END SUD

Together, we're ending substance use disorder.

April 13, 2021

The Honorable Frank Pallone, Jr.
Chair
Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
Ranking Member
Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

Dear Chair Pallone and Ranking Member McMorris Rodgers:

Thank you for holding a hearing on "An Epidemic within a Pandemic: Understanding Substance Use and Misuse in America." Urgent action is needed to stem the accelerating overdose crisis in the United States and we appreciate your prioritizing substance use disorder prevention, treatment, and recovery early in this session.

End Substance Use Disorder (End SUD) is a national, nonpartisan campaign that advances policies to prevent and treat substance use disorder. We are a nonprofit advocacy organization committed to doing what works to end the pain and suffering caused by substance use disorder so our loved ones can heal, earn a living, spend time with their families, and contribute to their communities. End SUD believes in science and in ethics: we support only policies backed by research and evidence and we do not take contributions from pharmaceutical companies, treatment facilities, or other organizations that make money on substance use disorder. End SUD leads coalitions of healthcare and behavioral health providers, people and families with substance use disorder, harm reduction advocates, law enforcement officers, social justice leaders, and local officials that serve millions of Americans.

The need for Congress to act is urgent: The United States just suffered the deadliest year on record for overdose deaths.[i] More than 88,000 Americans are estimated to have died of an overdose in the twelve months ending in August 2020, the vast majority from opioids.[ii] Drug overdose is a primary cause of death for new mothers[iii] and the leading cause of death for Americans under the age of 50.[iv] Veterans,[v] rural Americans,[vi] and persons of color[vii] all disproportionately suffer from the overdose crisis. Without action, hundreds of thousands more Americans will die from an overdose over the next decade.[viii]

To help end the overdose crisis, we strongly urge Congress to pass the Mainstreaming Addiction Treatment Act (H.R. 1384). We applaud you for including this legislation in the hearing and will look forward to working together to pass this bill in the House of Representatives. The Mainstreaming Addiction Treatment Act is a common-

sense solution that will cut through federal red tape to increase participation in treatment, help eliminate stigma, and reduce healthcare and criminal justice costs.[ix] The bill could save tens of thousands of Americans every year from overdose death and help them secure long-term recovery.[x]

The Mainstreaming Addiction Treatment Act will help build universal access to buprenorphine, a lifesaving treatment for opioid use disorder, by allowing all healthcare providers with a standard controlled medication license to prescribe buprenorphine just as they prescribe medications for other chronic medical conditions. The bill also launches a national education campaign to connect healthcare providers to publicly available training and mentorship resources on best practices for treating substance use disorder.

These actions are needed because as few as 1 in 5 Americans with opioid use disorder receive buprenorphine.[xi] Buprenorphine is a safe, effective treatment that cuts the risk of overdose death in half and helps people secure long-term recovery.[xii] The medication has been FDA-approved for nearly twenty years, is available in generic, and is one of the most cost-effective treatments for opioid use disorder.[xiii] Buprenorphine is safer and easier to manage than commonly prescribed medications like insulin and blood thinners.[xiv] And during the COVID-19 pandemic, buprenorphine is the only medication for opioid use disorder than can be initiated via telehealth. Public health officials recognize buprenorphine as one of the gold standards of care for opioid use disorder and as a necessary tool to help end the overdose crisis.[xv]

But despite the broad recognition of buprenorphine's safety and effectiveness, Americans with opioid use disorder still suffer from a severe lack of access to this lifesaving medication. The reason so few in need can access buprenorphine is that almost no healthcare providers can or actually do prescribe the medication for opioid use disorder. Fewer than 7 in 100 eligible healthcare providers have the federal registration required to prescribe buprenorphine for opioid use disorder.[xvi] Of those providers who have the federal registration, fewer than 1 in 3 actually prescribe buprenorphine.[xvii] And half of those providers who do prescribe buprenorphine treat five or fewer patients (while rejecting up to half of patients who request the medication).[xviii] In one of the worst public health crises in modern history, our healthcare providers are simply not equipped with or utilizing the tools we have to successfully treat opioid use disorder.

