



PFIZER RESPONDS TO ANALYSIS IN *PLoS ONE*, AN ONLINE PUBLICATION OF THE PUBLIC LIBRARY OF SCIENCE

Background

An analysis of CHANTIX post-marketing reports was published in the November 2 edition of the journal *PLoS One*, an online publication of the Public Library of Science. Authors Moore, Furberg and Singh suggest that CHANTIX is unsuitable for first-line use.

NEW YORK, N.Y., November 2, 2011 - Pfizer Inc. reaffirms the importance of CHANTIX (varenicline) as a first line treatment option for adult smokers who want to quit. The analysis of post-marketing reports by Moore et al, made available on line today in *PLoS One* does not offer reliable scientific information. Pfizer stands behind the benefit-risk profile of CHANTIX.

The US Food and Drug Administration (FDA) stated on October 24 in a Drug Safety Communication that "based on FDA's assessment of currently available data, the Agency continues to believe that the drug's benefits outweigh the risks and current warnings in the CHANTIX label are appropriate." This statement was issued in connection with the results of two FDA-sponsored observational studies conducted by the Department of Veterans Affairs and the Department of Defense.

The analysis by Moore et al is based solely on post-marketing reports of adverse events that have been available to the FDA for some time. Post marketing reports do not establish a cause and effect relationship between a medicine and a reported adverse event. These reports can come from any source ranging from patients to healthcare providers, and from phone calls to internet postings. Often these reports lack sufficient medical information to enable a meaningful

assessment. Due to these limitations, any conclusions based on comparisons between different drugs and reporting rates are not reliable.

Clinical trial information provides more reliable data; results from CHANTIX clinical trials to date do not show that CHANTIX causes these reported serious neuropsychiatric events. Pfizer is committed to studying CHANTIX in patients with a history of neuropsychiatric illnesses. Recently, Pfizer completed a small study of CHANTIX use in smokers with stable schizophrenia, results of which are available on clinicaltrials.gov. A study to evaluate the safety and efficacy of CHANTIX for smoking cessation in patients with depression is currently underway and results are expected in late 2012. Importantly, Pfizer is conducting a large, double blind placebo controlled safety clinical trial of CHANTIX to assess neuropsychiatric safety in patients with and without psychiatric disorders, and results of this large study are expected in 2017.

The health benefits of quitting smoking are immediate and substantial. Given the significant public health risks of smoking, treatment options are needed. CHANTIX is recommended as a first-line aid to smoking cessation treatment by the US Public Health Service in its Clinical Practice Guideline.

About CHANTIX

CHANTIX was approved by the FDA in May 2006 as an aid to smoking cessation treatment in adults 18 and older. CHANTIX has been shown to increase the likelihood of abstinence from smoking for as long as one year compared to treatment with placebo. Adults who smoke may benefit from quit smoking support programs and/or counseling during their quit attempt. It's possible that patients might slip up and smoke while taking CHANTIX. If patients slip up, they can stay on CHANTIX and keep trying to quit. The prescribing information for CHANTIX can be obtained at <http://labeling.pfizer.com/ShowLabeling.aspx?id=557>.

IMPORTANT SAFETY INFORMATION

Some people have had changes in behavior, hostility, agitation, depressed mood, suicidal thoughts or actions while using CHANTIX to help them quit smoking. Some people had these symptoms when they began taking CHANTIX, and others developed them after several weeks of treatment or after stopping CHANTIX. If you, your family or caregiver notice agitation, hostility, depression or changes in behavior, thinking, or mood that are not typical for you, or you develop suicidal thoughts or actions, anxiety, panic, aggression, anger, mania, abnormal sensations, hallucinations, paranoia or confusion, stop taking CHANTIX and call your doctor right away. Also tell your doctor about any history of depression or other mental health problems before taking CHANTIX, as these symptoms may worsen while taking CHANTIX.

Some people can have serious skin reactions while taking CHANTIX, some of which can become life-threatening. These can include rash, swelling, redness, and peeling of the skin. Some people can have allergic reactions to CHANTIX, some of which can be life-threatening and include: swelling of the face, mouth, and throat that can cause trouble breathing. If you have these symptoms or have a rash with peeling skin or blisters in your mouth, stop taking CHANTIX and get medical attention right away.

If you have a history of cardiovascular disease, tell your doctor if you experience new or worsening cardiovascular symptoms. You should seek immediate medical attention if you experience signs or symptoms of a heart attack.

The most common side effects include nausea (30%), sleep problems, constipation, gas and/or vomiting. If you have side effects that bother you or don't go away, tell your doctor. You may have trouble sleeping, vivid, unusual or strange dreams while taking CHANTIX. Use caution driving or operating machinery until you know how CHANTIX may affect you.

CHANTIX should not be taken with other quit smoking products. A lower dose of CHANTIX may be necessary in patients with kidney problems or who get dialysis.

Before starting CHANTIX, patients should tell their doctors if they are pregnant, plan to become pregnant, or if they take insulin, asthma medicines, or blood thinners. Medicines like these may work differently when patients quit smoking.

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