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)

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<tr>
<th></th>
<th>FY 2015 Actuals</th>
<th>FY 2016 Operating Plan</th>
<th>FY 2017 PB</th>
<th>FY 2017 Senate Markup</th>
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<td>$716,833</td>
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<td>TOTAL</td>
<td>$1,015,695</td>
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Currently under a C.R. until April 28, 2017
NIDA Program Level in Appropriated Dollars and Constant 1998 Dollars

30% of AIDS Budget, which is for AIDS research is re-competed based on NEW NIH HIV priorities

pr – preliminary
p -- projected
A bar graph showing NIDA program level in appropriated dollars and constant 1998 dollars, FY 1998 - (projected) FY2017. The FY 2017 projected budget for NIDA was $1,050,550, the same as the FY 2016 level, and when taking inflation (Biomedical Research and Development Price Index) into account, the FY 2017 budget was comparable to FY 1998 constant dollars.
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• Budget Update

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FACING ADDICTION IN AMERICA

The Surgeon General’s Report on Alcohol, Drugs, and Health

U.S. Department of Health & Human Services
Cancer research = $1.8 billion over 7 years
Precision Medicine Initiative = $1.455 billion over 10 years
BRAIN Initiative $1.511 billion over 10 years
Regenerative Medicine = $30 million over 4 years

• Funds need to be appropriated each year to be transferred to NIH, not to exceed these amounts:
  • FY 17: $10,000,000
  • FY 18: $86,000,000
  • FY 19: $115,000,000
  • FY 20: $140,000,000
  • FY 21: $100,000,000
  • FY 22: $152,000,000
  • FY 23: $450,000,000
  • FY 24: $172,000,000
  • FY 25: $91,000,000
  • FY 26: $195,000,000
**NIH Investment** from various Institutes, Centers, and Offices:

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Actual Budget</th>
<th>BRAIN Awards</th>
<th>21st Century Cures</th>
<th>ACD WG Recommendation</th>
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<td>FY14</td>
<td>$46.1M</td>
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<td>FY19</td>
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- Blueprint
- NCCIH
- NEI
- NIA
- NIAAA
- NIBIB
- NICHD
- NIDA
- NIDCD
- NIMH
- NINDS
- OBSSR
- OD
- ORWH

![Brain Initiative Image](image-url)
2013 April
President Announces BRAIN

2014 NIH BRAIN awards
• 58 awards, $46 million

2015 NIH BRAIN awards
• 67 awards, $38 million
• 130+ investigators, 8 countries outside the US

2016 NIH BRAIN awards
• 100+ awards, $150+ million
• 170 investigators in the United States and 8 other countries in FY16
• Since FY14, 13 countries total are involved in US BRAIN projects
<table>
<thead>
<tr>
<th>Department Category (for Contact and Multi PIs)</th>
<th>FY15</th>
<th>~FY16</th>
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<tbody>
<tr>
<td>Biochemistry</td>
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<td>Biology/cell</td>
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<tr>
<td>Biology/Microbiology/Pathology/Immunology</td>
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<td>36</td>
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<td>Chemistry</td>
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<td>Biostatistics/math/computer science</td>
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<td>Engineering (all categories)</td>
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<td>Neuroscience/ Neurology</td>
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<td>Bioimaging/ Imaging</td>
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</table>
FY2017 Funding Opportunities

- BRAIN Initiative Cell Census Network (BICCN): Cell Atlas Center (U19), Cell Phenotyping Collaboratories (U01), Cell Data Center (U24)
- Next-Generation Human Brain Imaging Tools and Technologies: Phase II (U01)
- Early-stage Next-Generation Human Brain Imaging (R01)
- BRAIN Initiative Fellows Training (F32) and Research Career Enhancement (K18)
- Data Informatics: Standards (R24), Archives (R24), Integration/Analysis BRAIN Data (R24)
- Ethical Implications of Advancements in Neurotechnology and Brain Science (R01)
- Integrated Approaches Research Projects: Targeted (R21, R01), Exploratory (U01), Team-based (U19)
- As well as numerous opportunities re-issued from FY16.
Report Released: January 12, 2017

Stakeholder Engagement Meeting
February 21, 2017
at the National Academy of Sciences building in Washington, DC.

