



Media Statement:  
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**Statement Regarding FDA Advisory Committees' Vote on  
CHANTIX<sup>®</sup>**

NEW YORK October 16, 2014 - Today, the U.S. Food and Drug Administration's (FDA) joint Psychopharmacologic Drugs and Drug Safety and Risk Management Advisory Committees voted that the FDA should wait until the completion of a Pfizer-sponsored, post-marketing requirement, Phase 4 clinical trial - anticipated in 2015 - to reassess removal of the Boxed Warning statements regarding the risk of serious neuropsychiatric events from the CHANTIX<sup>®</sup> (varenicline) label. The Committees discussed analyses of controlled clinical trial data and several large observational studies, which were added to the CHANTIX label in September. The FDA will take this vote into consideration when making a final determination.

Pfizer believes these data do not show evidence of an increased risk of serious neuropsychiatric events with CHANTIX compared to placebo or other smoking cessation medications, including prescription nicotine replacement therapies (NRT).

"Given the considerable health risks associated with smoking, and the substantial and immediate health benefits of quitting,<sup>1,2</sup> it

is vital that physicians and smokers are fully informed of the data included in the label, which we believe can help address concerns about the neuropsychiatric safety profile of CHANTIX," said Dr. Steven Romano, Senior Vice President and Head, Medicines Development Group, Pfizer Global Innovative Pharmaceutical Business. "The completion of our currently ongoing safety study will represent one more step forward in the process of accurately characterizing the neuropsychiatric safety of this important medication. CHANTIX is a highly effective aid to smoking cessation treatment for smokers who want to quit."

The additional CHANTIX safety study being awaited by the FDA Advisory Committees is a post-marketing requirement, Phase 4, randomized, double blind, placebo and active-controlled clinical trial, known as EAGLES, conducted by Pfizer. This study, involving 8,000 smokers, is evaluating the neuropsychiatric safety of CHANTIX versus placebo, NRT and bupropion in patients with and without prior history of psychiatric conditions. Results are expected in 2015.

The Boxed Warning, which was included in the CHANTIX label in 2009, was based on post-marketing reports of serious neuropsychiatric events. Post-marketing reports do not reliably establish a causal relationship to drug exposure. The data presented today by Pfizer, and recently included in the label, are from analyses of controlled clinical trials and observational studies that were specifically conducted to further evaluate this association.

The Advisory Committees' vote comes on the heels of FDA approval of updates to the Warnings and Precautions section of the CHANTIX label regarding the risk of neuropsychiatric events, which included addition of the following data:

- Results from a Pfizer meta-analysis of five placebo controlled clinical trials, which showed no increase in the incidence of suicidal ideation and/or behavior in patients treated with CHANTIX compared to patients treated with placebo.<sup>3</sup>
- Results from a Pfizer pooled analysis of 18 clinical trials, which showed a similar incidence of common psychiatric events of anxiety, depressed mood and other mood disorders in patients treated with CHANTIX compared to patients treated with placebo.<sup>3</sup>
- Results from four independently conducted, large observational studies, each of which included 10,000 to 30,000 CHANTIX patients with and without a psychiatric history. The studies assessed the risk of selected serious neuropsychiatric events between CHANTIX users and prescription NRT or bupropion users.<sup>3</sup>

Pfizer is committed to the ongoing study and safety monitoring of its medicines, including CHANTIX, in an effort to provide healthcare professionals and patients with the most accurate and up-to-date information.

#### **Public Health Impact of Smoking**

The continued addiction to smoking in the U.S. is a serious epidemic that severely impacts people's health.<sup>1,2</sup> Smoking is the leading preventable cause of death and disease in the U.S.<sup>1,2</sup> Studies indicate that, on average, smokers lose three months of life for every year quitting is delayed after the age of 35.<sup>4</sup> In addition, it is estimated that tobacco-related illnesses cost the U.S. nearly \$200 billion in healthcare expenses and lost productivity every year.<sup>2</sup>

#### **About CHANTIX**

CHANTIX was approved by the FDA in May 2006 as an aid to smoking cessation treatment in adults 18 and older. 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.

**Important CHANTIX (varenicline) 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 the CHANTIX patient, their family or caregiver notice any of these symptoms or behaviors, they should stop taking CHANTIX and call their doctor right away. They should tell their doctor about any history of depression or other mental health problems, which could get worse while taking CHANTIX.**

Some people had seizures during treatment with CHANTIX. Most cases happened during the first month of treatment. Patients should tell their doctor if they have a history of seizures. If a patient has a seizure during treatment with CHANTIX, he/she should stop taking CHANTIX and contact his/her healthcare provider right away.

Patients should decrease the amount of alcohol they drink while taking CHANTIX until they know if CHANTIX affects their ability to tolerate alcohol. Some people experienced increased drunkenness, unusual or sometimes aggressive behavior, or memory loss of events while consuming alcohol during treatment with CHANTIX.

Patients should not take CHANTIX if they've had a serious allergic or skin reaction to it. If they develop serious allergic or skin reactions, including swelling of the face, mouth, throat, or a rash, they should stop taking CHANTIX and see their doctor right away as some of these can be life-threatening.

Patients should tell their doctor if they have a history of heart or blood vessel problems or have any new or worse symptoms during treatment with CHANTIX. Patients should get emergency medical help right away if they have any symptoms of a heart attack or stroke.

Dosing may be different for patients who have kidney problems. Until the patient knows how CHANTIX affects them, they should use caution when driving or operation machinery. Common side effects include nausea, trouble sleeping and unusual dreams. CHANTIX should not be taken with other quit-smoking products. Patients should tell their doctor which medicines they are taking as these medicines may work differently when quitting smoking.

[Full prescribing information](#) and Medication Guide are available at [www.CHANTIX.com](http://www.CHANTIX.com).

**Pfizer Inc.: Working together for a healthier world™**

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has

worked to make a difference for all who rely on us. To learn more, please visit us at [www.pfizer.com](http://www.pfizer.com).

*DISCLOSURE NOTICE: The information contained in this release is as of October 16, 2014. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.*

*This release contains forward-looking information regarding CHANTIX, including its potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainty regarding the commercial impact of the Advisory Committees' recommendation regarding the boxed warning for CHANTIX; uncertainty regarding the outcome of the FDA's decision regarding the boxed warning for CHANTIX; the uncertainties inherent in research and development, including the ability to meet anticipated clinical study completion dates as well as the possibility of unfavorable study results; and competitive developments.*

*A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2013 and in our subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the SEC and available at [www.sec.gov](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).*

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<sup>1</sup> [www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/health\\_effects/effects\\_cig\\_smoking/index.htm](http://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/effects_cig_smoking/index.htm)

<sup>2</sup> U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014

<sup>3</sup> Pfizer Laboratories Div Pfizer Inc. CHANTIX® (varenicline) Prescribing Information

<sup>4</sup> Doll R, Peto R, Wheatley K, et al. Mortality in relation to smoking: 40 years' observations on male British doctors. *British Medical Journal*. 1994; 309: 901-911.