



Media Statement
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Statement Regarding the FDA's Drug Safety Communication on Chantix

“Pfizer has studied Chantix (varenicline) in a randomized, double-blind, placebo-controlled clinical trial in smokers with certain types of cardiovascular disease. These clinical study data, submitted to FDA and published in the journal *Circulation* (Vol 121, No 2, January 2010), showed that Chantix is an effective smoking-cessation treatment option for this population of smokers. The overall cardiovascular event rates reported in the study were low, but there was a small, increased incidence of certain cardiovascular events in patients taking Chantix compared to patients taking placebo. FDA is requesting a large, combined analysis (meta-analysis) of existing Chantix clinical data to evaluate the cardiovascular safety of Chantix. Pfizer will be discussing the details of the meta-analysis, as well as the product labeling, with the FDA.

“As stated by the FDA, patients should contact their healthcare professional if they experience new or worsening symptoms of cardiovascular disease. Smoking is a major risk factor for cardiovascular disease, which can lead to heart attack, stroke and peripheral arterial disease.

“Smoking is a major public health issue - it is the leading cause of premature death in the United States. The health benefits of quitting smoking are immediate and substantial.”

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