

## **FDA: studies do not tie Chantix to mental problems**

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(AP) -- Federal health officials said Monday that Pfizer's anti-smoking drug Chantix did not increase psychiatric problems like depression and suicidal thoughts in two studies, though the findings are not definitive.

The Food and Drug Administration has been investigating reports of mood disorders and erratic behavior among Chantix patients since 2007. The agency said in a statement that two federally-funded studies involving more than 26,000 patients did not show an increased rate of psychiatric hospitalizations among Chantix patients, compared with those using nicotine patches and smoking cessation treatments.

FDA regulators stressed that the studies only recorded psychiatric problems that resulted in hospitalization, meaning many issues likely went unreported. Additionally, the studies by the Department of Veterans Affairs and the Department of Defense were not large enough to pick up very rare side effects.

Groups like the Federal Aviation Administration have already banned the drug for pilots and air traffic controllers due to side effects that could interfere with their work.

The agency said it is continuing to study the problems and recommends patients consult their doctors if they experience side effects with the drug. Pfizer is conducting its own large-scale study of Chantix behavioral effects, but the results won't be available until 2017.

"Healthcare professionals should advise patients and caregivers that the patient should immediately stop taking Chantix and contact a healthcare professional if agitation, hostility, depressed mood, or changes in behavior or thinking that are not typical for the patient are observed," the FDA said in an online statement.

More than 8.9 million people in the U.S. have filled prescriptions for Chantix since it was approved in May 2006. Last year Pfizer reported \$755 million in sales for the drug, a decline of 14 percent since its peak sales of \$883 million in 2007.

Shares of Pfizer Inc. rose 30 cents to \$19.36, tracking broader increases on the S&P 500.

Chantix works by binding to the same spots in the brain that nicotine does when people smoke, blocking nicotine from those spots but causing release of a "feel-good" chemical, dopamine. The drug's label already carries a boxed warning, the most serious type, listing possible side effects including hostility, agitation, depression and suicidal thoughts and behavior.

New York-based Pfizer Inc. said in a statement: "We are reviewing this important information for smokers provided by the FDA."

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