New FDA label bolsters safety case for Chantix

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New government-approved labeling on Pfizer's drug Chantix suggests that the anti-smoking medication may not carry the risks of suicidal behavior that first earned it the Food and Drug Administration's strongest warning more than five years ago.

The FDA updated the drug's label Monday to include data from a number of recent studies that found little to no evidence of psychiatric problems or suicidal tendencies in patients taking the twice-a-day tablet.

The new labeling represents a victory for Pfizer Inc., which requested the update. Company executives say they will now ask the FDA to completely remove the drug's so-called "black box" label—the strongest type—which warns prescribers of links to hostility, agitation, depression and suicidal behavior.

"Based on all this new information, a boxed warning is not supported," said Pfizer senior vice president, Steve Romano, in an interview with The Associated Press. "The bottom line is that the label needs to reflect the most current understanding of the product's benefits and risks."

The FDA is convening a panel of its outside experts next month to review the latest data on Chantix's safety—prompted by Pfizer's request to update the label. The meeting comes more than a year after New York-based Pfizer paid $275 million last year to settle some 2,000 lawsuits alleging Chantix caused various psychiatric problems, injuries and suicides.

The FDA originally added the boxed warning about suicide in 2009, after receiving dozens of reports of suicide and hundreds of reports of suicidal behavior among patients taking the smoking-cessation drug.

At that time, the FDA also required Pfizer to conduct additional studies to determine the extent of the drug's psychiatric side effects.

The new drug labeling includes results of five Pfizer studies enrolling nearly 2,000 patients which showed no increase in suicidal tendencies based on a medical questionnaire. The FDA also updated the label with results from four large independent studies of between 10,000 and 30,000 Chantix users. Those studies found no difference in self-injury, hospitalization and other serious adverse events between people taking Chantix and those using other quit-smoking aids, including nicotine patches and the medication bupropion.

There were several limitations to these larger studies. First, they only recorded problems that resulted in hospitalization, meaning many issues likely went unreported. Additionally, the studies were conducted after news of Chantix's side effects had been widely reported, which means doctors may have steered patients with a history of psychiatric issues toward the alternate therapies.

The new FDA label isn't all positive. It also contains new information about risks of seizure and interactions with alcohol among Chantix 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 chemically as varenicline, blocks nicotine from binding to those spots and prevents the release of "feel-good" brain chemicals that make smoking so addictive.

The FDA first began investigating potential side effects with Chantix in 2007, the year after it hit the market.

The drug's labeling tells patients to stop taking Chantix immediately if they experience agitation, depressed mood, suicidal thinking and other behavioral changes. Doctors are advised to weigh the drug's risks against its potential benefit of helping patients quit smoking.

Chantix had global sales of $648 million last year. That was down about 26 percent from the drug's peak sales of $883 million in 2007.

Pfizer shares rose 28 cents to $30.34 in midday trading. It shares had slipped almost 2 percent through Tuesday's close since the start of the year.