

February 15, 2023

Before I begin, I would like to thank both the members of the Nonprescription Drugs Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee for holding a joint hearing on the benefits of naloxone as an over-the-counter treatment and for the opportunity to speak before you today. My name is Terry Wilcox. I am the CEO and Founder of Patients Rising: an organization that advocates on behalf of patients with rare and chronic diseases. We support reforms and legislation aimed at advancing patient access to affordable, quality healthcare. Formed in 2015, we have developed a significant following of over 110,000 patients and caregivers and have guided them on their journey to advocate for themselves and their loved ones to get the care and treatments they need to live a fulfilling life.

The opioid epidemic in America is far reaching and larger than it's ever been. Since 1999, opioid overdose deaths have been on a meteoric rise. Opioid overdose deaths in the year 2020 totaled¹ 68,630, dwarfing the death total in 1999 by a factor of nearly four. When examining NIH data², overdose deaths in general, which opioid-related overdoses comprise the lion's share of, are now so prevalent that they rank among the annual leading causes of death in the country. The root cause of this building crisis is tough to pin down and address, so the necessary course of action becomes preventing overdoses as they occur.

Fortunately, treatments such as naloxone are effective and largely available. The subject of the joint committee hearing at hand is whether or not the existing data support naloxone being able to be offered over the counter for purchase with no insurance required. There are data and reports which absolutely indicate this. A CDC report from September 2020 investigated relevant characteristics in 16,236 overdose deaths from January 2019 to June 2019. The findings reveal key insights for preventing deaths. Of those 16,236 deaths, over three in five overdose deaths (62.7%) "had evidence of at least one potential opportunity for intervention"³ and 37% "occurred with a bystander present"³.

Further, a different CDC report⁴ from 2015 shows a survey tracking naloxone kit distribution and its use in reversing opioid overdoses. In calendar year 2013, nearly 38,000 kits were given out and used to save over 8,000 lives. In this same report, from calendar year 1996 to June 2014, 26,463 opioid overdoses were prevented thanks to naloxone. The exact number of lives that would've been saved had naloxone been more readily available cannot be determined, but it's certainly an aspect of this discussion that deserves consideration in Federal rulemaking. These statistics point to a strong need for increased access to naloxone given the high potential to save someone's life in the event of an overdose. Designating naloxone as an over-the-counter treatment presents an opportunity to save thousands of lives, while keeping the treatment both accessible and affordable.

Designating naloxone as an over-the-counter treatment would not only increase its availability, it would also give a strong headway to combatting a major barrier to access: the stigma associated with addiction. It can be uncomfortable for someone with substance use disorder to pursue

¹[https://nida.nih.gov/research-topics/trends-statistics/overdose-](https://nida.nih.gov/research-topics/trends-statistics/overdose-deathrates#:~:text=Opioid%2Dinvolved%20overdose%20deaths%20rose,(Source%3A%20CDC%20WONDER).)

[deathrates#:~:text=Opioid%2Dinvolved%20overdose%20deaths%20rose,\(Source%3A%20CDC%20WONDER\). \(figure 3\)](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8145781/#:~:text=March%2021%2C%202021.-)

²<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8145781/#:~:text=March%2021%2C%202021.->

³[,The%20provisional%20leading%20cause%20of%20death%20rankings%20for%202020%20indicate,end%20of%20the%20data%20year](https://www.cdc.gov/mmwr/volumes/69/wr/mm6935a1.htm?s_cid=mm6935a1_w)

⁴ https://www.cdc.gov/mmwr/volumes/69/wr/mm6935a1.htm?s_cid=mm6935a1_w

⁵ https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6423a2.htm?s_cid=mm6423a2_e

treatments which prevent overdose because of these societal stigmas. The current order of operations for procuring naloxone requires discussions with doctors, insurance companies, and pharmacists. Any or all of these steps puts substance use disorder patients in an uncomfortable position while seeking a life-saving treatment. As a result, the people who need this treatment the most are, for lack of a better term, discouraged from seeking it. Being able to acquire naloxone independent of a doctor's or insurance company's approval would decrease the stigma, increase access & availability, and save lives.

In the wake of the ever-increasing epidemic of overdose deaths, there is a strong responsibility for Federal Administrations and stakeholders to take corrective measures. The potential that designating naloxone as an over-the-counter treatment presents in saving thousands of lives can neither be understated nor ignored. And it is my strong hope that both committees recommend proceeding with this course of action. In closing, thank you again for the opportunity to offer testimony today.