Current federal law stands in the way of healthcare providers prescribing buprenorphine for opioid use disorder. While all healthcare providers with a standard controlled medication license can prescribe buprenorphine to a person in pain, the Drug Addiction Treatment Act of 2000 ("DATA 2000") places onerous burdens on healthcare providers in prescribing the exact same medication to a person with substance use disorder.[xix] To prescribe buprenorphine for opioid use disorder, DATA 2000 requires that physicians, advanced practice registered nurses, and physician assistants undergo 8-24

hours of training, undertake a 2-3 month registration process with SAMHSA and the DEA, adhere to strict limits on the number of patients they can treat, have the ability to refer patients to counseling, mark prescriptions with an "X" using a special DEA number, and submit their patient records and offices to DEA inspection. These requirements are generally referred to as the "DATA 2000 Waiver" or the "X-Waiver."

The intent of DATA 2000 was to ensure that primary care physicians could prescribe buprenorphine for opioid use disorder in the normal course of their medical practice, but the law has instead imposed significant barriers to care. Congress passed DATA 2000 in part because, without DATA 2000, the Narcotic Addict Treatment Act of 1974 would have restricted buprenorphine's use to highly regulated opioid treatment programs. The Secretary of Health and Human Services requested at the time that Congress ensure physicians could prescribe buprenorphine in private practice.[xx] By imposing bureaucratic requirements on physicians, however, DATA 2000 did not expand access to buprenorphine to the extent needed to stop the opioid overdose crisis.

Soon after it became law, Congress recognized that DATA 2000 would not increase access to buprenorphine enough to prevent significant numbers of opioid overdose deaths. Since 2005, Congress has repeatedly tried to expand access to buprenorphine by expanding the type of providers who can obtain a DATA 2000 waiver, increasing the numbers of patients that waivered healthcare providers can treat, and exempting certain healthcare providers from the waiver requirements.[xxi] In addition, the federal government has spent millions of dollars to recruit more medical professionals to obtain the DATA 2000 waiver. All of these efforts reflect broad support for expanding access to buprenorphine.

We applaud the commitment to expanding access to buprenorphine, but these efforts have not resulted in widespread use of this life-saving treatment. Each of the federal requirements to prescribe buprenorphine to a person with opioid use disorder reinforces each other and dissuades providers from prescribing the medication. The requirements foster stigma towards people with opioid use disorder[xxii] and impose cumbersome regulations on healthcare providers that are outside the bounds of evidence and do not align with how healthcare providers learn and practice.[xxiii] Nearly 7 in 10 physicians surveyed state that the federally-mandated training course discourages providers from prescribing buprenorphine.[xxiv] And nearly 8 in 10 physicians surveyed report a lack of time as a reason not to prescribe buprenorphine.[xxv] Finding, paying for, and taking the training discourages providers from seeking to prescribe buprenorphine.[xxvi] Once registered, the patient limits, recordkeeping requirements, and DEA audits overly tax providers' time and disincentivize them from treating patients with opioid use disorder.[xxvii] All together, the federal requirements limit the number of healthcare providers who can prescribe buprenorphine for opioid use disorder, which creates a vicious cycle: The fewer healthcare providers who obtain the federal registration to prescribe buprenorphine, the

fewer healthcare providers who will seek to obtain that registration and actually prescribe the medication.[xxviii] At every step of the federal process, healthcare providers choose not to prescribe buprenorphine.

Moreover, healthcare providers who can prescribe buprenorphine are not equitably distributed across communities in need. According to the National Academy of Sciences, Engineering and Medicine, even if all healthcare providers who have the federal registration actually prescribed buprenorphine up to the full number of patients allowed under federal law, just half of people with opioid use disorder would receive treatment.[xxix] More than twenty million Americans live in a county without a provider who has the federal registration.[xxx] Rural Americans,[xxxi] veterans,[xxxii] pregnant people,[xxxiii] and persons of color[xxxiv] all suffer disproportionately from a lack of access to buprenorphine. This severe lack of access to buprenorphine is fueling the overdose crisis, causing multitudes of preventable deaths.

