DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL INSTITUTES OF HEALTH

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Hearing Title

Strengthening Federal Mental Health and Substance Use Disorder Programs:

Opportunities, Challenges, and Emerging Issues

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Chairwoman Murray, Ranking Member Burr, and members of the Committee, thank you for inviting the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), to participate in this hearing. NIDA's mission is to advance the science on the causes and consequences of drug use and addiction and apply that knowledge to improve individual and public health. I am pleased to speak to you today about the intersection of substance use and mental health.

The Administration is committed to addressing the unprecedented mental health, and substance use disorder crisis that is affecting adults and children of all races in urban and rural communities across the United States. During the State of the Union, President Biden announced his Unity Agenda. This includes a focus on fighting the overdose epidemic as well as addressing our national mental health crisis. The three pillars of the President's mental health strategy are: (1) Strengthen System Capacity; (2) Connect Americans to Care; and (3) Support Americans by Creating Healthy Environments. Today I will detail for you how NIDA science is advancing these goals.

We are experiencing the worst drug overdose crisis in the nation's history. Exacerbated by the COVID-19 pandemic, overdose deaths exceeded 100,000 from September 2020 to September 2021, the highest number ever recorded in a 12-month period and a staggering 50 percent increase over the previous two years. Large increases in many kinds of drug use have been seen over the course of the pandemic: Several reports have revealed increases in positive urine drug screens for fentanyl, cocaine, heroin, and methamphetamine.^{2,3,4} There have been increases in cannabis and alcohol use, especially among people with anxiety and depression and those experiencing COVID-19-related stress,^{5,6,7} underscoring the close relationship between drug use and mental health.

Substance use disorders (SUDs) are considered mental illnesses, and these conditions frequently co-occur with other mental illnesses including depression, anxiety, post-traumatic stress disorder (PTSD), and others. Half of people with mental illnesses will have an SUD at some point in their lives, and the reverse is also true. The reasons that SUDs often co-occur with other mental illnesses are complex. Sometimes they arise independently as a result of shared risk factors (common genetics, common environmental adverse factors). Their

¹ FACT SHEET: President Biden to Announce Strategy to Address Our National Mental Health Crisis, As Part of Unity Agenda in his First State of the Union | The White House

² <u>Millennium Health's Signals Report™ COVID-19 Special Edition Reveals Significant Changes in Drug Use During the Pandemic</u> (prnewswire.com)

³ Analysis of Drug Test Results Before and After the US Declaration of a National Emergency Concerning the COVID-19 Outbreak

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⁴ The Opioid Epidemic Within the COVID-19 Pandemic: Drug Testing in 2020 | Population Health Management (liebertpub.com)

⁵ Alcohol Consumption during the COVID-19 Pandemic: A Cross-Sectional Survey of US Adults (nih.gov)

⁶ <u>Increased alcohol use during the COVID-19 pandemic: The effect of mental health and age in a cross-sectional sample of social media users in the U.S. - ScienceDirect</u>

⁷ Changes in Alcohol Consumption Among College Students Due to COVID-19: Effects of Campus Closure and Residential Change: Journal of Studies on Alcohol and Drugs: Vol 81, No 6 (jsad.com)

development may also be intertwined, with one contributing to the other. Chronic, problematic drug use can disrupt the activity of the brain's reward, stress, and executive-control systems, making it more difficult for people to experience the pleasures associated with daily living and contributing to negative emotional states, such as depression, stress, and anxiety while impairing their capacity for self-regulation. In other cases, people use drugs to self-treat an underlying mental disorder. Over time, chronic drug use can lead to an SUD, which in turn can worsen the original mental illness. Genetics may also mediate the relationship between drug use and mental illness. For example, cannabis use raises risk of psychosis in those who have an underlying genetic vulnerability. Research also points to a concordance between increases in schizophrenia associated with cannabis use disorder and concurrent rises in cannabis use and cannabis potency over the past two decades.

