



FOR IMMEDIATE RELEASE

Telephone Counseling May Improve Effectiveness of Varenicline (Chantix™), According to Free & Clear® Study


Side Effects Examined in First “Real World” Study Since Industry-Sponsored Clinical Trials

SEATTLE, November 18, 2008 – For smokers interested in quitting tobacco with the use of varenicline (marketed as Chantix), telephone counseling may make it easier. According to a recent National Cancer Institute-funded study (CA071358), smokers using varenicline who received any telephone counseling were less likely to stop taking their medication than were those with online support only (15 percent versus 21 percent) during the first month of treatment. In addition, this study confirms previous clinical trial findings that side effects from varenicline, especially nausea, are relatively common and usually mild to moderate.

The study is the first “real-world” examination of side effects from varenicline since the original studies paid for by the manufacturer. In this study, 17 percent of participants reported at four weeks after starting the medication that they had discontinued using varenicline, with half of those stopping due to side effects. Medication discontinuation was strongly associated with a return to smoking.

This study was the result of a collaboration between SRI International, a non-profit independent research organization (Gary Swan, Principal Investigator); Free & Clear, a national leader in healthy behavior change; and Group Health Cooperative, a non-profit integrated health care system in the Pacific Northwest. The study evaluated 1,018 smokers using varenicline—all of them patients at Group Health—and was published on November 12 in the *Journal of Substance Abuse Treatment*.

“Our study shows that telephone counseling may improve tolerance of Chantix and reduce the rate of discontinuation due to mild to moderate side effects,” said Tim McAfee, MD, MPH, Free & Clear’s Chief Medical Officer, an affiliate investigator at Group Health Center for Health Studies, and an author of the study. “The personalized support of a telephone counselor appears to help smokers stay on the medication, which ultimately can help them quit tobacco for good. Our telephone counselors undergo 240 hours of in-depth tobacco cessation training to provide individualized support for people trying to quit, compared to an average of less than five hours for most doctors and health care workers.”



“The high rate of nausea symptoms, leading to discontinuation of medication and relapse to smoking among a large number of study participants, suggests the need for further work to help varenicline users minimize and cope with these symptoms,” said Abigail Halperin, MD, MPH, lead author on the study and Director of the University of Washington Tobacco Studies Program. “There has also been considerable concern recently that mood and behavioral disturbances might be related to use of the drug, leading to several FDA advisories. In this trial, we detected only one serious psychiatric event requiring hospitalization in a person with a previously undisclosed history of manic depression, out of more than 1,000 participants.”

Free & Clear’s Quit For Life[®] Program helps people overcome their addiction to tobacco using a combination of phone-based cognitive behavioral coaching, medication support, and web-based learning and social support. The Quit For Life Program has helped more than 200,000 Americans successfully quit smoking since 2004, translating to over two million years of life added and \$1 billion in cost savings. Free & Clear’s Quit For Life Program is currently offered by over 200 employer, health plan, and government clients.

About Free & Clear, Inc.

Free & Clear, Inc., the healthy behaviors company, specializes in phone-based cognitive behavioral coaching and web-based learning to help employers measurably improve the overall health and productivity of their workforces. Free & Clear’s evidence-based programs address modifiable health risks that contribute to chronic disease: tobacco use, poor nutrition, physical inactivity and stress. More than 50 million people have access to the Free & Clear Quit For Life[®] Program, the nation’s leading tobacco cessation program, which has had its proof of effectiveness published in multiple peer-reviewed, scientific journals over the course of more than 20 years. The Mind & Body™ Program has been developed by nationally recognized experts and is based on the most up-to-date, clinically proven science available on weight management and obesity prevention. Free & Clear is based in Seattle, Washington. More information about Free & Clear can be found at www.freeclear.com.

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