HEALTH REPORT

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STOP SMOKING DRUG MAY BE SOURCE OF SUICIDAL THOUGHTS, BEHAVIORAL CHANGES

The smoking cessation drug Chantix from Pfizer Inc. has been on the market for only 18 months and it is already the subject of a U.S. Food and Drug Administration "Safety Alert." The FDA advisory informed doctors, healthcare professionals and patients about reports of suicidal thoughts, aggressive actions and erratic behavior in persons using the drug as part of their attempts to stop smoking.

The FDA advisory states the following in addition to suicidal thoughts and altered behavior: "There are also reports of patients experiencing drowsiness that affected their ability to drive or operate machinery. The FDA is currently reviewing these cases, along with other recent reports. A preliminary assessment reveals that many of the cases reflect new-onset of depressed mood, suicidal ideation, and changes in emotion and behavior within days to weeks of initiating a treatment of Chantix. The role of Chantix in these cases is not clear because smoking cessation, with or without treatment, is associated with nicotine withdrawal symptoms and has also been associated with the exacerbation of underlying psychiatric illness. However, not all patients described in the cases had pre-existing psychiatric illness and not all had discontinued smoking."

It's quite likely that television viewers are becoming very familiar with Chantix ads that depict a "tortoise and hare" race to emphasize the benefits of the slow road to quitting smoking. According to the "Patient Information Sheet" posted by the FDA, a Chantix program begins by taking the drug for 7 days prior to a "quit date." It states that this allows time for the drug to build up in the body while the user continues to smoke. Patients are advised to take Chantix for at least 12 weeks and then ask their doctor if they may benefit from another 12 weeks of treatment.

While the FDA is collecting and evaluating further data, Chantix will continue to be available and marketed in the US. It is important that doctors, healthcare professionals and users of the drug be aware that suicidal thoughts, erratic behavior and aggressive tendencies have been noted by patients. One such case involved a Chantix user who was shot dead while attempting to break into a neighbor's home in Texas.

Persons who have adverse reactions are encouraged to present their own data to the FDA to be included in the upcoming evaluation of Chantix and its fitness for the market. Send personal accounts to the FDA's MedWatch Adverse Event Reporting program on-line at www.fda.gov/medwatch/report.htm.

Source: The U.S. Food and Drug Administration. November 2007. http://www.fda.gov/medwatch/safety/2007/safety07.htm#Chantix, http://www.fda.gov/cder/drug/early_comm/varenicline.htm, and http://www.fda.gov/cder/drug/InfoSheets/patient/varenicline PIS.htm.