Congress of the United States
Washington, DC 20515

March 23, 2023

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

Dear Administrator Milgram,

We write to you today asking that the Drug Enforcement Administration (DEA) take further public actions to help eliminate existing barriers for accessing medications for opioid use disorder (MOUD). We have heard countless stories of loved ones whose lives have been lost to drug overdoses. The tragic loss of life brought on by the overdose epidemic is felt in every community across the United States. Recent data from the Centers for Disease Control and Prevention (CDC) suggests that in the past year alone, more than 106,000 Americans died from a drug overdose.[i] Now more than ever, it is critical that the best treatments are made widely available and every barrier to treatment is broken down.

As you know, MOUD significantly reduce the risk of overdose death – a recent study of individuals with opioid use disorder found that they were 82 percent less likely of dying from an opioid overdose when they received treatment with buprenorphine or methadone, than when they did not.[ii] However, despite the effectiveness of MOUD, approximately 87 percent of individuals with opioid use disorder who may benefit from lifesaving MOUD treatment do not receive it.[iii]

As overdose deaths remain at record high levels, Congress is working to eliminate barriers to accessing evidence-based treatments to reduce overdose deaths. The recent passage of the Mainstreaming Addiction Treatment (MAT) Act in the Consolidated Appropriations Act of 2023[iv] has dramatically expanded the U.S. health care system's ability to treat opioid use disorder with buprenorphine, increasing the number of medical professionals who can prescribe buprenorphine for opioid use disorder from 130,000 to 1.8 million[v] with the removal of the X-Waiver.

Despite progress in eliminating this barrier to prescribing buprenorphine for opioid use disorder, prescribers and patients across the country are reporting difficulty getting buprenorphine prescriptions filled. A recent study of more than 5,000 pharmacies reported that less than half stocked buprenorphine,[vi] while another survey found that a fifth of pharmacies were unwilling to fill buprenorphine prescriptions.[vii] Another survey of addiction treatment providers found that 84 percent of their patients experienced a time delay in accessing their buprenorphine,[viii] a delay that can have life-threatening consequences for patients in treatment for opioid use disorder.

The lack of clear guidance to pharmacies, manufacturers, and distributors from the DEA has contributed to this gap in access for patients in need of buprenorphine. A survey on pharmacy access published by the American Society of Addiction Medicine found that commonly cited reasons by pharmacists for not filling buprenorphine prescriptions included a supplier shortage of the medication; the pharmacy's wholesale supplier limiting the amount of the medication that the pharmacy may order or stock; corporate policies restricting the dispensing of the medication, and a belief that the DEA has a cap on the quantity of buprenorphine that can be dispensed.[ix] Another recent survey of North Carolina Pharmacists found that 31 percent of pharmacy respondents did not stock buprenorphine due to perceived ordering limits imposed by the DEA.[x] DEA recently published a Q&A document that explains that the agency does not place quantitative thresholds or limits on the amounts of controlled substances, including MOUD, that a

pharmacy can order.[xi] However this single statement is not enough to guide manufacturers and distributors that are responsible for designing and operating systems to identify suspicious orders based on a non-exhaustive list of vague factors, which may not be appropriate for monitoring MOUD orders. There also continues to be uncertainty as to how DEA uses the Suspicious Orders Report System (SORS)[xii] and interprets other DEA rules for enforcement actions.

In report language included in the 2023 Commerce, Justice, Science, and Related Agencies Appropriations bill,[xiii] the House expressed its concern that DEA's lack of clarity is contributing to buprenorphine stocking issues. The report directs 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 we commend DEA's public comments supporting increased buprenorphine prescribing, it is imperative that the DEA clarify its policies around suspicious orders and the dispensing of buprenorphine for opioid use disorder. This clarity and transparency are critical not only for the public, pharmacies, manufacturers, and distributors, but also for DEA field office staff to ensure that policies are implemented equitably across all regions.

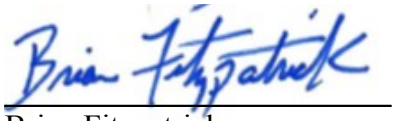
DEA must be committed to eliminating access gaps to MOUD. We urge DEA to respond to the following questions as soon as possible and inform us of steps DEA is taking to address the issue of buprenorphine access and stocking issues.

1. What are DEA's plans to communicate with regulated industries (e.g., pharmacies) to alleviate expressed concerns about stocking and dispensing buprenorphine?
2. Does DEA have a mechanism for identifying the scope of the issue of buprenorphine stocking or for tracking and monitoring buprenorphine orders separately from other controlled medications?
3. What does the DEA need from Congress to address this issue? Are there areas where DEA believes it cannot act and require a legislative response from Congress?
4. In response to the 2023 House report language, what steps is DEA taking to publicize its suspicious orders guidance? How is the DEA communicating its guidance to field staff?
5. Is DEA aware of examples of problems with stocking and dispensing buprenorphine? If yes, what barriers are involved?

Sincerely,

Paul Tonko
Member of Congress

Michael R. Turner
Member of Congress



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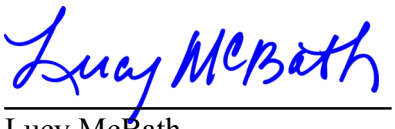

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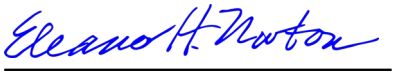

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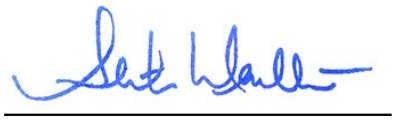

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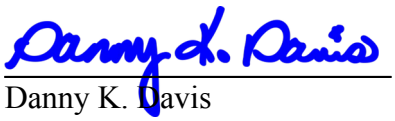

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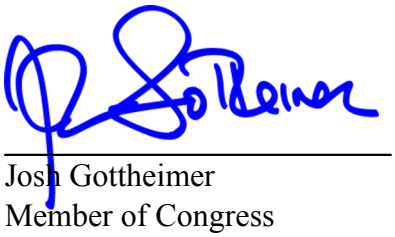

Josh Gottheimer
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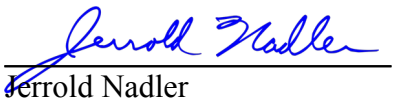

Jerrold Nadler
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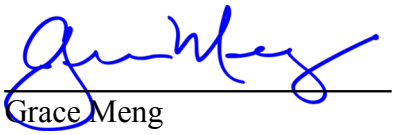

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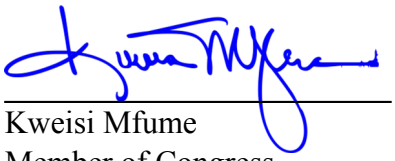

Kweisi Mfume
Member of Congress

Lori Trahan
Member of Congress

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