the weekly Standard

Up in Smoke

How an FDA warning harmed the fight against smoking.

Ike Brannon and Devorah Goldman

September 12, 2016

Smoking rates have fallen appreciably in the last decade, driven by sharply higher cigarette taxes, public smoking bans, and changing mores that have made the activity basically unacceptable in many social circles.

Millions of Americans have attempted to quit smoking during that time, with varying degrees of success. Smoking is addictive, making quitting a difficult task for most people. There are a variety of treatments for individuals trying to quit, with varying degrees of efficacy. Hypnosis is popular but not terribly effective, for example, and while nicotine substitutes like patches and e-cigarettes can work, these still subject the smoker's body to the harmful effects of nicotine, so some of the same risks remain.

There are also a variety of medicines that ease nicotine cravings. Of these, the smoking cessation drug Chantix has proven to be the most effective treatment for quitting tobacco.

The drug arrived on the market in 2006 with high expectations: After a high degree of success in clinical trials, it was given a priority FDA review because of its potential to provide a significant benefit to public health. Upon its approval in 2006, doctors widely prescribed it and annual sales grew quickly, approaching $1 billion after just one year on the market.

However, the drug's popularity fell off dramatically when a slew of dramatic stories appeared that linked the drug to serious neuropsychiatric side effects. It began with the tragic 2007 death of *New Bohemians* guitarist Carter Albrecht, who exhibited bizarre, violent behavior while taking Chantix and was mistakenly shot by a neighbor as a result. Derek De Koff also wrote in *New York Magazine* that he had experienced strange and frightening changes in his thinking, including suicidal ideation, while taking Chantix.

These and other reports led the FDA to issue a series of public health advisories and place a "black box" warning label on Chantix in 2009—the strictest FDA warning regarding the side-effects of a drug. Chantix use plummeted as a result.

However, scientific research has not shown any substantive evidence that Chantix causes such side effects. An FDA-ordered study released in April failed to find any evidence that users of Chantix experienced an increase in neuropsychiatric adverse events when compared to a placebo. The study's authors suggested that it was "highly unlikely" that Chantix use leads to neuropsychiatric side effects.

Unfortunately, these new findings come years after sensational stories and black box warnings have discouraged hundreds of thousands of Americans from using Chantix. That almost assuredly means that these people pursued a less effective or more harmful means to quit smoking, or opted not to try quitting at all.

In essence, the fear engendered by warnings of a bizarre but likely non-existent side-effect has led thousands of people to continue smoking, a substantial proportion of whom will assuredly become afflicted with emphysema, lung cancer, heart disease, or any number of other illnesses caused by smoking. In short, more people will likely die because of this warning: 2.4 million people already die of smoking-related illnesses each year.

The gains from getting people to stop smoking go beyond longevity. Illnesses caused by smoking account for nearly $170 billion in direct medical care for adults each year, and $156 billion in lost productivity.

The FDA has a responsibility to warn people about the possible side effects of approved drugs, but it should do so based on substantial evidence and should take into account the impact that such warnings could potentially have on overall public health. It should also be certain before it takes actions that could worsen public health, as the black box status of Chantix almost assuredly did.

Ike Brannon is a nonresident fellow at the Cato Institute and president of Capital Policy Analytics. Devorah Goldman is director of health analysis at the Capital Policy Analytics.