

United States Senate

WASHINGTON, DC 20510

February 8, 2024

Dr. Robert M. Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave,
Silver Springs, MD 20993-0002 DC 20530

Dear Commissioner Califf,

We are writing to request the addition of Medications for Opioid Use Disorder (MOUD), specifically buprenorphine and methadone, to the Food and Drug Administration's (FDA) [List of Essential Medicines](#). The opioid epidemic remains one of the most harrowing public health crises our nation has ever faced, causing significant loss of life and ravaging communities throughout the United States. The use of MOUD is a critical and comprehensive tool to support the recovery of people with Opioid Use Disorder (OUD). By including MOUD in the FDA's List of Essential Medicines, we can ensure that these life-saving treatments are available in emergency departments (ED) and inpatient settings in hospitals across the United States. This will enable health care providers to respond more effectively to the urgent needs of OUD patients, and potentially saving countless lives.

On December 19th, 2020, in response to [Executive Order 13944 \(EO\)](#), the FDA created the List of Essential Medicines as a way to ensure the United States is prepared for public health crises. The EO instructed the FDA to identify essential medicines, medical countermeasures, and critical inputs that are medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms.¹ MOUD are effective in treating OUD because they manage withdrawal symptoms and reduce cravings, making them a vital tool in addressing the opioid epidemic.² Including MOUD in the FDA's List of Essential Medicines will increase their availability and is a significant step towards reducing the impact of this crisis.

EDs across the United States are on the front lines of treating patients with OUD. ED visits and hospitalizations utilization due to OUD continue to rise³, which highlights the severity of this public health crisis. An important component of caring for patients that have OUD is ensuring that those patients can access drug rehabilitation and addiction recovery services in the inpatient setting. Data clearly demonstrates that MOUD significantly reduce the risk of overdose deaths – a recent study of individuals with OUD found they were 82% less likely to die from an opioid

¹ <https://www.fda.gov/news-events/press-announcements/fda-publishes-list-essential-medicines-medical-countermeasures-critical-inputs-required-executive>

² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9175946/>

³ <https://www.sciencedirect.com/science/article/abs/pii/S0376871621000636>

overdose when they received treatment with buprenorphine or methadone than when they did not.⁴ Despite the proven effectiveness of MOUD, many hospitals and EDs do not include MOUD in their formularies.⁵ This exclusion poses a significant challenge in the inpatient settings, particularly for providers who need to start new OUD patients on MOUD during their hospital stay. Additionally, gaps in treatment through MOUD can notably increase overdose risks and fatalities.⁶ This is especially concerning due to the increasing availability of highly potent synthetic opioids, such as fentanyl. It is absolutely crucial to ensure that access to MOUD is not interrupted if patients are in the hospital, and that the usage of these treatments is maintained consistently.

The World Health Organization's 2023 [list of essential medications](#) includes both methadone and buprenorphine. They have also included "Opioid Dependence" as a category of essential medications. Given that in 2017, the United States declared the opioid crisis a public health emergency, it is concerning that the FDA does not currently consider MOUD as "essential". We strongly urge the FDA to reconsider this and add MOUD to the FDA List of Essential Medicines.

Including MOUD on the FDA's List of Essential Medicines will make them more accessible to patients who have OUD, especially in the inpatient setting. The inclusion of MOUD is a crucial step forward in addressing this public health crisis and ensuring the well-being of our communities. We request that you add MOUD to the FDA's essential medicines list to ensure that OUD patients have access to MOUD while in the hospital. Thank you for your attention to this critical issue.

Sincerely,



Martin Heinrich
United States Senator

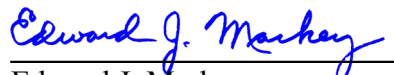


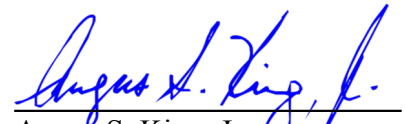
Mike Braun
United States Senator


⁴ Krawczyk, N., Mojtabai, 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>

⁵ Pham S, Haigh A, Barrett E. Statewide Availability of Buprenorphine/Naloxone in Acute Care Hospitals. *J Addict Med.* 2022;16(1):e48-e51. doi:10.1097/ADM.000000000000083

⁶ https://www.aclu.org/wp-content/uploads/legal-documents/20210625-mat-prison_1.pdf


Edward J. Markey
United States Senator


Angus S. King, Jr.
United States Senator


Jeffrey A. Merkley
United States Senator