

FDA approves first over-the-counter nasal spray for opioid overdoses

March 29 2023, by Robin Foster



The U.S. Food and Drug Administration on Wednesday approved the

over-the-counter use of a nasal spray that can reverse an opioid overdose.

Research has shown that wider availability of [naloxone](#) (Narcan) could save lives as the opioid epidemic rages on in this country.

"The FDA remains committed to addressing the evolving complexities of the overdose crisis. As part of this work, the agency has used its [regulatory authority](#) to facilitate greater access to naloxone by encouraging the development of and approving an over-the-counter naloxone product to address the dire public health need," FDA Commissioner [Dr. Robert Califf](#) said in an agency [news release](#).

"Today's approval of OTC naloxone nasal spray will help improve access to naloxone, increase the number of locations where it's available and help reduce [opioid overdose](#) deaths throughout the country," Califf said. "We encourage the manufacturer to make accessibility to the product a priority by making it available as soon as possible and at an affordable price."

Emergent BioSolutions, the Maryland company that makes the Narcan spray, made no mention of price in a statement it released after the FDA approval was announced, but the company's president applauded the move.

The approval "marks a historic milestone as we have delivered on our commitment to make this important emergency treatment widely accessible, given the alarming rates of opioid overdoses occurring across the country," [Robert Kramer](#), president and CEO of Emergent BioSolutions, said in a company [news release](#). "We are dedicated to improving [public health](#) and assisting those working hard to end the opioid crisis—so now with leaders across government, retail and [advocacy groups](#), we must work together to continue increasing access

and availability..."

Addiction experts also applauded the approval.

"Making the drug available over the counter could save more lives, [Dr. Scott Hadland](#), a pediatrician and addiction specialist at MassGeneral Hospital for Children in Boston, told *NBC News*.

Most overdose deaths among teens occur at home, he said, usually when there is someone nearby who could respond.

"Yet, most young people who overdose never receive Narcan and are pulseless by the time EMS arrives," Hadland explained. "Making it available over the counter will provide a new avenue of access, especially for [young people](#) and families who haven't been the targets of our widespread efforts to distribute Narcan across the country."

The approval process gained steam last month, when FDA advisers voted unanimously in favor of making the drug easier to access after a daylong meeting that focused on whether untrained users would be able to safely and effectively use the [nasal spray](#) in emergencies, the *Associated Press* reported.

The recommendation came despite concerns from some panel members about the clarity of the drug's instructions and packaging, which caused confusion among some people in a company study. Emergent BioSolutions said it would revise the packaging and labeling to address those concerns, according to the *AP*.

"Perfect should not be the enemy of the good, and the evidence we saw today provides clear indication that the drug can be used without the direction of a health care provider," panel member [Dr. Brian Bateman](#), of Stanford University, said at the time.

FDA officials who were at the meeting agreed, the *AP* reported.

"We believe that nonprescription naloxone may help address these barriers [in access]," said [Dr. Jody Green](#), the FDA's deputy division director for safety for the Division of Nonprescription Drugs. She noted that the switch would allow the drug to be sold in vending machines, convenience stores and supermarkets, the *AP* reported.

Although naloxone is already available without a prescription, it must be obtained directly from a pharmacist.

"Allowing it to be over-the-counter in the same manner in every state really clears up some confusion and hopefully clears up some of that red tape," said [Kirk Evoy](#), a clinical associate professor of pharmacotherapy at the University of Texas at Austin who has studied the issue.

In the year ending August 2022, more than 107,000 Americans died of a [drug](#) overdose. More than two-thirds of those deaths involved fentanyl and other synthetic opioids, according to the U.S. Centers for Disease Control and Prevention.

Naloxone has been approved by the FDA since 1971. It was first used in hospitals and by first responders to resuscitate those who might have otherwise died of an [overdose](#), *CNN* reported.

Good Samaritan laws in most states protect people who administer the medication to someone who is overdosing, *CNN* reported.

"The more you can administer naloxone, the more likely it is that we'll have positive results," Evoy told *CNN*. "And more likely we'll be able to save a life with this medication."

More information: The U.S. Centers for Disease Control and

Prevention has more on the [opioid overdose epidemic](#).

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