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

Nora D. Volkow, M.D.
Director
National Institute on Drug Abuse
May 10, 2022
<table>
<thead>
<tr>
<th></th>
<th>FY 2021 Final</th>
<th>FY 2022 Enacted</th>
<th>FY 2023 PB*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Base</strong></td>
<td>$1,206,321</td>
<td>$1,250,828</td>
<td>$1,437,883</td>
</tr>
<tr>
<td><strong>HEAL</strong></td>
<td>$269,484</td>
<td>$345,295</td>
<td>$405,443</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>$1,475,805</td>
<td>$1,596,123</td>
<td>$1,843,326</td>
</tr>
</tbody>
</table>

* The FY 23 President’s Budget proposal was released prior to the receipt of a full year FY 22 appropriation. The proposed budget included a $364m increase over the FY 22 Continuing Resolution level and contained a request for $196.3m in support of non-HEAL opioid and pain research.
FY 21 Funding Overview

Non-HEAL Research

- Therapeutics and Medical Consequences, 10%
- Epidemiology, Services & Prevention Research, 32%
- Neuroscience & Behavior, 46%
- Clinical Trials Network, 4%
- Office of the Director, 9%

HEAL Research*

- Office of the Director, 5%
- Neuroscience & Behavior, 6%
- Clinical Trials Network, 18%
- Therapeutics and Medical Consequences, 26%
- Epidemiology, Services & Prevention Research, 45%

*Includes all NIDA HEAL projects regardless of funding source
Adolescent Brain Cognitive Development Study

98.1 Percent Retained

As of April 2022
Intersection Between COVID-19 and Substance Use Disorders
Cannabis Use During the COVID-19 Pandemic

- **Adults:** Online survey of adults who used cannabis showed greater odds of increased non-medical use during the pandemic among those who reported monthly or less than weekly use prior to the pandemic (Assaf et al., 2022).

- **Pregnant Women:** Analysis of Kaiser Permanente Northern California data suggest elevated cannabis use by pregnant women after the onset of the pandemic (Young-Wolff et al., 2021).
Age-adjusted Drug Overdose Death\textsuperscript{a} Rates By Age, Sex and Race/Ethnicity Before and During the COVID-19 Pandemic In US

\textsuperscript{a} ICD-10 codes: X40-44 (unintentional) and Y10-14 (undetermined intent). NH = non-Hispanic. AIAN = American Indian or Alaska Native.
Drug Overdose Deaths* Continued to Increase in 2021

<table>
<thead>
<tr>
<th></th>
<th>ALL DRUGS</th>
<th>HEROIN</th>
<th>NAT &amp; SEMI SYNTHETIC</th>
<th>METHADONE</th>
<th>SYNTHETIC OPIOIDS (mainly illicit fentanyl)</th>
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<th>OTHER PSYCHO-STIMULANTS (mainly meth)</th>
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<tbody>
<tr>
<td>11/2020*</td>
<td>92,366</td>
<td>13,698</td>
<td>13,667</td>
<td>3,593</td>
<td>56,595</td>
<td>19,953</td>
<td>23,894</td>
</tr>
<tr>
<td>5/2021</td>
<td>101,075</td>
<td>11,633</td>
<td>13,909</td>
<td>3,802</td>
<td>64,871</td>
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</tr>
<tr>
<td>11/2021*</td>
<td>106,854</td>
<td>9,504</td>
<td>13,643</td>
<td>3,619</td>
<td>70,420</td>
<td>23,908</td>
<td>32,476</td>
</tr>
<tr>
<td>Percent Change</td>
<td><strong>15.7%</strong></td>
<td><strong>-30.6%</strong></td>
<td><strong>-0.2%</strong></td>
<td><strong>0.7%</strong></td>
<td><strong>24.4%</strong></td>
<td><strong>19.8%</strong></td>
<td><strong>36.0%</strong></td>
</tr>
</tbody>
</table>

* NCHS Provisional drug-involved overdose death counts are PREDICTED VALUES, 12 months ending in select months. [https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm](https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm)
Reduced Risk Overdose in Pregnant Women Given Medications for OUD


### FDA-Approved Medications

- **Methadone**
  - In use since the 1960s, the long-acting synthetic opioid is used to treat opioid addiction, it is only available in medically supervised clinics.

