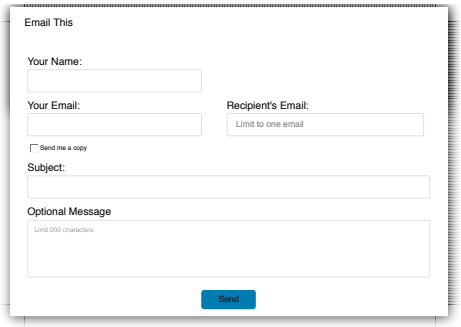
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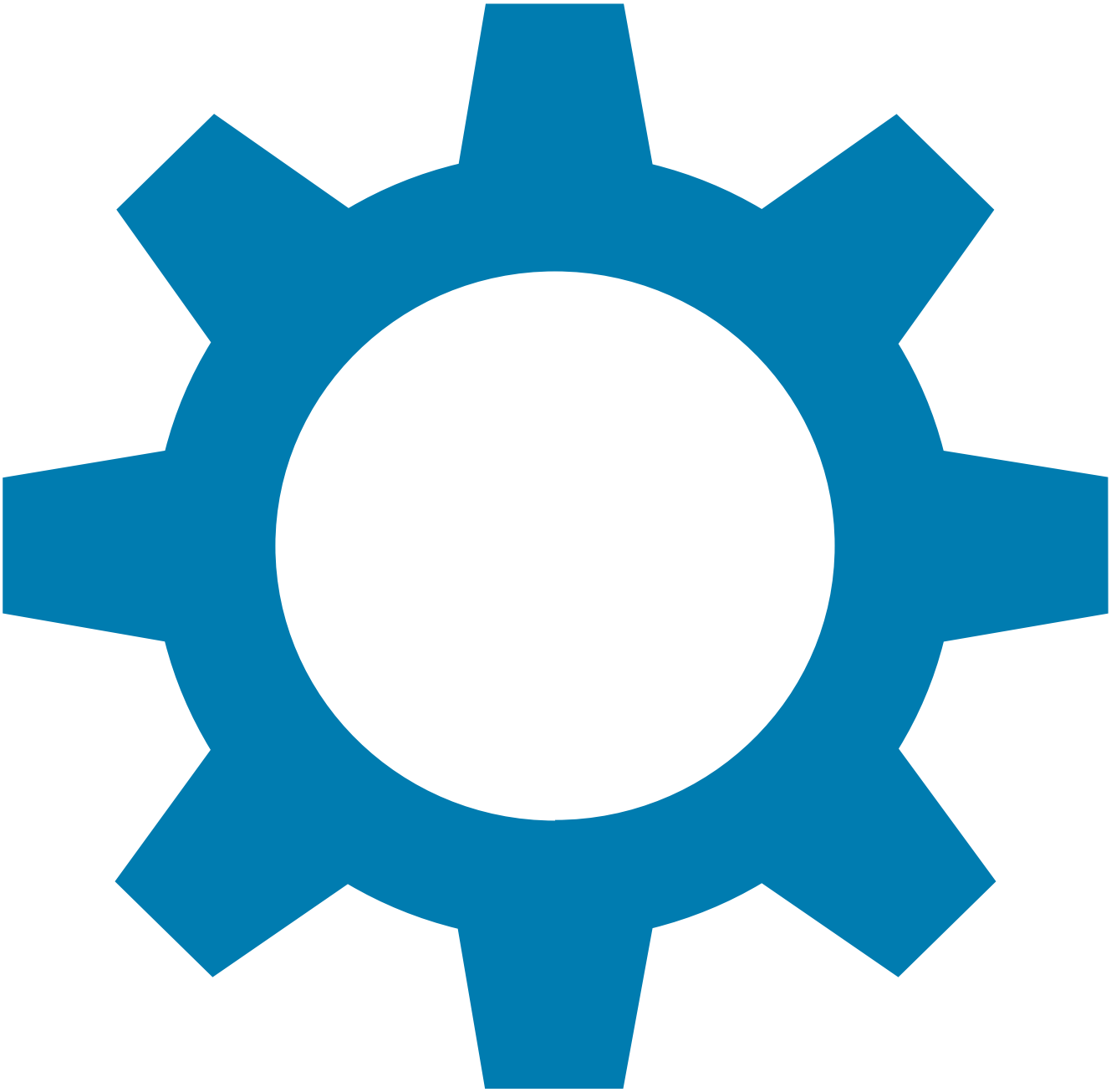


