United States Senate

WASHINGTON, DC 20510

May 3, 2023

The Honorable Anne Milgram
Administrator
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Dear Administrator Milgram,

We write to request that the Drug Enforcement Administration (DEA) take further action to remove barriers to access buprenorphine. In December 2022, Congress directed the DEA to clarify the difference between suspicious orders of opioids and suspicious orders of buprenorphine in the Suspicious Orders Report System (SORS).[1] We are concerned that the DEA has failed to develop and provide sufficiently clear guidance for pharmacists, wholesalers, distributors, and patients for accessing buprenorphine. We request that the DEA immediately initiate a multi-agency evaluation of buprenorphine with the Food and Drug Administration (FDA) and Substance Abuse and Mental Health Services Administration (SAMSHA) to eliminate access gaps to buprenorphine to reduce overdose and death from opioid use disorder.

The recent passage of the Mainstreaming Addiction Treatment (MAT) Act in the Consolidated Appropriations Act of 2023 has dramatically expanded our ability to treat opioid use disorder with buprenorphine. The Act increased the number of medical professionals who can prescribe buprenorphine for opioid use disorder from 130,000 to 1.8 million with the removal of the X waiver. However, prescribers and patients across the country continue to report difficulty filling buprenorphine prescriptions. A recent study of more than 5,000 pharmacies reported that less than half stocked buprenorphine, while another survey found that only one in five pharmacies were willing to fill buprenorphine prescriptions. An additional survey of addiction treatment providers found that 84% of their patients experienced a time delay in accessing their buprenorphine; a delay that can mean life or death for these patients.

According to the Centers for Disease Control and Prevention (CDC), more than 106,000 Americans died from a drug overdose in the past year alone.[2] Now more than ever, it is critical that the best treatments are made widely available and barriers to interventions are broken down. The data clearly demonstrates that prescriptions of medications for opioid use disorders (MOUDs) significantly reduce the risk of overdose deaths – a recent study of individuals with opioid use disorder found they were 82% less likely to die from an opioid overdose when they received treatment with buprenorphine or methadone than when they did not.[3] Despite the

[1] H.R. Rept. 117-395. (2023). https://www.congress.gov/congressional-report/117th-congress/house-report/395/1

[2] Centers for Disease Control. (2023). Provisional Drug Overdose Death Counts. National Center for Health Statistics. https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm#drug_specificity_1

[3] Krawczyk, N., M ojtabai, R., Stuart, E. A., Fingerhood, M., Agus, D., Lyons, B. C., Weiner, J. P., & Saloner, B. (2020). Opioid agonist treatment and fatal overdose risk in a state-wide US population receiving opioid use disorder services. *Addiction (Abingdon, England)*, *115*(9), 1683–1694. https://doi.org/10.1111/add.14991

demonstrated effectiveness of MOUDs, approximately 87% of individuals with opioid use disorder, who may benefit from lifesaving MOUDs treatment, do not receive it.[4]

A survey on pharmacy access published by the American Society of Addiction Medicine found the most-commonly cited reasons for not filling buprenorphine prescriptions included supplier shortages, the pharmacy's wholesaler limiting the amount of the medication they may order, corporate policies restricting the dispensing of buprenorphine, and an assumption that the DEA has a cap on the quantity of buprenorphine that can be dispensed.[5] A recent survey of pharmacists found that 31% of pharmacy respondents did not stock buprenorphine due to perceived ordering limits imposed by the DEA.[6] We recognize that the Department of Justice (DOJ) and the DEA Diversion Control Division jointly published a Suspicious Orders Q&A on January 20, 2023, which explains that the agency does not place quantitative thresholds or limits on the amounts of controlled substances that a pharmacy can order. [7] However, more is needed. Without formal guidance from the DEA, the absence of quantitative thresholds has created chilling effects on access to buprenorphine due to the perceived risks of crossing an undefined threshold by the DEA.

