

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

February 10, 2016

Nora D. Volkow, M.D., Director



National Institute
on Drug Abuse

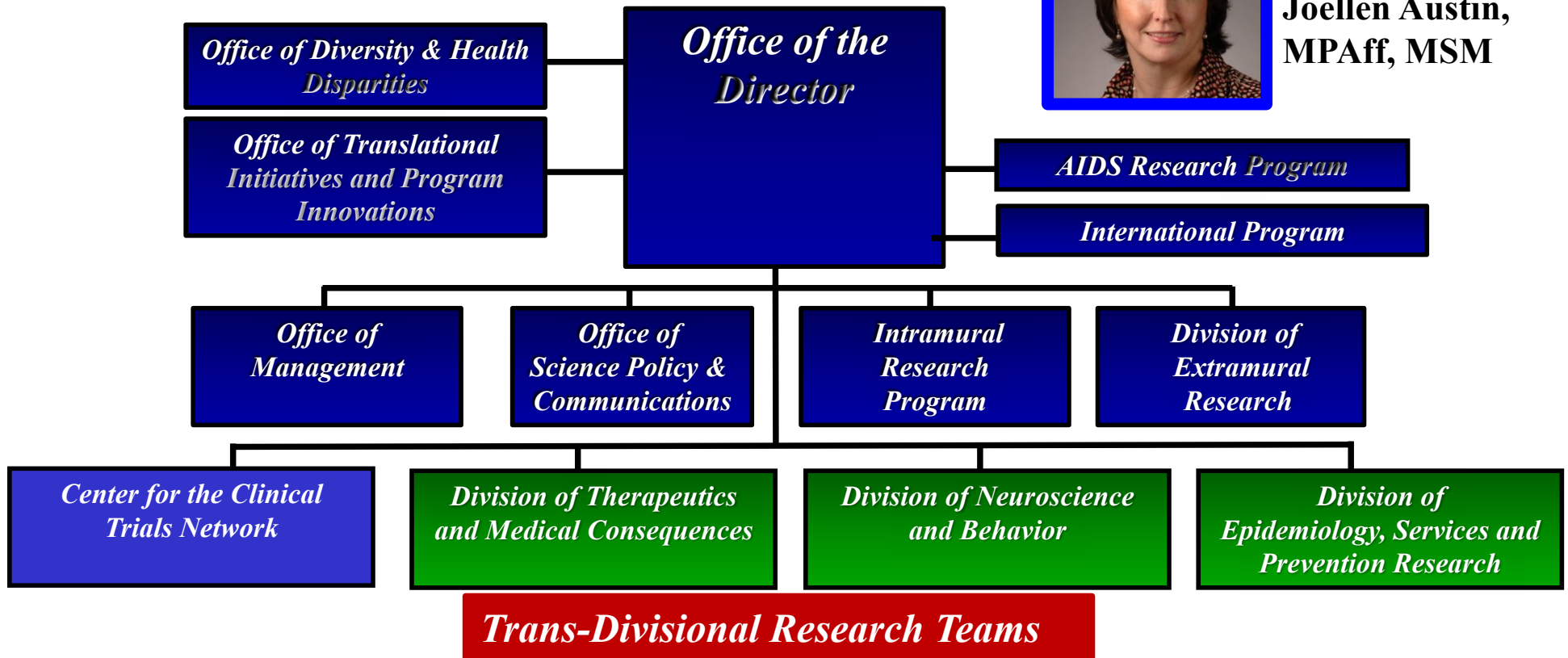


@NIDAnews

NIDA



**Executive Officer
Joellen Austin,
MPAff, MSM**



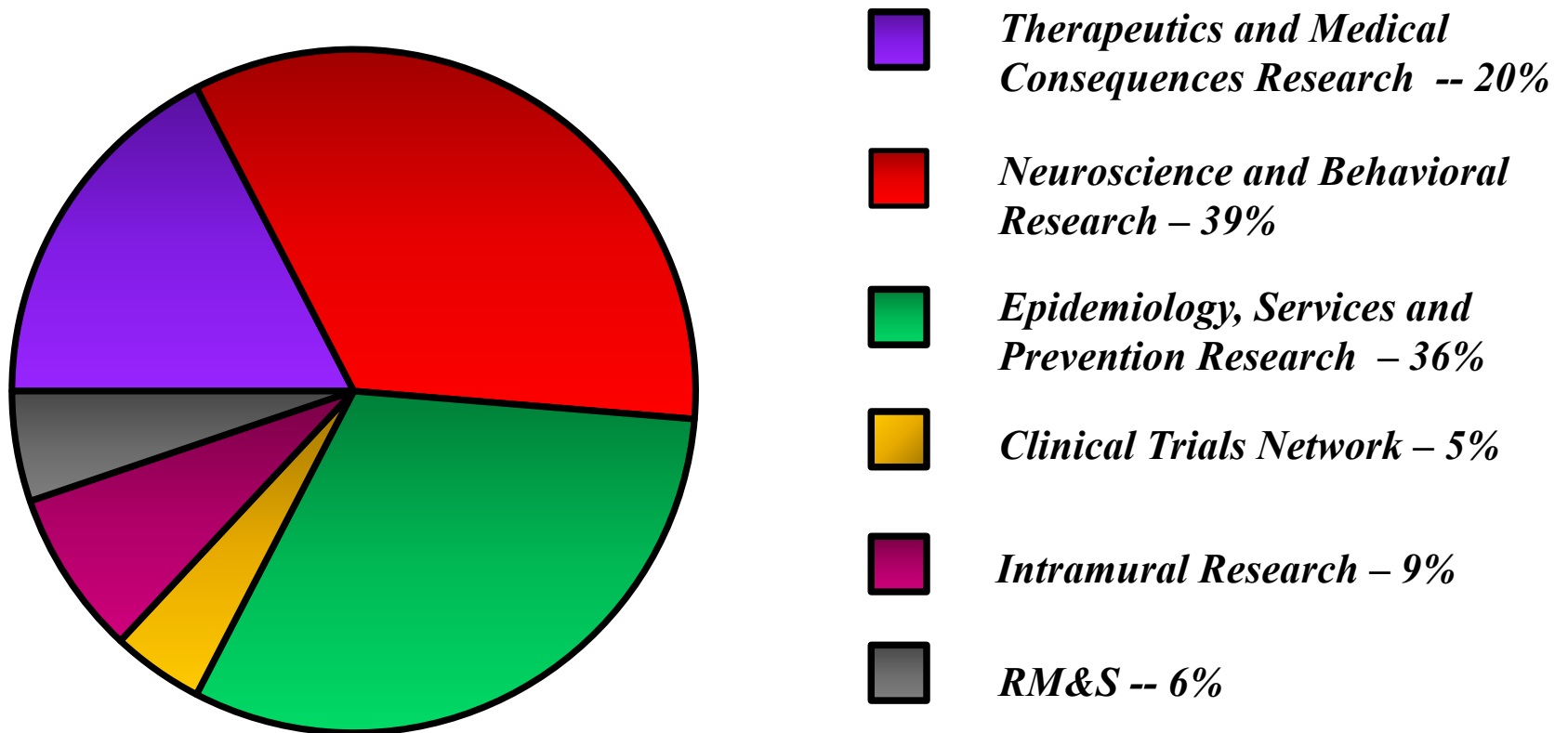
NIDA BUDGET

(Thousands)

	FY 2015 Actuals	FY 2016 Operating Plan	FY 2017 PB
NonAIDS	\$716,833	\$756,306	\$756,306
AIDS	\$298,862	\$294,244	\$294,244
TOTAL	\$1,015,695	\$1,050,550	\$1,050,550

National Institute on Drug Abuse Portfolio

FY 2015 Actual



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

- **Budget Update**

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

- **Recent NIDA
Activities & Events**

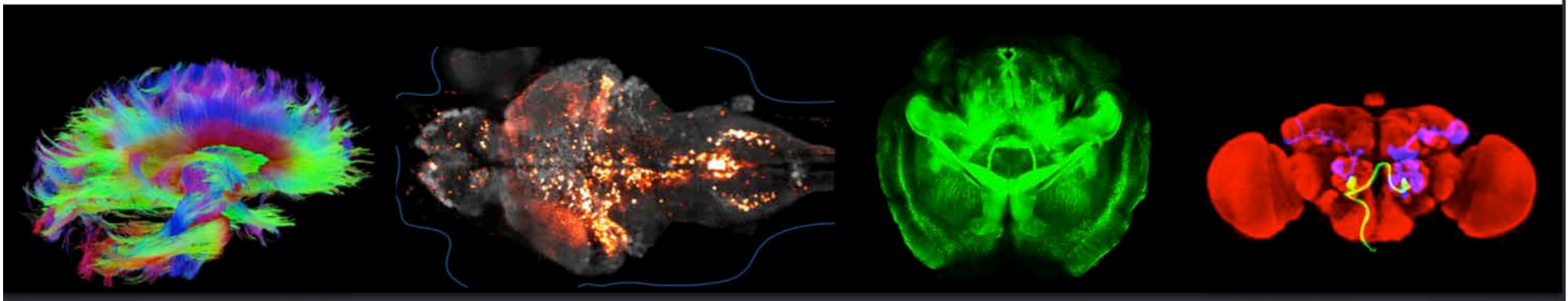
The BRAIN Initiative®

NIH Investment from various Institutes, Centers, and Offices:

