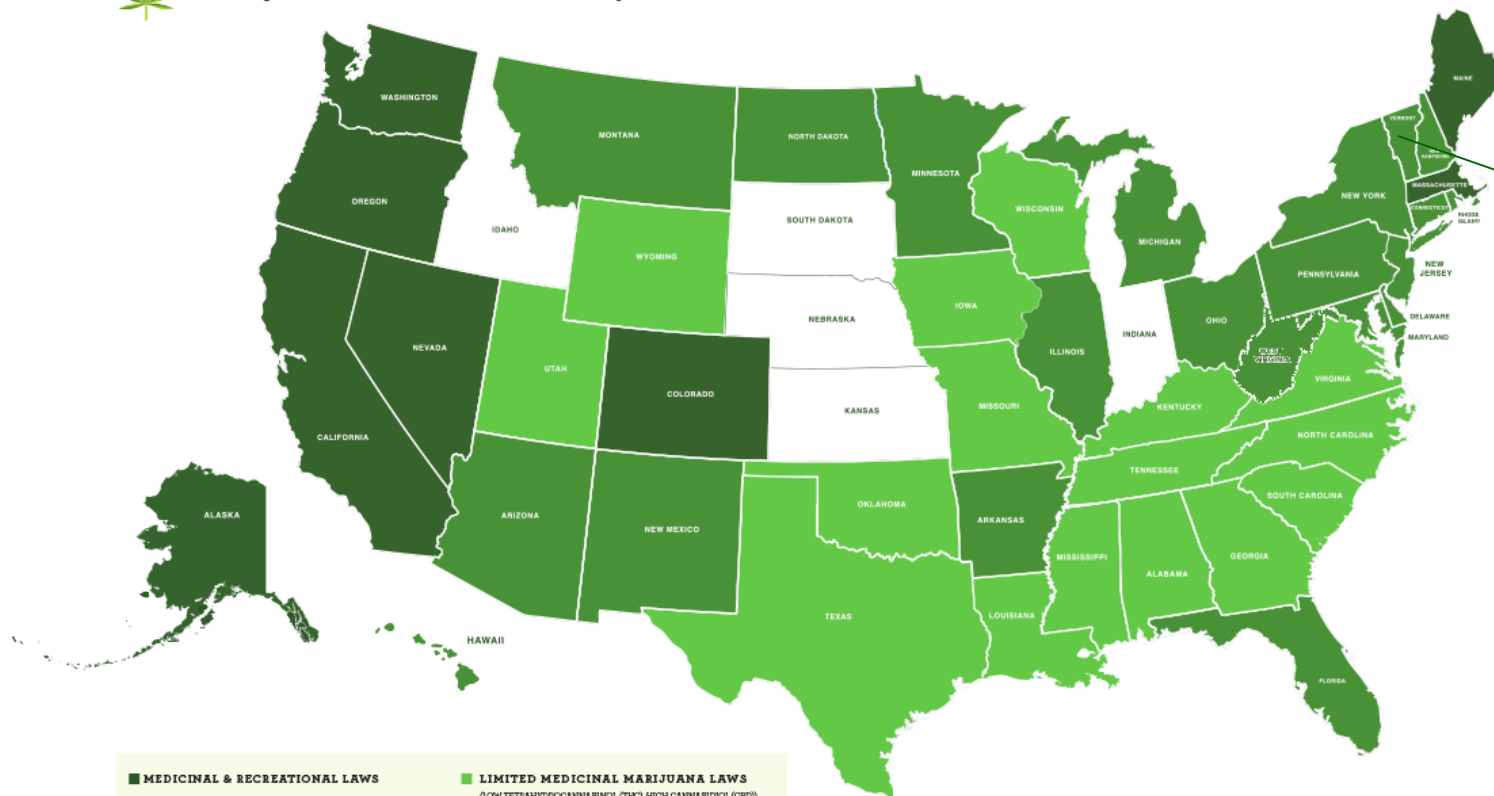


- Co-sponsored by **NIH Office of Behavioral and Social Sciences**
- 11 researchers with *diverse disciplinary perspectives*
- Developmental Effects of Social Media – opportunities:
 - *Understand effects of social media on the brain*
 - *Build on existing longitudinal studies*
 - *Key neurobiological, behavioral, social skill outcomes*
 - *Intensive measurement*
- Collaboration with other NIH components in meeting follow up

CANNABIS LAWS IN THE U.S.