In report language included in the 2023 Consolidated Appropriations bill,[8] Congress expressed its concern that the DEA's lack of clarity is contributing to buprenorphine stocking issues. The report directs the DEA to "clarify the difference between suspicious orders of opioids and suspicious orders of buprenorphine, clarify the difference between suspicious orders and caps or quotas, clarify that the DEA has no quotas or caps on buprenorphine, and clarify how distributor-imposed quotas or caps on opioids or buprenorphine do or do not satisfy suspicious order regulations." While the DEA has made public comments supporting increased buprenorphine prescribing, it is imperative that the DEA update its policies around suspicious orders and the dispensing of buprenorphine for opioid use disorder. This clarity and transparency is important for the public, pharmacies, manufacturers, and distributors, and also for the DEA field and office staff to ensure that policies are implemented equitably across all regions.

The opioid epidemic remains one of the greatest public health crises our nation has ever faced. We must ensure the necessary resources and policies are in place so that every American who needs it can find treatment and lifesaving care. Thank you for your prompt attention to this critical matter.

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[4] Krawczyk, N., Rivera, B. D., Jent, V., Keyes, K. M., Jones, C. M., & Cerdá, M. (2022). Has the treatment gap for opioid use disorder narrowed in the U.S.?: A yearly assessment from 2010 to 2019". *The International journal on drug policy*, *110*, 103786. https://doi.org/10.1016/j.drugpo.2022.103786

[5] American Society of Addiction Medicine (2022). Reducing Barriers to Lifesaving Treatment: Report on the Findings from ASAM's Pharmacy Access Survey. https://sitefinitystorage.blob.core.windows.net/sitefinity-production-blobs/docs/default-source/advocacy/reports/asam-pharmacy-access-survey-report-final-11.7.22.pdf?sfvrsn=6da97680_3

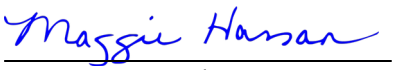
[6] Carpenter, D., Lambert, K. V., Harless, J. C., Wilson, C. G., Davis, S. A., Zule, W. A., & Ostrach, B. (2022). North Carolina community pharmacists' buprenorphine dispensing practices and attitudes. *Journal of the American Pharmacists Association : JAPhA*, *62*(5), 1606–1614. https://doi.org/10.1016/j.japh.2022.04.019

[7] Drug Enforcement Agency. (2023). Suspicious Orders (SORS) Q&A. Retrieved February 21, 2023 from, https://www.deadiversion.usdoj.gov/faq/sors_faq.htm

8 H.R. Rept. 117-395. (2023). https://www.congress.gov/congressional-report/117th-congress/house-report/395/1

Sincerely,

Martin Heinrich
United States Senator



Margaret Wood Hassan
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Lisa Murkowski
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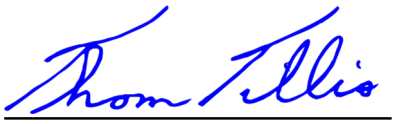

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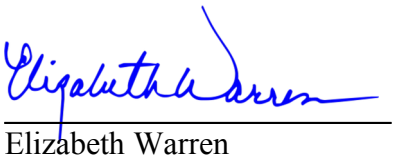
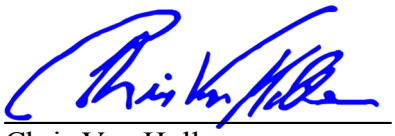
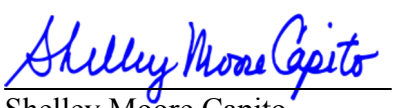


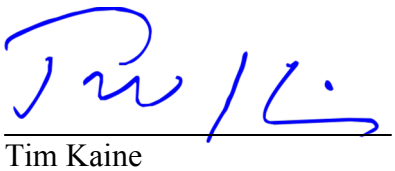
Elizabeth Warren
United States Senator



Chris Van Hollen
United States Senator



Shelley Moore Capito
United States Senator



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Jeffrey A. Merkley
United States Senator

Sherrod Brown
United States Senator

Cory A. Booker
United States Senator

Cc:

Miriam E. Delphin-Rittmon, Ph.D., Assistant Secretary for Mental Health and Substance Use

Robert M. Califf, M.D., Food and Drug Administration Commissioner