

# Congress of the United States

Washington, DC 20515

March 8, 2023

The Honorable Robert Califf, M.D.  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20903-0002

Dear Commissioner Califf:

We write to commend the U.S. Food and Drug Administration (FDA) Nonprescription Drugs Advisory Committee's and Anesthetic and Analgesic Drug Products Advisory Committee's unanimous vote recommending that Narcan (chemically known as naloxone) nasal spray be made widely available without a prescription through an over-the-counter (OTC) option. This recommendation could not have come at a more critical time, and we urge FDA to expeditiously adopt the Committees' recommendation so that any person suffering from a substance use disorder (SUD) can access this life-saving drug.

Nearly 1 million Americans have died from a drug overdose since 1999.<sup>1</sup> In addition, overdose deaths involving opioids, including prescription opioids, heroin and synthetic opioids such as fentanyl have increased by more than eight times since 1999.<sup>2</sup> These alarming trends compelled the U.S. Department of Health and Human Services (HHS) to declare the opioid crisis a public health emergency in 2017.<sup>3</sup>

Since then, Congress has passed a swath of bipartisan legislation aimed at addressing the opioid crisis, including the SUPPORT for Patients and Communities Act, which became law in 2018, and the Restoring Hope for Mental Health and Well-Being Act, which became law as part of the fiscal year (FY) 2023 omnibus package. Despite these actions, the opioid crisis has only worsened. From 2019 to 2020, at the height of the COVID-19 pandemic, the number of overdose deaths increased by nearly 30 percent.<sup>4</sup>

As you are well aware, Narcan is often used to reverse the effects of an opioid overdose and requires no assembly or specialized training to use.<sup>5</sup> Narcan has also been found to be safe and effective, even for infants, with almost no potential for misuse or abuse.<sup>6</sup> Additionally, Narcan has no effect on someone who does not have opioids in their system.<sup>7</sup> All 50 states, the District of Columbia and Puerto Rico also already have laws on the books that allow naloxone to be sold without a prescription at a pharmacy, but many pharmacies do not carry it, due in large part to its current prescription status.<sup>8</sup>

---

<sup>1</sup><https://www.cdc.gov/opioids/data/index.html>.

<sup>2</sup> Id.

<sup>3</sup> <https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioids.aspx>.

<sup>4</sup> <https://www.commonwealthfund.org/publications/podcast/2021/jun/its-really-truly-everywhere-how-opioid-crisis-worsened-covid-19>.

<sup>5</sup> <https://nida.nih.gov/publications/drugfacts/naloxone>.

<sup>6</sup> <https://www.nytimes.com/2023/02/15/health/narcan-naloxone-drug-stores.html>.

<sup>7</sup> <https://nida.nih.gov/publications/drugfacts/naloxone>.

<sup>8</sup> <https://www.cnn.com/2023/02/15/health/narcan-otc-fda/index.html>.

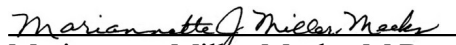
As such, Narcan has largely been administered by outreach workers, health care providers and emergency responders, and access to the drug has been elusive for many Americans suffering from SUDs and their loved ones.<sup>9</sup> FDA now has the opportunity to change that, and we encourage you to act the Committees' recommendation with the utmost haste.


The reality is that overdose deaths are preventable, but intervention must occur quickly. Putting Narcan directly into the hands of those impacted by SUD will save countless lives.

We consider this to be a step in the right direction, but acknowledge there is still more work to be done. We look forward to further action from FDA on this issue, and we stand ready to work with you on further policies to end the opioid epidemic.


Sincerely,

  
\_\_\_\_\_  
Angie Craig  
Member of Congress

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

  
\_\_\_\_\_  
Bennie G. Thompson  
Member of Congress

  
\_\_\_\_\_  
Shontel M. Brown  
Member of Congress

  
\_\_\_\_\_  
Salud Carbajal  
Member of Congress

---

<sup>9</sup> See note 6.



---

Raúl M. Grijalva  
Member of Congress



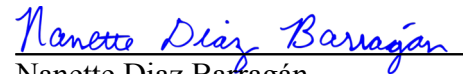
---

Rashida Tlaib  
Member of Congress



---

Bonnie Watson Coleman  
Member of Congress



---

Nanette Diaz Barragán  
Member of Congress



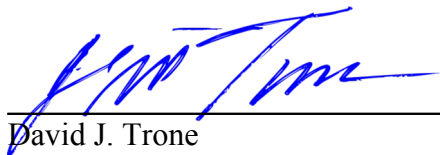
---

Chris Pappas  
Member of Congress



---

Ann McLane Kuster  
Member of Congress



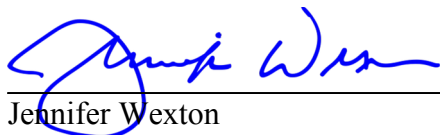
---

David J. Trone  
Member of Congress



---

Derek Kilmer  
Member of Congress



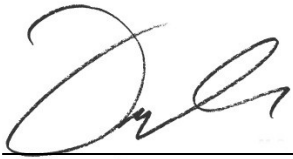
---

Jennifer Wexton  
Member of Congress



---

Kelly Armstrong  
Member of Congress



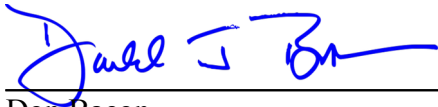
---

Troy Carter  
Member of Congress



---

Susie Lee  
Member of Congress



---

Don Bacon  
Member of Congress



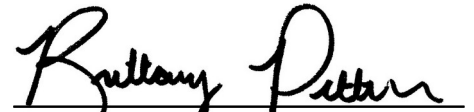
---

Lori Trahan  
Member of Congress



---

Tony Cardenas  
Member of Congress



---

Brittany Pettersen  
Member of Congress



---

Sharice L. Davids  
Member of Congress



---

Colin Z. Allred  
Member of Congress



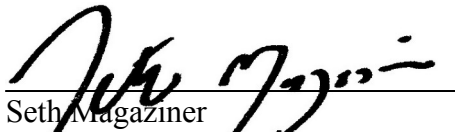
---

Adam B. Schiff  
Member of Congress




---

James P. McGovern  
Member of Congress



---

Seth Magaziner  
Member of Congress



---

Dan Crenshaw  
Member of Congress



---

J. Luis Correa  
Member of Congress