FDA Warnings about Chantix
Since Chantix came on the market in 2006, the FDA has issued several warnings about serious side effects tied to varenicline, including depression, unusual behavior, and suicidal ideation, as well as heart attacks and other cardiovascular problems. These FDA warnings about Chantix include:

November 2007 FDA Early Drug Safety Communication Regarding Investigation of Chantix Psychiatric Side Effects
The FDA announced it was investigating psychiatric side effects possibly linked to Chantix, including depression, suicidal ideation and suicidal behavior. At the time, the agency said it had received reports of 37 suicides and more than 400 reports of suicidal behaviors that might have been linked to Chantix.

February 2008 FDA Chantix Public Health Advisory
The FDA announced that its investigation of Chantix side effects indicated that there may be an association between Chantix and serious neuropsychiatric symptoms. As a result, the FDA requested that Pfizer, elevate the prominence of this safety information to the *Warnings and Precautions* section of the varenicline prescribing information, or labeling.

July 2009 FDA Announces Chantix Black Box Warning
The FDA announced that the most serious safety warning, a Black Box, would be added to the Chantix label regarding its association with serious psychiatric side effects, including changes in behavior, hostility, agitation, depressed mood, suicidal thoughts and behavior, and attempted suicide. According to the FDA, a review of its Adverse Event Reporting Database had revealed 153 of suicidal adverse events (116 involving suicidal ideation and 67 involving suicide) from the time varenicline was approved in 2006 to November 27, 2007. The agency also said that the true number of such adverse events was likely higher, as not all side effects are reported to the FDA database. The FDA warned that people taking Chantix should be closely watched for signs of suicidal thoughts, depression, hostility, or other changes in behavior.

June 2011 FDA Drug Safety Communication Regarding Chantix Heart Side Effects
The FDA warned that varenicline may be associated with a small, increased risk of certain cardiovascular adverse events in patients who have pre-existing heart disease, including heart attacks, Angina Pectoris, Coronary Revascularization and Peripheral Vascular Disease. Individuals were twice as likely to suffer from heart problems while taking Chantix as those taking a placebo during a recent study, the agency said. The safety information was added to the *Warnings and Precautions* section of the varenicline physician labeling.

Legal Help for Victims of Chantix Side Effects

If you or someone you loved experienced unusual behavior, including suicidal ideation, or suffered a heart problem while taking Chantix, Gilman Law is here to help. For a free evaluation of your case, please fill out the online form on the left or call Toll Free at 1-888-252-0048