

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

February 6, 2018

Nora D. Volkow, M.D., Director



National Institute
on Drug Abuse

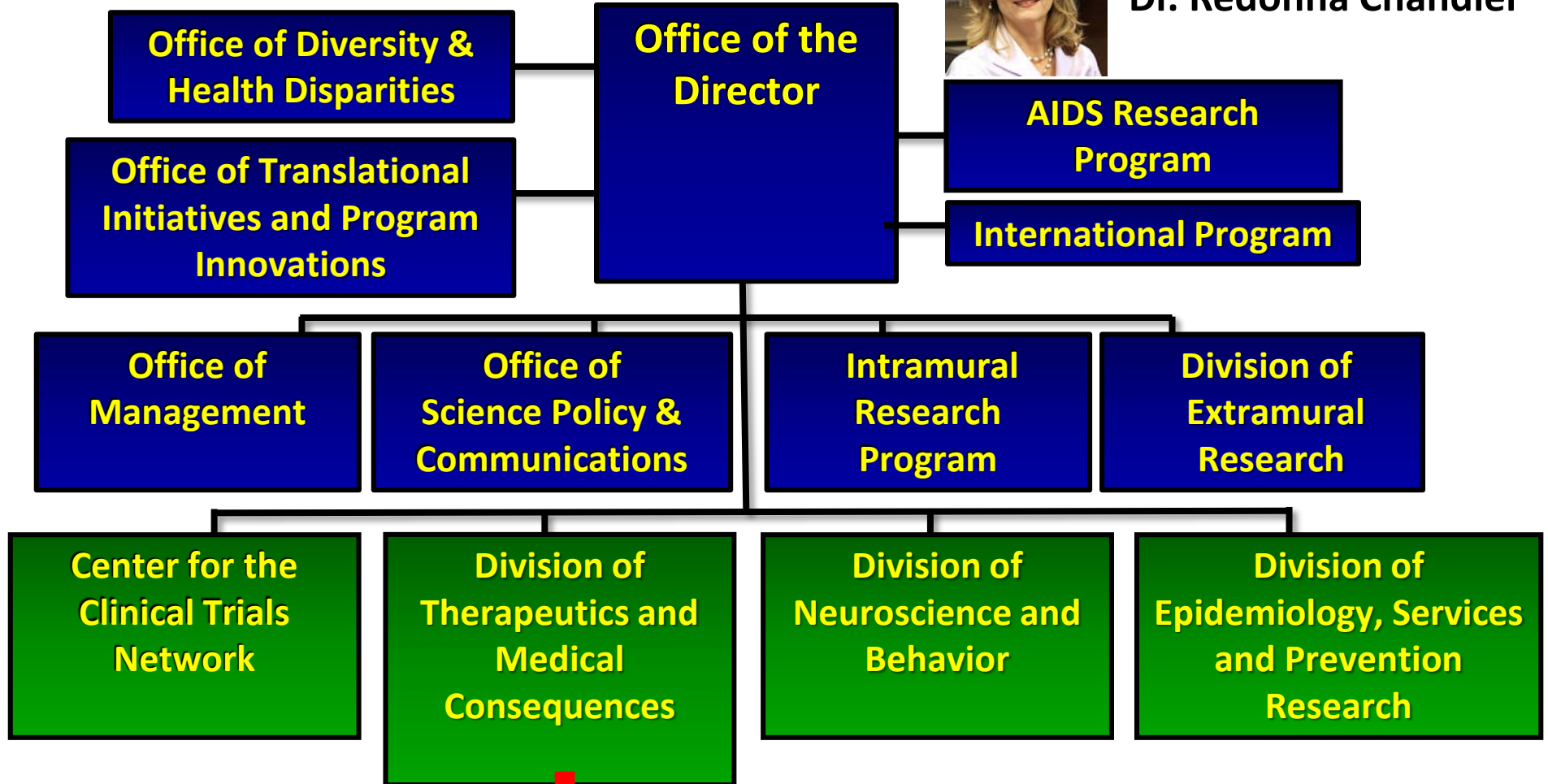


@NIDAnews

NIDA



Dr. Redonna Chandler



Search for DTMC Director

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

- **Budget Update**
- **What's New @ HHS/NIH?**
- **Recent NIDA
Activities & Events**

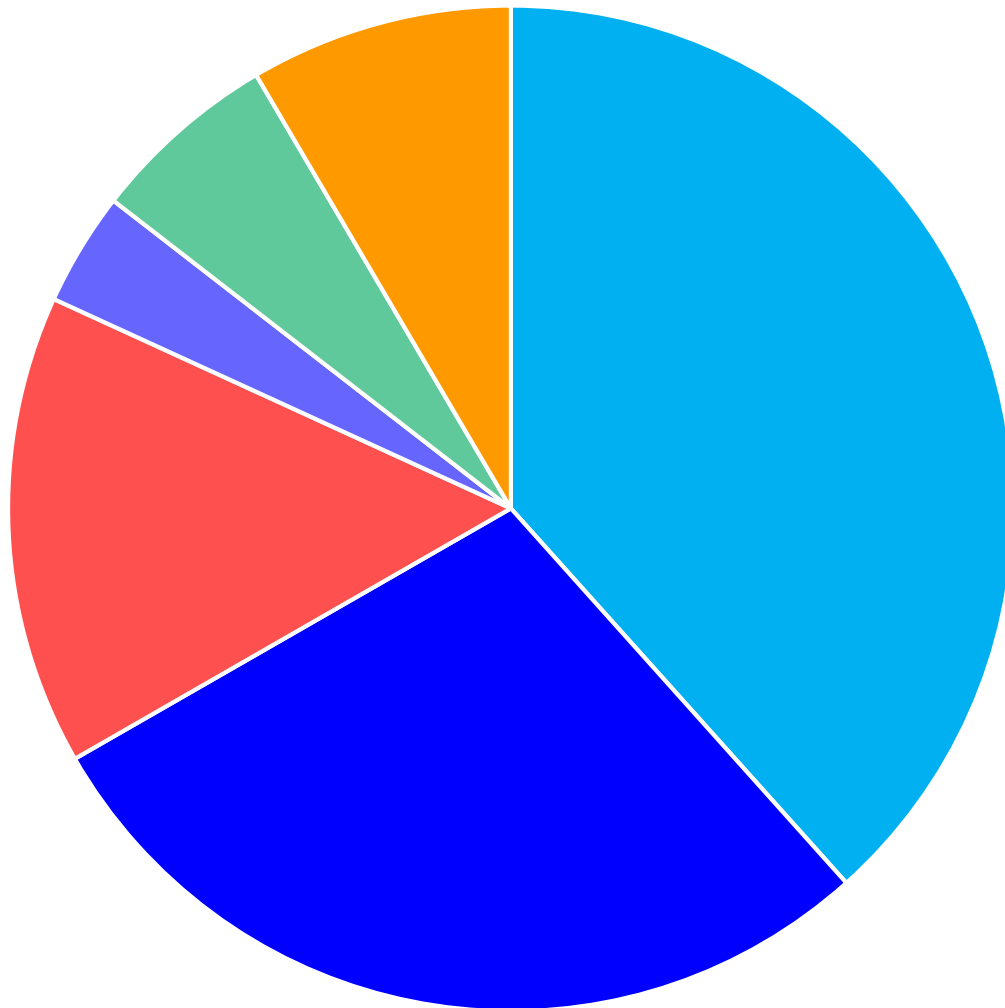
NIDA BUDGET

(Thousands)

| | FY 2016 Actuals | FY 2017 Actuals | FY 2018 PB |
|--------------|---------------------------|---------------------------|----------------------|
| NonAIDS | \$754,727 | \$794,102 | \$647,674 |
| AIDS | \$294,244 | \$276,711 | \$217,324 |
| TOTAL | \$1,048,971 | \$1,070,813 | \$854,998 |