Although genes play a role in some of the synergies between drug use and mental illness, many of the common risk factors are social determinants of health such as racial and other forms of discrimination, adverse childhood experiences like abuse and neglect, and economic deprivation including poverty and lack of access to quality education and healthcare. The stigma that attaches to both SUDs and other mental illnesses is another important factor, which contributes to and compounds adverse social determinants of health including social isolation, job loss, incarceration, and reluctance to seek care or difficulties accessing it.

Social isolation and stress have likely contributed to the rise in substance use and overdose observed over the course of the pandemic. Social isolation can make people with SUDs more vulnerable to negative outcomes because it interferes with many of the support systems that can help them to reach and sustain recovery. Although exposure to stress is a common occurrence for many of us, it is also one of the most powerful triggers for relapse to substance use for people with SUD, even after long periods of abstinence and for the exacerbation of depression and anxiety among with people with mental illnesses.

Notably, there are increased reports of mental distress since the COVID-19 pandemic emerged, including among individuals with no history of mental disorders and among younger adults, racial/ethnic minorities, essential workers, and unpaid adult caregivers. 8,9,10,11 This increased mental distress is occurring in the context of a drug supply that is dominated by potent synthetic opioids and psychostimulants, underscoring the need for focused investment in prevention and treatment to mitigate the impact of the pandemic on the ongoing overdose epidemic. Suicide is often linked to depression and other mental illnesses including SUDs, and in the United States, and it has significantly risen particularly among youth and, to a lesser extent, the elderly. Moreover, in a recent study, we found that although suicide by overdose

⁸ Mental Health - Household Pulse Survey - COVID-19 (cdc.gov)

⁹ Early Release of Selected Mental Health Estimates Based on Data from the January–June 2019 National Health Interview Survey (cdc.gov)

¹⁰ Mental distress during the COVID-19 pandemic among US adults without a pre-existing mental health condition: Findings from American trend panel survey - ScienceDirect

¹¹ Mental Health, Substance Use, and Suicidal Ideation During the COVID-19 Pandemic — United States, June 24–30, 2020 | MMWR (cdc.gov)

went down in most groups between 2015 to 2019 (the most recent year available), it rose in young people aged 15-24, in older adults aged 75-84, and in Black women. The highest suicide-by-overdose rate in all years studied was seen in women aged 45-64.¹²

NIDA Is Advancing Research on SUDs and Other Mental Illnesses

NIDA-supported research has led to the development of effective prevention and treatment interventions for SUD, providing hope for the more than 20 million people in the United States with SUD and their loved ones. Although significant strides in establishing evidence-based practices have been made, there is far more work to be done to develop new prevention and treatment interventions and to deliver existing effective interventions with fidelity, for diverse populations, and at scale. There is a particularly urgent need for interventions for comorbid SUD and mental illness; just as SUD and other mental illnesses may exacerbate one another, effective treatment for each of a person's psychiatric condition improves overall outcomes.

Prevention

Two large NIH-funded longitudinal studies, the Adolescent Brain Cognitive Development (ABCD) study and the HEALthy Brain and Child Development (HBCD) study, will add greatly to our understanding of risk and protective factors for SUDs and other mental illnesses. Launched last year, the HBCD study will examine, from the prenatal period through age 9-10, both normal brain development and how environmental factors, including social determinants of health, maternal drug exposure, substance use, and COVID-19 influence brain development and clinical outcomes. ABCD is following nearly 12,000 children from age 9-10 through the subsequent decade. This study, too, has been examining how childhood experiences affect brain development and social, behavioral, academic, and health outcomes, including substance use and COVID-19. Together, these studies will provide valuable information for the development and implementation of prevention interventions.

