



Media Statement

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Pfizer Statement Regarding Recent Analysis of Chantix Cardiovascular Events in the Canadian Medical Association Journal

Pfizer strongly believes in and supports Chantix as an important treatment option.

Pfizer disagrees with the interpretation of the data put forth by Singh et al in the Canadian Medical Association Journal. The analysis contains several limitations; most notably that it is based on a small number of events, which raises concerns about the reliability of the authors' conclusions. The authors acknowledge that their risk "estimates are imprecise owing to the low event rates."

The actual difference in cardiovascular event rates seen in the Singh analysis was less than one quarter of one percent (i.e., 1.06 percent with varenicline versus 0.82 percent with placebo). The health benefits of quitting smoking are immediate and substantial. Smoking is a major risk factor for cardiovascular disease, which can lead to heart attack, stroke and peripheral arterial disease. Each year, an estimated 5.4 million people worldwide die from smoking related causes.

Pfizer works with regulators, like the U.S. Food and Drug Administration (FDA), on a continual basis to review and monitor data for Chantix. In particular, we are working with FDA to conduct a combined analysis of clinical trial data (meta-analysis), which will help further evaluate the cardiovascular safety of Chantix.

Chantix is an important treatment option for smokers who want to quit. Patients should consult with their health care providers to determine what medications are right for them.

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. Nearly 13 million people have been prescribed CHANTIX worldwide.

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.

The most common side effects include nausea (30 percent), 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.

About Smoking

Tobacco use is a risk factor for six of the eight leading causes of death in the world, including heart disease, cancer, and chronic obstructive pulmonary disease.^{5,6} Smoking-related illness is the leading preventable cause of death in the United States, killing more than 443,000 people each year.^{7,8}

For more information, please visit:

www.pfizer.com/files/products/uspi_chantix.pdf for [full Prescribing Information](#) and http://www.pfizer.com/files/products/ppi_chantix.pdf for [Patient Medication Guide](#).

The EU Summary of Product Characteristics (SmPC) may be found at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000699/human_med_000696.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001d124

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Founded in 1849, Pfizer is the world's premier biopharmaceutical company taking new approaches to better health. We discover, develop, manufacture and deliver quality, safe and effective prescription medicines to treat and help prevent disease for both people and animals. We also partner with healthcare providers, governments and local communities around the world to expand access to our medicines and to provide better quality health care and health system support. At Pfizer, more than 80,000 colleagues in more than 90 countries work every day to help people stay happier

and healthier longer and to reduce the human and economic burden of disease worldwide.

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References

1. Pfizer data on file.
2. European Medicines Agency website. Committee for Medicinal Products for Human Use (CHMP): Monthly report. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/Committee_meeting_report/2011/03/WC500104259.pdf. Last accessed 22.06.11.
3. Tobacco Addiction, Disease Control Priorities Project, April 2006
4. Tobacco Free Initiative (TFI), World Health Organization (WHO). Facts and Figures About Tobacco, June 2007
5. World Health Organization. WHO Report on the Global Tobacco Epidemic, 2008: The MPOWER Package. Geneva, Switzerland: World Health Organization; 2008.
6. Mathers CD, Loncar D. Projections of global mortality and burden of disease from 2002 to 2030. PLoS Medicine, 2006;3(11):e442. (Additional information obtained from personal communication with CD Mathers).
7. Centers for Disease Control and Prevention. Surgeon General's 2004 Report: The health consequences of smoking on the human body. Centers for Disease Control and Prevention, U.S. Dept of Health and Human Services, Rockville, MD:2004.
8. Centers for Disease Control and Prevention. Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses- United States, 2000-2004. MMWR. 2008; 57(45); 1226-1228