Marijuana Laws Differ State by State



As of Jan. 22, 2018, the Vermont legislature passed adult-use legalization legislation and the governor signed the bill. The measure does NOT set up a regulatory system for sales or production.

REFERENCES

1. <http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx>
2. <http://www.ncsl.org/books/story/state-legislatures-magazine/marijuana-deep-dive.aspx>

STATE LAWS STATUS CURRENT AS OF DECEMBER 28,

LOCAL GOVERNMENT WEBSITES HAVE ADDITIONAL INFORMATION ON THE LAWS REGARDING MEDICINAL AND RECREATIONAL MARIJUANA ON A STATE-BY-STATE BASIS.

29 states have legalized medical marijuana along with D.C., Guam and Puerto Rico

States with MML vary on:

- Allowable conditions and routes of administration.
- Dispensaries/home growth and registries.
- Testing, regulatory requirements.

States with Recreational Laws vary on:

- Marketing, product labeling, distribution (home growth).
- Taxation.

National Institute on Drug Abuse

RECOMMENDATIONS FOR NIDA'S CANNABIS POLICY RESEARCH AGENDA

REPORT FROM THE
CANNABIS POLICY RESEARCH WORKGROUP

February 6, 2018

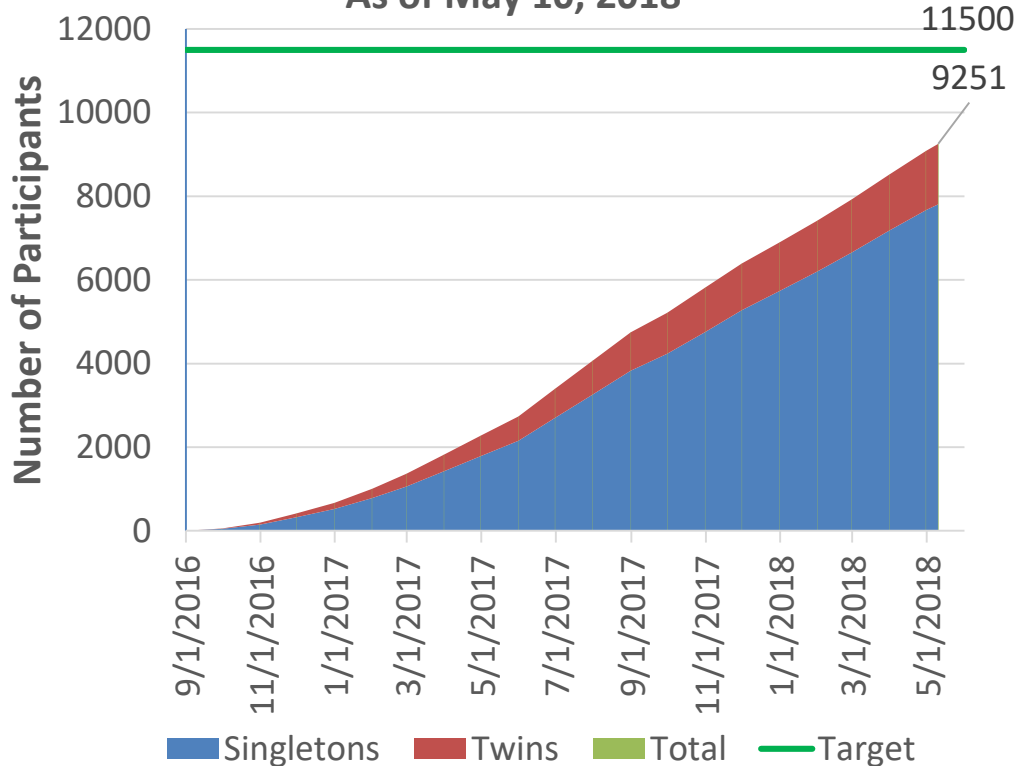


THE EIGHT PRINCIPLES

- The NIDA's research mission is understood to be inclusive, flexible, and public health oriented.
- Research must be neutral about actions, laws, and policies set by any jurisdiction regarding cannabis.