It is already clear that interventions in early childhood or adolescence can be beneficial for averting substance use and other mental illnesses later in life. Research has also provided evidence that interventions for low-income families can ameliorate some of the adverse neurobiological impacts of poverty. Substance use and behavioral disorders exact a monetary as well as a human cost, with impacts felt across sectors of society including healthcare, the justice system, education, and taxpayers in general. Studies of prevention's return on investment show that communities could not only save lives but save money by investing in prevention programs. A recent analysis of one state's healthcare costs incurred by various risky behaviors in pre-adolescents and adolescents pointed to great potential cost savings from

¹² Intentional Drug Overdose Deaths in the United States American Journal of Psychiatry 2022 179:2, 163-165

¹³ Family-centered prevention ameliorates the longitudinal association between risky family processes and epigenetic aging - Brody - 2016 - Journal of Child Psychology and Psychiatry - Wiley Online Library

implementing relatively low-cost measures including screening in primary care and referral to family-based prevention.¹⁴

Indeed, screening is crucial to better prevention of SUD and other mental illnesses, and it is an important area to focus our efforts. As it now stands, within primary and ambulatory care settings, rates of screening for depression are quite low.^{15, 16} Screening for depression and other mental health conditions needs to become part of standard practice along with asking about substance use. Only when providers screen for and diagnose all coexisting psychiatric conditions can treatment plans be developed that address the patient's unique and combined needs.

Under the Helping to End Addiction Long-term® or HEAL Initiative®, NIDA leads prevention research aimed at adolescent and young adult populations that are at highest risk for opioid misuse and opioid use disorder (OUD). Ongoing studies are modifying an existing alcohol and drug prevention intervention designed for American Indian/Alaska Native (AI/AN) youth to be appropriate for opioid prevention in young adults; preventing OUD among adolescents/young adults experiencing homelessness; exploring whether providing housing in addition to risk reduction services could improve outcomes; and leveraging technology that is appealing to adolescents and young adults to facilitate delivery of an emergency-department-based intervention via health coaches. Preventing harms related to substance use is another critical priority and includes strategies to prevent overdose and other medical consequences of substance use such as infectious diseases.

Behavioral Treatments

Only 13 percent of people with drug use disorders receive any treatment, and more than half of those with co-occurring conditions in a given year will receive treatment for neither. Behavioral therapies can be effective for treating SUDs. For example, contingency management, a therapy that provides incentives for behavior change, is the most effective treatment for stimulant use disorders, though it is unfortunately not widely available to patients. Other behavioral treatments, like cognitive behavioral therapy, have been shown to be effective in treating both SUDs and some other mental illnesses together. But by and large, treating SUDs and other mental illness will require a combined approach and coordination of care among different specialists. In a person with OUD and depression, for instance, it could mean a combination of buprenorphine and an antidepressant, ideally in combination with some form of behavioral therapy. Overall interventions need to be personalized to the severity of the disorder and the different needs of patients. NIDA is supporting research to develop behavioral treatments to

¹⁴ Addressing Barriers to Primary Care Screening and Referral to Prevention for Youth Risky Health Behaviors: Evidence Regarding Potential Cost-Savings and Provider Concerns | SpringerLink

¹⁵ National Rates and Patterns of Depression Screening in Primary Care: Results From 2012 and 2013 - PubMed (nih.gov)

Depression Screening Patterns, Predictors, and Trends Among Adults Without a Depression Diagnosis in Ambulatory Settings in the United States | Psychiatric Services (psychiatryonline.org)

¹⁷ Preventing At-Risk Adolescents from Developing Opioid Use Disorder | NIH HEAL Initiative

reduce substance use by addressing symptoms of anxiety and depression; to simultaneously intervene on substance use and symptoms of PTSD in adolescents; and to develop SUD treatment approaches that are tailored to the needs of people with schizophrenia or symptoms of psychosis.

Medication Development

Developing effective medications for SUDs is one of NIDA's highest priorities and is critical to improving treatment for people with addiction. While effective medications exist for OUD, these medications are underutilized. Suboptimal patient retention in treatment regimens, policy barriers that limit opioid prescribing, and stigma around opioid agonist medications all contribute to their underutilization. More options are needed to help people with OUD achieve long-term recovery. NIDA is supporting research on medication development for OUD and overdose, including through funds provided by the NIH HEAL Initiative. The NIH HEAL Initiative has allowed investigators to file 21 Investigational New Drug Applications with the Food and Drug Administration (FDA) in the past 2.5 years to initiate clinical trials. These studies focus on a variety of drug targets, as well as monoclonal antibodies and vaccines that could prevent opioids from entering the brain.

