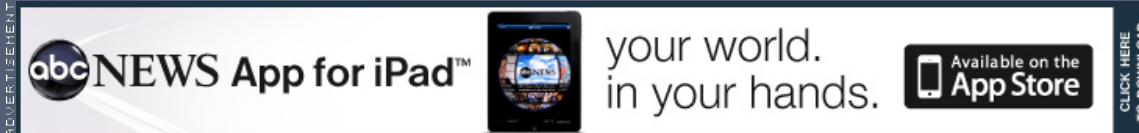


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# FDA Should Warn Smokers of Increased Danger of Chantix, Study Says



Psychological side effects linked to Chantix make it too dangerous to use as a first-line treatment for smoking, study says. (JB Reed/Bloomberg News/Getty Images)



By CARRIE GANN (@carrie\_gann), ABC News Medical Unit

Nov. 3, 2011

Scientists say the U.S. Food and Drug Administration (FDA) should take warnings about the stop-smoking drug Chantix up a notch, citing data showing that the drug increases suicidal behavior and depression far more than other drugs and methods designed to help smokers quit.

Chantix, also called varenicline, has been hotly debated since 2007, when experts first raised questions about the long-term safety of the drug and its connection to cardiovascular problems and vision lapses. Since then, studies have reported that patients taking Chantix are at increased risk of depression and suicidal thoughts. Anecdotally, patients report wild dreams, inexplicable violent behavior and other

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psychological disturbances while on the drug.

In 2009, the FDA placed a "black box" warning label on Chantix and another drug, Zyban, cautioning doctors and patients about the risk of depression, hostility and suicidal thoughts.

But some researchers say these warnings don't go far enough. Today, a study published in the journal PLoS One continued to sound the alarm against Chantix and urged the FDA to update Chantix's warning label, saying the psychological risks of the drug exceed those of nicotine replacement drugs or even its competitor, Zyban.

Dr. Curt Furberg, a professor of public health sciences at Wake Forest Baptist Medical Center and one of the study's authors, said people trying to kick their tobacco habit generally are at higher risk for psychological symptoms, but Chantix makes them far worse.

"The dramatic increase of these symptoms is caused by the drug. Among all the treatments we have for smoking cessation, Chantix is the worst," Furberg said.

In the study, Furberg and his colleagues analyzed more than 3,000 reports of suicidal behaviors or depression in people taking Chantix, Zyban, or nicotine replacement drugs, which were reported to the FDA through its Adverse Event Reporting System from 1998 through September 2010. Of those reports, 90 percent were linked to Chantix. In reports of completed suicides of people taking these stop-smoking treatments, the study said 92 percent were associated with Chantix.

"The FDA's own data show that Chantix is more dangerous than other treatments to stop smoking," Furberg said.

The FDA is unmoved by this latest report. A spokeswoman for the agency said the drug is a safe and effective way to help smokers quit. Additionally, the agency noted that this latest study failed to account for an uptick in reports of psychological side effects from Chantix that occurred as media coverage of the drug increased since 2007.

Pfizer, Chantix's manufacturer, also took issue with the data Furberg and his colleagues used in their study, saying that their reports of negative side effects are unreliable.

"Post-marketing reports can come from any source ranging from patients to healthcare providers, and from phone calls to internet postings and lawyers. Often these reports lack sufficient medical information to enable meaningful assessment," the company said in a statement.

Pfizer also noted that at the FDA's request, the company is conducting a

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clinical trial to study the link between Chantix and psychological side effects. The results are expected in 2017.

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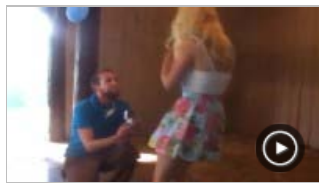
I'm here to tell you this stuff definitely works BUT you'll pay a price for using it - about 2 weeks into it I began having the most vivid dreams you'd ever imagine ... not pleasant dreams either! It became way too obvious to me that this stuff might help you quit smoking (and it will help with that I admit) ... but the strange thoughts, mood swings, and vivid scary dreams were way too much for me! I stopped using it - dreams went away immediately!

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