

## United States Senate

March 22, 2023

Hon. Robert M. Califf  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Commissioner Califf,

We write to urge the Food and Drug Administration (FDA) to swiftly approve the sale of over-the-counter (OTC) naloxone, also known by its brand name Narcan. As you know, naloxone is a life-saving medication used to quickly reverse opioid overdose, and has been widely used since the 1970s to save Americans from overdose death. In 2021 alone, a record 106,000 Americans lost their lives to the overdose crisis, including over 2,600 Hoosiers and over 1,400 West Virginians.<sup>1</sup> Given the severity of this epidemic, OTC naloxone should have been available to Americans long ago.

In a joint meeting on February 15, 2023, the FDA's Nonprescription Drugs and Anesthetic Committee and Analgesic Drug Products Advisory Committee voted, unanimously, to recommend that the FDA approve Emergent Biosolutions' OTC Narcan with proper instructions for usage.<sup>2</sup> Naloxone is safe, effective, and enables individuals that are suffering from opioid overdose to get to the hospital for comprehensive care, including treatment for substance use disorder and follow-up care. While FDA is expected to make a decision soon, we urge you to issue approval for OTC Narcan immediately so that this treatment may get on store shelves in the numerous communities across America that have been devastated by the opioid epidemic.

Your swift approval of OTC naloxone is a critical step towards fighting back against the opioid crisis. FDA's past inaction has facilitated the precipitous growth of America's opioid epidemic, and neither we nor the American people can abide business-as-usual any longer. Additionally, we ask you to work with the Centers for Medicare & Medicaid Services, as well as other relevant stakeholders, to facilitate the smooth introduction of OTC naloxone products.

We thank you for working expeditiously to make OTC Narcan and future generic versions of OTC naloxone widely available and accessible to those who need it, without any undue delay.

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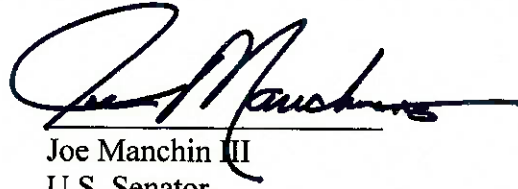
<sup>1</sup> National Center for Health Statistics Vital Statistics Rapid Release, *Provisional Drug Overdose Death Counts*, Centers for Disease Control and Prevention (Feb. 15, 2023), <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

<sup>2</sup> Emergent Biosolutions, *Emergent BioSolutions Reports FDA Advisory Committees' Unanimous Vote in Favor of NARCAN® (naloxone HCl) Nasal Spray for Over-the-Counter Use*, (Feb. 15, 2023), <https://investors.emergentbiosolutions.com/news-releases/news-release-details/emergent-biosolutions-reports-fda-advisory-committees-unanimous>

Sincerely,

A handwritten signature in blue ink that reads "Mike Braun". The signature is fluid and cursive, with the first name "Mike" and last name "Braun" clearly legible.

Mike Braun  
U.S. Senator

A handwritten signature in black ink that reads "Joe Manchin III". The signature is highly stylized and cursive, with a large initial "J" and "M".

Joe Manchin III  
U.S. Senator