An increased focus on patient wants and needs, as well as a growing understanding that SUD treatment needs to be personalized and responsive to patients' unique changing sets of symptoms, is leading to a broadened conception of treatment that can include addressing multiple co-occurring symptoms of a disorder. Sleep problems, depression, and anxiety, for instance, are among SUD-associated symptoms identified at patient-focused drug development meetings held by the FDA in partnership with NIDA to solicit input from SUD patient populations to help guide drug development. Studies are underway to investigate the possibility of repurposing existing medications for OUD indications, such as the FDA-approved insomnia medication, suvorexant, based on known overlaps between brain signaling systems involved in sleep and addiction.

We are also prioritizing the development of medications to treat stimulant use disorders for which there are currently no FDA-approved medications. Numerous compounds are being tested, and approaches span identifying novel biological targets for new medications, developing anti-cocaine and anti-methamphetamine vaccines, repurposing existing FDA-approved medications, and testing the benefits from medication combinations (i.e., naltrexone + buprenorphine for the treatment of moderate to severe methamphetamine use disorder). NIDA's medication development program is also supporting research on compounds that specifically address intersecting substance use and psychiatric symptoms, including potential treatments for mood disorder symptoms associated with cocaine use and co-occurring bipolar and cannabis use disorders.

More coordinated and targeted approaches to incentivize drug development related to addiction are sorely needed. The pharmaceutical industry has historically underinvested in research and development of substance use disorder treatments, due to the biological

complexity of these disorders, the stigma that surrounds them, and concerns around the profit potential of substance use disorder medications.

Harm Reduction

Abundant research shows the value of interventions and services aimed at reducing harms associated with drug use. Overdose deaths are significantly reduced in communities that distribute naloxone to people who use drugs and to their families or other potential bystanders. An important part of NIDA's medication-development research involves developing new and improved overdose reversal medications, particularly formulations of naloxone that are effective for high-potency opioids like fentanyl, as well as compounds that could reverse opioid overdoses involving other drugs such as methamphetamine. Syringe-services programs are effective at reducing the spread of HIV and other infectious diseases like hepatitis C, and they also help link people who inject drugs to addiction and HIV screening and treatment. NIDA continues to support research on these and other harm reduction practices such as drug checking technologies like fentanyl test strips.

Translating Research into Practice in Diverse Settings

Providing prevention and treatment services across health care, justice, and community settings is key to addressing SUD and is the most promising way to improve access to treatment. Persistent challenges continue to keep mental health care largely separate from general medical care, and addiction care is often further sequestered to specialized settings. This leads to difficulty in providing patients with coordinated, wholistic treatment. In order to promote provision of quality care, NIDA places a high priority on implementation research in diverse settings, including through the NIDA Clinical Trials Network (CTN), the Justice Community Opioid Innovation Network (JCOIN), and the HEALing Communities Study (HCS).

Clinical Trials Network

The primary goal of CTN, which comprises 16 research nodes and more than 240 community-anchored treatment programs across the country, is to bridge the gap between the science of drug treatment and its practice through the study of evidence-based interventions in real-world settings. NIDA's CTN allows medical and specialty treatment providers, treatment researchers, patients, and NIDA to cooperatively develop, validate, refine, and deliver new treatment options to patients. The CTN is conducting studies to evaluate strategies for integrating OUD screening and treatment into emergency departments, primary care clinics, infectious disease programs and rural and AI/AN communities. It also tests alternative models of care for SUD such as the use of pharmacies for delivering medication for OUD and the integration of telehealth for support of treatment. The CTN supports research based on data relevant to SUD by taking advantage of electronic health record (EHR) systems. It is currently developing and testing a clinical decision support tool that integrates with EHR systems to help doctors

diagnose OUD and provide treatment or refer patients to appropriate care. The CTN also supports research to examine the role of pharmacies in providing medications for OUD, an approach that could be especially useful in rural communities located far away from traditional treatment programs.

