

# FDA To Implement New Restrictions For Some Pain Pills

CNN News

February 09, 2009:

Original link to story

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WASHINGTON -(Dow Jones)- The Food and Drug Administration said Monday it will subject the makers of certain extended-release pain drugs to a new risk-management program designed to cut down on misuse and abuse of the products as new government figures show a rise in nonmedical use of prescription pain drugs among adults.

Opioid drugs formulated in extended release versions of OxyContin, morphine and fentanyl patches are meant for round-the-clock pain management for patients with cancer and other chronic conditions. FDA officials said they've seen reports of inappropriate prescribing by doctors amid the increase in misuse and abuse, both intentional and unintentional, of the products since they were first approved in the mid-1990s.

"We continue to see reports of an ankle sprain and [patients] are given a fentanyl patch," said John Jenkins, the director of FDA's office of new drugs.

He said a major part of the new program will be efforts to educate doctors about appropriate prescribing of the products. "This obviously is going to be the largest risk management program we've undertaken," he said.

Although Jenkins and other agency officials wouldn't speculate about what the final risk-mitigation program would look like, it could have elements of a program designed to limit the use of the acne drug isotretinoin (commonly known by the brand name Accutane) by women of child-bearing age because the product causes birth defects. That program requires doctors, pharmacists and patients to register and meet certain requirements in order to get a new prescription each month.

The agency sent letters to 16 manufacturers of 24 products including Purdue Pharma LP, the maker of OxyContin, which is available in an extended release form, a unit of Johnson & Johnson (JNJ) that makes a fentanyl patch and King Pharmaceuticals Inc. (KG), the maker of an extended-release form of morphine. The letters told the drug makers of agency plans to require a risk evaluation and mitigation strategy, or REMS, "to ensure that the benefits of the drugs continue to outweigh the risks."

The FDA said it would meet with the drug manufacturers next month to talk about developing a REMS and would then meet with other federal agencies, patient and consumer-advocacy groups and health-care professionals to get additional input in the coming months.

There will be no immediate changes for prescribers or users of extended-release pain pills. Other pain pills that are immediate release and most commonly prescribed for pain won't be affected.

The agency noted that previous efforts to cut down on abuse and misuse of extended-release products such as putting additional warnings on products labels haven't really worked.

"Despite these efforts, the rates of misuse and abuse, and of accidental overdose of opioids, have risen over the past decade," the agency said in a statement posted on its Web site. "The FDA believes that establishing a REMS for opioids will reduce these risks, while still ensuring that patients with legitimate need for these drugs will continue to have appropriate access."

The FDA can mandate the elements of a risk-management plan as part of legislation that took effect last year. Jenkins said that authority should make the new effort to cut down on abuse and misuse more effective than previous plans.

- By Jennifer Corbett Dooren, Dow Jones Newswires;