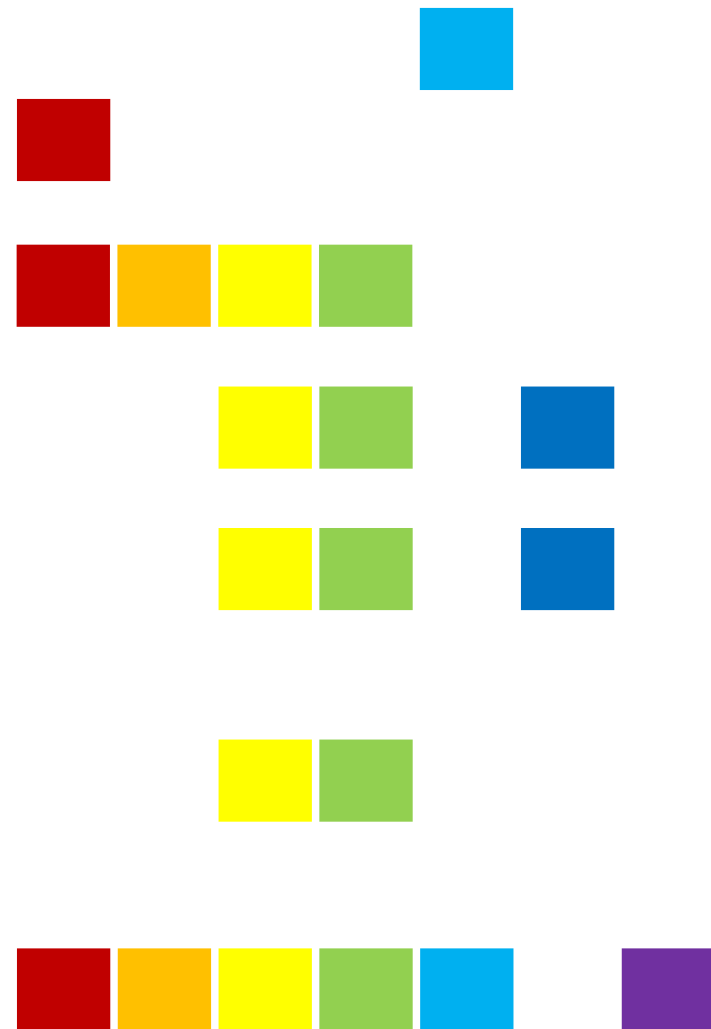
Fiscal Year	Actual Budget	ACD WG Professional Judgment Budget
FY14	\$46.1M	
FY15	\$85M	\$100M
FY16	\$150M* (est.)	\$190M
FY17		\$300M [churn year]
FY18		\$400M
FY19		\$500M

*\$85M FY16 Appropriations increase

- Blueprint
- NCCIH
- NEI
- NIA
- NIAAA
- NIBIB
- NICHD
- NIDA
- NIDCD
- NIMH
- NINDS
- OBSSR
- OD
- ORWH



BRAIN Projects: 58 in FY2014 & 67 in FY2015



Short Courses: 3 awards (MH-15-215)

Cell-Type Classification: 10 awards (MH-14-215)

Novel Tools – Cells and Circuits: 25 awards (MH-14-216; MH-15-225)

Next Generation Human Imaging: 14 awards (MH-14-217; MH-15-200)

Next Generation Human Invasive Devices (2 RFAs): 3 awards (NS-15-006/008)

Large-scale Recording & Modulation (5 RFAs): 53 awards (NS-14-007/008; NS-15-003/004; EY-15-001)

Integrating Approaches to Understand Circuit Function: 17 awards (NS-14-009; NS-15-005)

BRAIN Funding in FY2016: Opportunities



Short Courses: (MH-16-700)

Novel Tools – Cells and Circuits: (MH-16-775)

Foundations of Human Imaging: (MH-16-750)

Next Generation Human Invasive Devices:
(NS-16-009/010/011/018)

Large-scale Recording & Modulation: (NS-16-006/007;
EY-16-001)

Research Opportunities Invasive Neural Recording:
(NS-16-008)

Non-invasive Neuromodulation: (MH-16-810/815)

Technology Sharing and Propagation: (MH-16-725)

Theories, Models, Methods: (EB-15-006)

PRECISION MEDICINE INITIATIVE



- For 2016, the President proposed that **\$215 million** to the **PMI** **\$130 million** will be used to start building the PMI research cohort.
- A **PMI Working Group of the Advisory Committee to the NIH Director (ACD)**, was established to plan the creation and management of the PMI research cohort. **Recommendations delivered to ACD in Sept 2015.**



- **PMI Cohort Program Coordinating Center (U2C) (RFA-PM-16-001)** Issued: Nov16, 2015
- **PMI Cohort Program Healthcare Provider Organization Enrollment Centers (UG3/UH3) (RFA-PM-16-002)** Issued: Nov 16, 2015
- **PMI Cohort Program Participant Technologies Center (U24) (RFA-PM-16-003)** Issued Nov 16, 2015
- **PMI Cohort Program Biobank (U24) (RFA-PM-16-004)** Issued Nov 16, 2015

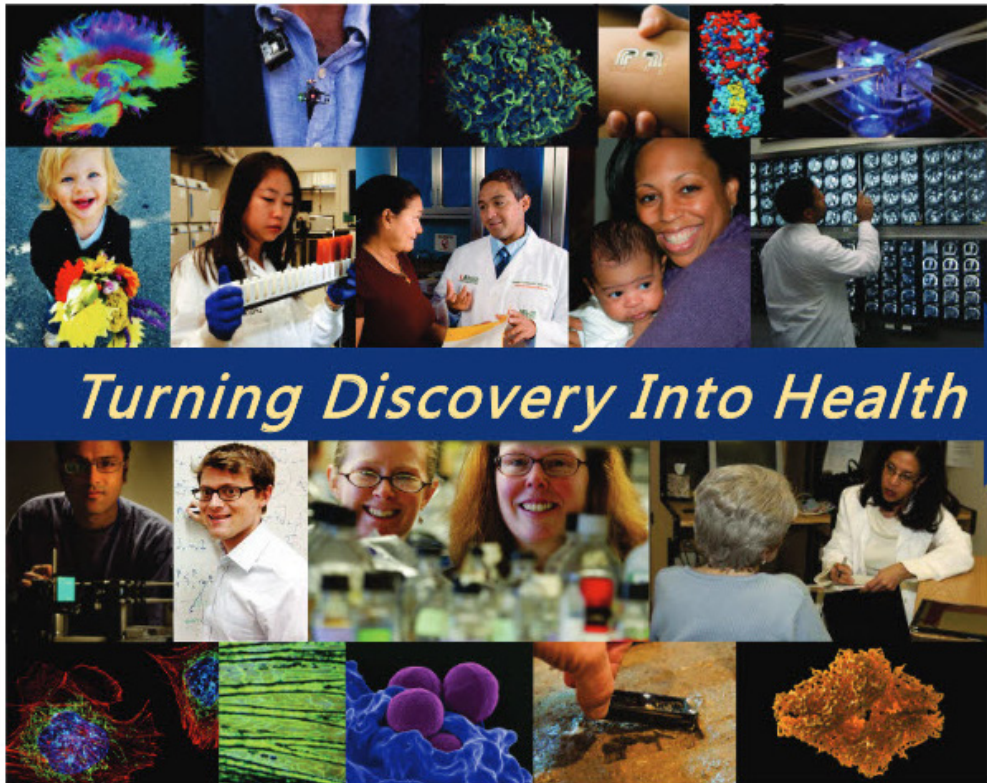
Recruitment for NIMH Director

ANNOUNCEMENT DEC 7, 2015

NIH-Wide Strategic Plan

Fiscal Years 2016-2020

RELEASED: December 16, 2015

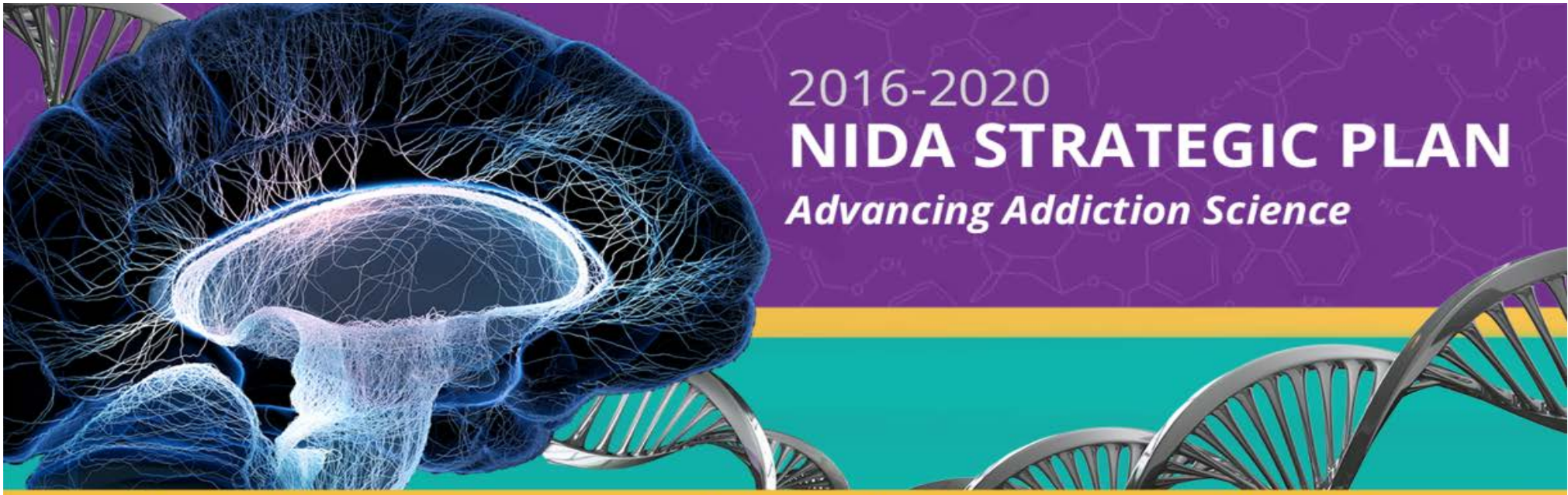


Turning Discovery Into Health

OBJECTIVES:

1. *advance opportunities* in biomedical research in fundamental science, treatment and cures, and health promotion and disease prevention;
2. *foster innovation* by setting NIH priorities to enhance nimbleness, consider burden of disease and value of permanently eradicating a disease, and advance research opportunities presented by rare diseases;
3. *enhance scientific stewardship* by recruiting and retaining an outstanding biomedical research workforce, enhancing workforce diversity and impact through partnerships, ensuring rigor and reproducibility, optimizing approaches to inform funding decisions, encouraging innovation, and engaging in proactive risk management practices; and
4. *excel as a federal science agency* by managing for results by developing the “science of science,” balancing outputs with outcomes, conducting workforce analyses, continually reviewing peer review, evaluating steps to enhance rigor and reproducibility, reducing administrative burden, and tracking effectiveness of risk management in decision making.