Stakeholder representatives and members of the committee will be given the opportunity to engage in discussions about the report’s recommendations and proposed opportunities to advance the cannabis research agenda.

The meeting is expected to run from 10am-4pm (EST) and will be webcast.

Priority Areas

Prevention Research
(Children & Adolescents)
genetics/epigenetics
development
environment
co-morbidity
2016 Monitoring the Future Study
Key Findings- Prevalence (2015 to 2016)

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Dr. Lloyd Johnston Retired from his post as PI after 42 years

Dr. Richard Miech New PI
Five infographics from NIDA’s website illustrate data on use of marijuana, prescription drugs, alcohol, cigarettes, and teens’ preference for e-cigarettes, from the Monitoring the Future survey of 2016. The first infographic ‘Past Month Marijuana Use Mostly Steady’ shows past month use of marijuana from 1996 to 2016 - for 8th, 10th, and 12 graders- with 12th graders showing the highest use consistently over the period. Use by 8th graders peaked in 1996 at 11.6 percent and declined significantly to 5.4 percent in 2016; use by 10th graders peaked in 1997 at 20.5 percent and declined to 14.0 percent in 2016; use by 12th graders peaked at 23.7 in 1997, declined over the next few years to 18.3 percent in 2006, and increased again over the years to 22.5 percent in 2016. The second infographic ‘Prescription/over-the-counter versus illicit drugs’ illustrates use in years 2012 to 2016. Among illicit drugs, use of marijuana is the highest at 35.6 percent, and among Prescription/over-the-counter drugs, amphetamines is the highest at 6.7 percent. A graph for Vicodin shows a decrease from 7.5 percent in 2012 to 2.9 percent in 2016. The third infographic is of past month alcohol use, showing a steady decline from 1996-2016 for all 3 age groups: from 26.2 percent to 7.3 percent for 8th graders, from 40.4 percent to 19.9 percent for 10th graders, and from 50.8 percent to 33.2 percent for 12th graders. The fourth infographic shows a graph of past month cigarette use from 1996-2016: Use declined in this period for these age groups: from 21.0 percent to 2.6 percent among 8th graders, from 30.3 percent to 4.9 percent for 10th graders, from 34.0 percent to 10.5 percent for 12th graders. The fifth infographic shows a graphic comparing teens past-month use of cigarettes with use of e-cigarettes in 2016: 2.6 percent versus 6.2 percent, 4.9 percent to 11 percent, and 10.5 percent to 12.5 percent, for 8th, 10th, and 12th graders respectively. A pie chart shows 62.8 percent of 12th graders thought the liquid in the e-cigarette was only flavoring and 24.9 percent of them thought it might contain nicotine. Some – 6.8 percent - thought it might contain marijuana or hash oil; others – 5.6 percent – did not know what the liquid was.
Two graphs show use of marijuana by 8th, 10th, and 12th graders. The first graph shows past year use of marijuana from 1991-2016; past year use in 2016 by 8th graders is at 9.4 percent which is a slight decline over the last 5 years but above the 6.2 percent of 1991; for 10th graders it is at 23.9 percent in 2016 -a decline from the last 5 years but above what it was in 1991 at 16.5 percent; for 12th graders it is at 35.6 percent (about the same as the last 5 years) and above the 23.9 percent of 1991.

The second graph shows daily use of marijuana for the same demographic age groups, for 1991-2016; daily use in 2016 by 8th graders is at 0.7 percent compared to 0.2 in 1991; for 10th graders is at 2.5 percent in 2016 compared to 0.8 percent in 1991; for 12th graders it is at 6 percent in 2016 compared to 2 percent in 1991. Over the last five years, daily use remained fairly steady for 8th and 12th graders and declined in 10th graders.
Legal Marijuana (28 states + DC)

Medical
Recreational

Regular Use Marijuana


SAMHSA, National Survey on Drug Use and Health, 2016.
A bar graph shows past month use of marijuana for the states that have legal recreational use, legal medical use, and no legality. Data from the 2014-2015 National Survey on Drug Use and Health shows past-month marijuana use among the population ages 12 and older, by state. Among states that had legalized Marijuana for recreational use at the time of the study - Colorado, Alaska, Oregon, Washington, and the District of Columbia, - past month use rates range from 16.6 percent to 11.2 percent.