- **Buprenorphine/Suboxone**
  - Approved in 2002, the long-acting opioid relieves drug cravings with fewer side effects than other opioids and is available in several forms from several doctors. Suboxone is designed to be taken once a day.

- **Naltrexone/Vivitrol**
  - Approved in pill form in 1984, it has been available since 2019 for once-a-week depot injection to treat addiction. Patients must be completely off all opioids for at least 7 days. Each dose is effective for 1 week, it does not block the oral receptor system, and does not cause physical dependence.

- **Naloxone**
  - Approved in 1975, the short-acting medication, also known as Narcan and EpiPen, reverses opioid overdoses but does not treat opioid addiction.

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**Percent Reduction in Risk**

<table>
<thead>
<tr>
<th>Weeks of MOUD</th>
<th>Reduced Risk</th>
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<tbody>
<tr>
<td>10</td>
<td>57</td>
</tr>
<tr>
<td>20</td>
<td>82</td>
</tr>
<tr>
<td>30</td>
<td>92</td>
</tr>
<tr>
<td>40</td>
<td>97</td>
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Among the 1.6 million people aged 12+ with past year OUD, **18% received MOUD**

- Retention rates for MOUD vary widely across treatment settings, medications, and behavioral therapy factors (Timko et al., 2016)

- Overall MOUD retention (for trial duration) based on meta-analysis of 79 RCT (Lim et al., 2022):
  - 64% for methadone (2 weeks-3 years)
  - 54% for buprenorphine (2 weeks-1 year)
  - 41% for naltrexone (2 months-9 months)
  - 30% for control (2 weeks-3 years)

Methadone superior to buprenorphine (RR = 1.22; 95% CrI = 1.06-1.40)
Buprenorphine superior to naltrexone (RR = 1.39; 95% CrI = 1.10-1.80)
All Medication superior to control

(NSDUH, 2019)
Enhancing the National Drug Abuse Treatment Clinical Trials Network to Address Opioids Expand research conducted by NIDA CTN to address emergent needs presented by the opioid crisis.

NIH HEAL Initiative

Justice Community Opioid Innovation Network Study quality care for OUD in justice populations. Help create partnerships between local and state justice systems and community-based treatment providers.

NIH HEAL Initiative

HEALing Communities Study is investigate coordinated approaches for deploying evidence-based strategies to prevent and treat OUD in 67 communities in 4 states.
CTN Progress: 9/2021 - Now

Studies addressing:

- Treatment Research among minority population
  7 active, 1 pending award
- Screening/prevention strategies in primary care
  2 active, 2 pending award
- Expand methadone for OUD in primary care
  2 active
- Optimize effective treatments in ED
  2 active, 3 trials and 3 ancillary studies completed
- Expand MOUD in community pharmacies
  1 pilot completed, 1 starting summer 2022
- Stimulants
  2 active, 2 pending study medications

Over 23,500 participants recruited

- 27% African American
- 15% Hispanic
- 6% Multi-race
- 3% Asian American
- 1% American Indian/AN
- 39% Women

CTN publications

- 606 – Total publications
- 66 – Last 12 months
- 69 – Pending journal review
Evidence Base to Improve Practice in Justice Settings

MEDICATIONS AT RE-ENTRY

Providing all FDA-approved MOUDs during incarceration could reduce overdose deaths & recidivism by ~30%

43% Jails in communities offer all 3 MOUDs
7% State prisons offer all 3 MOUDs

Sources: Evans et al., 2022; Scott et al., 2021, Macmadu et al., 2021

PILOT STUDY: EXTENDED-RELEASE BUPRENORPHINE

Extended-release buprenorphine prior to re-entry from jails increased adherence (69 vs. 35%) relative to sublingual buprenorphine

Sources: Lee et al. 2021

MEDICAID & INCARCERATION

Medicaid pre-enrollment prior to release increased Medicaid access 7-fold & decreased racial disparities.

