
3rd UPDATE: Panel Has Deep Concerns About New OxyContin

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(Updates with comments from FDA panel members and Purdue Pharma.)

By Jared A. Favole

Of DOW JONES NEWSWIRES

WASHINGTON -(Dow Jones)- A U.S. Food and Drug Administration panel on Monday expressed deep concerns about a purported abuse-resistant form of the powerful painkiller OxyContin, saying there is a "striking" lack of data about the drug's abuse-prevention qualities.

A majority of FDA panel members said that including information about the drug's resistance to abuse on a label would likely lead to more overdoses and deaths.

"I'm fascinated with the poor scientific rigor" of the data presented by Purdue Pharma LP, maker of OxyContin, FDA panel member Jeffrey R. Kirsch said. " It's almost insulting."

Stamford, Conn.-based Purdue Pharma is seeking FDA approval for the abuse- resistant form of OxyContin, which is of a lower strength than some other forms on the market. An FDA panel on Monday was charged with considering whether the drug has enough abuse-resistant features to be allowed on the market before required long-term studies are done, and whether those qualities should be included on the label. No vote, however, was scheduled or taken.

J. David Haddox, vice president of risk management for Purdue Pharma, said studies show a new formulation of OxyContin can't be easily crushed or dissolved, making efforts to tamper with the tablet "substantially more difficult."

The panel gave Purdue Pharma several suggestions on what it can do going forward. Panel members urged Purdue Pharma to conduct more frequent and rigorous tests of the drug's tamper-resistant qualities. The panel also suggested that any new form of OxyContin should be a different color than forms currently on the market, so physicians and patients will be able to distinguish which form they are taking.

Purdue Pharma said in a statement after the meeting that it intends to continue to work with the FDA for approval of the new form.

Larry Goldbom, a Florida pharmacist who hosts a radio show on prescriptions and addictions, said during the meeting that it is ludicrous for the FDA to even consider approving a new form of OxyContin.

"Every narcotics officer...every addict knows oxycodone and heroin are interchangeable. The FDA has, for 12 years, ignored that fact," Goldbom said. (Oxycodone is an active ingredient in OxyContin.)

OxyContin was launched in 1996 to treat severe chronic pain and was designed to be swallowed whole and digested over 12 hours. Drug abusers, however, realized they could crush the drug or dissolve it in water and inject it to get all the effects at once, creating a heroin-like high. Purdue Pharma came under heavy criticism for its marketing of the drug, and in May 2007 agreed to pay \$ 635 million to settle charges that it underplayed OxyContin's abuse potential.

Purdue Pharma says the new form of OxyContin can't be easily crushed and, when added to water, forms a jelly-like substance making it difficult to be sucked up a syringe.

Goldbom said it is estimated that 97% of all people who die from OxyContin take it whole, meaning a tamper-resistant form would address just 3% of the deaths associated with the drug.

Ellen and Peter Jackson told the FDA panel that they shouldn't approve the new form of OxyContin, citing statistics that OxyContin has led to numerous deaths.

"My daughter is one of those statistics and I am asking you not to turn your back on her," Peter Jackson said. The couple's daughter, Emily, died in 2006 after swallowing an OxyContin pill whole. A relative gave her the drug.

The FDA said labeling for this new form of OxyContin would have to be carefully crafted to avoid giving people a "roadmap" for how to defeat the drug's abuse-resistant features. The agency said that, while including the abuse-resistant qualities on the label might be valuable, it may lead health- care providers to believe that OxyContin doesn't carry risks of addiction or overdose. The agency also said it is concerned that approving the new form of OxyContin may create confusion because 60-milligram and 80-milligram tablets aren't yet reformulated.

Purdue Pharma said the new formulation isn't "tamper-proof" despite misconceptions in the

media that it is.

The FDA has encouraged companies such as Purdue Pharma to develop novel ways to prevent abuse of their drugs. "Unfortunately, successful new formulations have been elusive," FDA Director Bob A. Rappaport has said.

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