National Institute on Drug Abuse Portfolio

FY 2017 Actual



- Division of Neuroscience & Behavior -- 38%
- Division of Epidemiology, Services & Prevention Research -- 28%
- Division of Therapeutics and Medical Consequences -- 15%
- Center for the Clinical Trials Network -- 4%
- RMS -- 6%
- Intramural Research -- 8%

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

- **Budget Update**

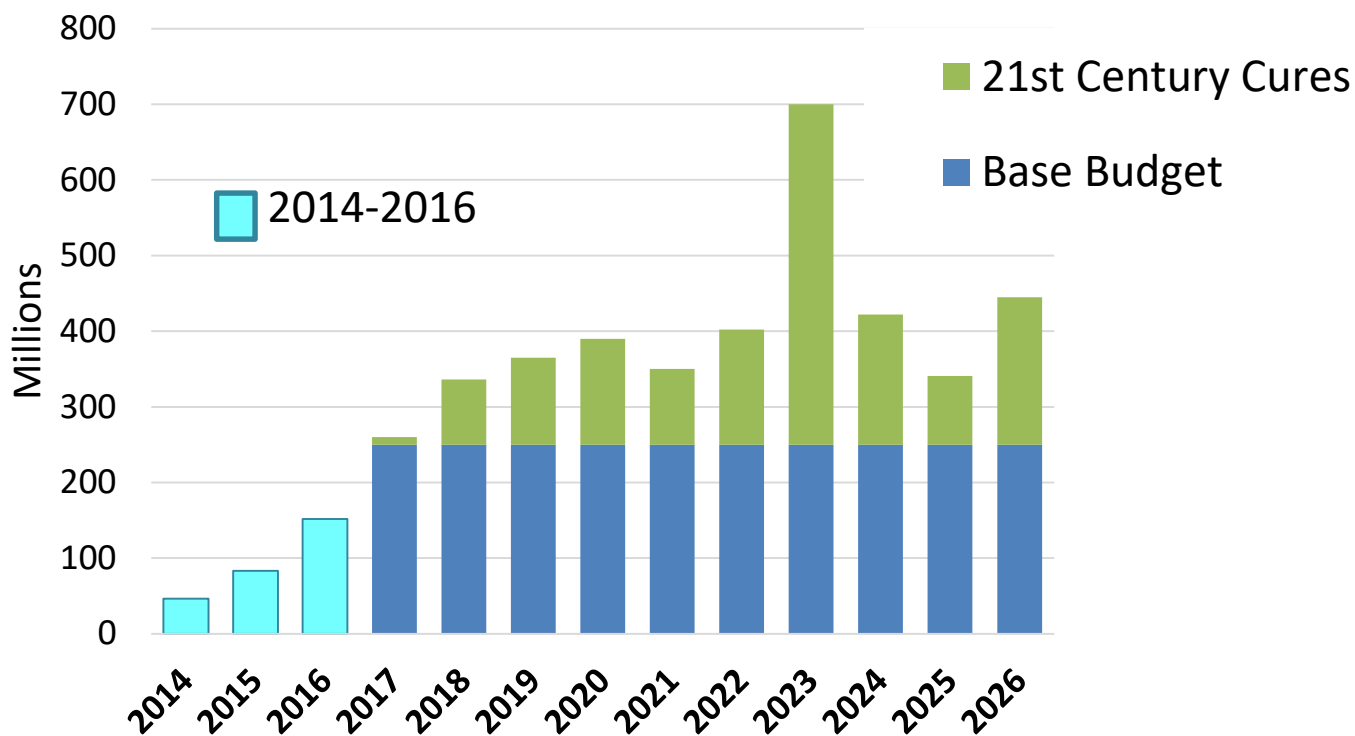
- **What's New @ HHS/NIH?**

- **Recent NIDA
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THE BRAIN INITIATIVE® BRAIN is Just Getting Started

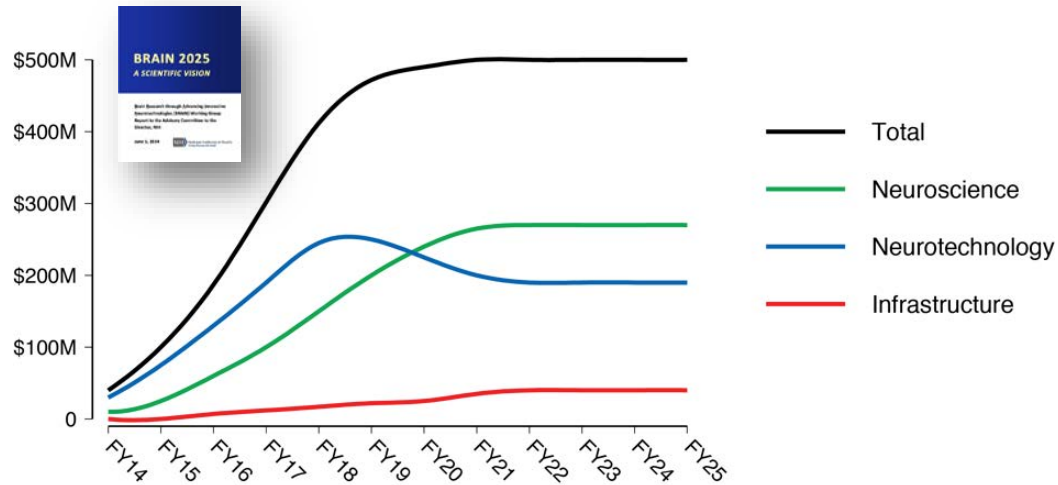


\$4.2B: Projected total for lifetime of BRAIN
\$550M: BRAIN Funding through 2017
~12% of the total



Revisiting BRAIN in 2020 and Beyond

THE BRAIN INITIATIVE®



BRAIN 2025 Report: *First years [should] emphasize technology development and validation, with a growing emphasis on problem-driven neuroscience after FY2020*

- NIH will **formally revisit BRAIN 2025's priorities** to provide an updated scientific vision to guide the second half of the Initiative
- Focus on specific **topics/questions that can now be interrogated** given the emerging set of tools and technologies

BRAIN Initiative: Notice of Support for Research on the Fundamental Neurobiology of Pain Processing

- NIH welcomes BRAIN Initiative applications targeting central nervous system nociceptive and pain circuits, as appropriate to the goals and requirements of specific BRAIN Initiative FOAs.
- It is expected that the unique opportunities of the BRAIN Initiative will enable production of detailed maps of pain circuits, and the adoption of powerful new tools for monitoring and modulating pain circuit activity, leading to significant advances in the understanding of pain and nociception.

<https://grants.nih.gov/grants/guide/notice-files/NOT-NS-18-008.html>

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JOBS@NIH—DISCOVER A CAREER AT NIH: IT'S ABOUT LIFE

DIRECTOR: BRAIN INITIATIVE

National Institute of Neurological Disorders and Stroke (NINDS)

APPLICATIONS WILL BE REVIEWED STARTING

March 5, 2018 (Applications accepted until position is filled.)

