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FDA Calls for Opana ER's Removal Due to Abuse Concerns

June 12, 2017 03:40 pm News Staff (mailto:aafpnews@aafp.org) – On June 8, the FDA asked Endo Pharmaceuticals (https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm) to pull its opioid pain medication, reformulated Opana ER (oxymorphone hydrochloride), from the market because of concerns that the drug's benefits may no longer outweigh its risks.

This is the first time the agency has taken steps to stop the sale of a currently marketed opioid pain medication based on the public health consequences of possible abuse.

"We are facing an opioid epidemic -- a public health crisis, and we must take all necessary steps to reduce the scope of opioid misuse and abuse," said FDA Commissioner Scott Gottlieb, M.D., in a news release announcing the agency's action. "We will continue to take regulatory steps when we see situations where an opioid product's risks outweigh its benefits, not only for its intended patient population but also in regard to its potential for misuse and abuse."

The FDA said its decision was based on a review of all available postmarketing data, which showed a substantial shift in the route of abuse of the drug -- from nasal to injection -- even after it was reformulated in 2012. That reformulation was intended to thwart physical and/or chemical manipulation that would allow the drug to be snorted or injected.

The agency noted that injection abuse of the reformulated Opana ER has been associated with a serious outbreak of HIV and hepatitis C infections, as well as cases of thrombotic microangiopathy.

"The abuse and manipulation of reformulated Opana ER by injection has resulted in a serious disease outbreak. When we determined that the product had dangerous unintended consequences, we made a decision to request its withdrawal from the market," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research, in the release. "This action will protect the public from further potential for misuse and abuse of this product."

The FDA said if Endo Pharmaceuticals doesn't voluntarily remove reformulated Opana ER from the market, the agency plans to formally require its removal by withdrawing approval of the drug.

This decision comes on the heels of a joint FDA advisory committee meeting (https://www.fda.gov/downloads

/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM547237.pdf) in March during which a group of independent experts decided in an 18-8 vote that the benefits of reformulated Opana ER no longer outweigh its risks.

The FDA first approved the drug in 2006 for the management of moderate-to-severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

At that time, despite meeting the regulatory standards for approval, the FDA determined that data on Opana ER didn't show that the reformulation could be expected to meaningfully reduce abuse and declined Endo Pharmaceuticals' request to include labeling that would have described the potentially abuse-deterrent properties of the drug.

Regarding the current development, Endo Pharmaceuticals issued a statement (http://www.endo.com/news-events/press-releases?c=123046&p=irol-newsArticle&ID=2279996) the same day as the FDA announcement saying it was aware of the agency's action and was reviewing the request and evaluating "the full range of potential options" as it determines its next steps.

In the meantime, the FDA is focusing its efforts on educating health care professionals about this request to remove Opana ER from the market.

"The FDA will continue to examine the risk-benefit profile of all approved opioid analgesic products and take further actions as appropriate as a part of our response to this public health crisis," the news release said.

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