

Early Communication About an Ongoing Safety Review Varenicline (marketed as Chantix)

This information is not current. The FDA has issued new information about this safety issue, please see <http://www.fda.gov/cder/drug/infopage/varenicline/default.htm>

This information reflects FDA's current analysis of available data concerning these drugs. Posting this information does not mean that FDA has concluded there is a causal relationship between the drug products and the emerging safety issue. Nor does it mean that FDA is advising health care professionals to discontinue prescribing these products. FDA is considering, but has not reached a conclusion about whether this information warrants any regulatory action. FDA intends to update this document when additional information or analyses become available.

FDA has received reports of suicidal thoughts and aggressive and erratic behavior in patients who have taken Chantix, a smoking cessation product.

Suicidal Thoughts

The manufacturer of Chantix, Pfizer, Inc., recently submitted to FDA postmarketing cases describing suicidal ideation and occasional suicidal behavior. FDA currently is reviewing these cases, along with a number of recent reports in the popular press and internet sites. A preliminary assessment reveals that many of the cases reflect new-onset of depressed mood, suicidal ideation, and changes in emotion and behavior within days to weeks of initiating Chantix treatment. The role of Chantix in these cases is not clear because smoking cessation, with or without treatment, is associated with nicotine withdrawal symptoms and has also been associated with the exacerbation of underlying psychiatric illness. However, not all patients described in these cases had pre-existing psychiatric illness and not all had discontinued smoking.

Aggressive and Erratic Behavior

FDA is aware of a highly-publicized case 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 this specific case, FDA asked Pfizer for additional cases that might be similar. We are currently evaluating the material Pfizer submitted in response to our request.

Drowsiness

FDA is evaluating reports from Pfizer of drowsiness in patients taking Chantix. Reports described patients who experienced drowsiness that affected their ability to drive or operate machinery.

FDA recommends the following:

- Healthcare professionals 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 quitting smoking with Chantix may affect them.

This early communication is in keeping with FDA's commitment to inform the public about its ongoing safety reviews of drugs. FDA is working with Pfizer, Inc., to further evaluate the potential association between Chantix and suicidal thoughts, aggressive and erratic behavior, and impairment that affects one's ability to drive or operate machinery. FDA is working to complete the analysis of the materials submitted by Pfizer. As soon as this analysis is completed, FDA will communicate its conclusions and recommendations to the public.

The FDA urges both healthcare professionals and patients to report side effects from the use of Chantix to the FDA's MedWatch Adverse Event Reporting program

- online at www.fda.gov/medwatch/report.htm
- by returning the postage-paid FDA form 3500 available in PDF format at www.fda.gov/medwatch/getforms.htm to 5600 Fishers Lane, Rockville, MD 20852-9787
- faxing the form to 1-800-FDA-0178
- by phone at 1-800-332-1088

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