DIRECTOR: NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH

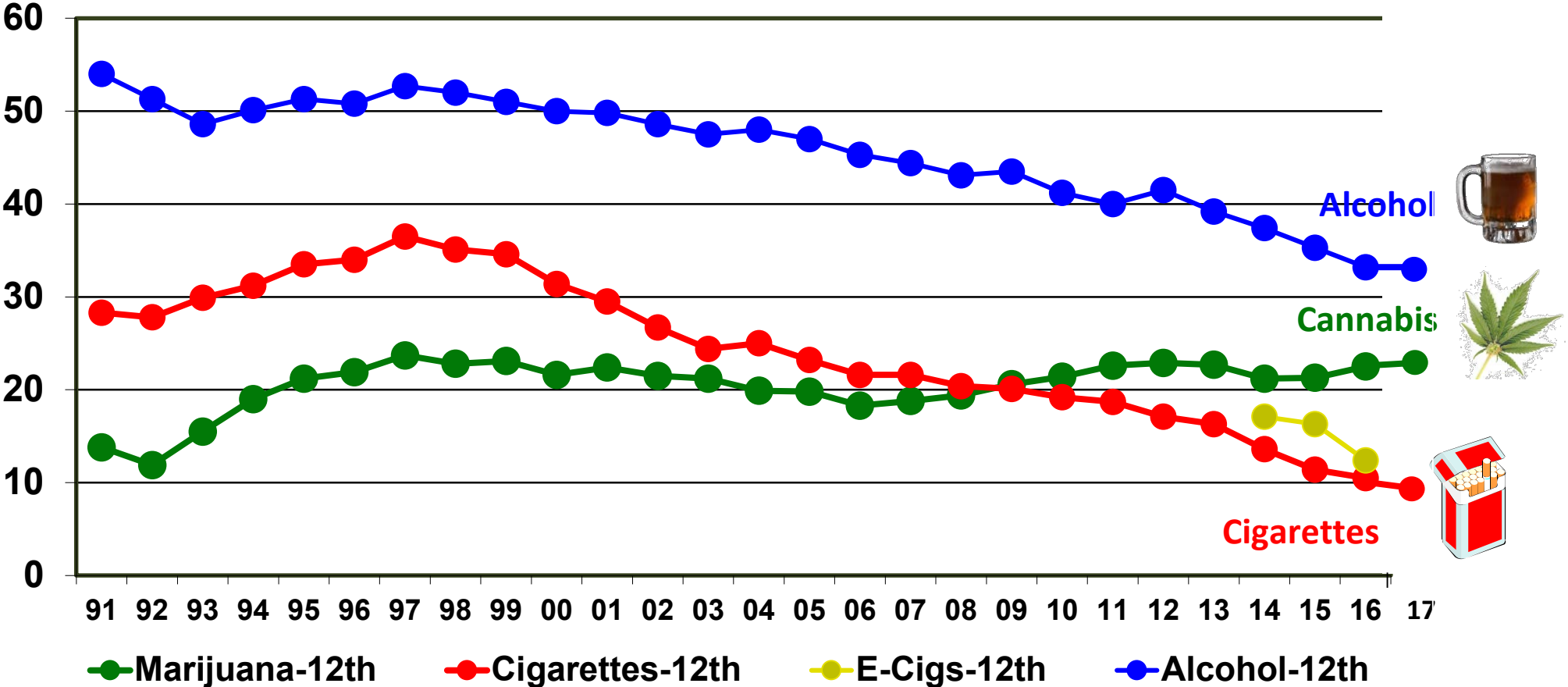
APPLICATION BY March 1, 2018 at 11:59 p.m., ET

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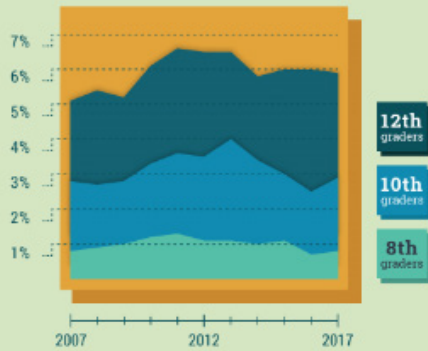
Past Month *Marijuana Use Remains Steady* while Alcohol and Cigarette Use Declining among High School Seniors



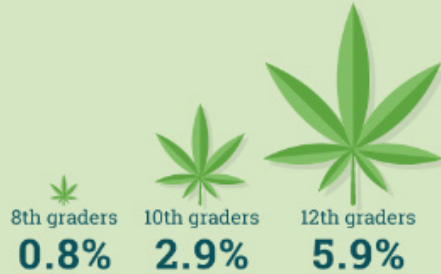
SOURCE: University of Michigan, 2017 Monitoring the Future Study

DAILY MARIJUANA USE MOSTLY STEADY

2007 – 2017



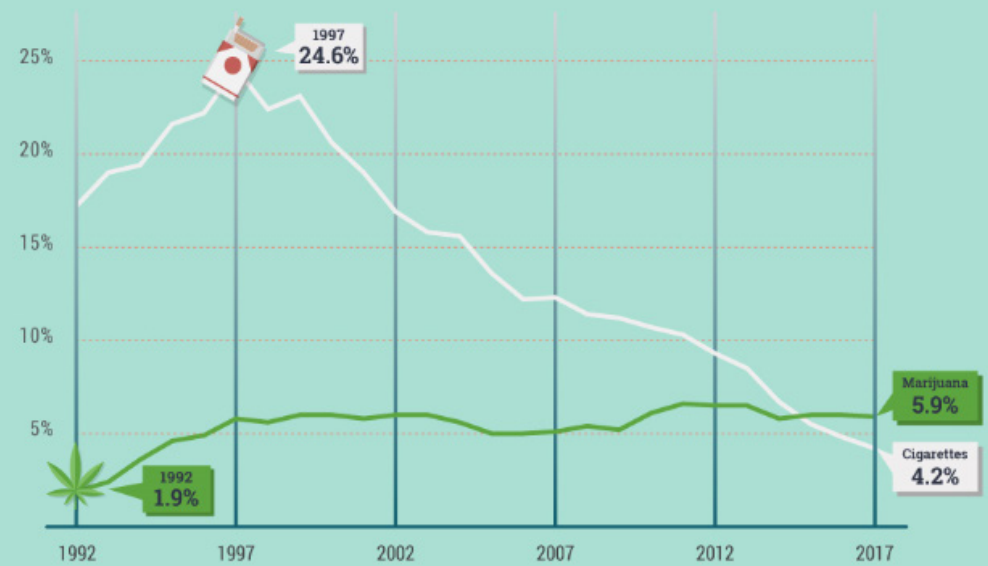
2017



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

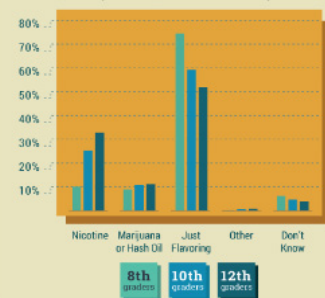
Daily use among 12th graders



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

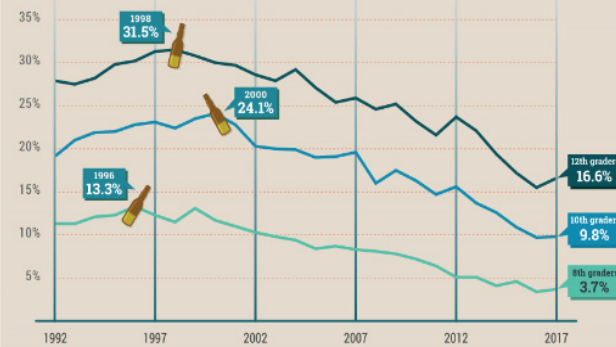


When asked what they thought was in the e-vaporizer mist students inhaled the last time they smoked, these were their responses:



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.