Among states that had legalized marijuana for medical use (22 states) Vermont, Maine, Rhode Island, and New Hampshire have the highest past month use ranging from 14.7 percent to 12.1 percent. For comparison, past month overall use in the U.S. was 8.3 percent.
Since legalization, pot use in Colorado has steadily climbed, well outpacing the national average.

<table>
<thead>
<tr>
<th>Average change per period</th>
<th>U.S. average</th>
<th>Colorado</th>
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<tbody>
<tr>
<td>2010-2011</td>
<td>4.7%</td>
<td>10.8%</td>
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Youth use has also steadily risen in Colorado since legalization, in contrast to the national average.

<table>
<thead>
<tr>
<th>Average change per period</th>
<th>U.S. average</th>
<th>Colorado</th>
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<tbody>
<tr>
<td>2010-2011</td>
<td>-1.5%</td>
<td>0.9%</td>
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<td>2014-2015</td>
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</table>

Source: NSDUH state estimates.
NIDA has launched a new Council Workgroup on Policy Research Related to Cannabis Legalization

Purpose: to provide advice and guidance to NIDA on critical research questions/priority areas related to the changing legal landscape for cannabis.

Chair: John Carnevale

Members: Ken Mackie Rosalie Pacula Jonathan Caulkins Mark Ware Stu Gitlow Deborah Hasin

NIDA staff involved: Katia Howlett Steve Gust Marsha Lopez
ABCD Update

Since September 2015, the ABCD Consortium has:

- Received cIRB approval (local IRB approval where needed);
- Developed policies and procedures, data informatics, outreach materials, and school-based recruitment strategies;
- Conducted a multi-site pilot study;
- Refined the baseline protocol;
- Certified 18 sites to launch;
- Added 2 new sites (University of Wisconsin Milwaukee; Medical University of South Carolina);
- Begun enrollment
- Conducted analyses of preliminary data to validate measures.
Priority Areas

Prevention Research
(Children & Adolescents)
genetics/epigenetics
development
environment
cor morbidity

Treatment Interventions
(New Targets & New Strategies)
During 2015, **drug overdoses** accounted for 52,404 U.S. deaths, 63.1% involved an opioid.

From 2014 to 2015, the death rate from heroin increased by **20.6%**.
Two graphs of CDC data (with trend lines and bars) show the number of deaths by gender, from prescription opioids and from heroin. In 2014 and 2015 the number of deaths from overdose in prescription opioids rose in both years to 18,893, and 22,598, respectively; and for women the number was 8,786 in 2015, and 13,812 for men in 2015. The number of deaths from heroin in these years was 10,574 in 2014 and 12,989 in 2015, with 3,108 deaths for women and 9,881 for men, in 2015. The trend in these deaths for women, and for men, is upwards especially in recent years.
Overdose Deaths Involving Opioids, by Type of Opioid, United States, 2000-2015

- Any Opioid
- Heroin
- Natural & Semi-Synthetic Opioids (e.g., fentanyl, tramadol)
- Other Synthetic Opioids
- Methadone

According to the CDC/NCHS statistics, in the period 2000-2015 trend lines showing overdose deaths from any opioid since 2000 have risen to more than 10 per 100,000 population in 2015; with heroin and synthetic opioids including fentanyl (but not methadone) contributing to the increase. Trend lines for deaths from heroin, natural and semi-synthetic opioids, other synthetic opioids, and methadone are also shown for this period.
Fentanyl seizures have been increasing particularly in the Northeast.

Fentanyl seizures mirror fentanyl-related deaths (Ohio)
According to the NFLIS 2014 report on statistics from 2009 to 2014, there has been a dramatic increase in fentanyl reported in the years 2013-14, especially in the midwest, northeast and south; reports in the west remained relatively stable. A second graph shows that, in Ohio, fentanyl seizures mirror fentanyl-related deaths, both showing a sudden upward trend starting in late 2013. A map of the US shows fentanyl reports by state in the first half of 2014, with reports of 100 or more clustering among states in the Northeast.
Limited Capacity for Opioid Agonist Medication-Assisted Treatment in the USA

In 2012, the difference between the number of individuals with OUD and MAT capacity was approximately 914,000. These results in long waiting lists and drug relapse.