In addition to restricting access to lifesaving care, the DATA 2000 requirements are outside the bounds of evidence. The National Academy of Sciences, Engineering and Medicine has noted that "no evidence base supports the waiver process itself," regardless of questions as to why healthcare providers may or may not obtain a waiver or prescribe buprenorphine once they have the waiver.[xxxv] Indeed, there is no other disease in the country for which medical treatment is subject to these registration requirements and patient limits.[xxxvi]

To build universal access to buprenorphine, we urge Congress to pass the Mainstreaming Addiction Treatment Act (H.R 1384). The bill will remove the DATA 2000 waiver and expand access to mentorship and education resources on treating patients with substance use disorder. To further expand access to care, Congress can also improve insurance coverage for the medication by removing prior authorization requirements and improving reimbursement rates.

We look forward to working together to enact the solutions proven to end death and disability caused by substance use disorder so our families can stay together and our communities can thrive.

Sincerely,

Erin Schanning
President
End Substance Use Disorder (End SUD)

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[i] Lev Facher, *The 'other' epidemic: Amid Covid-19, addiction experts fear Biden could back-burner the overdose crisis*, STAT News (Mar. 2, 2021) (" '2020 has by far the highest number of deaths ever recorded,' Nora Volkow, the director of the National Institute on Drug Abuse, said in an email. 'It's quite dramatic.'").

[ii] Centers for Disease Control and Prevention ("CDC"), *12 Month-Ending Provision Number of Drug Overdose Deaths* (Apr. 12, 2021); CDC, *Overdose Deaths Accelerating During COVID-19: Expanded Prevention Efforts Needed* (Dec. 17, 2020).

[iii] Max Jordan Nguemeni Tiako, M.S. et al., *Prevalence and Geographic Distribution of Obstetrician-Gynecologists Who Treat Medicaid Enrollees and Are Trained to Prescribe Buprenorphine*, 3(12) JAMA Network Open (Dec. 11, 2020).

[iv] CDC, *Underlying Cause of Death 1999-2018 on CDC WONDER Online Database*.

[v] U.S. Government Accountability Office ("GAO"), *Report to Congressional Committees: Veterans Healthcare, Services for Substance Use Disorders, and Efforts to Address Access Issues in Rural Areas*, at 1 (Dec. 2019) ("Veterans are 1.5 times more likely to die from opioid overdose than the general population, according to VA and Centers for Disease Control and Prevention data.").

[vi] U.S. Dep't Health and Human Svcs. ("HHS"), *Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder* (2020) ("In total, 1,119 counties had high indicators for at least two of the three opioid misuse and abuse measures (i.e., drug overdose mortality, nonmedical use of pain relievers, and opioid prescribing) included in our analysis, thereby meeting OIG's definition of 'high need.'...More than half (61 percent) of these high-need counties are in rural areas.").

[vii] Substance Abuse and Mental Health Svcs. Admin. ("SAMHSA"), *The Opioid Crisis and the Black/African American Population: An Urgent Issue*, at 3-5 (2020) ("From 2011-2016, compared to all other populations, Black/African Americans had the highest increase in overdose death rate for opioid deaths involving synthetic opioids like fentanyl and fentanyl analogs."); SAMHSA, *The Opioid Crisis and the Hispanic/Latino Population: An Urgent Issue*, at 4 (2020) ("From 2014-2017, among the Hispanic population drug overdose death rates involving all types of opioids increased, with the sharpest rise from synthetic opioids. Death rates involving synthetic opioids increased by 617 percent, and was the second highest for Hispanics compared to all other race/ethnicities."); RADM Michael E. Toedt, MD, FAAFP, Chief Medical Officer, Indian Health Service, *Testimony Before the Senate Committee on Indian Affairs, Oversight Hearing: "Opioids in Indian Country: Beyond the Crisis to Healing the Community"* (Mar. 14, 2018) ("The Centers for Disease Control and Prevention (CDC) reported that American Indians and Alaska Natives had the highest drug overdose death rates in 2015 and the largest percentage increase in the number of deaths over time from 1999-2015 compared to other racial and ethnic groups. During that time, deaths rose more than 500 percent among American Indians and Alaska Natives. In addition, because of misclassification of race and ethnicity on death certificates, the actual number of deaths for American Indians and Alaska Natives may be underestimated by up to 35 percent.").