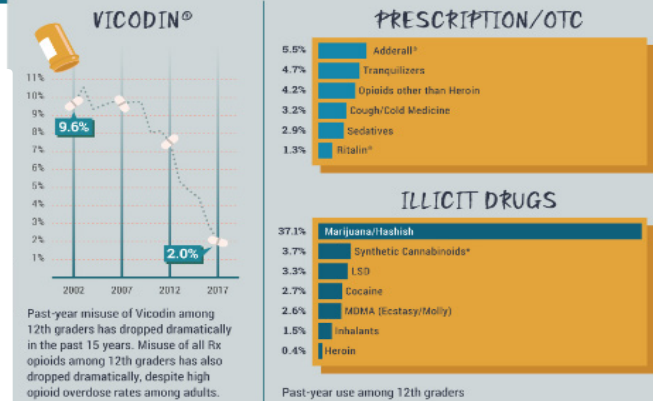
BINGE DRINKING RATES STEADY AFTER DECADES OF DECLINE



*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

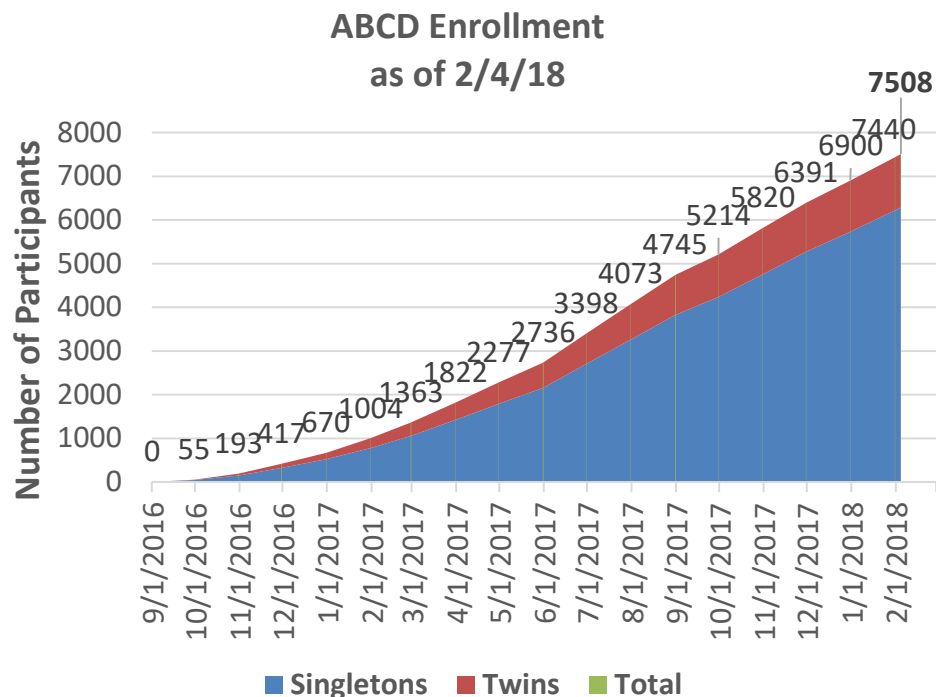


STUDENTS REPORT LOWEST RATES SINCE START OF THE SURVEY

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

ABCD Update



ABCD Study Fast Track Data

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

The ABCD Study is releasing fast-track neuroimaging data from ABCD Study participants on an ongoing basis - DICOM images from ~4,000 participants currently available.

Annual Curated Data Release

Interim data on the first 4,500 participants will be released in early 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, and
- Biological data (e.g., pubertal hormone analyses).



Adolescent Brain Cognitive Development

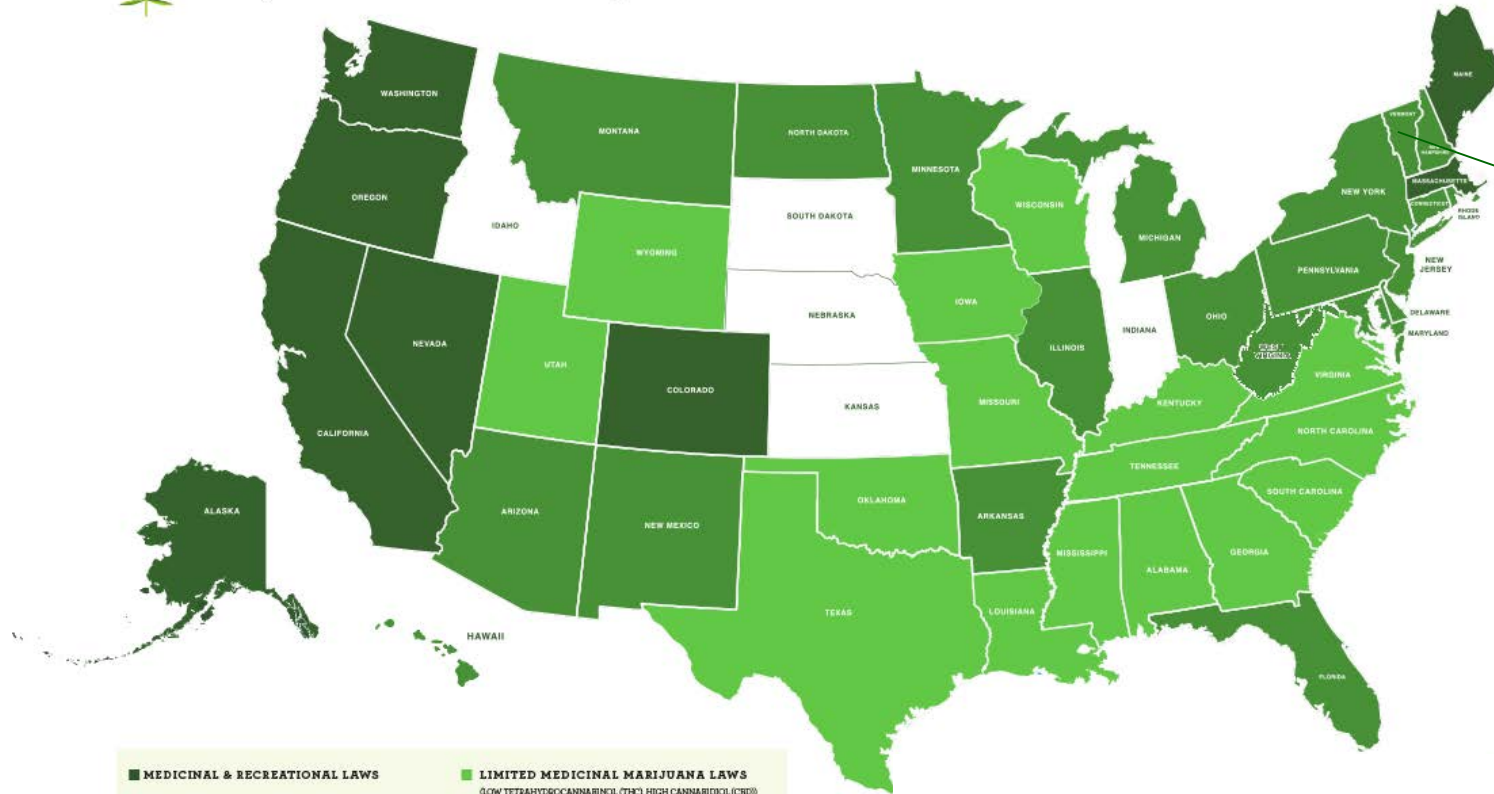
Teen Brains. Today's Science. Brighter Future.



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/other/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.