- Priority should be given to research that will remain germane under a wide range of policy frameworks.
- Research should focus on behaviors and consequences that are associated with the greatest harms or benefits and the policies that ameliorate or exacerbate those harms.
- Research should consider both short-and long-term effects.
- Research should be sensitive to the realities of cannabis laws and policies.
- Research should be sensitive to the realities of cannabis production, marketing, and use.
- Research should acknowledge that, sometimes, large gaps can emerge between a law or policy as written and its implementation.

ABCD Update

ABCD Enrollment
As of May 10, 2018



ABCD Study Fast Track Data

DICOM images from ~6,000 participants currently available.

Interim curated data on first 4,500 participants released Feb 2018!

- 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 related to residential density/walkability, crime, area deprivation, population density, and satellite-based pollution measures



NIMH Data Archive

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

New NIDA FOAs

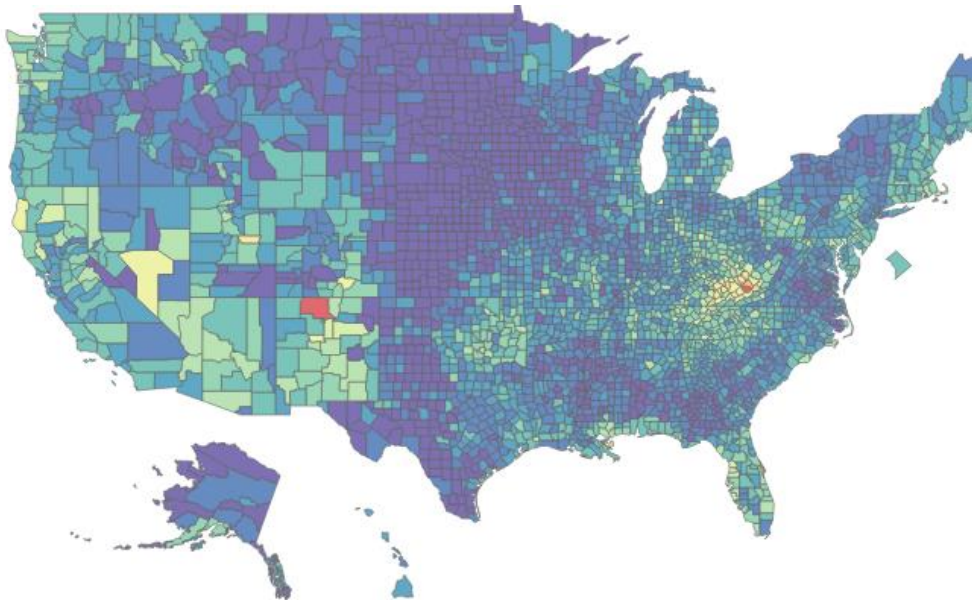
Workshop on the Use of Adolescent Brain Cognitive Development (ABCD) Data (R25 Clinical Trial Not Allowed)
(RFA-DA-19-006)

Issued: March 28, 2018; Application Receipt/Submission Date(s): July 25, 2018.