2016-2020
NIDA STRATEGIC PLAN
Advancing Addiction Science

Released December 2015!



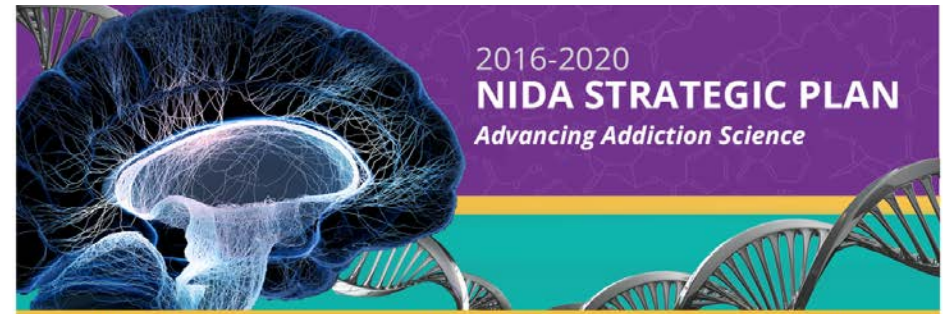
Priority Focus Areas

Cross-Cutting Themes

Trans-NIH Initiatives

Goals

1. **Basic Science:** Identify the biological, environmental, behavioral, and social causes and consequences of drug use and addiction across the lifespan
2. **Prevention:** Develop new and improved strategies to prevent drug use and its consequences
3. **Treatment:** Develop new and improved treatments to help people with substance use disorders achieve and maintain a meaningful and sustained recovery
4. **Public Health:** Increase the public health impact of NIDA research and programs



Priority Areas

1. Understanding the complex **interactions** of factors influencing drug use trajectories
2. Accelerating development of **treatments**
3. Addressing real-world **complexities**
4. Advancing bidirectional **translation**

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

Priority Areas

Prevention Research

(Children & Adolescents)

genetics/epigenetics

development

environment

co-morbidity



2015 Monitoring the Future Study

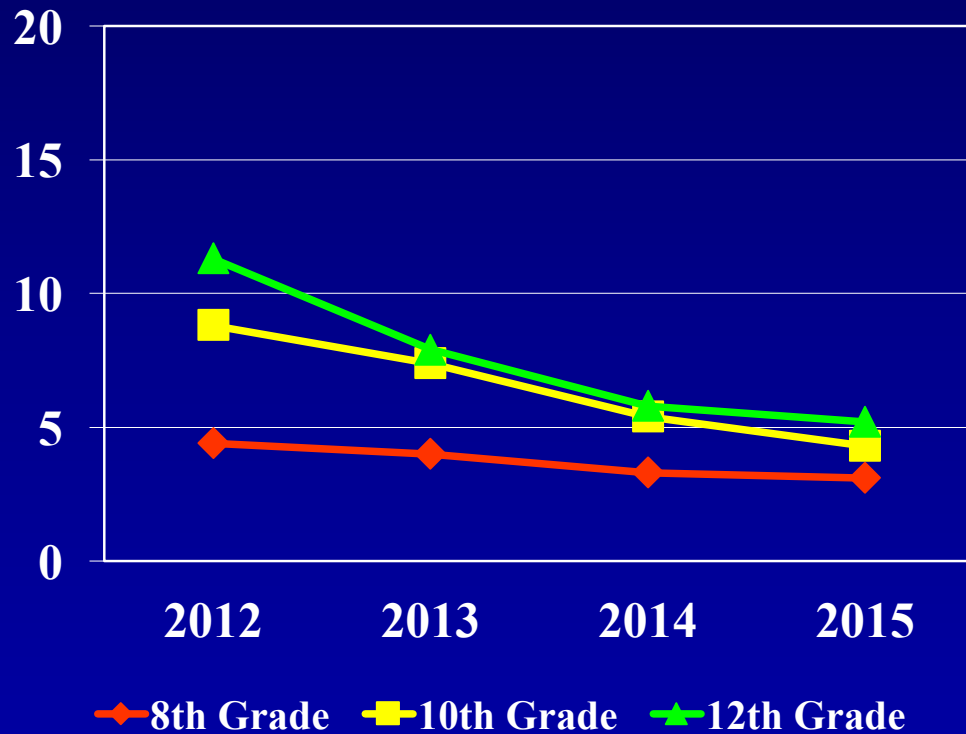
Prevalence of Past Year Drug Use Among 12th graders

Drug	Prev.	Drug	Prev.
Alcohol	58.2	Vicodin*	4.4
Marijuana/Hashish	34.9	Hallucinogens	4.2
Hookah	19.8	OxyContin*	3.7
Small cigars	15.9	Sedatives*	3.6
Amphetamines*	7.7	MDMA (Ecstasy)	3.6
Adderall*	7.5	LSD	2.9
Snus	5.8	Hall other than LSD	2.9
Narcotics o/t Heroin*	5.4	Cocaine (any form)	2.5
Synthetic Cannabinoids	5.2	Ritalin*	2.0
Tranquilizers*	4.7	Inhalants	1.9
Cough Medicine*	4.6	Salvia	1.9