*John Carnevale, Workgroup Chair, will be presenting
a summary of the report findings this afternoon...*

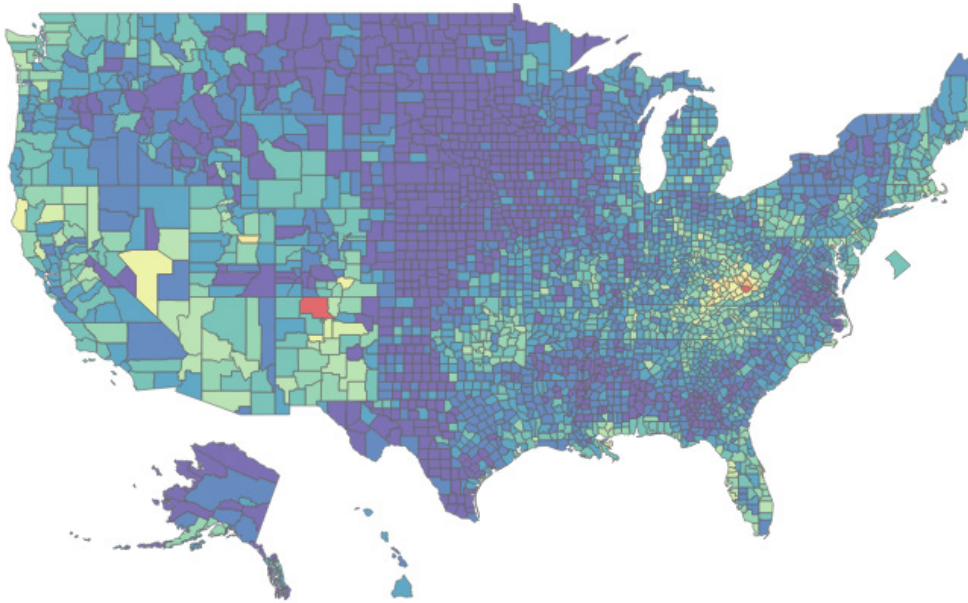
RECOMMENDATIONS FOR THE NIDA'S CANNABIS POLICY RESEARCH AGENDA

NATIONAL ADVISORY COUNCIL ON DRUG ABUSE
CANNABIS POLICY WORKGROUP

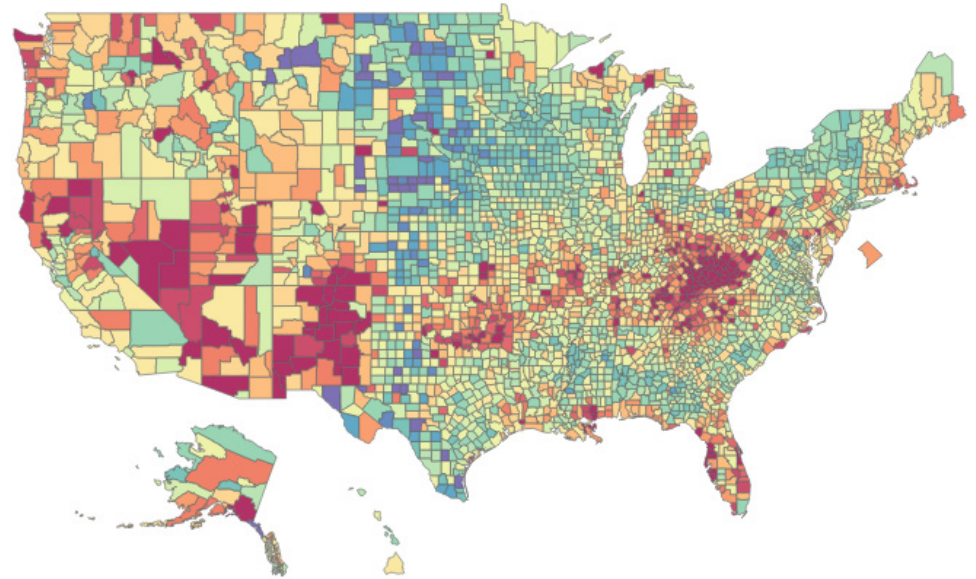
FEBRUARY 6, 2018

Overdose Death Rates

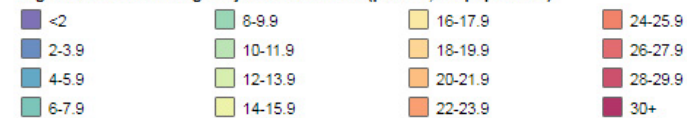
1999



2016

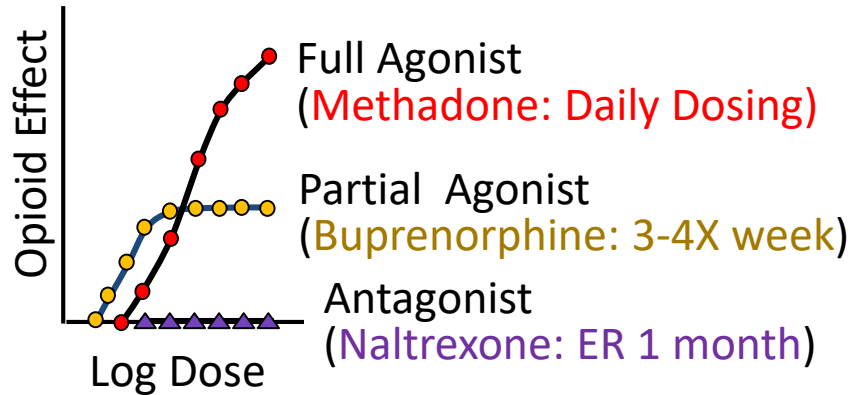


Legend for estimated age-adjusted death rate (per 100,000 population)



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

Medication Assisted Treatment (MAT)



DECREASES:

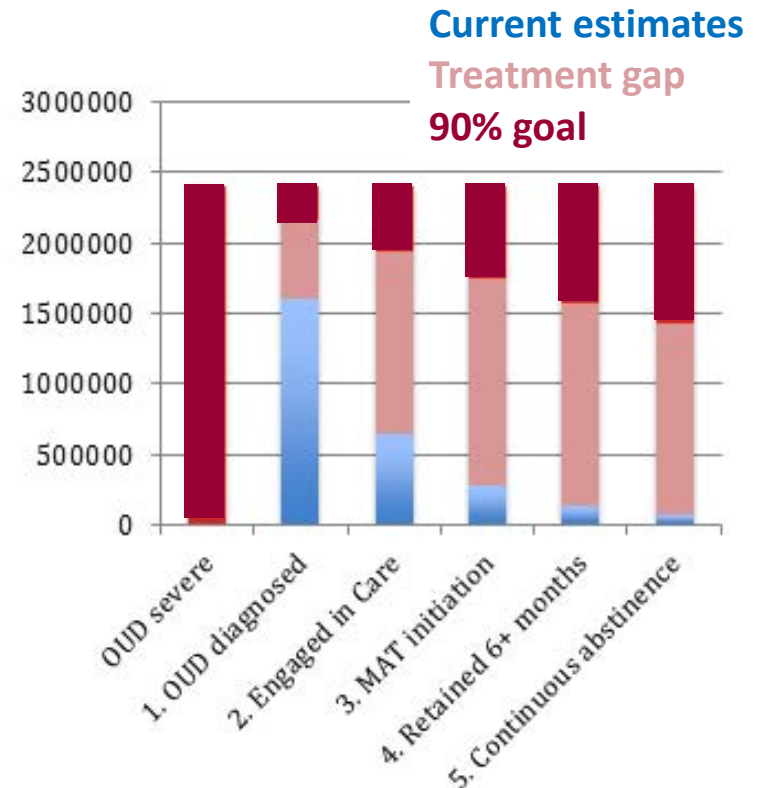
- Opioid use
- Opioid-related overdose deaths
- Criminal activity
- Infectious disease transmission

INCREASES

- Social functioning
- Retention in treatment

But MAT is highly underutilized!
Relapse rates are very high!

