

US drops bold warning from anti-smoking pills Chantix, Zyban

December 16 2016, by Matthew Perrone

U.S. health regulators on Friday removed a bold-letter warning from Pfizer's anti-smoking drug Chantix about risks of dangerous psychiatric side effects.

The Food and Drug Administration action follows nearly a decade of scrutiny into the neurological effects of the smoking-cessation pill, which received the agency's most stringent warning in 2009 after reports of suicidal tendencies, hostility and depression among some patients.

The FDA decision stems from an 8,000-patient study of smokers that found no elevated risk of psychiatric problems among Chantix users who had no prior history of mental illness. European regulators previously removed their own warning from the drug based on the same data.

The study was jointly funded by Pfizer and GlaxoSmithKline PLC, which markets a competing smoking-cessation drug, Zyban. The FDA also removed similar warning language about psychiatric events from Zyban's label, according to an agency statement.

Chantix and Zyban will still list reports of psychosis, paranoia, anxiety and other problems on their labels. But those problems will not be highlighted in a so-called black box warning, a prominent [warning](#) displayed at the top of FDA drug labels.

"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," the FDA stated in an online post.

Quitting smoking, with or without medication, can cause significant withdrawal symptoms, including irritability, mood swings and depression. In addition, psychiatric conditions are more common in smokers than nonsmokers.

Many doctors and smokers trying to quit were scared off by warnings on Chantix and Zyban, about "changes in behavior, hostility, agitation, depressed mood, and suicidal thoughts or actions" in some patients.

Pfizer's drug works by binding to the same spots in the brain that are activated by nicotine when people smoke. The drug, known generically as varenicline, blocks nicotine from binding to those spots and prevents the release of "feel-good" brain chemicals that make smoking so addictive.

Zyban is known generically as bupropion, an antidepressant [drug](#) long available in lower-cost versions.

Shares of New York-based Pfizer Inc. rose 9 cents to close at \$32.84.

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