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Date: 6/4/08

Re: ***IMPORTANT--PLEASE READ--
 CHANTIX***

cc:

Urgent For Review Please Comment Please Reply Please Recycle

Below you will find the statement by FMCSA concerning the prescription medication Chantix

YOUR DOT DOCTORS NEED TO HAVE A COPY OF THIS. PLEASE PRINT THIS OFF AND GIVE TO THE CLINIC PERSONNEL. THE FMCSA NO LONGER WANTS THE MEDICAL EXAMINERS TO CLEAR ANYONE TAKING THIS MEDICATION. PLEASE MAKE SURE YOUR CLINICS HAVE THIS AND ARE AWARE OF THE NEW RULING.

Friday, May 23, 2008

FMCSA ISSUES WARNING ADVISORY ON USE OF PRESCRIPTION DRUG BY DRIVERS

There has been a lot of confusion in the media recently about Chantix (Varenicline), a prescription drug that the Federal Aviation Administration has now banned for pilots.

The Wall Street Journal reported on May 23rd that the Federal Motor Carrier Safety Administration had banned the drug for commercial drivers. Late in the day on May 23rd, FMCSA issued a statement (below) that clarifies that report. Also, please find, below this FMCSA statement, the FDA advisory about Chantix. FMCSA's May 23, 2008 Statement

"The Federal Motor Carrier Safety Administration's (FMCSA) regulations for the medical qualification of interstate truck and bus drivers prohibit the use of prescribed substances or drugs that adversely affect the driver's ability to safely operate a commercial motor vehicle."

"The U.S. Food and Drug Administration (FDA) approves medications for use, and has recently issued a public health advisory on Chantix (Varenicline). FMCSA's rules defer to the physicians and health care professionals to determine driver medical fitness for duty, which includes when a medication has actual and potential side effects that could impact safe driving."

"While we do not name any medications, such as Chantix, in FMCSA regulations, it appears that medical examiners should not certify a driver taking Chantix because the medication may adversely affect the driver's ability to safely operate a commercial motor vehicle."

"We are committed to ensuring safety on America's highways and we will continue our ongoing effort to review all FMCSA medical standards, including prescription drugs."

The FDA's May 16 advisory

Public Health Advisory -- Important Information on Chantix (varenicline)

[5/16/2008]: The issues described in this communication have been addressed in the product labeling and FDA has approved the Medication Guide. If either you, your family or caregiver notice agitation, depressed mood, or changes in behavior that are not typical for you, or if you have suicidal thoughts or actions, stop taking Chantix and call your doctor right away

FDA is issuing this public health advisory to alert patients, caregivers, and healthcare professionals to important changes to Chantix prescribing information. Chantix is a medicine used to help patients stop smoking.

At the request of FDA, Pfizer, the manufacturer of Chantix, has updated the Chantix prescribing information to include warnings about the possibility of severe changes in mood and behavior in patients taking Chantix. FDA is highlighting the following related important safety information on Chantix:

Patients should tell their doctor about any history of psychiatric illness prior to starting Chantix. Chantix may cause worsening of a current psychiatric illness even if it is currently under control and may cause an old psychiatric illness to reoccur.

Healthcare professionals, patients, patients' families, and caregivers should be alert to and monitor for changes in mood and behavior in patients treated with Chantix. Symptoms may include anxiety, nervousness, tension, depressed mood, unusual behaviors and thinking about or attempting suicide. In most cases, neuropsychiatric symptoms developed during Chantix treatment, but in others, symptoms developed following withdrawal of varenicline therapy.

Patients taking Chantix should immediately report changes in mood and behavior to their doctor. Patients taking Chantix may experience vivid, unusual, or strange dreams. Patients taking Chantix may experience impairment of the ability to drive or operate heavy machinery.

While Chantix has demonstrated clear evidence of efficacy, it is important to consider these safety concerns and alert patients that they are possible.

FDA first informed the public about the possibility of severe changes in mood and behavior in the November 20, 2007 FDA Early Communication About an Ongoing Safety Review. At that time, information about severe changes in mood and behavior in patients taking Chantix was added to the Chantix label with an explanation that the link between Chantix and these symptoms was unclear. As FDA's review of the data has progressed it has become increasingly likely that the severe changes in mood and behavior may be related to Chantix. As a result, FDA worked with Pfizer, the manufacturer of Chantix, to add warnings to the Chantix label about the possibility of severe changes in mood and behavior so healthcare professionals and patients can be more alert to this information. In addition, FDA is working with Pfizer to finalize a Medication Guide for patients.

FDA will update the public about any new information from FDA's continuing review of the data or new information that it receives on Chantix and severe changes in mood and behavior. FDA may consider additional changes to the Chantix prescribing information as the data review and conclusions warrant.