



May 22, 2008

F.A.A. Bans Antismoking Drug, Citing Side Effects

By STEPHANIE SAUL

The Federal Aviation Administration said Wednesday it would no longer permit pilots or air traffic controllers to use the smoking cessation drug Chantix, citing potential side effects that could pose a threat to the safe operation of aircraft.

The Food and Drug Administration issued a public health advisory in February, saying that some Chantix users had developed a variety of serious psychiatric symptoms, and that some had committed suicide.

An F.A.A. spokeswoman, Laura Brown, said the agency had approved the use of Chantix for airline pilots and flight controllers last year, but was notifying 150 pilots and 30 air traffic controllers known to be using it that the drug was no longer acceptable and should be discontinued.

Ms. Brown said the decision was based on emerging data on the drug, including a report from a watchdog group, the Institute for Safe Medication Practices, linking Chantix to a wide array of health and safety problems. They include accidents and falls, potentially lethal heart rhythm disturbances, heart attacks, seizures, diabetes and various psychiatric disturbances.

The institute's findings, which were based on an analysis of adverse events reported to the F.D.A., said that from May 2006 through December 2007, there were 227 reports of suicide attempts or suicides, 397 cases of possible psychosis and 525 reports of hostility or aggression. Those reports included 28 suicides and 41 mentions of homicidal thoughts, 60 cases of paranoia and 55 cases of hallucinations.

The data, the report said, "provide a strong signal" that the risks of treatment with varenicline, the active chemical in Chantix, have been underestimated. This year, Public Citizen's Health Research Group, another consumer watchdog organization, had called for a black-box warning — F.D.A.'s strongest drug alert — on Chantix.

Chantix, made by Pfizer, was approved in 2006 for sale in this country and the European Union. Worldwide sales of the drug were \$883 million last year, and an estimated 6.5 million people have used it.

Pfizer issued a statement Wednesday saying that the current labeling for Chantix reflected the product's safety profile, including warnings that it had the potential to cause psychiatric problems and might impair driving.

"There are few things that provide greater health benefits than quitting smoking," said the Pfizer statement, issued by a company spokesman, Francisco Gebauer. "When considering the use of Chantix for their patients, health care providers should discuss the risks of smoking, the health benefits of quitting smoking, and the product's efficacy and safety profile."

In after-hours trading Wednesday, Pfizer's shares fell 22 cents, to \$19.79, a 1.1 percent decline.

Dr. Timothy Anderson, a pharmaceutical analyst for Sanford C. Bernstein & Company, responded to Wednesday's report by downgrading estimates for Chantix sales in 2012, to \$700 million, from \$1.6 billion.

Chantix, taken in pill form, partly blocks and partly stimulates a nicotine receptor in the brain and in clinical studies was shown to help smokers quit. Potential problems associated with Chantix were first publicized last September when a Dallas musician, Jeffrey Carter Albrecht, was shot to death after he began behaving bizarrely while taking Chantix.

The Institute for Safe Medication Practices study noted that some of the reports of adverse events it analyzed could have been spurred by that publicity and by a November 2007 early warning about the drug from the F.D.A.

An F.D.A. spokeswoman, Susan Cruzan, said the agency was also conducting a special safety review of Chantix and was requiring pharmacists to distribute a medication guide to patients, warning of the potential side effects.

The F.A.A. was also planning to notify associations representing both commercial and private pilots that Chantix was no longer permitted, Ms. Brown said.

Copyright 2008 The New York Times Company

[Privacy Policy](#) | [Search](#) | [Corrections](#) | [RSS](#) | [First Look](#) | [Help](#) | [Contact Us](#) | [Work for Us](#) | [Site Map](#)
