FDA Approves *Narcan* Nasal Spray to Treat Opioid Overdose

Troy Brown, RN | |November 18, 2015

An intranasal form of naloxone hydrochloride (*Narcan*, Adapt Pharma, Inc), a drug that stops or reverses opioid overdose, has been approved by the US Food and Drug Administration (FDA) under a fast-track approval process.

Naloxone hydrochloride has long been given by intramuscular injection to stop or reverse the effects of opioid overdose, in particular respiratory depression. It usually works within 2 minutes but must be given quickly to prevent death.

The nasal form will be easier for first responders and others to deliver, and will eliminate the threat of contaminated needle sticks. Until now, unapproved naloxone kits have combined the injectable form of naloxone with an atomizer to administer the drug nasally.

No assembly is required for the approved naloxone nasal product, and anyone can administer it, even those without medical training. The product can be given to adults and children. It is sprayed into one nostril while the patient lies on his or her back, and can be repeated if needed. The FDA cautions that the person administering the drug should still seek immediate medical attention for the patient.

Drug overdose deaths have risen steadily for the past decade and now surpass motor vehicle crashes as the leading cause of injury death in the United States. The increase is due in large part to prescription drug overdoses, as well as a rise in heroin use.

"Combating the opioid abuse epidemic is a top priority for the FDA," Stephen Ostroff, MD, acting FDA commissioner, said in an FDA news release. "We cannot stand by while Americans are dying. While naloxone will not solve the underlying problems of the opioid epidemic, we are speeding to review new formulations that will ultimately save lives that might otherwise be lost to drug addiction and overdose."

The approval follows an expedited review of data from clinical trials in which nasal administration achieved the same or higher levels of naloxone as those obtained with intramuscular injection, and in about the same amount of time.

The FDA's priority review program facilitates approval of drugs that are expected to significantly improve the safety or effectiveness of the prevention, treatment, or diagnosis of a serious medical condition. The FDA approved the nasal spray in less than 4 months.

"We heard the public call for this new route of administration, and we are happy to have been able to move so quickly on a product we are confident will deliver consistently adequate levels of the medication — a critical attribute for this emergency life-saving drug," Janet Woodcock, MD, director of the FDA's Center for Drug Evaluation and Research, said in the FDA news release.

The National Institute on Drug Abuse (NIDA) designed and conducted clinical trials to determine that the intranasal formulation worked as quickly and effectively as the injectable form. NIDA then worked with its partners in the private sector to obtain approval from the FDA.

"This easy-to-use intranasal formulation will no doubt save many lives," Nora Volkow, MD, director, National Institute on Drug Abuse at the National Institutes of Health, explained in the news release. "While prevention is the ultimate goal, the drug's successful development illustrates how public/private scientific partnerships can play an important role in responding to a national crisis right now."

Health and Human Services Secretary Sylvia M. Burwell proposed a targeted strategy for addressing the opioid epidemic that includes increasing access to and use of naloxone in March. In July the FDA sponsored a public workshop at which addiction and advocacy groups demanded expanded availability of the lifesaving drug.

Naloxone nasal spray can cause severe opioid withdrawal in patients who are opioid dependent.

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