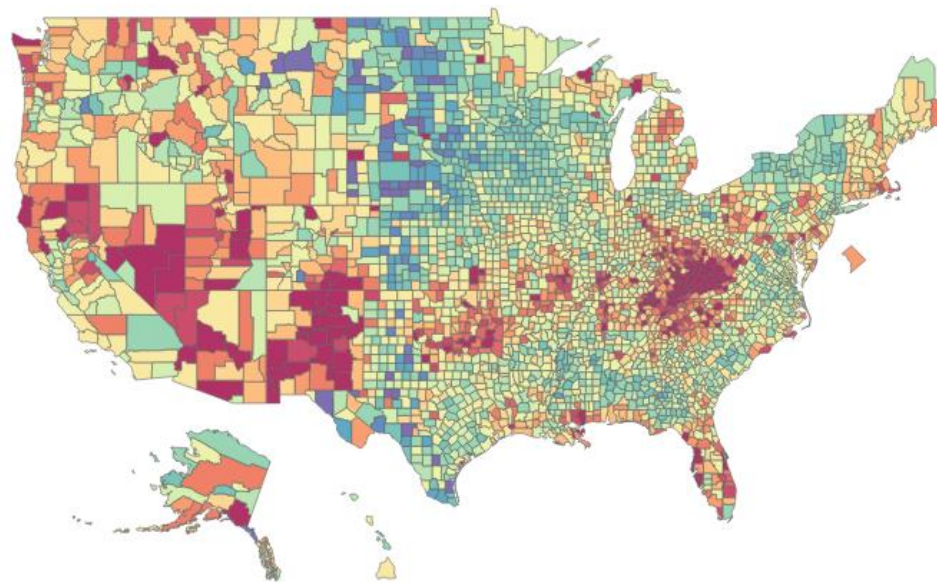
FOA will support creative educational activities with a primary focus on courses for skills development that will allow participants to explore the hands-on use of ABCD data, through cooperative or competitive approaches.