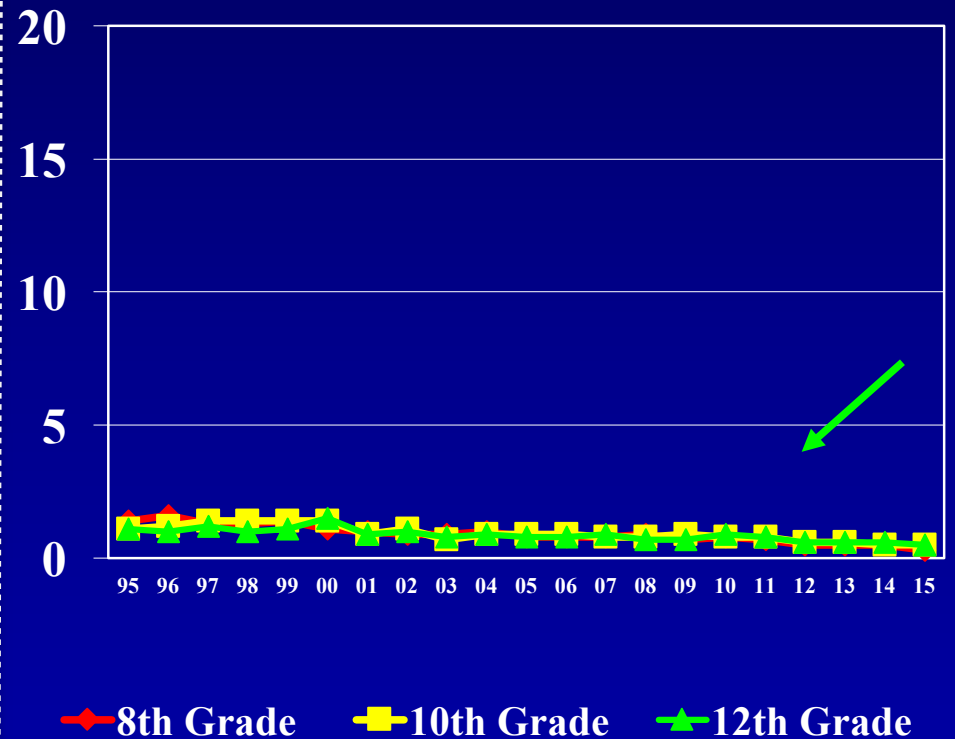
* Nonmedical use

Categories not mutually exclusive

% Students Reporting Use of Synthetic Cannabinoids in Past Year

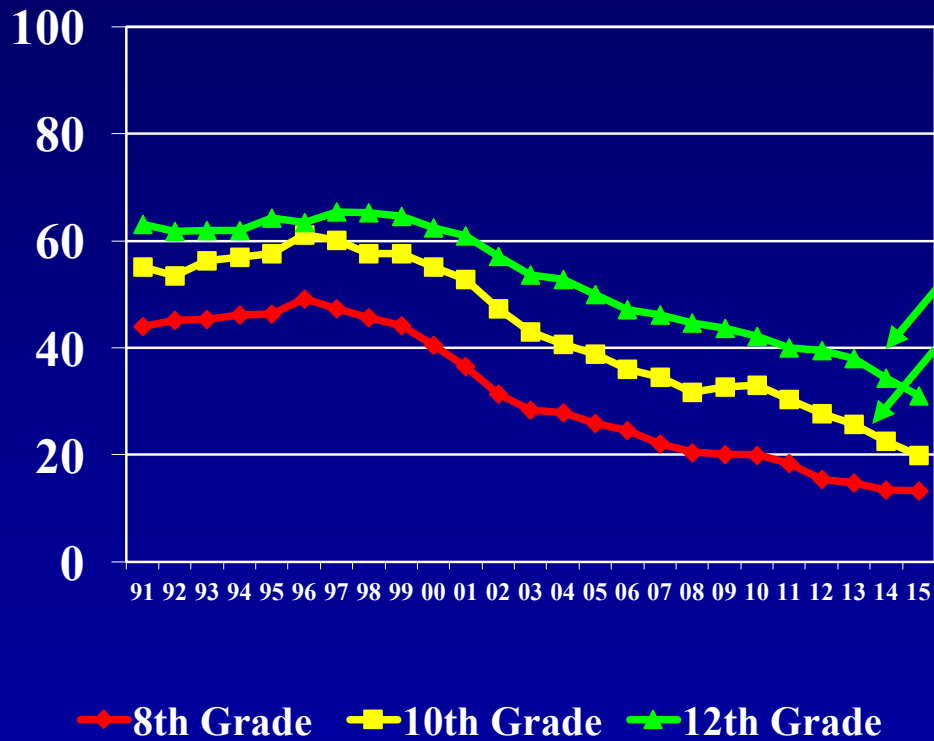


% Students Reporting Use of Heroin in Past Year

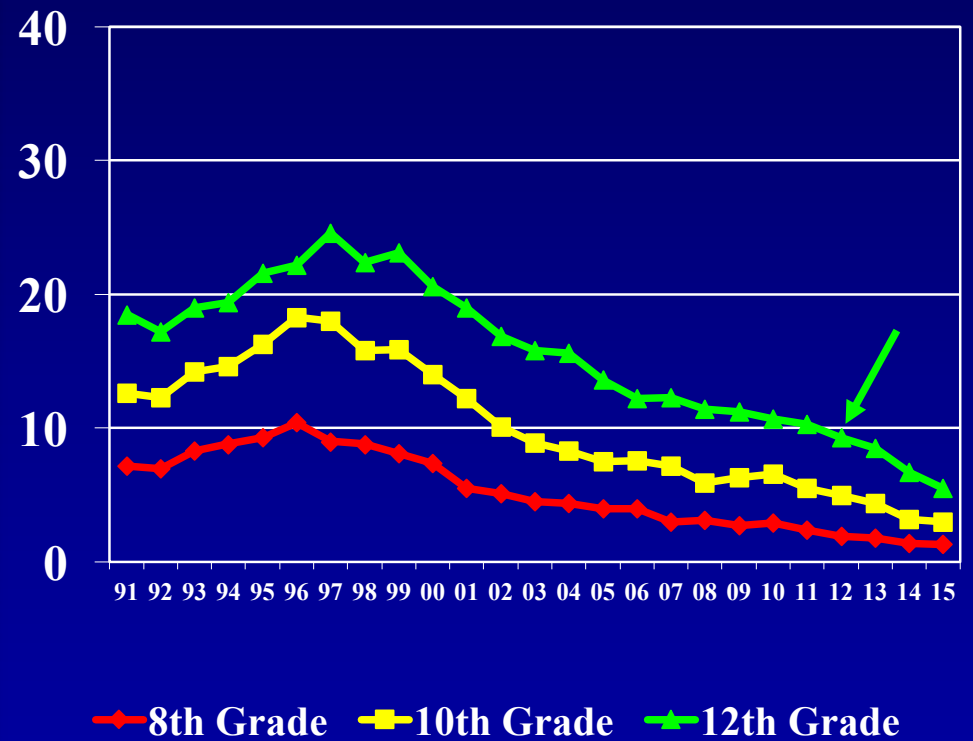


SOURCE: University of Michigan, 2015 Monitoring the Future Study

% Students Reporting Smoking Cigarettes in Lifetime, by Grade



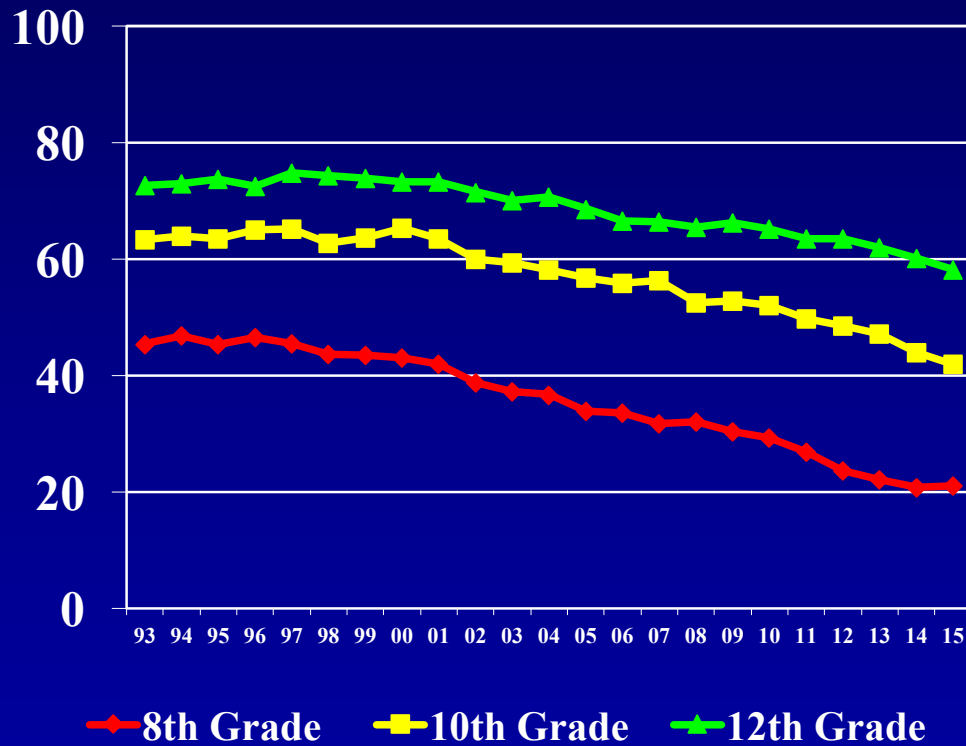
% Students Reporting Daily Cigarette Use



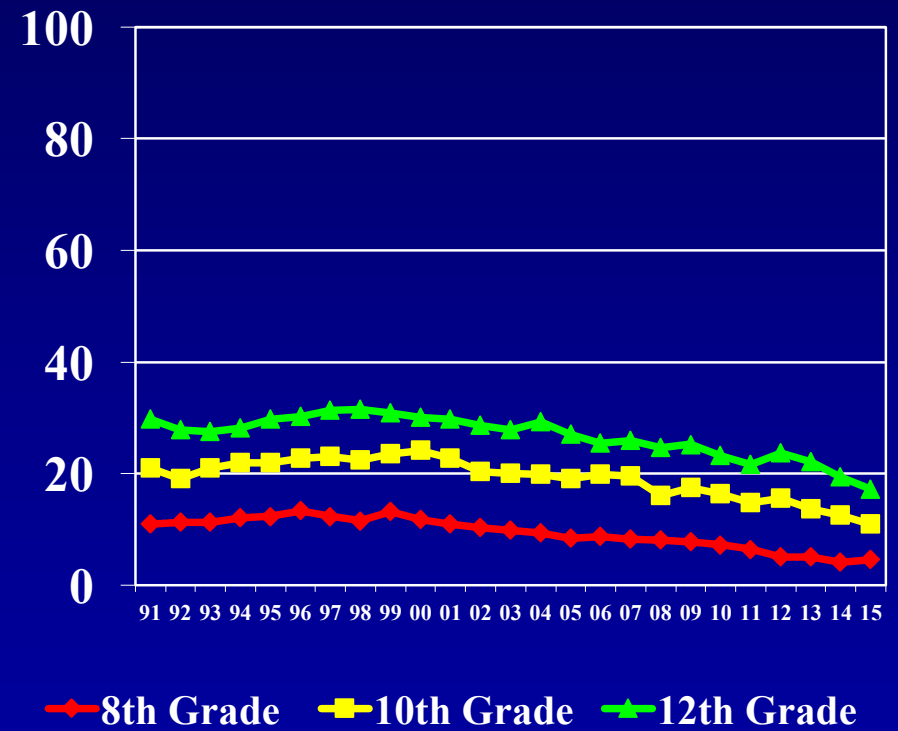
Denotes significant difference between 2014 and 2015

SOURCE: University of Michigan, 2015 Monitoring the Future Study

% Students Reporting Use of Alcohol Past Year



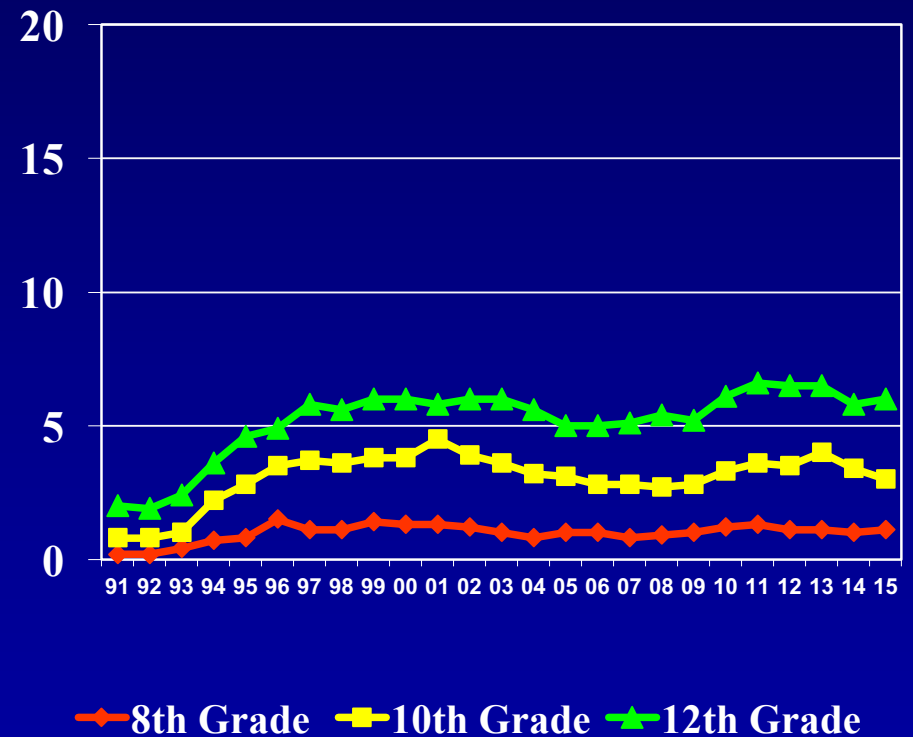
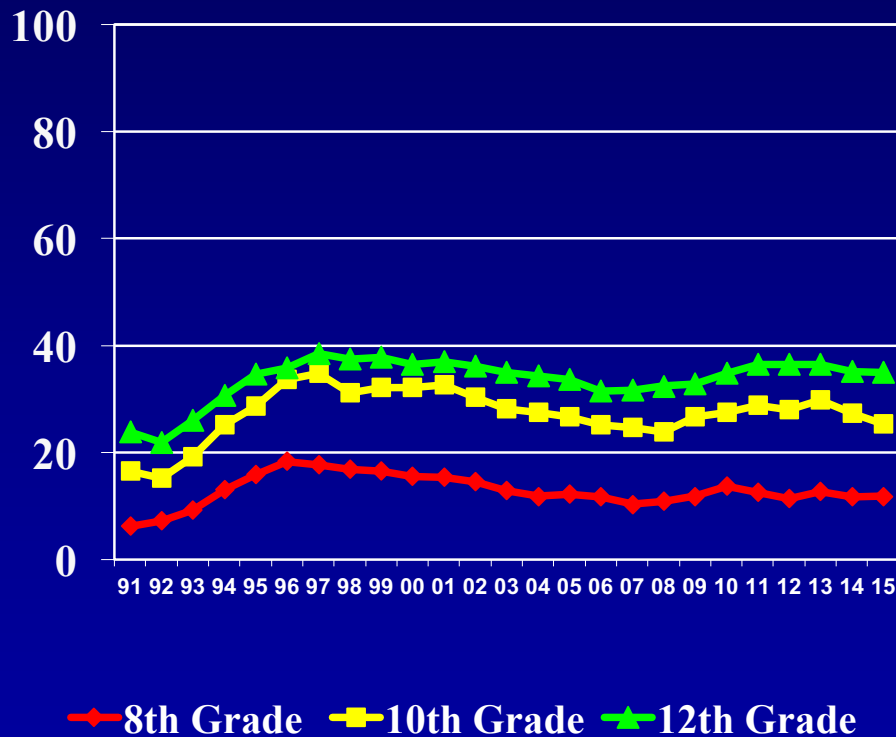
% Students Reporting 5+ Drinks in a Row in Last Two Weeks