[viii] Max Blau, *Opioids could kill nearly 500,000 Americans in the next decade*, STAT News (Jun. 27, 2017).

[ix] National Academy of Sciences, Engineering, and Medicine, *Consensus Study Report: Medications for Opioid Use Disorder Save Lives*, Nat'l Acad. Press (2019).

[x] Kevin Fiscella, M.D., M.P.H., Sarah E. Wakeman, M.D., Leo Beletsky, J.D., M.P.H., *Buprenorphine Deregulation and Mainstreaming Treatment for Opioid Use Disorder: X the X Waiver*, 76(3) JAMA Psychiatry 229-30 (2018).

[xi] Rebecca Haffajee, Ph.D., J.D., M.P.H. et al., *Policy Pathways to Address Provider Workforce Barriers to Buprenorphine Treatment*, 54 Am. J. Prev. Med. S230-42 (2019).

[xii] National Academy of Sciences, Engineering, and Medicine (2019).

[xiii] Congressional Research Service, *Buprenorphine and the Opioid Crisis: A Primer for Congress* (2018); National Academy of Sciences, Engineering, and Medicine (2019); SAMHSA, *Treatment Improvement Protocol (TIP) 63: Medications for Opioid Use Disorder* (2020).

[xiv] Sarah E. Wakeman, M.D. and Michael L. Bennett, M.D., *Primary Care and the Opioid-Overdose Crisis – Buprenorphine Myths and Realities*, 379 New England J. of Med. 1-4 (2018).

[xv] *See* National Academy of Sciences, Engineering, and Medicine (2019); National Academy of Sciences, Engineering, and Medicine, *Consensus Study Report: Opportunities to Improve Opioid Use Disorder and Infectious Disease Services*, Nat'l Acad. Press (2020); U.S. Dept. Health & Human Svcs., Office of the Surgeon General ("U.S. Surgeon General"), *Facing Addiction in America: The U.S. Surgeon General's Spotlight on Opioids* (2018).

[xvi] In January 2021, there were approximately 91,000 physicians, advanced practice registered nurses, and physicians assistants with a DATA 2000 Waiver. Lev Facher, *Trump administration will let nearly all doctors prescribe addiction medicine buprenorphine*, STAT News (Jan. 14, 2021). There are approximately 1.4 million of those providers in the United States. Kaiser Family Foundation, *Professionally Active Physicians* (Mar. 2020); Letter from American Assoc. of Nurse Practitioners ("AANP") and American Academy of Physician Assistants ("AAPA") to the Hon. Alex Azar (Jan. 15, 2021).

[xvii] National Academy of Sciences, Engineering, and Medicine (2019).

[xviii] *Id.*; Andrew S. Huhn, Ph.D. and Kelly E. Dunn, Ph.D., *Why Aren't Physicians Prescribing More Buprenorphine?*, 78 J. Substance Abuse Treatment, 1-7 (2017).

[xix] DATA 2000, Publ. Law No. 106-310 (2000).

[xx] Drug Addiction Treatment Act of 1999*, Hearing Before the Subcommittee on Health and Environment of the Committee on Commerce*, 106th Congress 10-20 (Jul. 30, 1999).

[xxi] Pub. Law 109-56, 119 Stat. 591 (2005); Pub. Law 109-469 § 1102, 120 Stat. 3540 (2006); Comprehensive Addiction and Recovery Act of 2016 ("CARA"), Pub. Law 114-198, 130 Stat. 720-23 (2016); Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities ("SUPPORT") Act, Pub. Law 115-271 § 3201, 132 Stat. 3843-44 (2018); Further Continuing Appropriations Act, 2021, and Other Extensions Act, Pub. Law No. 116-125 § 1302, 134 Stat. 1046 (2020) (provisions known as the "Easy MAT Act").