Overdose Death Rates

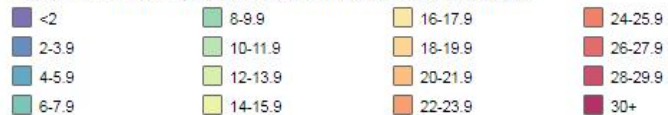
1999



2016

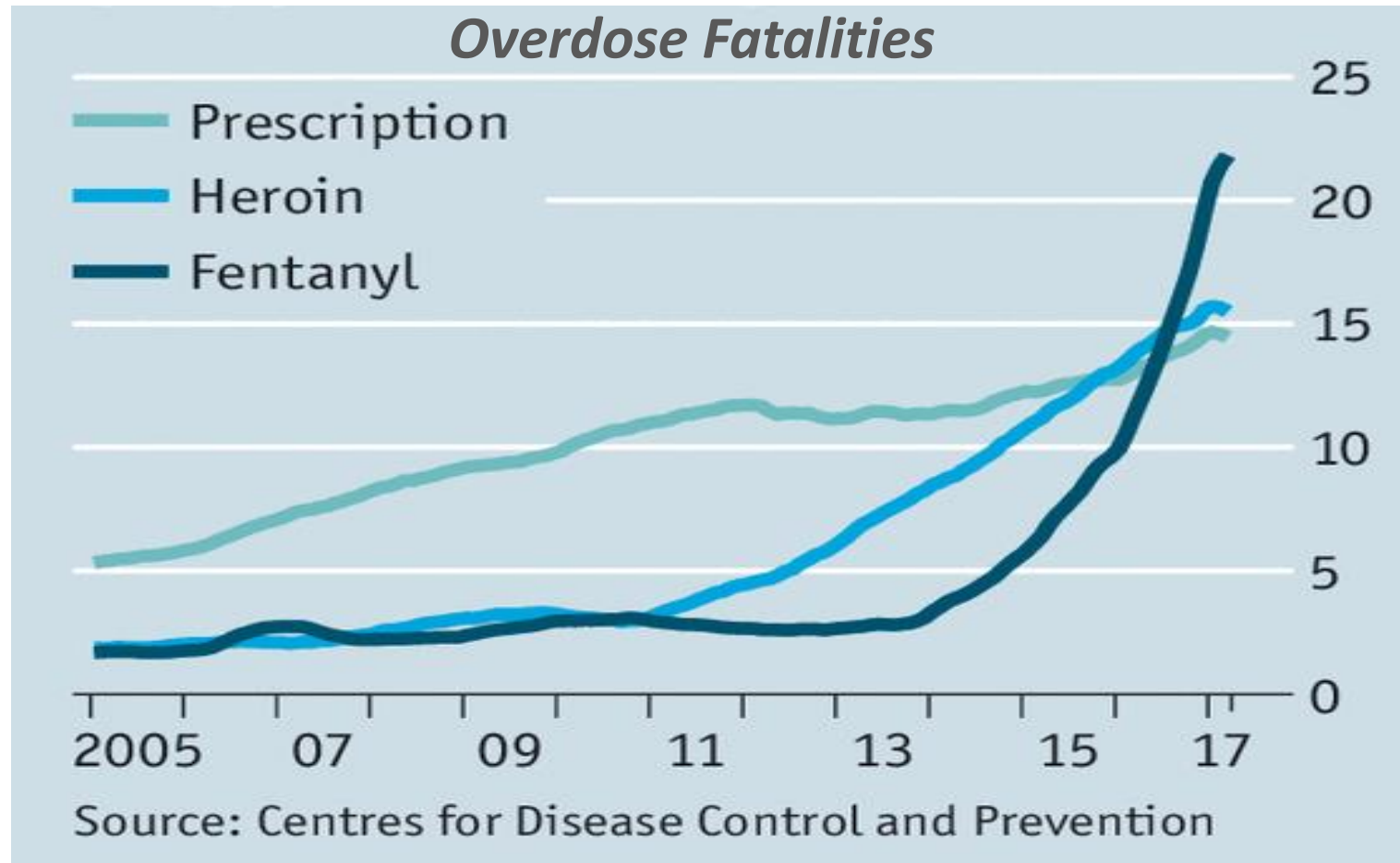


Legend for estimated age-adjusted death rate (per 100,000 population)



Source: <https://www.cdc.gov/nchs/data-visualization/drug-poisoning-mortality/index.htm>