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FDA Asks Endo Pharma to Take *Opana ER* Off the Market

Megan Brooks
DISCLOSURES | June 08, 2017

The US Food and Drug Administration (FDA) has asked Endo Pharmaceuticals to remove its abuse-deterrent extended-release formulation of oxymorphone (*Opana ER*) from the market.

"After careful consideration, the agency is seeking removal based on its concern that the benefits of the drug may no longer outweigh its risks," the FDA said in a statement.

This marks the first time the FDA has taken steps to remove a currently

marketed opioid pain medication from sale because of the public health consequences of 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," FDA Commissioner Scott Gottlieb, MD, said in a statement.

"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," Dr Gottlieb said.

The FDA's decision is based on a review of available postmarketing data, which demonstrated a significant shift in the route of abuse of Opana ER from nasal to injection after the product's reformulation. Injection abuse of reformulated Opana ER has been associated with an outbreak of HIV infection and hepatitis C, 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, MD, director of the FDA's Center for Drug Evaluation and Research. "This action will protect the public from further potential for misuse and abuse of this product."

As previously reported by *Medscape Medical News*, on March 17, an FDA advisory panel of independent experts voted 18 to 8 that the benefits of reformulated Opana ER for relief of severe pain no longer outweigh its risks.

Opana ER was first approved in 2006 for the management of moderate-to-severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period. In 2012, Endo replaced the original formulation of Opana ER with a new formulation intended to make the drug resistant to physical and chemical manipulation for abuse by snorting or injecting.

"While the product met the regulatory standards for approval, the FDA determined that the data did not show that the reformulation could be expected to meaningfully reduce abuse and declined the company's request to include labeling describing potentially abuse-deterrent properties for Opana ER. Now, with more information about the risks of the reformulated product, the agency is taking steps to remove the reformulated Opana ER from the market," the agency explains in the statement.

The FDA has requested that the company voluntarily remove reformulated Opana ER from the market. Should the company choose not to remove the product, the FDA said it will take steps to formally require its removal by withdrawing approval.

The agency 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."

In a statement, Endo Pharmaceuticals said it was aware of the FDA's request. "Endo is reviewing the request and is evaluating the full range of potential options as we determine the appropriate path forward."

While the benefits of opioids in treating and managing pain are widely recognized, the misuse and abuse of these products have increased greatly in the United States, the statement notes. "As a pharmaceutical company with a demonstrated commitment to the improvement of pain management, Endo feels a strong sense of responsibility to improve the care of pain for patients while at the same time taking comprehensive steps to minimize the potential misuse of its products.

"Despite the FDA's request to withdraw OPANA ER from the market, this request does not indicate uncertainty with the product's safety or efficacy when taken as prescribed," the company adds. "Endo remains confident in the body of evidence established through clinical research demonstrating that OPANA ER has a favorable risk-benefit profile when used as intended in appropriate patients."

The statement also refers to the FDA advisory committee meeting looking at the pre- and postmarketing data on abuse of their product and generic oxymorphone products.

"While the Advisory Committee members voted 18 to eight, with one abstention, that the benefits of reformulated OPANA ER no longer outweigh its risks, more than half expressed their preference that OPANA ER remain on the market, but with additional regulatory restrictions to mitigate the risks of misuse and abuse," the statement points out.

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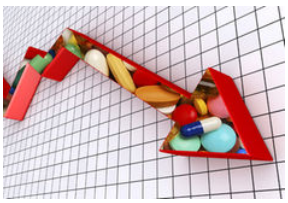

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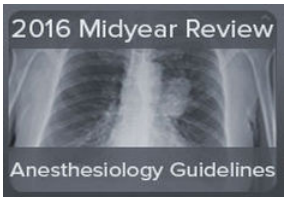

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