SOURCE: University of Michigan, 2015 Monitoring the Future Study

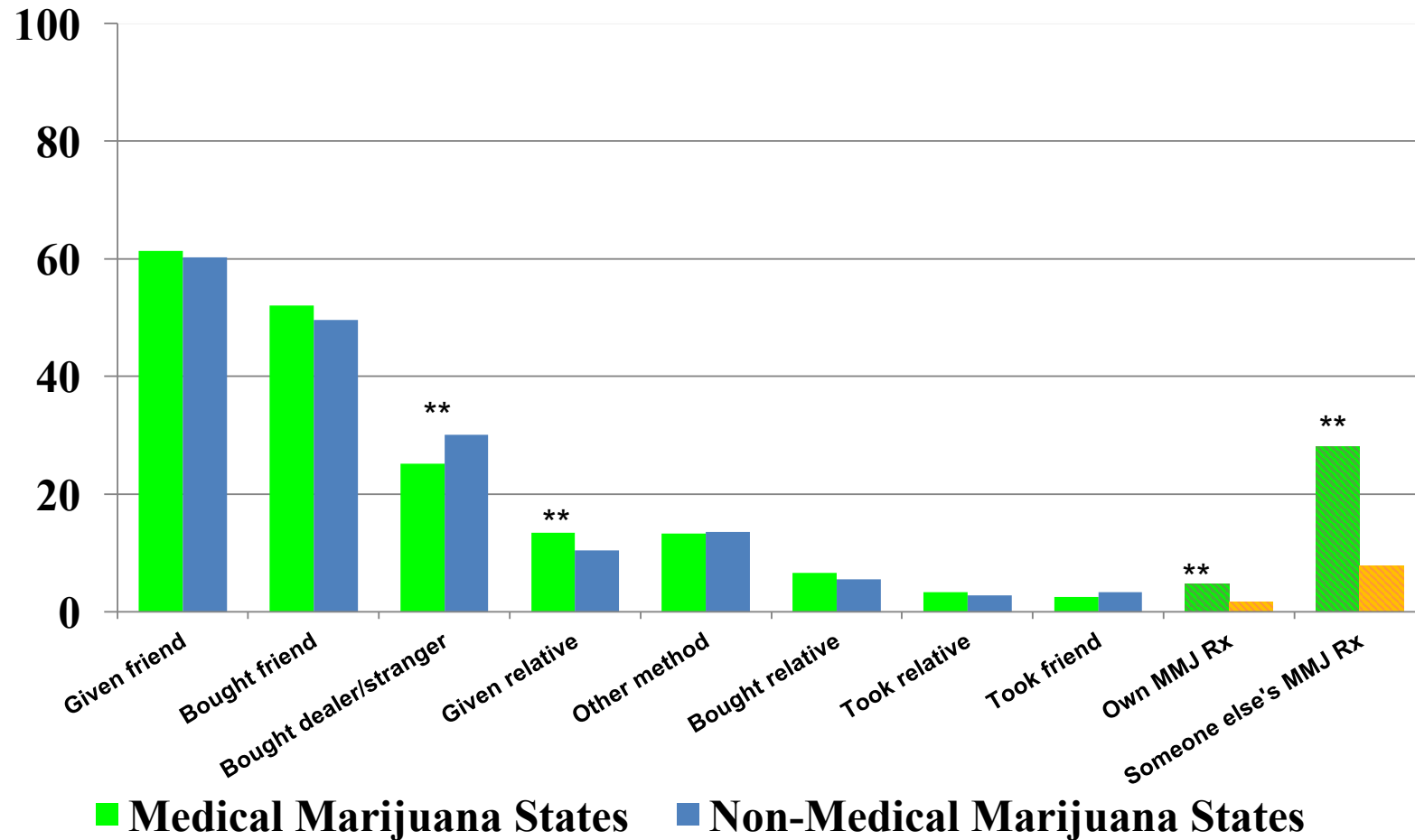
% Students Reporting Use of Marijuana in Past Year

% Students Reporting Daily Use of Marijuana



SOURCE: University of Michigan, 2015 Monitoring the Future Study

Source of Marijuana* among 12th Graders in 2012-2015, by State Policy



*Categories not mutually exclusive
 ** Statistically significant difference

SOURCE: University of Michigan, 2015 Monitoring the Future Study

Adolescent Brain Cognitive Development (ABCD)

An NIH Collaboration: NIDA, NIAAA, NCI,
NIMH NIMHD NICHD NINDS OBSSR



Adolescent Brain Cognitive Development

Teen Brains. Today's Science. Brighter Future.

Priority Areas

Prevention Research

(Children & Adolescents)

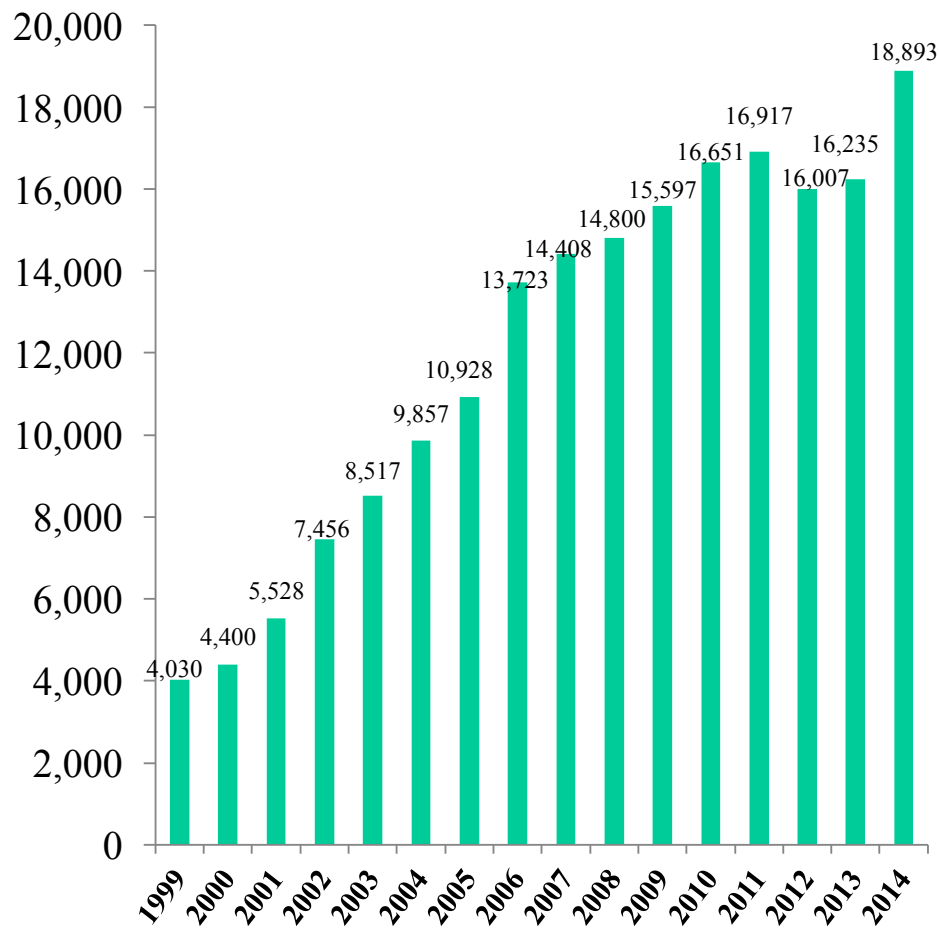
genetics/epigenetics
development
environment
co-morbidity