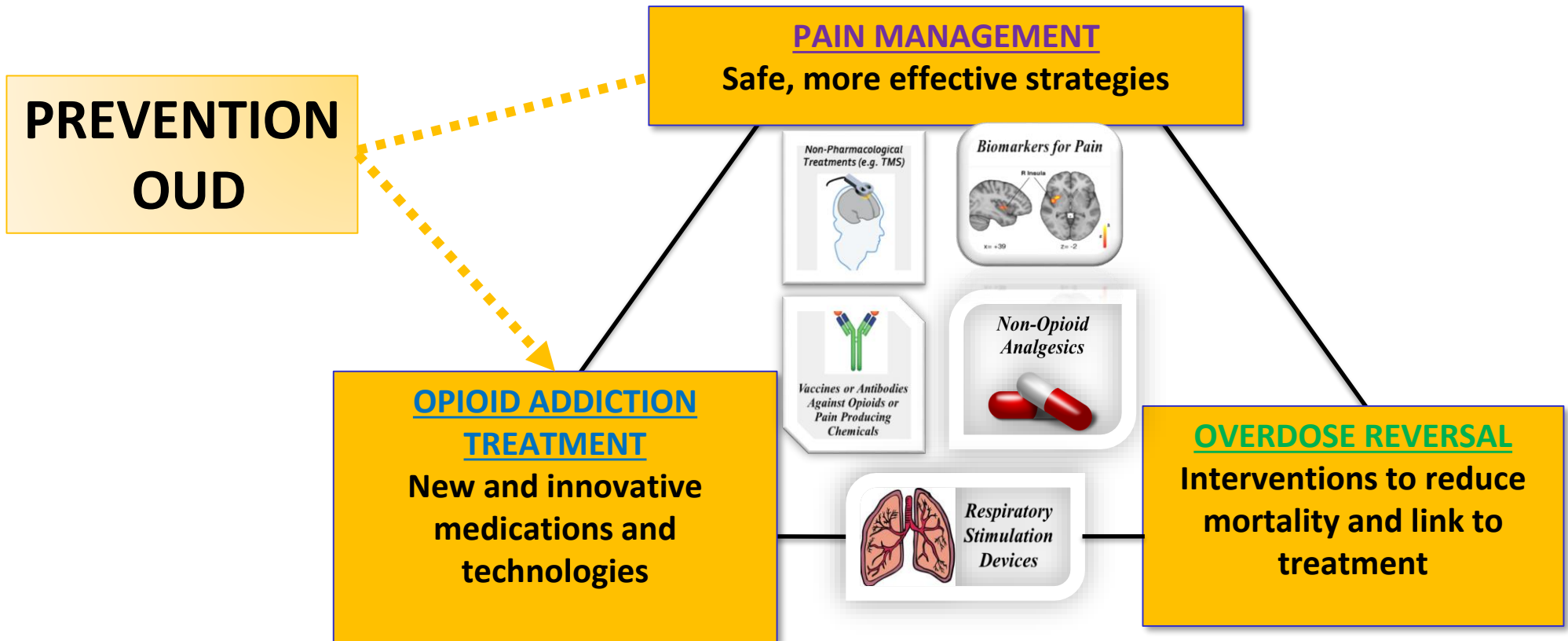
Evolution of the Opioid Crisis



- 1. Over prescription of opioid medications led to misuse*
- 2. Addiction to prescription opioids led to heroin*
- 3. Emergence of fentanyl(s), with higher potency and greater profitability in the black market than heroin.*

NIH OPIOID RESEARCH INITIATIVE

Using Research to End the Opioid Crisis



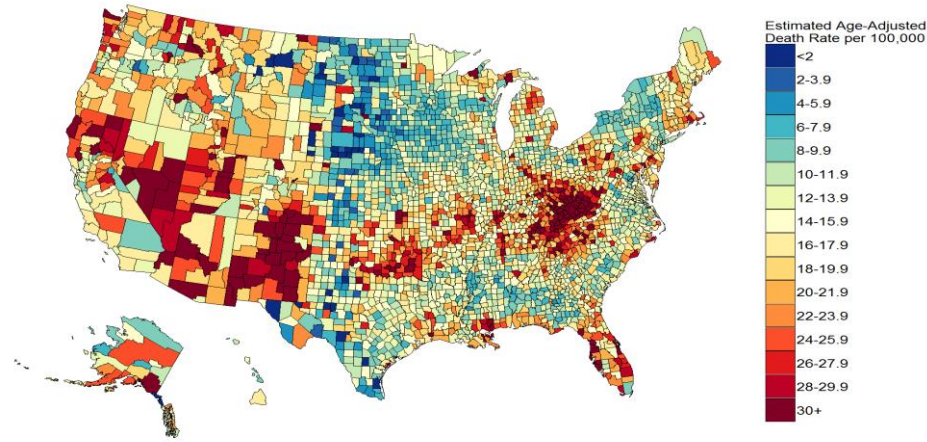
New NIH Initiative to Address the Crisis:

HEAL: *Helping to End Addiction Long-term*

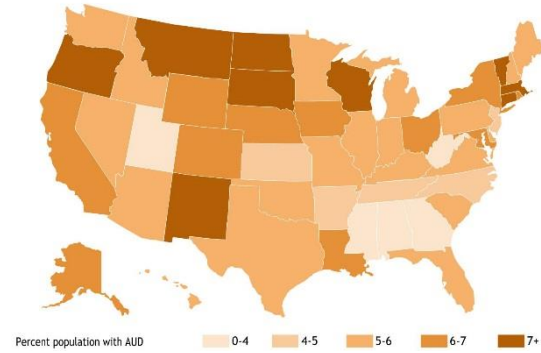
- Collaborative, cross-cutting research
 - From basic to behavioral – and everything between
 - Innovative partnerships – across agencies, sectors, organizations – will ensure rapid progress
- \$500M just added by Congress
 - **Adds to \$600M** current funds = \$1.1B for FY18
 - Will propel HEAL
- Advances national priorities for pain, addiction research...