OUD Cascade of Care in USA



*Williams AR, Nunes E, Olfson M.
Health Affairs Blog, 2017*

Expand access to MAT

Healthcare system

Criminal Justice system

Improve Compliance and Retention

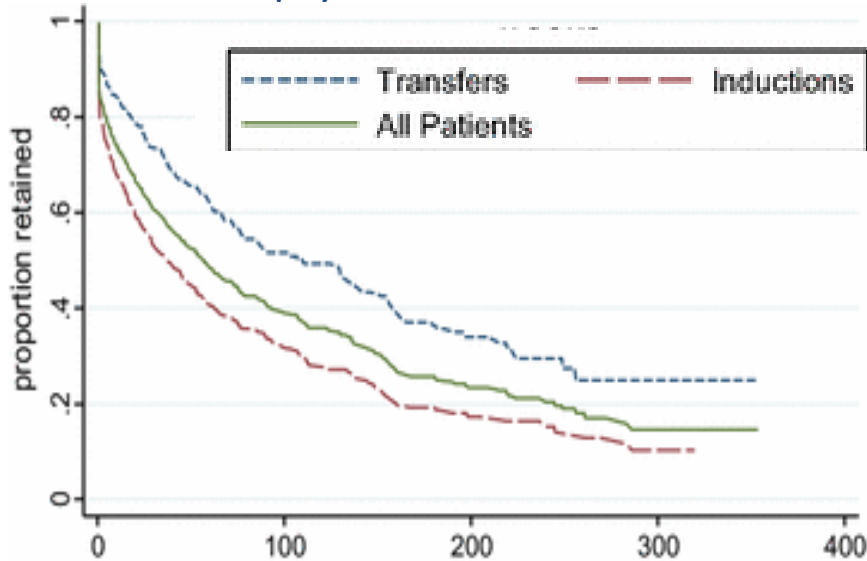
Extended release formulations

Drug combinations

Additional interventions

Public Sector Low Threshold Office-Based Buprenorphine Treatment in Primary Care

Unobserved induction,
At most weekly visits,
No psychosocial treatment.



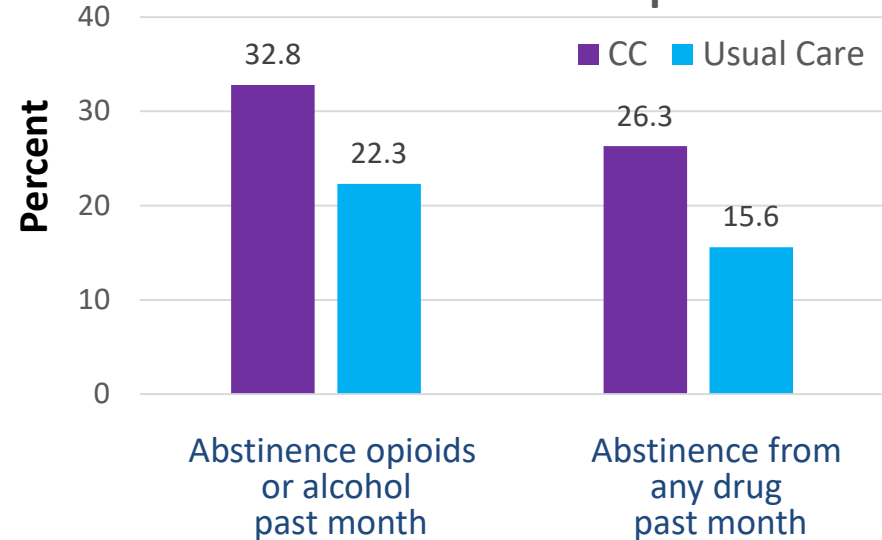
- Treatment retention of 38 weeks is equivalent to that of office-based opioid treatment.
- Low threshold treatment protocols, as compared to national guidelines, may expand access to buprenorphine

Bhatraju EP et al., *Addict Sci Clin Pract.* 2017 Feb 28;12(1):7.

Collaborative Care for Opioid and Alcohol Use Disorders in Primary Care (FQHC)



Participant Outcomes at 6-Month Follow-up



- In primary care, collaborative care intervention increased *abstinence from alcohol and drugs* compared to usual care.
- *Treatment for OAUDs can be integrated into primary care settings.*

Watkins KE et al., *JAMA Intern Med.* 2017;177(10):1480-1488.

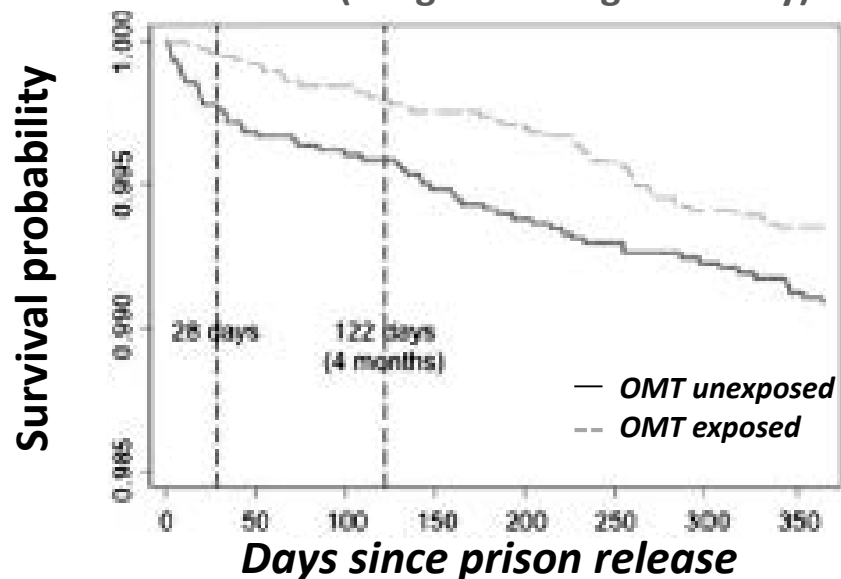


Opioid Medication Therapy (OMT) In Prison

Postincarceration Overdose Deaths After Implementing OMT in a Statewide Correctional System (Rhode Island)

Mortality Post Release

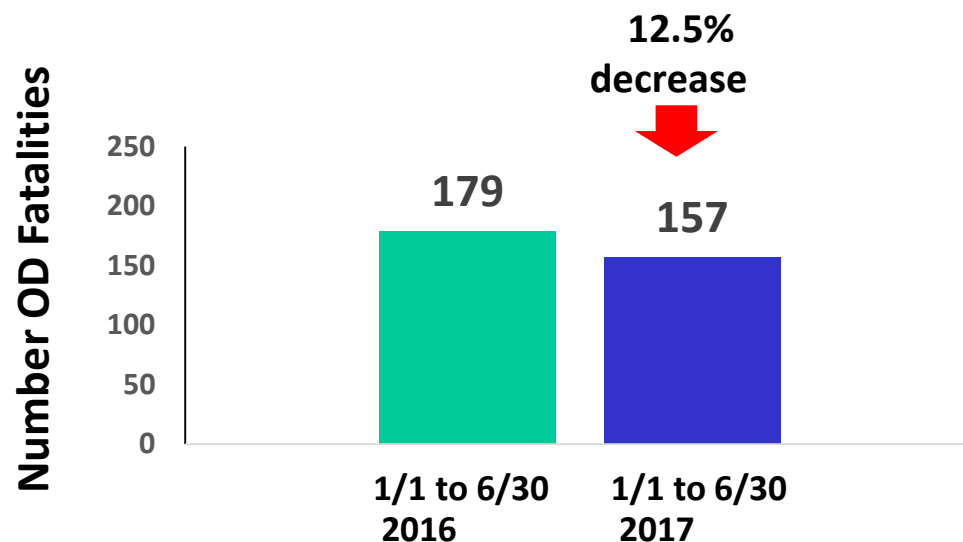
Survival Curve During the Year Following Release (Drug-Poisoning Mortality)



OMT resulted in a 75% reduction in mortality (85% reduction in overdoses) in the first month post release

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

Statewide Overdose Deaths



OD fatalities in those who had been incarcerated in 2017 decreased by 60% compared to 2016 (5.7% vs 14.5%)

Green TC and Clarke J. *JAMA Psychiatry* 2018;75(4).