Receiving MOUDs while incarcerated doesn’t change Medicaid costs, but decreased costs from emergency care

Sources: Burns et al., 2020, Howell et al. 2021, Hochstatter, 2021
HCS Intervention Accomplishments

• Implemented EBPs for OEND, MOUD, and safer prescribing in Wave 1 communities
• Communication campaigns completed on:
  • Overdose education and naloxone
  • MOUD
  • Accessing and staying in treatment
• Developing sustainability plans to maintain HCS activities

Images of People in the Community

Wave 1 communities are implementing the Communities That Heal intervention through June 2022. Wave 2 communities will start implementation on July 1, 2022.
### Drug Overdose Deaths* Continue to Increase in 2021

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**Percent Change 11/20-11/21**
- ALL DRUGS: 15.7%
- HEROIN: -30.6%
- NAT & SEMI SYNTHETIC: -0.2%
- METHADONE: 0.7%
- SYNTHETIC OPIOIDS: 24.4%
- COCAINE: 19.8%
- OTHER PSYCHO-STIMULANTS: 36.0%

* NCHS Provisional drug-involved overdose death counts are PREDICTED VALUES, 12 months ending in select months.
Fentanyl-involved and Non-Fentanyl Overdose Death Rates In US Youth Aged 15-19 Prior To and During The Covid Pandemic

Number of Pills Containing Fentanyl Seized by Law Enforcement in the United States, 2018 – 2021

Estimates based on data reported by the Office of National Drug Control Policy’s High Intensity Drug Trafficking Areas program

Addressing Overdose Deaths in 2022

- **Pain** treatments crucial but not sufficient.
- Treatment **Opioid Use Disorders** crucial but not sufficient.
  - Retention
  - Recovery
- Treatment of **other Substance Use Disorders**
- Overdose treatment: drug combinations, **stimulant overdoses**
- **Prevention** drug use including but not limited to opioids
  - Screening and appropriate treatment intervention for SUD (mild-severe)
- **DATA**: Timely reporting of fatal and non-fatal overdoses
  - Emerging new drugs and drug mixtures (xylazine)
- Social Determinants of Health
Measures to define and detect Pre-Addiction
• This is a research need
• Meanwhile, DSM 5 diagnoses are reliable and easy to implement. Criteria for “Mild to Moderate” SUD are reasonable starting points for defining “pre-addiction”

Effective interventions for Pre-Addiction
• Treatments designed for severe SUD are usually inappropriate for mild cases.
• Payers support screening and 1-4 motivational counseling sessions, which are effective in reducing alcohol misuse. However, less data exists for other SUD. Also, more intensive interventions are likely needed for more severe symptoms.
• Need to develop pre-addiction interventions and test their effectiveness.
NIDA’s Office of Translational Initiatives and Program Innovation

Primary Prevention
focuses on root causes and key predictors of substance use and substance use disorder, and how to safely and effectively manage pain.

Harm Reduction
focuses on reducing risks associated with substance use, including overdose and infectious disease transmission.

Evidence-Based Treatment
focuses on providing the most effective, evidence-based treatments without delay, stigma, or other barriers.

Recovery Support
focuses on funding, reimbursing, training workforces for, and developing protocols around peer, employment, and housing supports.

Overdose Prevention Strategy

Invistics
Sound Life Sciences
S:3 Research
Biobot Analytics
appliedVR
Workit Health
Sober Grid
Woebot
Marigold Health
we the Village
emocha
prapela
Can Virtual Reality Help Ease Chronic Pain?

V.R. treatments may provide relief similar to intravenous opioids—a tantalizing prospect for the millions of Americans living with chronic pain.

“…pervasive stigma against people with substance use disorders (SUDs) remains a major barrier to treatment.

Language is a powerful driver of negative bias; even the word “abuse,” may perpetuate stigma against people who use drugs and deter people with SUD from seeking treatment.

As a step toward reducing that stigma, **NIDA is proposing that the Institute be renamed the ‘National Institute on Drugs and Addiction.’**”