Drug Poisoning Deaths

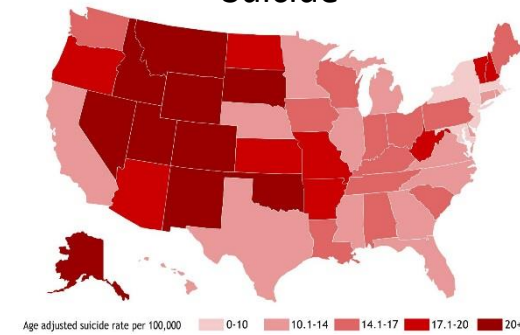
2016



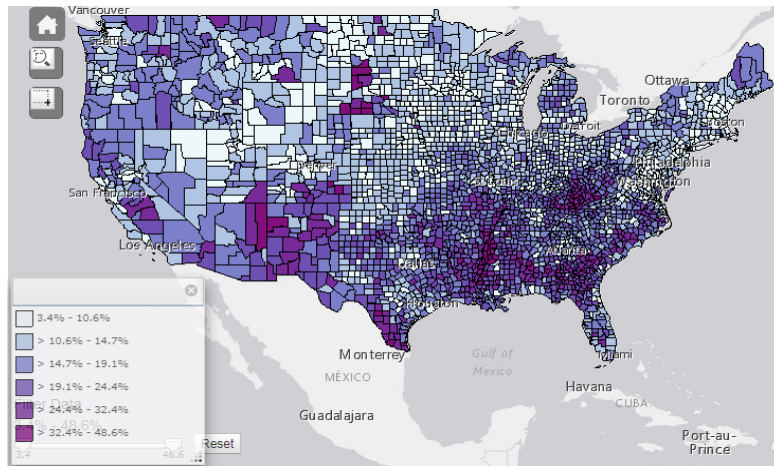
Alcohol Use Disorder



Suicide



All Ages in Poverty



Obesity



Source: CDC NCHS, census.gov

NIDA Topics of Special/Continuing Interest (DAT)

Funding	
Funding Opportunities	▼
Clinical Research	▼
Post-Award Concerns	▼
General Information	
Grant & Contract Application Process	▼
Funding Priorities	▼
<ul style="list-style-type: none"> NIDA Funding Strategy NIDA Topics of Special/Continuing Interest (DAT) Technology Transfer 	
Research Training	▼

NIDA Topics of Interest (DAT)

Important: Please contact the Program Official/Contact(s) before submitting an application.

NIDA is attempting to limit the number of Program Announcements we issue each year; however, we remain committed to informing applicants about emerging and continuing areas of research interest. The Drug Abuse Topics (DATs) of interest will leverage existing parent funding opportunity announcements to solicit topic-specific application within areas of emerging interest to the Institute. Note that we continue to encourage investigator-initiated projects in topic areas not listed here, and that applications submitted in response to the Relevant Funding Opportunities are NOT limited to the research and development areas described below.

This website only lists scientific/research topics and contains instructions for linking applications to specific topic interest to NIDA (DATs). What is not included are additional application instructions, eligibility restrictions, review criteria, selection criteria, or other items related to the completeness or compliance of an application. These are found in the SF424 application guide.

Instructions for submitting applications:

- Insert "DAT-" (four characters) in the beginning of the Project Title of the application. [Note: NIH limits the Project Title to 200 characters (including spaces and punctuation)].
- Insert the DAT Code (e.g., DAT18-01) before the first sentence of the abstract. (This is for internal NIDA tracking purposes only).

Topic	Code	Contacts
Neuroimmune Signaling and Function in Substance Use Disorders (R01, R21) (PDF, 84KB)	DAT18-01	Roger G Sorensen, Ph.D., MPA
Drug Abuse Prevention Intervention Research (R01, R03, R21) (PDF, 89KB)	DAT18-02	Jacqueline Lloyd, Ph.D., MSW
Epidemiology of Drug Abuse (R01, R03, R21) (PDF, 100KB)	DAT18-03	Marsha F. Lopez, Ph.D., MHS
Effects of Cannabis Use and Developing Brain (R01, R03, R21) (PDF, 90KB)	DAT18-04	Da-Yu Wu, PhD
Gene-Environment Interplay in Substance Use Disorders (R01, R21) (PDF, 108KB)	DAT18-05	Karen Sirocco, Ph.D. Naimah Weinberg, M.D. Amy C. Lossie, Ph.D.

NIH **HEAL** Initiative: Some Priorities

Prevention

- Understand Origins of Chronic Pain
- Develop New Non-Addictive Treatments for Pain
- Build Clinical Trial Network for Chronic Pain
- Enhance Precision Pain Management

Treatment

- Improve Therapeutic Approaches to Addiction
- Evaluate Treatments, Consequences of NODS
- *Optimize Effective Treatments through Pilot Demonstration Projects*



The HEALing Communities Study

Multisite Implementation Research Study



Purpose: To test the implementation of an integrated evidence based intervention demonstration project to prevent and treat OUD and prevent overdose death in 2-3 high-impact areas of the Nation.

