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Suicidal Thinking Reported With Chantix

FDA, Pfizer Investigating Reports of Suicidal Thoughts in People Taking Quit-Smoking Drug Chantix

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WebMD Medical News

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Nov. 20, 2007 -- The FDA today announced that it's investigating reports of suicidal thinking, aggressive and erratic behavior, and drowsiness in people taking the quit-smoking drug Chantix.

Here are the FDA's recommendations:

- ❖ Health care workers should monitor patients taking Chantix for behavior and mood changes.
- ❖ Patients taking Chantix should contact their doctors if they experience behavior or mood changes.
- ❖ Patients should use caution when driving or operating machinery until they know how Chantix may affect them.

Chantix, [which the FDA approved in May 2006](#), is made by the drug company Pfizer.

FDA Eyeing Chantix

The FDA says Pfizer recently submitted to the FDA reports describing suicidal thinking and "occasional suicidal behavior" in people taking Chantix following the drug's approval.

The FDA is investigating "approximately 100 cases" of suicidal thinking, Bob Rappaport, MD, tells WebMD. He directs the FDA's Division of Anesthesia, Analgesia, and Rheumatology Products.

The FDA states that its preliminary assessment shows that in many cases, the patients' [depression](#), suicidal thinking, and emotional and behavioral changes began within days or weeks of starting Chantix.

But the FDA doesn't yet know if Chantix caused those problems, and Rappaport says the FDA doesn't yet have a firm number on the cases of behavioral changes not related to suicide.

Nicotine withdrawal has been tied to a worsening of underlying psychiatric illnesses. But not all of the patients in the reported cases had pre-existing psychiatric illnesses and not all of them had quit smoking, according to the FDA.

The FDA also says it's aware of a highly publicized report of erratic behavior leading to the death of a patient using Chantix to attempt to quit smoking.

Although other factors, including alcohol consumption, appear to have played a part in that specific case, the FDA asked Pfizer for additional cases that might be similar. The FDA is reviewing that material.

The FDA is also evaluating reports from Pfizer of drowsiness in patients taking Chantix. In those cases, people said their drowsiness impaired their ability to drive or operate machinery.

"We received a relatively small number of cases, but they all describe very similar situations where the patient said they felt drowsy and felt like it was difficult for them to drive," the FDA's Celia Winchell, MD, tells WebMD.

She is the team leader for the Addiction Drug Products branch of the FDA's Division of Anesthesia, Analgesia, and Rheumatology Products.

The FDA and Pfizer are working on the investigation. A Pfizer spokesperson wasn't immediately available for comment.

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