

FDA: 'limited' benefit with tamper-proof OxyContin

September 22 2009, By MATTHEW PERRONE , AP Business Writer

(AP) -- Federal health officials say a new version of the painkiller OxyContin that is designed to be harder to abuse offers some improvements over the original pill.

Purdue Pharma LP has touted the new pill's plastic-like coating, which is designed to make the drug harder to crush and snort or inject.

[Food and Drug Administration](#) scientists said Tuesday that the drug's resistance to abuse is "limited," but "may provide an advantage over the currently available OxyContin."

A panel of advisers to the FDA said last year that the company needed to do more testing to demonstrate the drug's tamper resistance.

The FDA will ask the same panel Thursday whether the drug should be approved based on new data submitted by Stamford, Conn.-based Purdue Pharma.

OxyContin, the nation's top-selling prescription [painkiller](#) last year with sales of more than \$2 billion, was hailed as a breakthrough treatment for severe [chronic pain](#) when it was introduced in 1996. A time-release version of the narcotic oxycodone, it was designed for use over 12 hours to keep a steady state of the painkiller in the bodies of seriously ill patients.

However, Oxycontin and similar drugs were quickly adapted by drug

abusers who discovered they could get a heroin-like high by crushing the pills and snorting or injecting the entire dose at once.

A federal survey conducted in 2007 found that 5.2 million people in the U.S. reported using prescription pain drugs inappropriately.

The FDA has made a number of public service advisories on the problem with little success, and more recently started pressuring companies to make pain relievers more difficult to abuse.

In August, drugmaker King Pharmaceutical's Embeda became the first painkiller to win FDA approval as a tamper-proof medication.

When Purdue Pharma came before the FDA's panel last year, the company said it planned to offer tamper-proof versions of lower dose OxyContin, while keeping higher doses in their original form.

The FDA panel said that was a bad idea since doctors and physicians might mistakenly assume that all doses had been reformulated.

The company has now said it will make the changes to all doses of the drug.

In documents posted online, Purdue Pharma acknowledged that no formulation "will prevent all methods of tampering that may lead to abuse." But the company says the new version should significantly discourage abuse by making the pills more difficult and more time-consuming to manipulate.

OxyContin was the top-selling prescription painkiller in the U.S. last year with sales of nearly \$2.3 billion, according to medical research firm IMS Health. The drug accounts for more than half the market for codeine-derived drugs, which also includes Vicodin and various generic

medications.

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