Using Science to Inform Practice and Policy: A Coordinated Approach to Research Priority Setting

Sponsored by the National Institute on Drug Abuse in Partnership with ECRI Institute



Priorities for Future Research

- ***Strengthen connection between research and practice***
 - Learning health care system to translate evidence-based practices
 - Large-scale implementation pilot
- ***Explore, maximize, and expedite available data sources and study designs***
 - Observational and secondary data sources in addition to clinical trials
 - Consider barriers to using the data, including confidentiality issues
- ***Engage citizen scientists to help develop outcome and quality measures***
 - Need standardized metrics that patients and families can use to report on patient experience and treatment outcomes
- ***Determine criteria to indicate inpatient vs outpatient treatment***
 - Collect longer-term outcomes data to understand the utility of different treatments settings and modalities
- ***Treatment interventions for mild OUD or subclinical opioid misuse***
- ***Research to address cost and sustainability***

Expand access to MAT

Healthcare system

Criminal Justice system

Improve Compliance and Retention

Extended release formulations

Drug combinations

Additional interventions

SUBLOCADE™
(Buprenorphine ER),
Once-Month Injectable
FDA Approval 11.30.2017

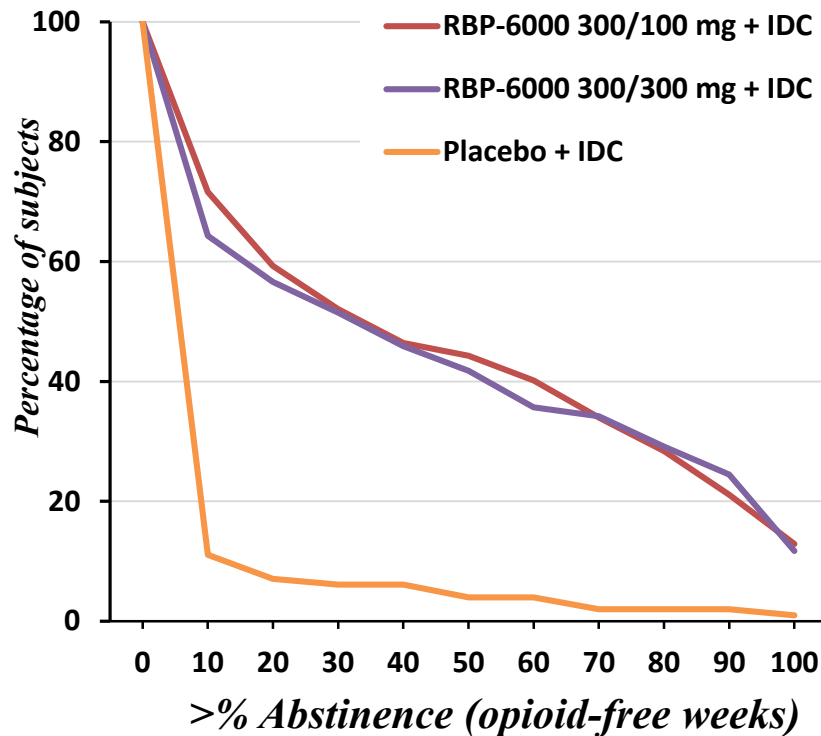


CAM2038:
Subcutaneous ER
Buprenorphine



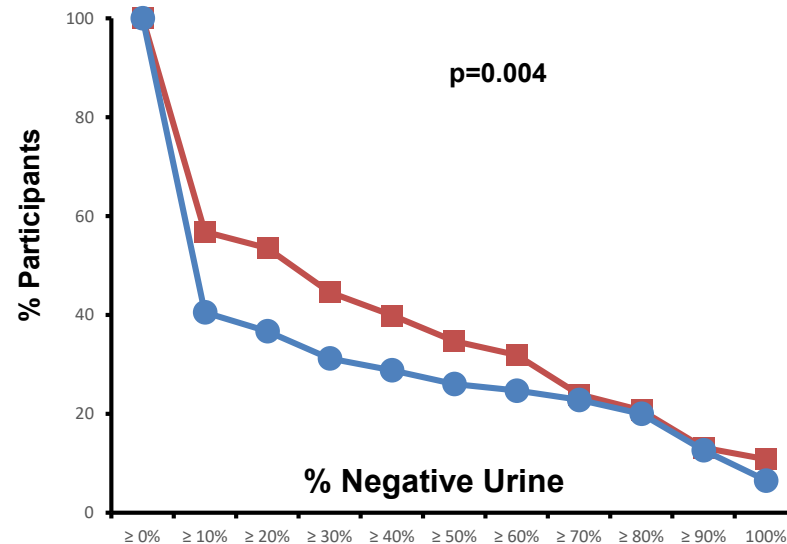
Weekly or monthly injection

% urine samples negative
for opioids (Weeks 5 to 24)



Heidbreder et al., CPDD 2017

Comparison CAM2038 versus Daily SL BPN



Establishment of the NIDA Advisory Council Workgroup on Opioids

Mission: To provide guidance on the development and implementation of NIDA's public-private response to help end the opioid crisis.

Chair: Edward V. Nunes, M.D.

Next Steps:

- Appoint members - February***
- Convene workgroup - March***
- Conduct assessment - March - May***

- Complete and issue final report - June - July***
- Update Council - On - going***



Development of Medications to Prevent and Treat Opioid Use Disorders and Overdose (UG3/UH3) (Clinical Trial Optional) RFA-DA-19-002

Issued: December 14, 2017; Open Date: January 25, 2018

- Support discovery and development of medications to prevent and treat opioid use disorders (OUD) and overdose.
- The UG3/UH3 Phase Innovation Awards Cooperative Agreement involves 2 phases:
 - UG3:** will support a project with specific milestones to be accomplished by the end of the 2-year period.
 - UH3:** will provide funding for 3 years to a project successfully completed in UG3.
- Investigators responding to this FOA must address both UG3 and UH3 phases.

FDA Patient-Focused Drug Development (PFDD) Initiative

In 2012, **patient voices** joined the science

- 5 patient-centered, community-led Guidances for Industry written:
 - Artificial Pancreas Device Systems (2012);*
 - Chronic Fatigue Syndrome, Myalgic Encephalomyelitis (March 2014);*
 - Duchenne Muscular Dystrophy (June 2015);*
 - Amyotrophic Lateral Sclerosis, ALS (Draft, 2016),*
 - Amyloidosis (Draft, December 2016).*
- On November 30, 2017, NIDA and Addiction Policy Forum (NGO) submitted LOI to FDA indicating the intent to lead a PFDD meeting for OUD.
- On December 22, 2017, FDA determined that “*gathering patient perspectives on OUD will be of great value ..*”. FDA accepted NIDA/APF LOI and proposed the transition of the meeting from externally-led into FDA-led. FDA will host the meeting and lead planning, working closely with APF and NIDA.