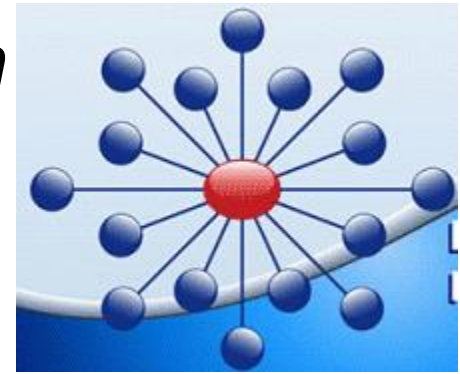
Aims in FY 2018:

- **Coordinating Center (grant):** Facilitate Research Center activities, data harmonization, analysis, and outcome synthesis and dissemination (\$6M in FY2018 funding)
- **Research Centers (2-3) (grant):** Conduct studies based on implementation of an array of evidence-based interventions along a continuum of care framework (\$90M in FY2018 funding)

Budget (FY 2018): \$96,250,000

Total Proposed Budget (FY2018-FY2021): \$361,000,000

NIDA Clinical Trials Network (CTN) Expansion



Purpose: Expand size and scope of research conducted by NIDA's CTN, to develop, validate, refine, and deliver new treatments for OUD

Aims in FY 2018:

- ***Infrastructure Development (supplements): Incorporation of new sites and investigators into existing Nodes to add expertise in critical clinical and scientific areas; expansion of Coordinating and Data Centers (\$8M in FY2018 funding)***
- ***Active Studies (supplements): Expansion of current studies to address "next step" research questions on OUD (\$3.4M in FY2018 funding)***
- ***New Studies (supplements): Improve access to care and quality of care for OUD (\$11.9M in FY2018 funding)***
- ***Dissemination Efforts (supplements): Clinical and research training opportunities (\$5M in FY2018 funding)***

Budget (FY 2018): \$29,000,000

Total Proposed Budget (FY2018-FY2023): \$381,900,000

Justice Community Opioid Innovation Network



Purpose: To establish a network of research investigators to rapidly conduct studies to improve access to treatment and quality care within local and state justice systems to address the opioid crisis.

Aims in FY 2018:

- ***National Survey (supplement): Snapshot of current state of treatment delivery within justice system (\$2M in FY2018 funding)***
- ***Coordinating Center (supplement): Coordination and data harmonization infrastructure (\$1M in FY2018)***
- ***Clinical Research Studies (supplements): Studies on effectiveness and implementation of new medications, interventions, and technologies in justice settings (\$2M in FY2018 funding)***
- ***Methodology Studies (supplements): Explore innovative methods to leverage existing data sources and identify innovative approaches and methods to maximize impact (\$0.5M in FY2018 funding)***

Budget (FY 2018): \$5,750,000

Total Proposed Budget (FY2018-FY2023): \$208,500,000

Medications Development



Purpose: Accelerate the research that is currently underway in NIDA's Medications Development Program.

Aims in FY 2018: Fund a total of 15-20 new research studies leading to about 15 Investigational New Drug Applications and 5 New Drug Applications.

Focus areas:

- 1. Stronger, longer-acting formulations of antagonists to counteract overdose from high-potency opioids (\$10M in FY2018 funding)**
- 2. New formulations of existing medications to improve treatment compliance and/or reduce diversion (\$20M in FY2018 funding)**
- 3. Exploring new targets (\$15M in FY2018 funding)**
- 4. Interventions against respiratory depression induced by opioids alone or in combination with other substances (\$10M in FY2018 funding)**
- 5. Immunotherapies (vaccines and monoclonal antibodies) to prevent relapse by stimulating the body to generate antibodies that bind to opioids or using highly efficient anti-drug antibodies to neutralize the drug while still in the bloodstream (\$15M in FY2018 funding)**

Budget (FY 2018): \$70,250,000

Total Proposed Budget (FY2018-FY2023): \$424M