FDA Takes Steps to Make Naloxone an OTC Drug

Posted 17 January 2019 | By Zachary Brennan

The US Food and Drug Administration (FDA) on Thursday announced new steps to try to increase the availability of the decades-old opioid overdose antidote naloxone.

The announcement comes as more than 72,000 died of opioid overdose deaths in 2017 and as naloxone sales have doubled from about 2.5 million units sold in 2013 to about five million units sold in 2017.

And although naloxone is not yet an over-the-counter (OTC) product, CVS told *Focus* that it has pharmacy locations in 48 states (Wyoming and Hawaii do not) that currently have a standing order or similar protocol allowing pharmacists to dispense naloxone to patients without an individual prescription. That figure is up from 20 states in 2016.

New Efforts

Now, FDA said that for the first time, it has proactively developed and tested two Drug Facts Labels (DFLs) to support development of nasal spray and injectable OTC naloxone products.

“We proactively designed, tested, and validated the key labeling requirements necessary to approve an OTC version of naloxone and make it available to patients. One of the key components for OTC availability is now in place. In short, we’ve crafted model labeling that sponsors can use to

obtain approval for OTC naloxone and increase its access," FDA Commissioner Scott Gottlieb said.

The agency's model DFL includes easy-to-understand pictograms on how to use naloxone, and FDA also conducted label comprehension testing to ensure the instructions were simple to follow.

"Overall, the study demonstrated that the model DFL was well-understood by consumers and is acceptable for use by manufacturers in support of their OTC naloxone development programs. Using this information, naloxone manufacturers can now focus their efforts on final label comprehension testing of how well consumers understand the product-specific information that hasn't been already tested in the model DFL," Gottlieb said.

The Department of Health and Human Services' Office of Inspector General (OIG) also said earlier this week that it would look into how Medicaid could play a significant role in addressing the issue of naloxone access because the program covers nearly 40% of nonelderly adults with opioid addiction. The office will also determine how the cost-per-dose for naloxone under Medicaid compares to other available prices.

The work by FDA and OIG comes as a recent FDA advisory committee narrowly voted, 12-11, in favor of adding labeling language that recommends the co-prescription of naloxone for all or some patients prescribed opioids.

The close vote was the result of some advisory committee members questioning whether co-prescribing necessarily addresses the opioid crisis at hand, while others said that co-prescribing is already the standard of care for high-risk populations and therefore should be added to the labeling.

Information about Naloxone

Categories: Regulatory News

Regulatory News

VIEW ALL NEWS →