Justice Community Opioid Innovation Network

NIDA's JCOIN, which is funded though the NIH HEAL initiative, is testing strategies to expand effective OUD treatment and care for people in justice settings in partnership with local and state justice systems and community-based treatment providers. ¹⁸ JCOIN includes a national survey of addiction treatment delivery services within the justice system; studies on the effectiveness and adoption of new medications, prevention and treatment interventions, and technologies; and use of existing data sources in novel ways to understand care in justice populations. Together, these studies are generating real-world evidence to address the unique needs of individuals with OUD in justice settings. JCOIN also responded in real time to the COVID-19 pandemic with additional research to study COVID testing protocols in justice-involved populations.

HEALing Communities Study

The HEALing Communities Study, also funded through the NIH HEAL Initiative, is a multisite implementation research study investigating coordinated approaches for deploying evidence-based strategies to prevent and treat opioid misuse and OUD and prevent overdose deaths that is tailored to the needs of local communities. Research sites are partnering with 67 communities highly affected by the opioid crisis across four states (NY, MA, KY, and OH) to measure the impact of these efforts. ¹⁹ The ambitious goal of the study is to reduce opioid-related overdose deaths by 40 percent over three years. Despite the impacts of COVID-19 on research and its severe exacerbation of the overdose crisis, the HEALing Communities study was able to launch a key aspect of its program, a diverse communications campaign to increase awareness and demand for evidence-based practices and to reduce stigma against people with OUD and those taking medications for OUD. ²⁰

Leveraging Telehealth, Digital Solutions, and Innovation to Expand Access to Care

A component of translating research into practice is leveraging existing opportunities and developing new ways to bring healthcare to hard-to-reach populations. The COVID-19 pandemic brought about significant drug treatment policy changes that expanded telehealth and facilitated access to medications for OUD—including by facilitating remote prescribing of buprenorphine and take-home dosing of methadone. These flexibilities were rapidly implemented by providers, and evidence to date suggests that they were not associated with

¹⁸ Justice Community Opioid Innovation Network | NIH HEAL Initiative

¹⁹ HEALing Communities Study | NIH HEAL Initiative

²⁰ Introduction to the special issue on the HEALing Communities Study - ScienceDirect

an increase in adverse outcomes. NIDA is funding research on telehealth utilization and the effects of recent changes in policy and practice.

NIDA is also leveraging the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs and other funding mechanisms to help biotech startups develop technologies that connect people with SUDs to care, provide or support treatment, help individuals sustain their recovery, and even facilitate overdose prevention. For example, a smartphone app originally designed to connect patients to open acute care beds has been adapted to facilitate referrals to addiction treatment facilities and is currently being used by several state governments and hospital systems. NIDA has also helped develop tools that put evidence-based psychosocial treatment for SUDs right in the hands of anyone with a smartphone. For example, reSET and reSET-O are apps that deliver cognitive behavioral therapy in conjunction with treatment that includes buprenorphine and contingency management to people with non-opioid SUDs (reSET) and OUD (reSET-O), and were the first prescription cognitive behavioral therapy mobile apps to receive FDA clearance to help increase retention in an outpatient treatment program. A NIDA SBIR grant is now being used to make these apps more accessible by converting them into a game. Other apps help doctors and patients monitor and maintain their OUD medication, and connect individuals to behavioral therapies, peer support groups, and community interventions. Research is also ongoing to develop automatic overdose detection devices that can inject naloxone when a person overdoses, along with tools and methods to accurately assess types of drugs detected in blood or urine for use in healthcare or by medical examiners and coroners, among many other innovations. These and other innovative products demonstrate that pairing sound science with biotechnology entrepreneurship has great potential to expand the research of addiction treatments and support services.

Addressing Health Inequities and Disparities

Disparities by race, socioeconomic status, sex, and geography have always created an inequitable landscape in care for SUDs and other mental illnesses. For example, Black people are much less likely to be prescribed buprenorphine for OUD than white people. And despite parity laws, insurance coverage for SUD and other mental health treatment remains limited, meaning that less advantaged populations have less access to needed, potentially life-saving services. The COVID pandemic has illuminated and, in many ways, exacerbated many of these disparities. However, flexibilities in healthcare practice adopted during the pandemic (e.g., expanded telehealth) along with new tools to facilitate telehealth may help overcome some of the existing barriers to finding SUD treatment and psychiatric care, particularly for currently underserved populations. Ongoing research will help optimize the most cost-effective interventions to mitigate the exacerbation of health disparities due to COVID-19. Indeed, finding solutions to reduce and ultimately eliminate health disparities, especially those related to structural racism, is a NIDA research priority. Racial disparities also persist in the addiction science workforce. NIDA's Racial Equity Initiative is working to identify disparities and systemic barriers and implement programs and funding opportunities to equitably enhance, promote,

and sustain engagement of people from diverse backgrounds, including those from historically underrepresented groups, in addiction science.

