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Safety advocates seek stronger warnings on Chantix (Update)

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Public safety advocates are asking the federal government to strengthen warnings on Pfizer's anti-smoking drug Chantix, even as the drugmaker prepares to argue that a bold-letter warning about psychiatric problems should be removed from the medicine's label.

Five advocacy groups petitioned the Food and Drug Administration on Wednesday to expand Chantix's boxed warning, calling for more detailed language about potential side effects like suicidal behavior, hostility and depression. The groups also say that the prominent warnings should include information about blackouts, convulsions and other problems reported in some patients.

"It would be illogical to discount the reports of thousands of consumers who told of frightening or destructive experiences with Chantix," states the petition, filed by Consumer Reports, Public Citizen, the National Center for Health Research, National Physicians Alliance and the Institute for Safe Medication Practices.

The groups urge the FDA to revisit the boxed warning, first added in 2009, arguing that it "substantially underestimated the psychiatric adverse effects and accident risks of Chantix." They also argue that Chantix should be contraindicated for people working in critical or hazardous occupations, like pilots, air traffic controllers, police and military personnel. The petition notes that the Federal Aviation Administration and the Department of Defense already restrict the use of Chantix among certain employees.

A spokesman for Pfizer Inc. noted that the petition is based on patient reports of injury "which have several limitations, including missing data, reporting biases, and no ability to determine that the adverse event was caused by the drug." The company reiterated that its own studies "do not show evidence of an increased risk of serious neuropsychiatric events" in patients taking Chantix, versus other smoking-cessation products.

The move by safety advocates comes just over a week before the FDA meets publicly to review Chantix's risks. Pfizer has conducted several studies showing no link between its drug and suicidal behavior and the FDA added information from those studies to the drug's label last month. Company executives say they plan to use next Thursday's FDA advisory panel meeting to argue that the boxed warning is no longer warranted. The FDA will hear input from the company, a panel of outside experts and members of the public.

New York-based Pfizer has paid roughly $300 million to settle more than 2,500 lawsuits alleging that Chantix caused various psychiatric problems, injuries and suicides. Two experts who studied Chantix for the Institute for Safe Medication Practices—one of the petitioning groups—also served as paid expert in the litigation against Pfizer.

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.

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.

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 59 cents to $29.38. Its shares are down more than 4 percent in the year to date.