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## Quit-Smoking Drug May Raise Suicide Risk

FDA asks maker of Chantix to revise warning on product label

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FRIDAY, Feb. 1 (HealthDay News) -- There's increasing evidence that the smoking-cessation drug Chantix is linked to serious "neuropsychiatric" side effects, including agitation, depressed mood and even suicide, U.S. health officials said Friday.

The U.S. Food and Drug Administration has asked Chantix's manufacturer, Pfizer Inc., to make the warning about these potential problems more prominent on prescribing information and on the drug's label. The agency is also working with Pfizer to produce a Medication Guide for patients, officials said.

"We have become increasingly concerned as we have seen a number of compelling cases that truly look as if they are the result of exposure to the drug and not to other causes," Dr. Bob Rappaport, director of the FDA's Division of Anesthesia, Analgesia and Rheumatology Products, said during an afternoon teleconference.

"These cases involve abnormal behaviors, changes in mood, and suicidal ideation and suicide," Rappaport said.

The FDA knows of 491 cases of suicidal behavior associated with Chantix, said Dr. Celia Winchell, a team leader in the FDA's Division of Anesthesia, Analgesia and Rheumatology Products.

"Of these, 420 are from the United States," Winchell said. "There are 39 that involve completed suicides, 34 in the United States."

According to Pfizer, 5 million patients have taken Chantix, whose generic name is varenicline.

Friday's warning follows a Nov. 20 FDA statement that the agency was "evaluating post-marketing adverse event reports on Chantix related to changes in behavior, agitation, depressed mood, suicidal ideation, and actual suicidal behavior."

At that time, Pfizer said there had never been a cause-and-effect relationship shown between Chantix and these symptoms. The company also said that part of the problem may be due to nicotine withdrawal.

Last month, Pfizer agreed, after consulting with the FDA, to update packages of Chantix sold in the United States to more prominently display a warning that users should be monitored for suicidal behavior, depressed mood, and other mental health symptoms.

The FDA approved Chantix in May 2006 as a smoking-cessation drug. It acts in areas of the brain affected by nicotine and may ease withdrawal symptoms and block the effects of nicotine if users resume smoking.

On Friday, FDA officials advised patients to tell their doctor about any history of psychiatric illness before starting Chantix. The drug can cause current psychiatric illness to get worse even if it is under control. Chantix may also cause the recurrence of an old psychiatric illness, the officials warned.

Patients should also report changes in mood and behavior to their doctor. Symptoms to look out for include anxiety, nervousness, tension, depressed mood, unusual behaviors and thinking about or attempting suicide, the FDA officials said.

In most cases, these symptoms developed while taking Chantix, but they can also appear after stopping the drug, the officials noted.

"We are continuing with the review process over the next several months as we try to pin down to what extent these problems are being seen with Chantix," Rappaport said.

Vivid, unusual, or strange dreams may occur while taking the drug. Patients may also experience impaired ability to drive or operate heavy machinery, the officials said.

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