Substance use impacts women differently than men, conferring unique challenges that warrant particular attention. Women are more likely to use substances to cope, progress more quickly from use to addiction, and have greater co-occurrence of addiction with symptoms of mood disorder. This increased vulnerability bears out in women experiencing homelessness, who have higher rates of substance use than their male counterparts and are a group more likely to have been victim to physical and sexual abuse. Worldwide, women are less likely than men to receive treatment for their SUD. Negative outcomes associated with substance use are also a serious concern among women; women who use drugs experience gender-related violence at much higher rates than those who do not, women have a greater likelihood than men of contracting blood-borne infections from injection drug use, and women are more likely than men to intentionally overdose. These elevated risks not only impact women who use drugs, but their children and family units as well. It is imperative that the specific needs of women are considered—from biological differences, through childcare, personal safety, and transportation needs—to ensure that addiction prevention and treatment are as effective as possible.

Building Partnerships

Partnerships are critical to make a positive impact on public health, and NIDA is engaged in productive collaborations at all levels of government. We value our partnerships with our sister agencies in HHS, including the Substance Abuse and Mental Health Services Administration (SAMHSA), the Health Resources and Services Administration (HRSA), as well as the FDA, which is crucial to our efforts to develop medications and devices for SUD medications. NIDA also partners closely with the Centers for Medicare & Medicaid Services (CMS) to build the evidence base for healthcare funding decisions, with the Office of National Drug Control Policy (ONDCP) to advance the far-ranging goals of the National Drug Control Strategy, and with the Department of Justice to improve addiction care in incarcerated populations and promote research on controlled substances.

Collaborations also provide valuable and complementary perspectives and infrastructures that NIDA leverages to advance research and maximize its benefit for all people. Some of the largest

²¹ <u>Full article: Women and Addiction: The Importance of Gender Issues in Substance Abuse Research</u> (tandfonline.com)

²² Sex differences in vulnerability to addiction - ScienceDirect

Women, Homelessness, And Substance Abuse: Moving Beyond the Stereotypes - Lisa J. Geissler, Carol A. Bormann, Carol F. Kwiatkowski, G. Nicholas Braucht, Charles S. Reichardt, 1995 (sagepub.com)

²⁴ Recognizing and responding to women experiencing homelessness with gendered and trauma-informed care | BMC Public Health | Full Text (biomedcentral.com)

²⁵ WDR21 Booklet 2.pdf (unodc.org)

²⁶ Women who inject drugs more likely to be living with HIV | UNAIDS

²⁷ Intentional Drug Overdose Deaths in the United States | American Journal of Psychiatry (psychiatryonline.org)

projects funded under the NIH HEAL Initiative rely on such collaboration with our federal partners and others. The HEALing Communities Study is led by NIDA in close partnership with SAMHSA to ensure that this research is poised to impact service delivery toward ameliorating the opioid crisis in hard hit areas. JCOIN fosters collaboration between investigators, justice, and behavioral health stakeholders in search of creative ways for improving the capacity of the justice system to respond to the opioid crisis.

Conclusion

The issues of substance use and SUD are inseparable from the larger landscape of mental health and mental illness. Consequently, we cannot hope to make headway against the drug overdose crisis unless we make screening, preventing, and treating all mental illness, including SUDs, one of our top priorities. Continued research is also critical, and NIDA is actively supporting research in each of these areas with a focus on SUDs, their entwined psychiatric problems, and overcoming the various infrastructural barriers and stigma that have historically impeded these goals. Thank you for the opportunity to address these critical issues.