Treatment Interventions

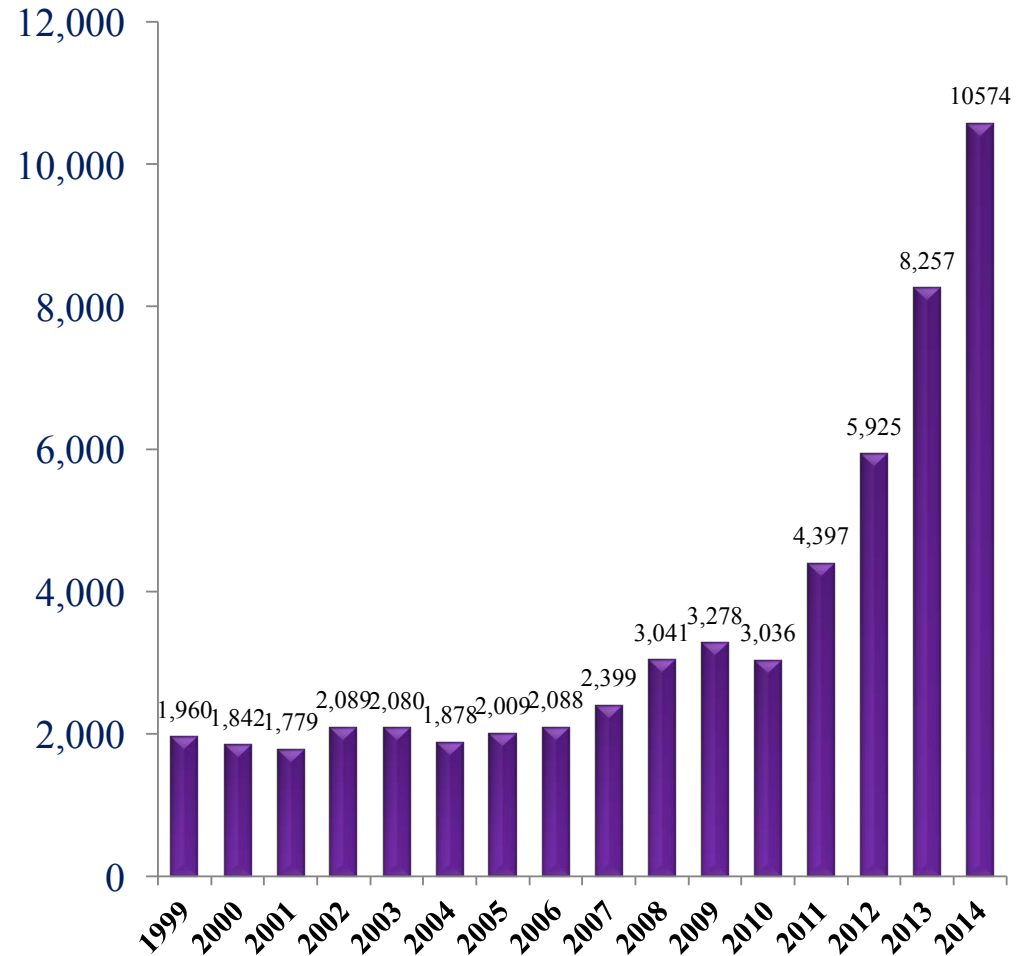
(New Targets & New Strategies)



Opioid Analgesic Overdose Deaths in the USA



Heroin Overdose Deaths in the USA



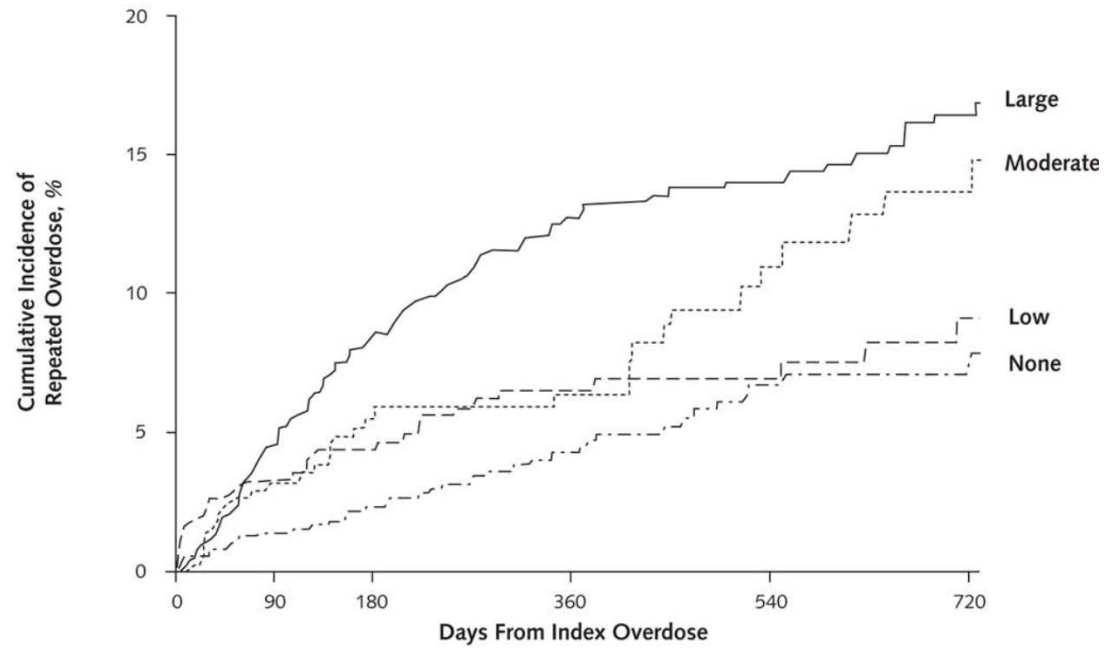
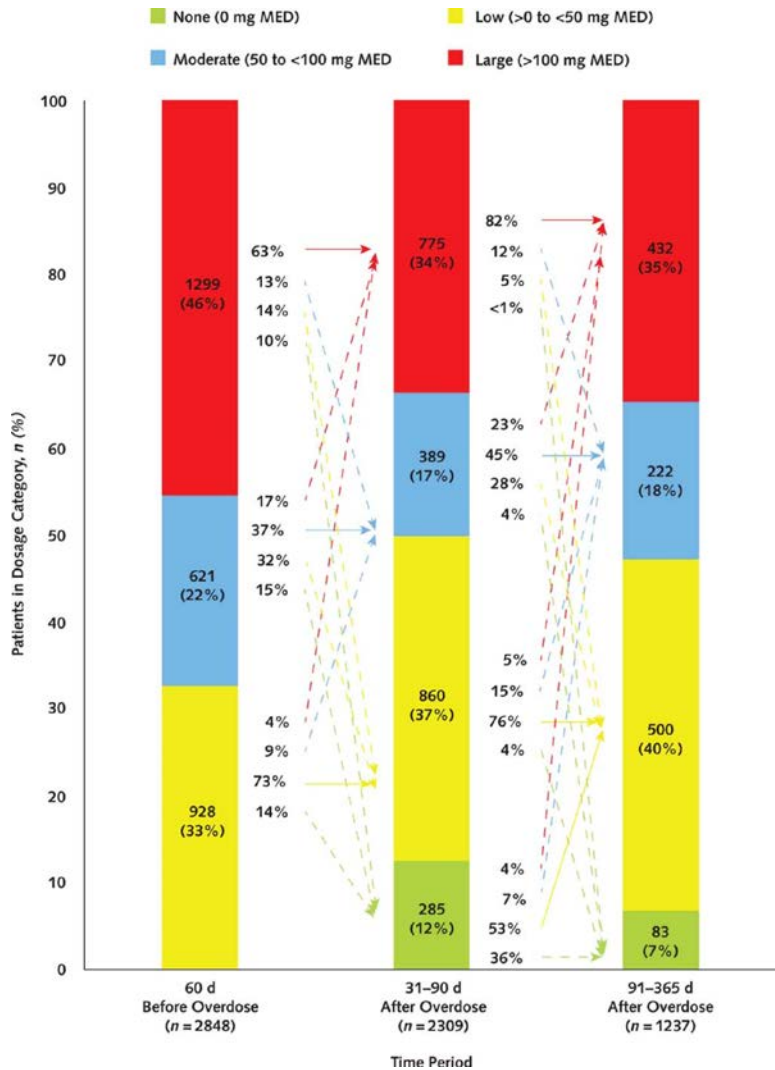
Centers for Disease Control and Prevention. Wide-ranging Online Data for Epidemiologic Research (WONDER), Multiple-Cause-of-Death file, 2000–2014. 2015 (http://www.cdc.gov/nchs/data/health_policy/AADR_drug_poisoning_involving_OA_Heroin_US_2000-2014.pdf)



HHS Strategy To Address Opioid-Drug Related Overdose, Death and Dependence

- **Providing training and educational resources, including updated prescriber guidelines, to assist health professionals in making informed prescribing decisions**
- **Increasing use of naloxone**
- **Expanding the use of Medication-Assisted Treatment (MAT)**

Opioid Prescribing After a Nonfatal OD: Association With Repeated Overdose (n=2900)



Despite the fact that opioid discontinuation after overdose is associated with lower risk for repeated overdose almost all patients continue to receive prescription opioids after an overdose.

Larochelle, et al, Ann Intern Med. 2016;164(1):1-9.

NIH Pain Consortium
Centers of Excellence in Pain Education



Coordinated by NIDA as part of NIH's Pain Consortium, the Centers of Excellence in Pain Education (**CoEPEs**) **act as hubs for the development, evaluation, and distribution of pain management curriculum resources** for medical, dental, nursing, and pharmacy schools.

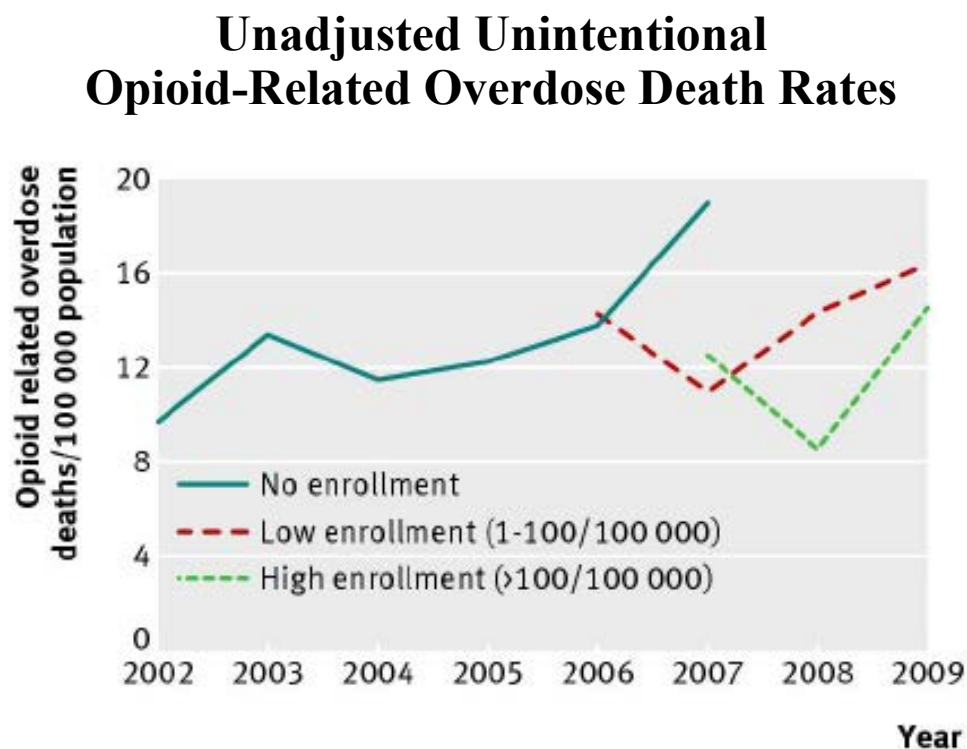
Centers must *develop materials to create one case-based education module per year* as the main deliverable. The CoEPEs must also *test the efficacy and impact of these modules and disseminate their findings.*

11 CoEPEs funded in September 2015:

University of Alabama at Birmingham
University of California, San Francisco
University of Connecticut
Harvard University
University of Iowa
Johns Hopkins University

University of Pennsylvania
University of Pittsburgh
University of Rochester
Southern Illinois University Edwardsville
University of Washington.