Jones et al., AJPH, 2015

Abstinence from Illicit Opioids over 12 Weeks with Interim Buprenorphine

Two graphs show results from studies of treatment capacity for opioid abuse or dependence. The first graph (on NSDUH data public use files from 2003-2012, and restricted-use data from 2009 to 2012) shows trend lines for past year opioid abuse or dependence and treatment capacity with opioid-agonist medication-assisted treatment and with buprenorphine, for 2003 to 2012. Past year opioid abuse or dependence increased significantly from 1,507,130 people aged 12 years and older in 2003 to 2,319,213 in 2012, and in 2012 the difference between the number of people with opioid use disorder and the treatment capacity was 914,000. The second graph from a study on interim buprenorphine treatment (using 50 patients wait-listed for comprehensive treatment) shows the abstinence percentage of patients with interim buprenorphine treatment falling over a 12 week period compared to those with no treatment; and the frequency of illicit opioid-intake over 30 days falling with buprenorphine.
21st Century Cures Act

- Enacted in December 2016; provides funding for biomedical research; streamlines the drug approval process

- Provisions related to mental health and substance use disorders include:
  - Increasing Providers in Underserved Areas
  - Pediatric Mental Health Care
  - Eating Disorders Awareness, Training and Parity
  - Community Resources
  - Grants to Address Opioid Abuse--The Act authorizes $1 billion in federal grants to states for use in carrying out opioid abuse prevention and treatment programs
  - HIPAA Clarifications
  - Federal Leadership
Priority Areas

Prevention Research
(Children & Adolescents)
genetics/epigenetics
development
environment
cor morbidity

Treatment Interventions
(New Targets & New Strategies)

HIV and Drugs
Prevention
Treatment
New NIDA FOAs

Optimizing the HIV Care Continuum for Substance Abusing Populations at High-Risk and/or Living with HIV (R01)  
(RFA-DA-17-024)
Issued: December 6, 2016; Open Date: April 9, 2017; Application Due Date(s): May 9, 2017.

Encourages research that examines the optimization of multiple components of the care continuum, such as HIV testing (identification) status, linkage and retention in care, and viral suppression for individuals with HIV for substance abusing populations at high-risk and/or living with HIV.

Nicotinic Immune Modulation in the Presence of HIV-1 Infection (R01) (RFA-DA-17-020)
Issued: October 19, 2016; Open Date: December 17, 2016; Application Due Date(s): January 17, 2017.

Encourages the submission of research project applications to determine nicotine’s modulatory effects on peripheral and central immune system functions in the presence of HIV-1 infection.
Several Previously Cleared Concepts are being reissued as RFAs:

- Advancing Exceptional Research on HIV/AIDS and Substance Abuse (R01)—Jacques Normand

- NIDA Avant-Garde Award Program for HIV/AIDS and Drug Use Research (DP1)—Jacques Normand

- Avenir Award Program for Research on Substance Abuse and HIV/AIDS (DP2)—Jacques Normand
Recent Congressional Activities

9/19/16  FON Hill Briefing on ABCD Study

10/5-7/16  NIDA and NCI Directors visited KY


2/6/17  Capitol Hill Briefing conducted by the Bipartisan Task Force to Combat the Heroin Epidemic, focused on synthetic drugs, especially synthetic opioids

2/6/17  NIH Visit House Appropriations Committee members

2/14/17  Briefing for Bipartisan Staff Energy and Commerce Oversight and Investigations Subcommittee
January 26, 2017

- 52 schools participated
- Nearly 10,000 questions were submitted
- More than 60 scientists and science writers answered almost 2500 questions in a 10 hour Web Chat with teens

More than 2100 events from around the country and around the world were held (e.g. 125 events from Mexico)
• NIDA has been working with HBO on an hour long documentary that will air probably this spring

  Working Title: “Warning: This Drug May Kill You”

• It portrays an emotional description of the consequences of opioid addiction through the eyes of families who have lost loved ones, or who are still struggling to help family members

• HBO has asked NIDA to partner with them on building an online resource page to offer more information on MAT and evidenced based treatment