

U.S. Sen. Baldwin: Maloney, Hassan, King, Fitzgerald lead bipartisan, bicameral group in calling on drug manufacturers to make Naloxone available over the counter

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WASHINGTON, D.C. – Today, U.S. Senator Tammy Baldwin (D-WI) and Representative Carolyn B. Maloney (D-NY), Chairwoman of the House Committee on Oversight and Reform, along with Senators Maggie Hassan (D-NH) and Angus King (I-ME) and Representative Brian Fitzpatrick (R-PA), led a bicameral, bipartisan group of colleagues in sending letters to seven major manufacturers of naloxone, the opioid overdose reversal medication, urging them to apply for over the counter (OTC) status for their products to help increase access and save lives. Despite the effectiveness of naloxone to reverse active opioid overdoses and the [Food and Drug Administration's \(FDA\) public support](#) for making the product available over the counter, the medication is not currently available over the counter because drug manufacturers have resisted applying. This step is expected to lower the cost of the medication and increase access both at the pharmacy counter and for community organizations working to distribute this life-saving tool.

“One of the most important actions that can be taken right now is for manufacturers to submit applications to make naloxone available over the counter without delay,” **said the Members of Congress.** “Further, a formal switch to OTC status will help reduce stigma and encourage the widespread use of this critical medication.”

The Members of Congress continued, “Now the responsibility lies with manufacturers to submit the paperwork needed to make this switch. By doing so, [the drug manufacturer] will be taking an important step in the ongoing effort to prevent deadly opioid overdoses.”

The series of letters comes as the COVID-19 pandemic has dramatically exacerbated the opioid epidemic and substance use disorder crisis in this country, with the United States experiencing more than 100,000 overdose deaths in a 12-month period for the first-time ever last year. A study found that substantially increased access to naloxone reduced opioid overdose mortality rates by [46 percent](#).

The letters were sent to the CEOs of Pfizer, Emergent Biosolutions, Teva Pharmaceuticals, Hikma, Akorn, Adamis Pharmaceuticals, and Amphastar Pharmaceuticals.

The letter was also signed by Senators Joe Manchin (D-WV), Susan Collins (R-ME), Sheldon Whitehouse (D-RI), Shelley Moore Capito (R-WV), Elizabeth Warren (D-MA), Lisa Murkowski (R-AK), Amy Klobuchar (D-MN), Ben Ray Lujan (D-NM), Richard Blumenthal (D-CT), Ed Markey (D-MA), Sherrod Brown (D-OH), Brian Schatz (D-HI), Jeanne Shaheen (D-NH), and Patrick Leahy (D-VT) and Representatives Mark Desaulnier (D-CA), Peter Meijer (R-MI), Katie Porter (D-CA), Mariannette J. Miller-Meeks, M.D. (R-IA), Jim Cooper (D-TN), Peter Welch (D-VT), Alexandria Ocasio-Cortez (D-NY), Cori Bush (D-MO), Rashida Tlaib (D-MI), Ayanna Pressley (D-MA) and Jimmy Gomez (D-CA).

The letters are supported by The American Medical Association, the American Society for Addiction Medicine, and the Remedy Alliance.

“Naloxone is a remarkably effective and safe medication,” **said Dr. Brian Hurley, President-Elect of the American Society of Addiction Medicine (ASAM).** “In response to the impact of the devastating opioid overdose epidemic, all 50 states and the District of Columbia have passed legislation designed to improve naloxone access. But such actions are not enough. Now is the time to designate a naloxone product as an over-the-counter medication, and ASAM thanks Senator Baldwin and others members of Congress for their leadership on this issue.”

“Much of the creativity for reducing barriers to naloxone access can be traced back to harm reduction programs,” **said Maya Doe-Simkins, Director of the Remedy Alliance.** “We eagerly await the strategic and innovative ways that naloxone access barriers- including cost and prescription status barriers- can be further dismantled with the help of pharmaceutical manufacturers and distributors. We thank these Members of Congress for championing naloxone access in their letters.”

“Equitable and cost-effective strategies to increase access to all forms of naloxone is the next step in addressing the opioid overdose and addiction epidemics,” **said Jesse Heffernan, RCP, of Appleton, Wisconsin, a recovery coach and person in recovery.** “Naloxone should be in every household, business and campuses across the country in the same way we have smoke detectors, AEDs, and first AID Kits. When families and individuals are equipped with it, people are given opportunities to move into recovery and treatment. Overdose is preventable and reversible. The expedited advancement of an OTC version will save lives and reduce the discrimination toward individuals with a substance use disorder. Thank you to Senator Baldwin and her colleagues for her important leadership in increasing access to naloxone.”

Full text of the letters can be found [here](#) or below:

Dear [CEO],

Given our nation’s alarming opioid overdose rates, we write to urge [company name] to submit an application to the Food and Drug Administration (FDA) for over-the-counter (OTC) status for your naloxone product, a desperately needed step to ensure widespread and affordable access to this critical overdose reversal medication. We ask that you act quickly given the scale of need at this moment. Lives are at stake.

The COVID-19 pandemic has dramatically exacerbated the opioid and substance use disorder epidemic in this country, with reported overdoses and deaths spiking to historic levels. In fact, alarming data show that last year, the United States experienced a record 100,306 overdose deaths. These trends show no signs of abating as overdose deaths continue to rise.

Given the scale of need at this moment, it has never been more important to adopt

opioid overdose prevention and reversal strategies on a wide scale. This includes steps to increase access to affordable naloxone, which is a proven, effective tool to reduce medical emergencies, drug overdoses, and deaths. A study conducted in Massachusetts found that substantially increased access to naloxone reduced opioid overdose mortality rates by 46 percent. With the support of naloxone manufacturers, we can significantly increase access to the medication and help mitigate the worsening crisis of drug overdose deaths.

One of the most important actions that can be taken right now is for manufacturers to submit applications to make naloxone available over the counter without delay. While many states have standing orders and workarounds that allow individuals to acquire naloxone without a prescription, regulatory hurdles continue to create unnecessary barriers. Further, a formal switch to OTC status will help reduce stigma and encourage the widespread use of this critical medication during emergencies. Additionally, market prices for naloxone remain prohibitively high, putting additional financial strain on community organizations working to reduce overdoses. Creating additional OTC naloxone options will help to reduce prices for those who need it, as well as for first responders and other good Samaritans, and increase the supply in at-risk communities.

The FDA strongly supports this change and has proactively created, tested, and validated the key labeling information and data needed to approve an OTC version of naloxone. As part of this effort to expedite the application process, the FDA has provided model OTC labels and usage instructions for the nasal spray and auto-injector versions of naloxone. Now the responsibility lies with manufacturers to submit the paperwork needed to make this switch. By doing so, [company name] will be taking an important step in the ongoing effort to prevent deadly opioid overdoses.

We strongly urge you to support the widespread access to naloxone, and request that you quickly apply to the FDA for OTC status.

Sincerely,

An online version of this release is available [here](#).