

United States Senate

WASHINGTON, DC 20510

February 4, 2021

Dr. Nora D. Volkow
Director, National Institute on Drug Abuse
National Institutes of Health
301 North Stonestreet Ave
Bethesda, MD 20892

Dear Dr. Volkow,

We write to follow-up on the January 13, 2021 National Institute on Drug Abuse (NIDA) announcement detailing potentially promising research findings related to medication treatment options for methamphetamine use disorder. We are encouraged by this news and request additional information regarding current efforts at NIDA to foster the development of basic and translational research for medications to treat methamphetamine use disorder, including additional details on future phases of the Accelerated Development of Additive Pharmacotherapy Treatment for Methamphetamine Use Disorder (ADAPT-2) study.

The global COVID-19 pandemic and the resulting social distancing measures have placed a significant strain on Americans in recovery from substance use disorders (SUD). In recent years, the national conversation regarding the addiction crisis has centered on opioids. While we have made progress in treating opioid-related overdoses and opioid use disorder, the country is experiencing a surge in methamphetamine-related overdose deaths with limited tools available to address the need. Multiple studies indicate that development and increased use of U.S. Food and Drug Administration (FDA) approved medications are associated with a reduction of the number of opioid-related deaths. The development and dissemination of three FDA-approved medication options for opioid use disorder – buprenorphine, methadone, and naltrexone – have given physicians and patients the tools necessary to curb opioid addiction. For example, access to opioid agonist treatments such as buprenorphine is associated with reduced use of opioids and a significant reduction in opioid-related overdose deaths. While we still have a long way to go to ensure all individuals struggling with opioid use disorder have access to medication treatment, the existence of these medications has helped to limit the number of opioid-related overdose deaths and improve opioid rehabilitation outcomes.

Unfortunately, comparable treatment options are not available to those fighting the methamphetamine crisis. Further, concurrent use of methamphetamine and opioids, which can derail gains made in addressing the opioid crisis and add to the need and complexity of medication treatment, is on the rise. Because there are no FDA-approved medication options for methamphetamine use disorder, treatment often relies on behavioral intervention, which has been significantly complicated by the COVID-19 pandemic. A Centers for Disease Control and Prevention (CDC) health advisory reported overdose deaths from methamphetamine and other psychostimulants increased by 34.8 percent in the 12-month period ending May 2020 compared to the prior 12-month period, with even higher rates expected as the COVID-19 pandemic continues. The number of deaths involving psychostimulants now exceeds cocaine-involved

deaths. Native Americans and Alaska Natives experience the highest death rates from methamphetamine and cocaine and the largest rate increase. Compounding this issue are delays both at the basic research level, with university closures, and in clinical trials unable to access and enroll participants. With the complications surrounding the ongoing COVID-19 pandemic, it is important that we focus our effort on developing additional effective options to treat all manner of SUD.

We are aware of several clinical trials investigating the use of drugs such as naltrexone, bupropion, and dexamethylphenidate to treat methamphetamine use disorder similar to medications used for opioid use disorder. In the recently published ADAPT-2 study conducted by NIDA's Clinical Trial Network, participants given a combination of bupropion and naltrexone responded to treatment and reported fewer cravings and improvements to their lives at rates greater than those receiving the placebo. Though the efficacy was low, participants responded to this treatment at levels similar to other medical treatments for mental health disorders. This is a promising step and indicates effective medication options for methamphetamine use disorders are worth additional focus.

In order to better understand how NIDA is leading the charge in advancing research to develop treatment options for methamphetamine use disorder, we ask that you please respond to the following questions:

1. How much funding has NIDA allocated to research and development of medications for methamphetamine use disorder?
 - a. Of the money recently appropriated to NIDA for addiction-related research for FY21, what percent do you plan to allocate toward medications for opioid use disorder versus medications to treat SUD related to other addictive substances, including methamphetamine?
 - b. What, if any, additional support or authority from Congress does NIDA require to allocate resources necessary to the research and development of treatments for methamphetamine use disorder? What funding is required to both build and expand on this work in FY22?
 - c. Has Congress provided sufficient flexibility in these resources to respond to changes in substance use disorder rates and treatment needs?
2. How many NIDA-sponsored clinical trials focused on prospective medications for methamphetamine use disorder are currently in operation, and in what stages are such trials?
 - a. How does NIDA plan to increase the number of NIDA-sponsored clinical trials on prospective medications for methamphetamine over the next 5 years?
 - b. Is NIDA partnering with any other agencies, such as the Office of National Drug Control Policy, FDA, Drug Enforcement Agency (DEA), Indian Health Service (IHS), or other institutes at NIH in any aspect of research, drug development, or clinical trial implementation?
3. What steps has NIDA taken to ensure clinical trials for medications for methamphetamine use disorder are conducted across diverse populations?
 - a. Is NIDA currently sponsoring or conducting intramural research that examines methamphetamine use disorder among populations that are disproportionately impacted, such as Native Americans and Alaska Natives?

- i. If not, what are NIDA's plans to do so across the next 5 years?
4. Is NIDA engaged on medications for methamphetamine use disorder through the NIH HEAL Initiative?
 - a. Are there other dedicated initiatives for addressing psychostimulant, like methamphetamine, use disorders at NIDA or NIH at-large?
5. As we wait for the development and approval of potential medications for the treatment of stimulant use disorder, what are the best current approaches to stimulant use disorder?
 - a. How is NIDA partnering with providers and states to share information about these current evidence-based practices?
6. How is NIDA addressing COVID-19-related delays in basic, translational, or clinical research on medications for methamphetamine use disorder?
 - a. In what ways can Congress provide support to continue this research?

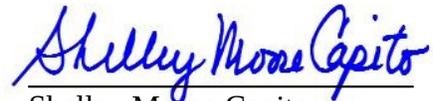
The usage of medications, as evidenced by numerous studies, has been a powerful tool in the effort to combat opioid addiction. Supporting basic and translational research around the development of medications for methamphetamine use disorder is critical to addressing the increase in methamphetamine-associated deaths. We are encouraged by the results of the ADAPT-2 trial and ask that you keep us updated on the efforts at NIDA and its partners in the development of treatments to address methamphetamine use disorder.

Thank you for your prompt attention to this matter. We look forward to continuing to collaborate with NIDA and other federal partners on this critical public health issue.

Sincerely,



Sherrod Brown
United States Senator



Shelley Moore Capito
United States Senator



Robert P. Casey, Jr.
United States Senator



Joni K. Ernst
United States Senator

Mazie K. Hirono

Mazie K. Hirono
United States Senator

Jeanne Shaheen

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United States Senator

Tammy Duckworth

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Amy Klobuchar

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Tammy Baldwin

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Dianne Feinstein

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Jon Tester

Jon Tester
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Steve Daines

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