

Workers' Comp

How Naloxone Can Help Fight the Opioid Crisis

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FDA Approves First Generic Opioid-Antagonist Naloxone Nasal Spray

As the U.S. looks for ways to stem the opioid crisis, one major strategy that has emerged is the use of naloxone to counteract opioid overdoses. The FDA's recent approval of the generic form of Narcan®, which is the first generic formulation for naloxone nasal spray, provides another avenue to reverse the impact of the opioid crisis. According to the CDC, almost 400,000 people died from an opioid overdose between 1999 and 2017. On average, more than 130 Americans die from an overdose every day, both from prescription (e.g., oxycodone, fentanyl, morphine, hydrocodone) and illicit (heroin, synthetic fentanyl) opioids. An opioid overdose leads to breathing difficulties, whereby breathing becomes shallow or even stops completely, and may lead to death if there is no immediate medical intervention. If a person administers naloxone immediately, the drug can counteract opioid overdose effects, usually within minutes.

Insights into Naloxone

In the United States, naloxone is available without a prescription in <u>every state except Hawaii</u>. Generic injectable formulations of naloxone have been available for many years, typically used in healthcare settings. The generic form of Narcan® is the first generic naloxone nasal spray approved for use in the community, by individuals lacking medical training. In April 2017, the U.S. Department of Health and Human Services announced its <u>5-Point Strategy</u> to combat the opioid crisis. Included in its strategy is better targeting of overdose-reversing drugs. In April 2018, Surgeon General Jerome M. Adams <u>issued an advisory</u> encouraging more individuals, including family, friends and those at risk of an opioid overdose, to carry naloxone at all times.

FDA Approval of Generic Narcan®

In a statement released by the FDA in April 2019, after approval of the generic of Narcan® by the FDA, Douglas Throckmorton, M.D. said, "In the wake of the opioid crisis, a number of efforts are underway to make this emergency overdose reversal treatment more readily available and more accessible. In addition to this approval of the first generic naloxone nasal spray, moving forward we will prioritize our review of generic drug applications for naloxone." Throckmorton is the deputy center director for regulatory programs in the FDA's Center for Drug Evaluation and Research. The cost of generic injectable naloxone vials is very low. However, the price of two auto-injectors (brand name Evzio®) in the U.S. has increased from \$575 in 2014 to \$4,100 in 2019. The cost of Narcan® Nasal Spray (two-pack) is approximately \$125. The price for generic naloxone nasal spray (two-pack) is anticipated to be approximately \$40.

Future of Opioid Crisis

The FDA has determined that further expanding availability and access to overdose-reversing drugs could help address the public health emergency. Approval of generic naloxone nasal spray is one way the FDA is working to increase access to life-saving treatments. For the workers' compensation industry, opioids continue to pose a challenge to stakeholders and injured workers. This approval of generic Narcan® and the availability of other naloxone generics provide hope for saving lives as we continue to battle this epidemic.



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