FDA Seeks to Curb Opioid Deaths by Making Overdose Drug Naloxone OTC

Despite heightened collective awareness, the opioid epidemic in this country continues to rage without improvement. Quite th contrary, a new report by the National Safety Council shows that the lifetime odds of accidental death due to an opioid overdo the U.S. have now surpassed the odds of dying in a motor vehicle accident. This is the first time that opioid fatalities (1 in 96) edged out auto fatalities (1 in 103) on the list. As in previous years, opioid-related death is more likely than death involving fire falls or drowning or pedestrian events. Only the odds of suicide (1 in 88) are still higher than opioid overdose.

According to the Centers for Disease Control and Prevention (CDC), more than 70,000 deaths in the nation in 2017 (the same year of the Safety Council's study) were attributed to drug overdose (48,000 due to opioids, both prescription and illicit). And t CDC pointed to illegally manufactured fentanyl as the reason for the surge (63,600 people died due to drug overdose in 2016)

FDA head explains the agency's effort in statement

Dr. Scott Gottlieb, the Commissioner of the U.S. Food and Drug Administration (FDA), recently released a statement that spe to what he calls an "unprecedented" move toward providing some relief for the incredibly dire national crisis of opioid-related deaths.

Gottlieb has announced the FDA's plan to make naloxone (a drug used in the prevention of opioid overdose and currently onl available with a prescription) more readily and widely accessible by making it an over-the-counter medication (OTC). Naloxon used to counter the effects of opioid overdose, but it must be administered rapidly if it is to reverse the loss of consciousness breathing associated with dangerous opioid levels. In his statement, Gottlieb opined that the stigma of substance abuse disor may dissuade many individuals from seeking a doctor's care, thereby putting up a major obstacle between naloxone and the people who most need to have it on hand.

The FDA Commissioner went on to explain that for naloxone to go from prescription to OTC would require a change in labelin For now, the prescribed version is given to the patient with usage instructions on the label, but not with Drug Facts labeling (D a requirement for OTC medications. And in order for a product to earn that DFL, drug companies are required to conduct stud and ultimately demonstrate that the public will be able to use the product as it is intended and without the assistance of a physician. And specifically, OTC naloxone's labeling must be clear enough that an "untrained bystander" would be able to administer it to a patient in an emergency.

"Some stakeholders have identified the requirement to perform these studies as a barrier to the development of OTC naloxon products," Gottlieb wrote in his statement.

FDA developed pictograms to educate public on naloxone use

The FDA has found a potential way around that, according to Gottlieb . . . what he calls an "unprecedented step": simple picto representations that demonstrate how the drug should be used.

"This is the first time the FDA has proactively developed and tested a DFL for a drug to support the development of an OTC product," Gottlieb's statement announced. "[W]e've crafted model labeling that sponsors can use to obtain approval for OTC naloxone and increase its access."

The FDA statement is embedded with links to model DFL's for OTC naloxone, one that depicts instructions for using an auto-injector and the other for the nasal spray option.

Gottlieb's statement was released during the partial government shutdown, and he addressed that fiscal backdrop as well: "During this period without a FY19 appropriation for the FDA, we've been focused on making sure that we continue critical aspects of our work, to the extent permitted by law." He went on to explain that the review of applications of certain products (including naloxone) are paid for by "limited carryover user fee balances."

Study of new DFL shows strong consumer comprehension

The FDA reported that the DFL has been tested for consumer comprehension by an independent contractor. The study used more than 700 participants ranging from people actively using prescription opioids or heroin, as well as those with loved ones using opioids, and the general public too. The agency reviewed the final report of that study and "determined that the comprehension results were satisfactory" and that the majority of participants understood the proposed OTC instructional labeling.

"I personally urge companies to take notice of this pathway that the FDA has opened for them and come to the Agency with applications as soon as possible," Gottlieb wrote.

Of course, naloxone can not on its own change the course of the nation's opioid tragedy, as Gottlieb pointed out, but it *can* save lives. He reminded the public that his agency is also working on preventative measures, like better pain management and greater access to treatment for those struggling with substance use disorder.

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