



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

[Posted 12/16/2016]

FDA 審視大型的臨床試驗，藉以評估戒菸藥物 Chantix (varenicline) 和 Zyban (bupropion) 在沒有和有精神疾病病史的患者中，其神經精神方面的安全性，結果證實戒菸藥品 Chantix (varenicline) 和 Zyban (bupropion) 在情緒、行為和思維等嚴重副作用風險低於先前的懷疑。神經精神症狀的副作用風險仍存在，尤其是目前正接受治療的精神疾病患者，如憂鬱症、躁鬱症、精神分裂症；或是過去曾接受過治療的精神疾病患者。然而，大部分經歷情緒、行為和思維等副作用的人沒有引發更嚴重後果，如導致住院或死亡。故臨床試驗的結果證實戒菸的益處大於戒菸藥物可能產生的副作用風險。

FDA 因此刪除 Chantix (varenicline) 和 Zyban (bupropion) 於仿單上標註「戒菸者可能經歷嚴重的神經精神症狀」的黑框警示，同時也更新 Chantix (varenicline) 和 Zyban (bupropion) 仿單上現有的警語，即臨床試驗的結果，可能經歷情緒、行為和思維等副作用風險。這項決定與 FDA 諮詢委員會外部專家的建議一致。

### **建議**

醫療人員應該告訴患者戒菸的益處，以及如何尋求戒菸的幫助，並與患者討論使用戒菸藥物的利弊風險。

使用戒菸藥物 Chantix (varenicline) 和 Zyban (bupropion) 的患者，如果察覺有情緒、行為和思維等副作用時，應立即停用藥品並盡速告知醫療人員。

## **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 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).