

## 'Abuse-Resistant' Form of OxyContin May Be Near

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THURSDAY, Sept. 11 (HealthDay News) -- Researchers say they've developed an "abuse-resistant" formulation of the widely prescribed opioid pain medication OxyContin.

The U.S. Food and Drug Administration has granted Remoxy priority review, meaning that action could come as soon as early December, said Dr. Nadav Friedman, chief operating officer of Pain Therapeutics Inc., which developed Remoxy.

If approval is granted, said Friedman, who is also co-author of two studies being presented this week at the American Academy of Pain Management's annual meeting, the drug could get on the market "very quickly."

Pain Therapeutics Inc., based in San Mateo, Calif., funded both studies.

Abuse of prescription OxyContin is a major public health issue in the United States, particularly among adolescents and young adults. A federal report issued last week found that while cocaine and methamphetamine use among young adults in the United States fell in 2007 compared with 2006, abuse of prescription pain relievers by young adults rose 12 percent, to 4.6 percent.

And Remoxy isn't the only such abuse-resistant form of oxycodone (the generic name for OxyContin) on the pharmaceutical drawing board. According to the Associated Press, Purdue Pharma in May got a cool reception from an advisory panel at the U.S. Food and Drug Administration for its version of an abuse-resistant oxycodone. However, the company said at the time that it would continue to work on the product.

And in late March, Northvale, N.J.-based Elite Pharmaceuticals, Inc., announced that it planned a phase III clinical trial of a drug that combines oxycodone with the anti-addiction drug naltrexone.

As for Remoxy, Dr. Scott Fishman, chief of the division of pain medicine and professor of anesthesiology at the University of California, Davis and president of the American Pain Foundation, called the new study results "a nice step, but it needs to be approved."

Dissolving control-release OxyContin tablets in alcohol is one way users bypass the time-control mechanism to deliver the drug immediately, a tactic called "dose dumping."

But Remoxy is designed to thwart that tactic, depriving the user of the quick high he or she seeks.

For the first study, 37 volunteers ingested one Remoxy 40 milligram tablet while drinking 240 milliliters of either water alone, a four-percent ethanol (alcohol) mixture, a 20-percent ethanol mixture or a 40-percent ethanol mixture.

Even combining Remoxy with up to 40 percent ethanol did not interrupt the drug's controlled-release mechanism, the researchers report.

A second paper essentially found that the new formulation relieves pain as it should.

In the study, 412 patients with moderate-to-severe osteoarthritis pain of the hip or knee were randomized to receive either Remoxy or a placebo over the course of 12 weeks.

Those participants taking Remoxy reported lower pain intensity scores as compared to participants on the

placebo.

"This shows that Remoxy does control moderate-to-severe pain," Friedman noted.

According to the researchers, the study is the first such trial to demonstrate the effectiveness of any twice-daily formulation of oxycodone over three months in patients with chronic pain.