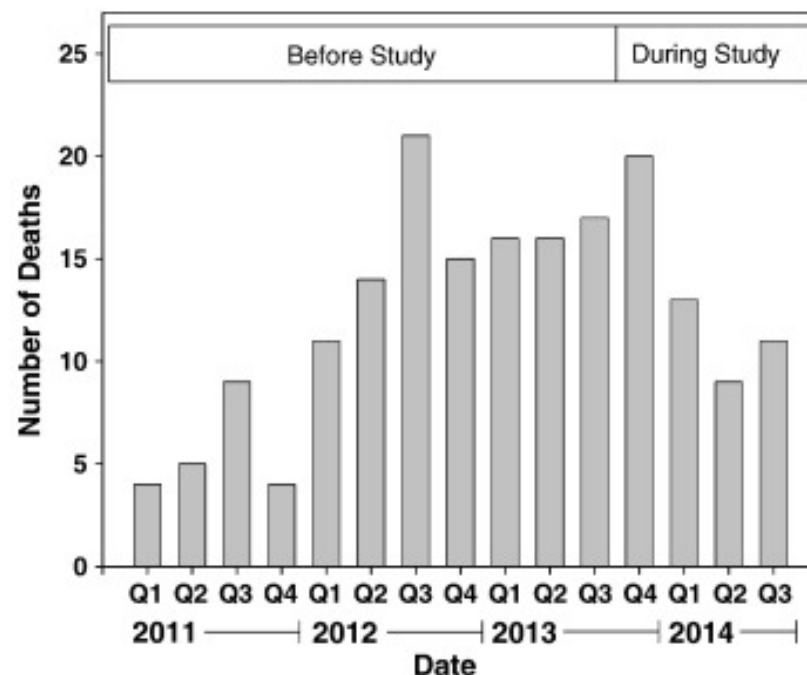
Opioid OD Death were Reduced In Communities that Implemented Nasal Naloxone Distribution Program



Unadjusted Opioid-Related Acute Care Hospital Utilization Rates

Walley AY et al., *BMJ* 2013; Published 31 January 2013.

Intranasal Naloxone Administration By Police First Responders In Ohio



Intranasal naloxone administration by police first responders is associated with decreased OD deaths

Rando et al., *Am J Emerg Medicine* 2015.

Easier To Administer Naloxone

- **Naloxone Nasal Spray Development**
Needle-free, unit-dose, ready-to-use
opioid overdose antidote.



➤ *Adapt Pharma NARCAN
nasal spray APPROVED BY
FDA, November 18, 2015.*



Image courtesy of
ADAPT Pharma, Inc.

- **\$37.50 per 4mg NARCAN Nasal Spray device.**

NEW THERAPEUTICS for Opioid Use Disorder

Extended release medications (improve compliance)

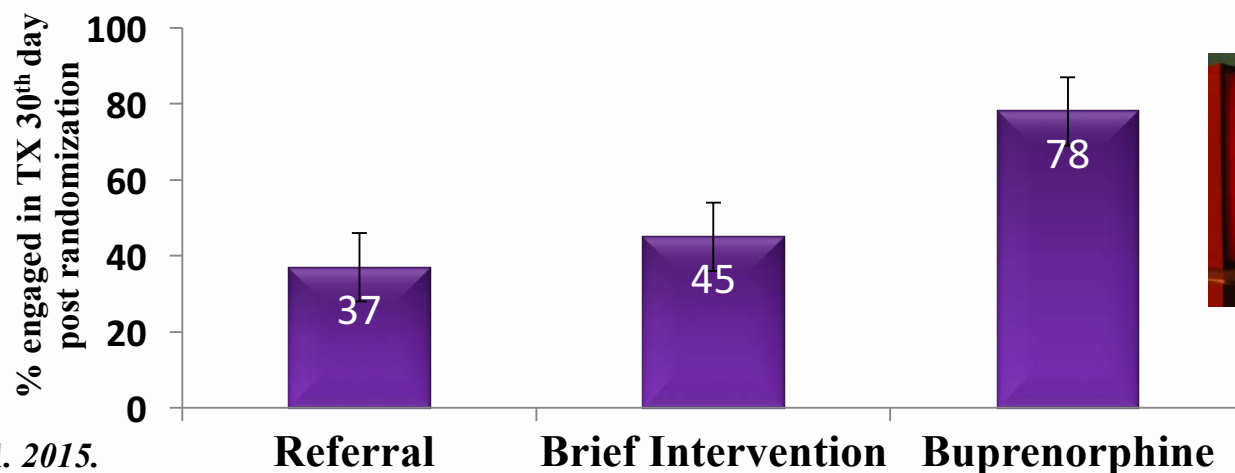
IMPLANTABLE Buprenorphine Probuphine™ (6 months)



FDA's Final Decision Expected February 27, 2016

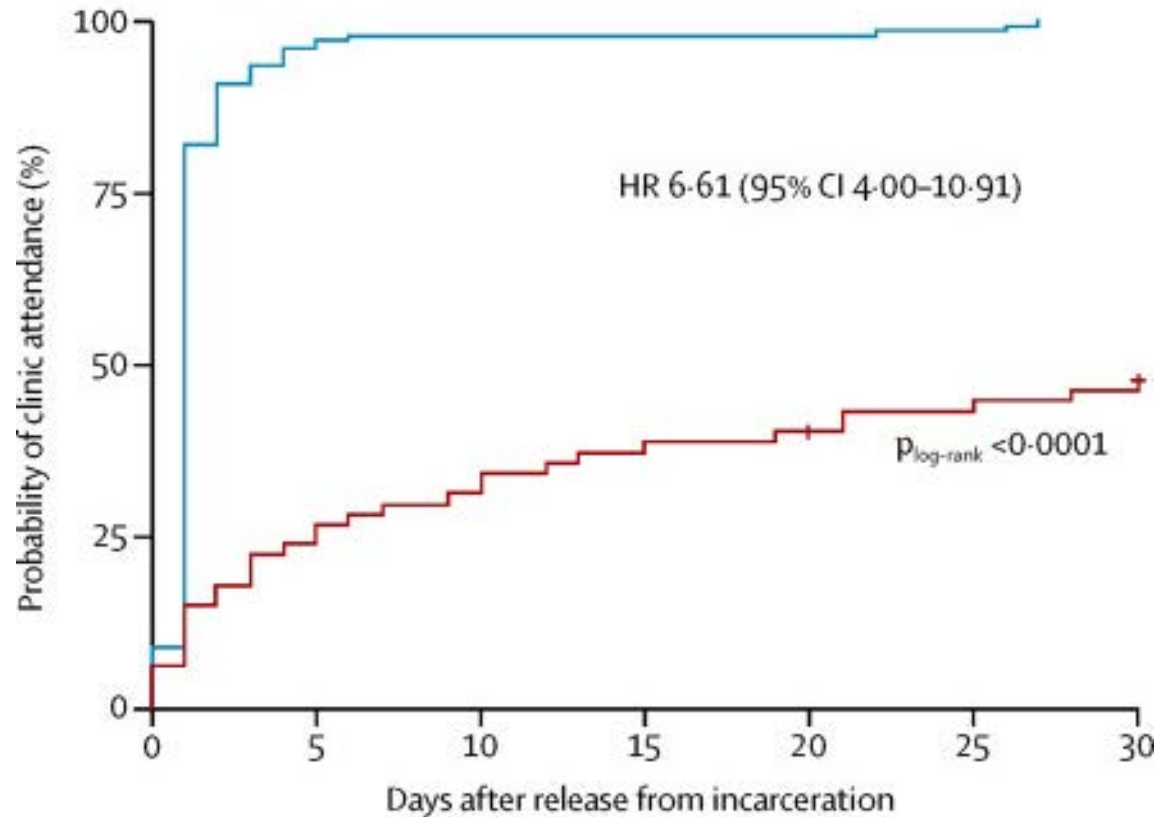
IMPLEMENTATION SCIENCE Expanding MAT

ED-initiated Buprenorphine Increased Engagement In Addiction Treatment, Reduced Self-reported Illicit Opioid Use, & Decreased Use Of Inpatient Addiction Treatment Services



D'Onofrio JAMA. 2015.

Methadone Continuation Versus Forced Withdrawal On Incarceration In A Combined US Prison and Jail: A Randomized, Open-label Trial



Continuation of methadone maintenance during incarceration as compared to forced withdrawal increased the likelihood of re-engaging in methadone treatment

Rich et al., The Lancet Published online May 29, 2015.