[xxii] *See* National Academy of Sciences, Engineering, and Medicine (2020); Kevin Fiscella, et al. (2018); Haffajee, et al. (2019); Sonia Mendoza, et al.*, Shifting blame: Buprenorphine prescribers, addiction treatment, and prescription monitoring in middle-class America*, 53(4) Transcult Psychiatry 465-87 (2016).

[xxiii] National Academy of Sciences, Engineering, and Medicine (2019); National Academy of Sciences, Engineering, and Medicine (2020); Haffajee, et al. (2019).

[xxiv] Mendoza, et al. (2016).

[xxv] JR DeFlavio, et al., *Analysis of barriers to adoption of buprenorphine maintenance therapy by family physicians*, 15 Int'l J. Rural and Remote Health, Research, Education, Practice and Policy 3019 (2015).

[xxvi] Haffajee, et al. (2019).

[xxvii] National Academy of Sciences, Engineering, and Medicine (2019); National Academy of Sciences, Engineering, and Medicine (2020); De Flavio, et al. (2015); Haffajee, et al. (2019); Huhn and Dunn (2017).

[xxviii] *See* De Flavio, et al. (2015); Haffajee, et al. (2019); Eliza Hutchinson, M.D. et al., *Barriers to Primary Care Physicians Prescribing Buprenorphine*, 12(2) Annals of Family Medicine (2014); Mendoza, et al. (2016).

[xxix] National Academy of Sciences, Engineering, and Medicine (2019).

[xxx] Nat'l Inst. of Health, *Physician-pharmacist collaboration may increase adherence to opioid addiction treatment* (2021).

[xxxi] HHS, *Geographic Disparities* (2020), at 9 ("In total, 72 percent of counties with low-to-no patient capacity are in rural areas (for comparison purposes, 63 percent of counties nation-wide are rural). The lack of waivered providers in rural areas may reflect a wider problem with shortages and maldistribution of primary care and other providers.").

[xxxii] GAO (2019), at 26-27 ("Across all 140 VHA health care systems, veterans with an opioid use disorder received medication-widoassisted treatment (in specialty and nonspecialty settings) at a higher rate in urban locations (34 percent) than in rural locations (27 percent) in fiscal year 2018…Despite the similar rates of waivered providers in rural and urban areas, as previously mentioned, rural veterans with opioid use disorder use medication-assisted treatment at a lower rate.").

[xxxiii] Tiako, et al. (2020) ("Despite its effectiveness, buprenorphine remains inaccessible for many women with OUD who are pregnant. A study of treatment episodes for prescription OUD during pregnancy showed that medication for OUD was administered only during a third of treatment episodes, and a more recent study of women enrolled in Medicaid who were pregnant noted that nearly half of pregnant patients with OUD receive no medication for OUD.").

[xxxiv] Tiako, et al. (2020) ("Studies have shown that, as a result of racial segregation, buprenorphine availability is associated with a greater proportion of White residents at the neighborhood and county levels, and methadone availability is associated with greater proportions of Hispanic and Black residents…Within the context of pregnancy, a study reported that Black and Hispanic women (both overrepresented among Medicaid recipients) are less likely to receive any pharmacotherapy for OUD."); Pooja A. Lagisetty, M.D., M.Sc. et al., *Buprenorphine Treatment Divide by Race/Ethnicity and Payment*, 76(9) JAMA Psychiatry 979-81 (2019) ("This study demonstrates that buprenorphine treatment is concentrated among white persons and those with

private insurance or use self-pay."); Martha Bebinger, *Opioid Addiction Drug Going Mostly To Whites, Even As Black Death Rate Rises*, NPR (May 8, 2019) ("White drug users addicted to heroin, fentanyl and other opioids have had near exclusive access to buprenorphine…'White populations are almost 35 times as likely to have a buprenorphine-related visit than black Americans,' says Dr. Pooja Lagisetty, an assistant professor of medicine at the University of Michigan Medical School and the study's corresponding author.").

[xxxv] National Academy of Sciences, Engineering, and Medicine (2019).

[xxxvi] Christine Vestal, *Waiting Lists Grow for Medicine to Fight Opioid Addiction*, The Pew Charitable Trusts (Feb. 11, 2016).