PFDD Meeting will take place on April 17, 2018



Priority Areas

Prevention Research

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

Treatment Interventions

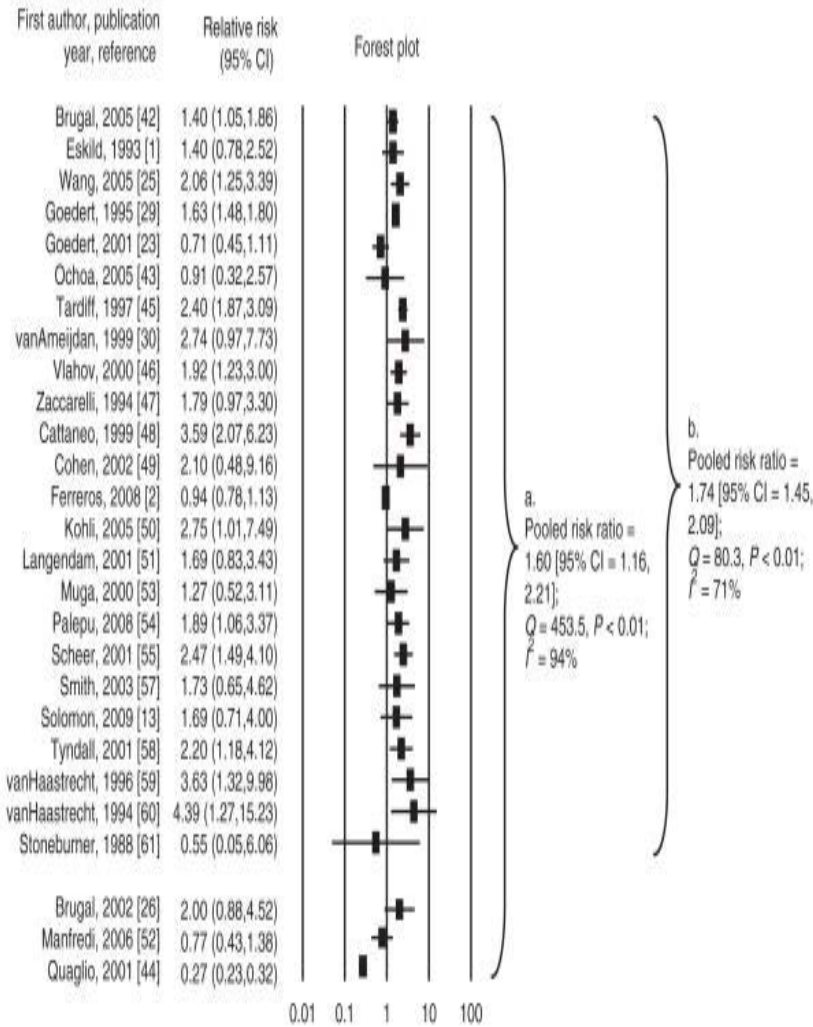
(New Targets & New Strategies)

HIV and Drugs

Prevention
Treatment



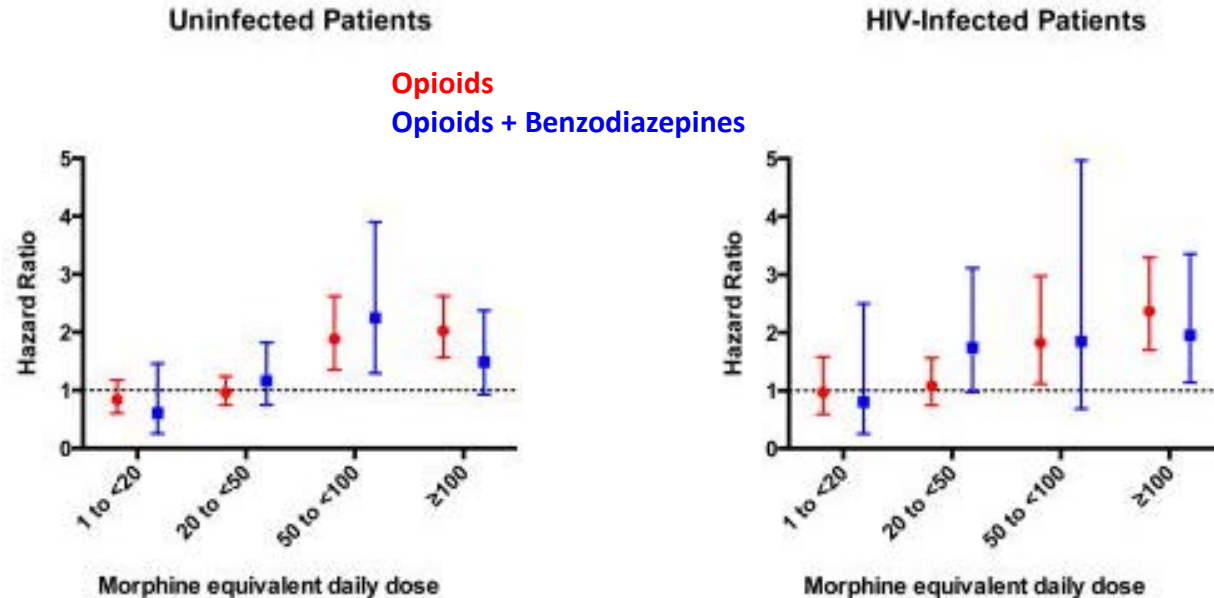
HIV infection and risk of overdose: meta-analysis



HIV+ associated with increased risk of overdose mortality (risk ratio 1.74)

Green et al., AIDS. 2012 26(4): 403–417.

Long-term prescription opioids and/or benzodiazepines and mortality among HIV-infected and uninfected patients



Significant interaction between opioid receipt and HIV with mortality: HR was 1.46 in HIV+ and 1.25 in HIV- (p < 0.01).

Mortality risk was increased for patients receiving both opioids and benzodiazepines

Weisberg et al., J Acquir Immune Defic Syndr. 2015 Jun 1; 69(2): 223–233.

New NIDA FOAs

***NIDA Avant-Garde Award Program for HIV/AIDS and Drug
Use Research (DP1, Clinical Trial Optional)***
(RFA-DA-18-019)

Issued: December 6, 2017; Application Receipt/Submission Date(s): April 17, 2018.



March 29, 2017

Presidential Executive Order Establishing the *President's Commission on Combating Drug Addiction and the Opioid Crisis*

November 1, 2017

56 Recommendations on:

- ***Federal Funding and Programs***
- ***Opioid Addiction Prevention***
 - ***Prescribing Guidelines, Regulations, Education***
 - ***PDMP Enhancements***
 - ***Supply Reduction and Enforcement Strategies***
- ***Opioid Addiction Treatment, Overdose Reversal, and Recovery***
- ***Research and Development***



**THE PRESIDENT'S COMMISSION
ON COMBATING DRUG
ADDICTION AND THE OPIOID
CRISIS**

Roster of Commissioners

Governor Chris Christie, Chairman
Governor Charlie Baker
Governor Roy Cooper
Congressman Patrick J. Kennedy
Professor Bertha Madras, Ph.D.
Florida Attorney General Pam Bondi





National Institute
on Drug Abuse for Teachers
Advancing Addiction Science



NATIONAL DRUG AND ALCOHOL FACTS WEEK®

2320 events Including 180 events in **16 countries outside the U.S.**, including Pakistan, Afghanistan, Myanmar, Mexico, Northern Mariana Islands, South Africa, the UK, Ireland, Zimbabwe, Ghana, Nigeria, Micronesia, the Ukraine and Zambia.

