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

*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.

Updated 2/18/20
National Institute on Drug Abuse Portfolio
Annual Appropriation FY 2019 Actual

Excludes HEAL

- Division of Neuroscience & Behavior: 39%
- Division of Epidemiology, Services, & Prevention Research: 12%
- Division of Therapeutics & Medical Consequences: 18%
- Center for the Clinical Trials Network: 3%
- Office of Translational Initiatives & Program Innovations: 3%
- RMS: 6%
- Intramural Research: 3%

HEAL*

- Division of Epidemiology, Services, & Prevention Research: 47%
- Division of Therapeutics & Medical Consequences: 30%
- Center for the Clinical Trials Network: 18%
- Office of Translational Initiatives & Program Innovations: 5%
- RMS: 1%

*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.

Updated 2/18/20
CIGARETTE SMOKING (PAST MONTH) DECLINES OVER PAST TEN YEARS

ALCOHOL USE CONTINUES ITS DECLINE

PAST YEAR ALCOHOL USE
Significant long-term decrease in all grades

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**
  - Measured for the first time in 2019
  - 8th graders: 1.9%
  - 10th graders: 6.9%
  - 12th graders: 11.7%

**THC**

- **THC VAPING**
  - Past month use
  - 2019: 14%
  - 2018: 12.6%
  - 2017: 3.9%

*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)*

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2019 Past Month Nicotine Vaping Equates to:

- **1 IN 4** – 12TH GRADERS
- **1 IN 5** – 10TH GRADERS
- **1 IN 10** – 8TH GRADERS
Percent of Students Reporting Marijuana, Cigarette, Vape Use in Past Month, 12th 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

To subscribe: email 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
<table>
<thead>
<tr>
<th>DM24</th>
<th>PZM21</th>
<th>MOR biased agonist</th>
<th>Oxy/Fentanyl nano-vaccine</th>
<th>Fentanyl vaccine</th>
<th>Heroin/Fentanyl vaccine</th>
<th>Fentanyl mAb</th>
<th>Methocinnamox MOR antag</th>
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<tbody>
<tr>
<td>MOR/DOR het antagonist</td>
<td>MOR biased agonist</td>
<td>MOR biased agonist</td>
<td>AT-121 NOP/MOR partial agonist</td>
<td>PTPRD inhibitor</td>
<td>R-methadone prodrug</td>
<td>Muscarinic M5 NAM</td>
<td>MOR antag</td>
</tr>
<tr>
<td>SBI-553 NT-1 biased PAM</td>
<td>NAN/NAQ MOR modulator</td>
<td>GPR151 antagonist</td>
<td>LYN-014 Long acting methadone</td>
<td>KNX100 Unknown mechanism</td>
<td>AP007 Extd-release nalmefene</td>
<td>AP007 Extd-release nalmefene</td>
<td>AP007 Extd-release nalmefene</td>
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<tr>
<td>IIT-333 MOR PA/SHT2a antagonist</td>
<td>NaN/NAQ MOR antag</td>
<td>NORS-033 Nalmefene prodrug</td>
<td>NYX-783 NMDA modulator</td>
<td>Heroin Vaccine</td>
<td>AP007 Extd-release nalmefene</td>
<td>NP10697 GluN2B antagonist</td>
<td>NP10697 GluN2B antagonist</td>
</tr>
<tr>
<td>KLS13019 CBD analogue</td>
<td>C4X3256 GSS1α R antag</td>
<td>Mor, Her, Oxy, Hydro vaccine</td>
<td>Cannabidiol</td>
<td>Tradipitant NK-1 antagonist</td>
<td>AZD4041 OX-1 antagonist</td>
<td>AZD4041 OX-1 antagonist</td>
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<td>ANS6637 ALDH2 inhibitor</td>
<td>Ketamine NMDA antagonist</td>
<td>Semiglutide GLP-1R agonist</td>
<td>Lorcanerin 5HT2c agonist</td>
<td>Gabapentin VDCC blocker</td>
<td>Heroin Vaccine</td>
<td>Tradipitant NK-1 antagonist</td>
<td>Tradipitant NK-1 antagonist</td>
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<td>Guanfacine α2 adren agonist</td>
<td>Pregab + Lofex VDCC inh/α2 agonist</td>
<td>Suvorexant OX-1/2 antagonist</td>
<td>Naltrexone 2 mo injection</td>
<td>Naltrexone 2 mo injection</td>
<td>Heroin Vaccine</td>
<td>Tradipitant NK-1 antagonist</td>
<td>Tradipitant NK-1 antagonist</td>
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<tr>
<td>OPPNT003 Nasal nalmefene</td>
<td>BICX102 3 mo naltr implant</td>
<td>Bupren/Nalox Oral, long acting</td>
<td>Bupren/Nalox Oral, long acting</td>
<td>Bupren/Nalox Oral, long acting</td>
<td>Naltrexone 6 mo implant</td>
<td>Naltrexone 6 mo implant</td>
<td>Naltrexone 6 mo implant</td>
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<tr>
<td>Olani 6 mo naltr implant</td>
<td>LAAM Oral, re-intro</td>
<td>Brixadi Bupr 1 wk/1 mo inj</td>
<td>AP003 Mit-dose nlx nasal spray</td>
<td>AP003 Mit-dose nlx nasal spray</td>
<td>Naloxone Hi-dose nasal spray</td>
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Justice Community Opioid Innovation Network (JCOIN)

- 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

18 States + Puerto Rico
88 communities
>25,000 justice-involved individuals
<table>
<thead>
<tr>
<th>Month</th>
<th>Activity</th>
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<tbody>
<tr>
<td>April, 2019</td>
<td>Grants Funded</td>
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<tr>
<td>May, 2019</td>
<td>Decision to Develop Single Protocol</td>
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<td>May – July, 2019</td>
<td>Development of Intervention &amp; Protocol</td>
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<tr>
<td>July – December, 2019</td>
<td>s-IRB Approvals</td>
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<tr>
<td>October, 2019</td>
<td>Randomization of Communities</td>
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<tr>
<td>November, 2019 – January, 2020</td>
<td>Baseline Data Collection</td>
</tr>
<tr>
<td>December, 2019</td>
<td>Phase 0 Meetings with all Communities</td>
</tr>
<tr>
<td>January, 2020</td>
<td>Phase 1 Meetings with Wave 1 Communities</td>
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HEALthy Brain and Child Development Study (HBCD)

Progress Update for Phase I

29 planning grants awarded in September 2019

PI meeting May 4-5th, 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
Ongoing HEAL Funding Opportunities

New funding opportunities planned for 2020: www.heal.nih.gov
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)

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

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 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.