United States Senate
WASHINGTON, DC 20510

July 21, 2022

Dr. Robert M. Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Dr. Califf,

As the ongoing opioid epidemic continues to claim more and more lives every year, we write to urge the Food and Drug Administration (FDA) to help save lives by taking necessary steps to improve access to critical, fast-acting medical interventions. During an opioid overdose, every second counts. Administering naloxone, an opioid overdose antidote, before first responders arrive can mean the difference between life and death. The FDA should address regulatory ambiguity that is preventing public health organizations from obtaining and distributing this life-saving treatment.

Ambiguous regulations impede the capacity of public health organizations to purchase and distribute naloxone. Under FDA regulations, only licensed wholesale distributors may distribute prescription drugs unless an exception applies.[1] One exception is the distribution of prescription drugs for "emergency medical reasons."[2] Suppliers are uncertain if public health organizations qualify for this exception, and refuse to sell naloxone to organizations that are not licensed wholesale distributors.

The FDA recently provided some context on what activities meet this exception, but this has not fully resolved the issue.[3] We urge the FDA to immediately issue a public statement clarifying that public health organizations that distribute injectable or nasal spray naloxone fit the emergency medical reasons exception, and therefore do not need a license to obtain or distribute naloxone. Subsequently, the FDA should issue guidance to further explain what activities fall under this exception.

All 50 states, the District of Columbia, and Puerto Rico have taken steps to expand public access to injectable or nasal spray naloxone.[4] We urge the FDA to minimize barriers that still impede its purchase, distribution, or use. We look forward to continue to work with you on ways to address the substance misuse epidemic.

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[1] Definitions, 21 C.F.R. § 205.3; Wholesale Drug Distributor Licensing Requirement, 21 C.F.R. § 205.4.

[2] 21 C.F.R. §§ 205.3, 205.4.

[3] Food and Drug Administration, "National Standard for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers," *Federal Register* 87, no. 24 (February 4, 2022): 6715, https://www.govinfo.gov/content/pkg/FR-2022-02-04/pdf/2022-01929.pdf.

[4] "Naloxone Access: Summary of State Laws," Legislative Analysis and Public Policy Association, September 2020, https://legislativeanalysis.org/wp-content/uploads/2020/10/Naloxone-summary-of-state-laws-FINAL-9.25.2020.pdf.

With every good wish,

Margaret Wood Hassan
United States Senator

Rand Paul, M.D.
United States Senator