Priority Areas

Prevention Research

(Children & Adolescents)

genetics/epigenetics
development
environment
co-morbidity

Treatment Interventions

(New Targets & New Strategies)

HIV and Drugs

Prevention
Treatment



NIH Overarching AIDS Research Priorities

(August 12, 2015)

Critical to ensure that NIH AIDS funds are supporting the highest priorities for next 3-5 years:

- 1. Reduced **incidence**, including vaccines**
- 2. Next generation of HIV therapies with better safety and ease of use**
- 3. Research toward a cure**
- 4. HIV-associated **comorbidities** and co-infections**

*Cross cutting areas: Basic research, **health disparities**, and training*



NIDA Council HIV Workgroup

Eric Verdin, M.D.
Gladstone Institutes

Davey Smith, M.D.
UCSD

Julio Montaner, M.D.
UBC

Steffanie Strathdee, Ph.D.
UCSD

Nichole Klatt, Ph.D.
U of Washington

Anto Bonci, M.D.
NIDA IRP

Judy Auerbach, Ph.D.
UCSF

Carlos del Rio, M.D.
Emory Univ

Justin McArthur, Ph.D.
Johns Hopkins

James Hildreth, MD, Ph.D.
Meharry Medical College

Lisa Metsch, Ph.D.
Columbia

First meeting September 22, 2015

Charged with providing advice and making recommendations on future directions for NIDA's HIV/AIDS research priorities.

Suggestions contributed to NIDA's issuing 5 RFAs in FY16 & 5 RFAs for FY17.

Next meeting late spring to work on new areas for FY18



New NIDA FOA

HIV/AIDS High Priority Drug Abuse Research (R01) (PAS-16-018)

Issued: October 30, 2015.

To stimulate high priority research relevant to drug abuse and HIV/AIDS including:

- Studies on optimization of seek, test, treat, & retain (STTR) : **Reduced incidence**
- Implementation research on integration of drug abuse treatment and HIV care to optimize HIV outcomes: **HIV-associated comorbidities**
- Implementation of STTR in prison & jail settings (where minorities are disproportionately represented) and upon release: **HIV-associated comorbidities**
- Studies on drug-drug interactions between current or potential new HIV/AIDS antiretrovirals & drugs of abuse, medications to treat addiction, & hepatitis C (HCV) medications: **HIV-associated comorbidities**
- Studies to determine how exposure to drugs & cycles of abuse & withdrawal affect latency & reservoir size and persistence: **HIV-associated comorbidities**

Fiscal Year 16 FOAs

- ◆ **RFA: Effects of drugs of abuse on latent HIV reservoirs in CNS**
- ◆ **RFA: Exploring Epigenomic and Non-Coding RNA Regulation in HIV/AIDS and Substance Abuse**
- ◆ **RFA: Systems Biology Approaches in HIV/AIDS and Substance Use**
- ◆ **RFA: Integration of Infectious Diseases and Substance Abuse Intervention Services for individuals Living with HIV**
- ◆ **RFA: Seek, Test, Treat, and Retain for youth and Young Adults living with or at High Risk for Acquiring HIV**

Fiscal Year 17 FOAs

- ◆ **RFA: Mechanisms of Immune Activation and Inflammation in Drug-Abusing HIV-Infected Patients on ART**
- ◆ **RFA: Mobilizing Seek, Test, Treat and Retain Approaches in Rural Injection Drug Use Epidemics**
- ◆ **RFA: Seek, Test, Treat, Retain: Optimizing the HIV Care Continuum for Substance Abusing Populations Living with HIV**
- ◆ **Implication of Nicotinic receptors' Regulation of Immune Functions in HIV Infectivity and Pathogenesis**
- ◆ **Coordination Center for HIV/AIDS & Substance Use Cohorts**



National Drug & Alcohol Facts Week January

We are happy that **NIAAA** joined us in an expanded National Drug Facts Week

We broke all records and stimulated the country and in **14 other countries** -- some of the international events were stimulated by our Humphrey Fellows

We created **toolkits** if event holders wanted to focus on specific drugs, like tobacco, alcohol or synthetics



National Drug & Alcohol Facts Week

January 25–31, 2016



- January 26, 2016
- Held remotely because of the storm
- **NIAAA, NIMH and FDA CTP** also participated
- Over **7,000 questions** were submitted -- nearly **1,500** were answered
- The transcript can soon be found on the **“NIDA for Teens” Website**

Save the Date!

Registration Opens
January 2016



National Institutes of Health

MARIJUANA AND CANNABINOIDS: A NEUROSCIENCE RESEARCH SUMMIT

March 22-23, 2016

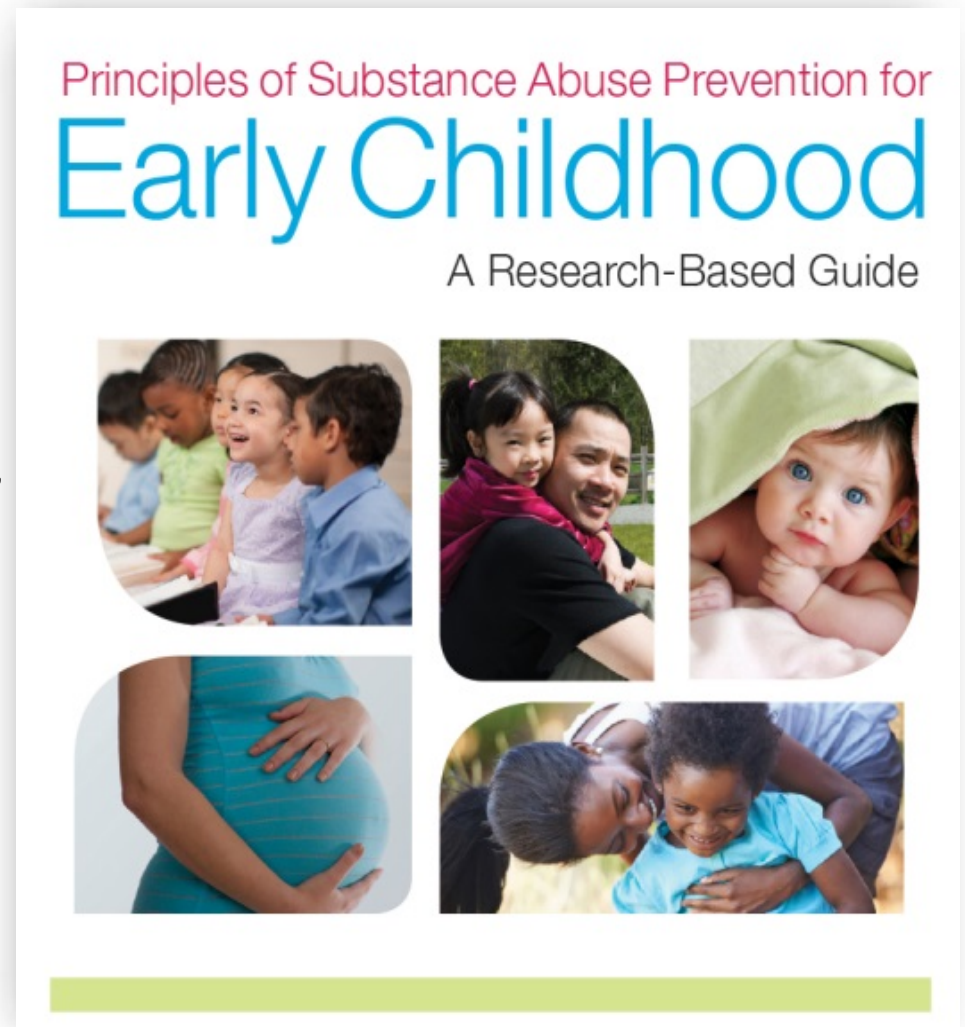
Natcher Conference Center, Building 45
NIH Campus, Bethesda, MD

National Institute on Drug Abuse
National Institute on Alcohol Abuse and Alcoholism
National Center for Complementary and Integrative Health
National Institute of Mental Health
National Institute of Neurological Disorders and Stroke



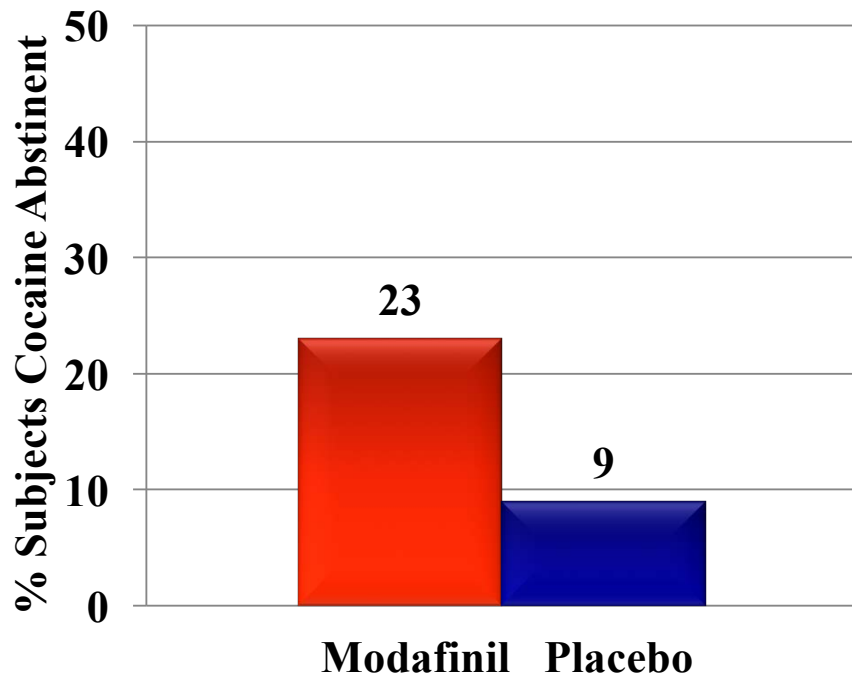
Principles of Substance Abuse Prevention for Early Childhood

- **Fourth in a series of evidence-based principles produced by NIDA:**
 - Principles of Drug Addiction Treatment
 - Principles of Adolescent Substance Use Disorder Treatment
 - Principles of Drug Abuse Treatment for Criminal Justice Populations
- **Supplemental sections** for researchers, policymakers and practitioners.
- **Web-based** with easy-to-navigate, print-friendly chapters viewable on desktop, phone or tablet.
- **Selected resources** with information on research-based early childhood drug prevention programs.



Modafinil for the Treatment of Cocaine Dependence

Percent Of Subjects Abstinent From Cocaine During Weeks 6–8



Modafinil-Treated Subjects' Ratings of "very much improved"

