

## OxyContin maker bows out of meeting on harder-to-abuse drug

June 30 2015, by Matthew Perrone

The makers of the potent painkiller OxyContin have pulled out of a federal meeting to review the company's harder-to-abuse version of the much-debated drug.

An executive for Purdue Pharma says the company wants more time to review and analyze its data. As a result, the company has withdrawn its application that was slated to be reviewed before a Food and Drug Administration committee next week.

"Given the complexity of epidemiological research and the unprecedented nature of this exercise, we've made the decision to complete additional analyses," said Dr. Richard Fanelli, the company's head of regulatory affairs, in an emailed statement.

FDA meetings are typically planned months in advance and cancellations are highly unusual.

OxyContin was re-formulated in 2010 to discourage patients from crushing the tablets for snorting or injection. Purdue Pharma discontinued the older version of the drug, which was long associated with problems of addiction, overdose and death.

Next week's two-day meeting was intended to evaluate whether those abuse-deterrent features actually translate into reduced rates of abuse by pain patients.



The FDA required Stamford, Connecticut-based Purdue Pharma to conduct long-term, follow-up studies tracking rates of abuse, addiction, overdose and death with an updated drug.

The FDA has been urging companies to design new painkillers with tamper-resistant features to make them more difficult to abuse. Deaths linked to opioid pain medications like OxyContin and Vicodin have quadrupled since 1999 to an estimated 16,000 in 2013, the most recent year for which the Centers for Disease Control and Prevention reports figures.

Doctors prescribe these co-called opioids for a wide range of ailments, from post-surgical pain to arthritis and migraines. Medical experts continue to disagree over the appropriate role of the drugs, with some arguing that they should only be used for the most severe pain cases, such as cancer pain or end-of-life care.

OxyContin was the first in a class of long-acting opioids designed to deliver around-the-clock pain relief. The pills and tablets are formulated to slowly release their drug contents over 12 or more hours. But abusers often try to get a massive, heroin-like high by releasing the entire dose at once via chewing, snorting or injecting crushed tablets' contents.

Purdue Pharma's harder-to-abuse version of OxyContin can still be abused if chewed or simply swallowed.

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