FDA adds heart warning to Pfizer anti-smoking pill

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(AP) -- Federal health regulators are warning doctors and patients that Pfizer's anti-smoking drug Chantix may slightly increase the risk of heart attack and other cardiovascular problems.

The Food and Drug Administration said Thursday a study of 700-heart disease patients taking Chantix showed a small uptick in heart problems among those taking the smoking-cessation drug versus those taking placebo. The agency stressed that the drug helped patients quit smoking and that this benefit "should be weighed against its potential risks when deciding to use the drug in smokers with cardiovascular disease."

Chantix is a twice-daily tablet that works by binding to nicotine receptors in the brain, reducing the symptoms of withdrawal.

The FDA will add new warnings to the drug's label about the study's findings. Patients will also receive an updated medication guide with their Chantix prescription that talks about the heart risks.

Drugmaker Pfizer will be required to analyze a large group of studies to further define the heart risk, according to the FDA. The company said in a statement that "the overall cardiovascular event rates reported in the study were low."

Approved in May 2006, Chantix has been used by millions of patients in the U.S., though sales have declined since 2008 when the drug was first linked to psychological side effects, including depression and suicidal

thoughts. It currently carries a boxed warning, the most serious type, about those risks. GlaxoSmithKline's competing drug, Zyban, carries the same warning.

New York-based Pfizer Inc. reported sales of $755 million for Chantix last year. Most of the drug's new sales have been driven by patients outside the U.S. Company shares dipped 5 cents to $20.14 in afternoon trading.