

Article Link:

<http://www.webmd.com/pain-management/news/20080506/fda-panel-nixes-abuse-proof-oxycontin>

## Pain Management Health Center

### FDA Panel Nixes 'Abuse-Proof' OxyContin

#### Experts Say Special Coating May Not Stop Abuse of Pain Relief Drug

By [Todd Zwillich](#)

Reviewed by [Louise Chang, MD](#)

WebMD Medical News

May 6, 2008 -- A panel of expert advisors to the FDA took a dim view Monday of efforts by OxyContin's manufacturer to market a new form of the prescription painkiller designed to cut down on tampering and abuse.

The deliberations were a setback for the firm, Purdue Pharma. It was stung a year ago when the company and three of its executives pleaded guilty to illegally hiding the addictive potential of the drug, which is a narcotic.

The company now wants to sell a new form of the drug coated in a plastic-like polymer that prevents potential drug abusers from easily grinding tablets into a fine powder. That makes it hard to snort the drug or "cook" it for intravenous injection.

When it is "cooked," it forms a gelatin ball that is difficult to draw into a syringe. But the coating does not affect how the tablets dissolve in the gut, so patients would still be able to use the drug for [pain](#) relief, the company said.

#### Sales and Abuse Up

Sales of [oxycodone](#), including several generic forms as well as Purdue Pharma's brand name [OxyContin](#), have shot up since its extended-release form was approved in 1996. According to the FDA, sales peaked at 42.2 million [prescriptions](#) last year, and with them abuse rates have also gone up.

More than 12% of 18- to 25-year-olds reported using the drug for nonmedical reasons in 2006, according to federal figures. Those figures also estimate that 500,000 Americans try oxycodone recreationally for the first time each year.

Purdue Pharma officials tried to show that the polymer cut down on the amount of active drug that an addict could extract from a tablet.

"We can argue that we have met some degree of tamper resistance. But the abuse resistance is yet to be determined," said J. David Haddox, MD, Purdue Pharma's vice president of risk management and health policy.

#### Data Criticized

But while experts supported the idea of tablets that are hard to misuse while keeping OxyContin available for pain patients, they said the company failed to show that the new form would cut down on abuse in the real world.

The company did not show, for instance, whether motivated addicts with some facility in chemistry would be able to find ways around the polymer coating, experts said.

Panelist Lewis Nelson, MD, said the product could present doctors and regulators with a "false sense of security" that oxycodone is now safe, despite the fact that most overdoses follow the drug being swallowed orally.

"This new product doesn't bring any solution to the vast majority of deaths that occur with this product," said Nelson, director of the medical toxicology program at New York University School of Medicine.

#### Data Criticized continued...

At some points the criticism crossed over into ridicule. Jeffrey R. Kirsch, MD, a member of the panel, said he was "fascinated" with the "poor scientific rigor" or Purdue Pharma's claims that the new OxyContin was truly tamper-resistant.

"Almost to the point of being insulting," added Kirsch, a professor of anesthesiology from Oregon Health and Science University.

"The data presentation I would not allow in an honors undergraduate thesis to go forward," added Ruth S. Day, PhD, a panelist from Duke University.

The panel did not take any formal votes. But it was nearly unanimous that Purdue Pharma should not be allowed to proceed with a plan to sell lower OxyContin doses in the coated form while still selling higher, 60- and 80-milligram doses in the original form.

Doing so would confuse physicians and drive addicts to seek out the old forms of the drug, experts said.

In a statement, the company said it "will continue to work with the FDA on our New Drug Application (NDA) for a new formulation of OxyContin (oxycodone HCl controlled-release) Tablets."

"Untreated and undertreated pain is a serious public health issue in the United States," the statement said.

Three Purdue Pharma executives and the company agreed to pay a combined \$634.5 million in fines after pleading guilty to illegally promoting OxyContin to doctors and withholding data on its abuse potential.

[View Article Sources](#) 

© 2008 WebMD, LLC. All rights reserved.

SHARE  
[What is this?](#)

Digg [submit](#)

 [del.icio.us](#) [More...](#)

©2005-2007 WebMD, Inc. All rights reserved.

WebMD does not provide medical advice, diagnosis or treatment.

My Notes:



**WebMD**  
Better Information. Better Health.  
**men's health**

Daily insights and ideas to improve your physical and mental well-being

[CLICK HERE](#)

