



## Pilots, air-traffic controllers, truck and bus drivers barred from taking smoking-cessation drug varenicline

MAY 23, 2008 | Shelley Wood

**Washington, DC** - The US governmental body in charge of civil aviation safety—the **Federal Aviation Administration** (FAA)—announced May 21 that pilots and air-traffic controllers are no longer permitted to take the smoking-cessation drug **varenicline** (Chantix, Pfizer). The move follows an **FDA** public-health advisory, issued earlier this year, warning of a suicide risk, aggressive or erratic behavior, and other serious psychiatric symptoms in people taking the drug.

And on May 22, the US **Federal Motor Carrier Safety Administration**, which oversees the interstate trucking and bus industry, followed suit, issuing a warning advising medical examiners to not qualify anyone currently using varenicline for commercial motor vehicle licenses.

FAA spokesperson **Les Dorr** told **heartwire** that the organization had previously permitted pilots and air-traffic controllers to take the drug; by their estimate, about 150 pilots and 30 air-traffic controllers were taking varenicline at the time of the group's decision. They have now been told to stop taking it and to stay away from work for 72 hours, Dorr said.

Dorr explained that the FAA had made the decision in response to a recent report issued by the **Institute for Safe Medication Practices** (ISMP) [1] and based on adverse-event reports collected by the FDA. According to the ISMP report, there were 227 domestic reports of suicidal acts, thoughts, or behaviors; 397 cases of possible psychosis; and 525 reports of hostility or aggression in people taking varenicline. Included in these totals were 28 suicides, 41 "mentions of homicidal ideation," 60 cases of paranoia, and 55 cases of hallucination. Moreover, the report also cites "other kinds of serious harm for which no warnings now exist," either from the company or the FDA. These include accidents and injuries (173 events); vision disturbances (148 events); heart-rhythm disturbances (224 events); seizures and muscle spasms/movements (458 cases); skin reactions (338 cases); and diabetes (544 cases).

Authors of the report, led by ISMP senior scientist **Thomas J Moore**, conclude: "We have immediate safety concerns about the use of varenicline among persons operating aircraft, trains, buses, and other vehicles or in other settings where a lapse in alertness or motor control could lead to massive, serious injury."

According to Dorr, it was a member of the press that alerted the FAA to the ISMP's report and, after taking a day to review the findings and consulting with the FAA's Civil Aerospace Medical Institute, in Oklahoma City, OK, the federal air surgeon recommended that the FAA ban the use of the drug by pilots and controllers. It has also contacted other aviation groups to "spread the word" about the decision.

"Obviously, we are always open to new data," Dorr said, adding that the administration would continue to consider any new data. That said, he added, "if we're going to err, we're going to err on the side of caution."

In response, Pfizer has issued a statement, quoted in the *New York Times* [2], pointing out that the labeling for its product includes warnings about its potential to trigger psychiatric problems and to impair driving. The

company also highlights the health benefits of quitting smoking and suggests that these must be weighed against the drug's risks.