

# Chantix (varenicline) and Zyban (bupropion): Drug Safety Communication - Mental Health Side Effects Revised

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**AUDIENCE:** Internal Medicine, Pharmacy, Psychiatry

**ISSUE:** Based on an FDA review of a large clinical trial that FDA required the drug companies to conduct, FDA determined the risk of serious side effects on mood, behavior, or thinking with the stop-smoking medicines Chantix (varenicline) and Zyban (bupropion) is lower than previously suspected. The risk of these mental health side effects is still present, especially in those currently being treated for mental illnesses such as depression, anxiety disorders, or schizophrenia, or who have been treated for mental illnesses in the past. However, most people who had these side effects did not have serious consequences such as hospitalization. The results of the trial confirm that the benefits of stopping smoking outweigh the risks of these medicines. See the [Drug Safety Communication \(/Drugs/DrugSafety/ucm532221.htm\)](#) for a data summary.

As a result of the large clinical trial review, FDA is removing the Boxed Warning, FDA's most prominent warning, for serious mental health side effects from the Chantix drug label. The language describing the serious mental health side effects seen in patients quitting smoking will also be removed from the Boxed Warning in the Zyban label. FDA is also updating the existing warning section in both labels that describes the side effects on mood, behavior, or thinking to include the results from the clinical trial. This decision is consistent with the recommendations of external experts at a September 2016 FDA Advisory Committee meeting. The patient Medication Guide that explains the risks associated with the use of the medicines will continue to be provided with every patient prescription; however, the risk evaluation and mitigation strategy (REMS) that formally required the Medication Guide will be removed.

**BACKGROUND:** FDA review of the clinical trial results also confirmed that Chantix, Zyban, and nicotine replacement patches were all more effective for helping people quit smoking than was an inactive treatment called a placebo. These medicines were found to better help people quit smoking regardless of whether or not they had a history of mental illness.

**RECOMMENDATION:** Health care professionals should counsel patients about the benefits of stopping smoking and how they can get help to quit, and discuss the benefits and risks of using medicines to help them quit smoking.

Patients should stop taking Chantix or Zyban and call their health care professionals right away if they notice any side effects on mood, behavior, or thinking. Patients should also talk to their health care professionals for help and information about stopping smoking, including about whether stop-smoking medicines may help or if they have any questions or concerns about taking a medicine (See Related Information for more quit smoking resources).

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: [www.fda.gov/MedWatch/report](http://www.fda.gov/MedWatch/report) (<http://www.fda.gov/MedWatch/report>)
- [Download form \(/Safety/MedWatch/HowToReport/DownloadForms/default.htm\)](/Safety/MedWatch/HowToReport/DownloadForms/default.htm) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[12/16/2016 - [Drug Safety Communication \(/Drugs/DrugSafety/ucm532221.htm\)](/Drugs/DrugSafety/ucm532221.htm) - FDA]

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