Congress of the United States

Washington, DC 20515

February 8, 2023

The Honorable Robert Califf, MD
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

We write to you today regarding the Food and Drug Administration's (FDA) consideration of an over-the-counter (OTC) status for naloxone.

Increasing access to naloxone is a critical component in addressing the fentanyl crisis that is devasting communities and families across this country. Just last year, the Drug Enforcement Administration (DEA) seized more than 10,000 pounds of fentanyl powder and 50.6 million illegal fentanyl tablets.[1] That is twice the number of tablets seized in 2021, when more than 71,000 people died from fentanyl or fentanyl-related substances.[2] If not for naloxone, tens of thousands of additional Americans would have died. Since President Biden took office, U.S. Customs and Border Protection has seized enough fentanyl to kill over 21.3 times the U.S. population.[3] This is a crisis that is impacting every single one of us and the communities we call home.

Given this deadly crisis and the rapidly increasing scale of need, it is crucial that we increase access to overdose prevention and reversal strategies. This includes steps to increase access to naloxone, which is a proven, effective tool to reduce medical emergencies, drug overdoses, and deaths. Studies show that increasing access to naloxone reduces mortality rates in communities by up to 46 percent.[4] With the support of the FDA, we can work towards mitigating the fentanyl crisis that is plaguing our country.

As the fentanyl crisis continues to devastate our country, there is no moral, medical, or safety-related reason for these life-saving overdose reversal agents to remain locked under prescription regulations. Furthermore, it is important to note that at the time of need, access to naloxone can be the difference between life or death. While many states have standing orders and workarounds that allow individuals to acquire naloxone without a traditional prescription, obstacles still exist. A formal switch to OTC can encourage widespread use of this critical medicine, which would be a crucial step towards reducing the number of deaths in our nation.

While we commend the FDA's effort to proactively provide model OTC label and usage instructions for the nasal spray and auto-injector versions of naloxone, there is still much work to be done. We urge the FDA to take these facts into consideration and support widespread access to naloxone.

---

[1] https://www.dea.gov/press-releases/2022/12/20/drug-enforcement-administration-announces-seizure-over-379-million-deadly
[2] https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm
[3] https://www.cbp.gov/newsroom/stats/drug-seizure-statistics
[4] Walley A Y, et al. Opioid Overdose Rates and Implementation of Overdose Education and Nasal Naloxone Distribution in Massachusetts: Interrupted Time Series Analysis BMJ 2013; 346 :f174 doi:10.1136/bmj.f174

Sincerely,

Earl L. "Buddy" Carter
Member of Congress

Mariannette Miller-Meeks, M.D.
Member of Congress