

## Chantix – the No-Smoking Pill That Comes with a Price

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Anyone who has ever tried to quit smoking or to put a similar addiction behind them knows that any assistance is more than welcome. The known health risks of smoking combined with the increasing price of the habit have lead many to turn to smoking cessation assistance. Assistance comes in many forms, including working with a friend, exercising programs, acupuncture, lozenges and gums, and now prescription drugs.

One of the most well-known anti-smoking medications is Pfizer's Chantix. According to the Chantix webpage, the pill is a non-nicotine medication believed to block nicotine receptors. In a study comparing Chantix to Zyban, another stop-smoking drug, and a placebo, 44 percent of Chantix users quit smoking as compared to 30 percent of Zyban users and just 18 percent of those on the placebo.<sup>1</sup>

The US Public Health Service called Chantix the most effective smoking cessation drug on the market in its quit-smoking guidelines, but it also noted the need to use caution due to reports of adverse psychological side effects.<sup>2</sup>

Despite this positive publicity, Chantix has lately come under fire as reports of side effects and adverse effects have increased. A report by the Institute for Safe Medication Practices (ISMP)<sup>3</sup> reviewed the adverse drug event reports and noted reports of injuries of a variety of types, including severe falls, seizures, diabetes, and psychosis. In the fourth quarter of 2007, the Food and Drug Administration (FDA) received 988 serious injury reports relating to Chantix, more than it received for any other individual drug; the closest other drug was Interferon Beta with 640 reports. Between May 2006 and December 2007, FDA received 227 reports of suicidal acts, thoughts or behaviors, 397 cases of possible psychosis, and 525 reports of hostility or aggression. The ISMP study of Chantix was triggered when the drug produced more serious reports than any other drug for a variety of event types.<sup>4</sup>

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<sup>1</sup> *About Chantix*, available at: [http://www.chantix.com/content/About\\_Chantix.jsp?printFriendly=true](http://www.chantix.com/content/About_Chantix.jsp?printFriendly=true) (last accessed May 27, 2008).

<sup>2</sup> Marrecca Fiore, *Doctors: Chantix Benefits Outweigh Risks*, FOX NEWS, May 8, 2008, available at: [http://www.foxnews.com/printer\\_friendly\\_story/0,3566,354602,00.html](http://www.foxnews.com/printer_friendly_story/0,3566,354602,00.html) (last accessed May 27, 2008).

<sup>3</sup> ISMP describes itself as, "We are a nonprofit healthcare agency comprised of pharmacists, nurses, and physicians. Founded in 1994, our organization is dedicated to learning about medication errors, understanding their system-based causes, and disseminating practical recommendations that can help healthcare providers, consumers, and the pharmaceutical industry prevent errors. . . . As a nonprofit agency, we rely on charitable donations, unrestricted grants, subscriptions to our newsletters, and fees from our consulting and educational services. We are not funded by the pharmaceutical industry and do not accept advertising in any of our publications." See *Facts about ISMP*, available at: <http://www.ismp.org/about/default.asp>. A list of donors was not readily available.

<sup>4</sup> *Strong Safety Signal Seen for New Varenicline Risks*, THE INSTITUTE FOR SAFE MEDICATION PRACTICES, available at: <http://www.ismp.org/docs/vareniclineStudy.asp> (last accessed May 27, 2008). ISMP reported only on US data. The report noted that 1608 foreign reports consistent with the US adverse drug event reports had been made.

In its review of the clinical studies performed by Pfizer on Chantix, ISMP noted that patients with recent histories of psychiatric treatment and those with a history of drug or alcohol abuse were among those precluded as study subjects, potentially limiting the safety information gleaned from the clinical trials.<sup>5</sup>

Adverse events reported for Chantix included: accidents and injuries; rapid skin and tissue swelling; irregular heartbeat; convulsions; strokes; involuntary movements, tremors, and muscle restlessness; high blood sugar and diabetes; hostility/aggression; psychosis and psychotic disorders; suicide/self-injury; severe skin adverse reactions; and vision disturbance. Seventy-eight deaths in the United States were reported with Chantix as the principal suspect drug, with 28 reports of suicide and numerous reports relating to cardiac causes of death.<sup>6</sup>

ISMP noted that the reports do not prove causality and that many of the patients involved were on one than one drug, but the large numbers indicate some safety concerns. ISMP recommended limiting or banning use of Chantix for persons operating heavy machinery and recommended caution in others using Chantix. Further FDA warnings about the drug were also recommended.<sup>7</sup>

After reviewing the ISMP report, the Federal Aviation Administration banned the use of Chantix by pilots and air traffic controllers. Financial forecasts for the drug were also revised as reports of adverse events became more public.<sup>8</sup> The Federal Motor Carrier Safety Administration warned medical examiners not to qualify anyone using Chantix for commercial motor vehicle licenses.<sup>9</sup>

Proving that bad publicity for one drug is merely an opening for another competitor, GlaxoSmithKline responded to the Chantix controversy by offering its Commit nicotine lozenges free of charge for all licensed pilots and air traffic controllers.<sup>10</sup>

Following news of the ISMP report came stories of traffic accidents linked to Chantix. In one, a passenger in the car stated that the driver's eyes rolled back in his head and he seemed frozen when he suddenly swerved left while driving. Several dozen reports of highway accidents linked to Chantix were mentioned in the media. In response, the

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<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

<sup>8</sup> Shannon Pettypiece, *Pfizer's Chantix Tied to 3,000 Side Effects Reports (Update 3)*, BLOOMBERG, May 21, 2008, available at:

<http://www.bloomberg.com/apps/news?pid=20670001&refer+home&sid+aY7AqjMpHas> (last accessed May 27, 2008); Jacob Goldstein, *FAA Bans Chantix for Pilots, Air Traffic Controllers*, HEALTH BLOG, WALL STREET JOURNAL, May 21, 2008, available at: <http://blogs.wsj.com/health/2008/05/21/faa-bans-chantix-for-pilots-air-traffic-controllers/trackback/> (last accessed May 27, 2008).

<sup>9</sup> *Trucking regulators warn against Chantix*, UNITED PRESS INTERNATIONAL, May 23, 2008, available at: [http://www.upi.com/NewsTrack/Science/2008/05/23/trucking\\_regulators\\_warn\\_against\\_chantix/5134](http://www.upi.com/NewsTrack/Science/2008/05/23/trucking_regulators_warn_against_chantix/5134) (last accessed May 27, 2008).

<sup>10</sup> Jacob Goldstein, *Glaxo Leaps Into Chantix Smackdown*, Health Blog, WALL STREET JOURNAL, MAY 23, 2008, available at: <http://blogs.wsj.com/health/2008/05/23/glaxo-leaps-into-chantix-smackdown/trackback/> (last accessed May 27, 2008).

military began considering further precautions regarding Chantix, which it had already banned for use by flight and missile crews.<sup>11</sup>

As American society turns to the medical professions to solve more and more of our problems, the number of so-called lifestyle drugs will only increase. This rise is also fueled by the need for drug companies to find new and more marketable blockbuster drugs as the fight over prescription drug costs becomes fiercer. It is this background initially that brought the drug companies into the non-smoking arena.

We have seen in the past few years that clinical trials and FDA new drug application reviews do not catch all potential side effects of a drug, even when all parties are being forthright. Issues of unknown side effects are even more important in cases like Chantix, where other, less risky options were available, including trying to quit without chemical aides. The need for better and more up-to-date information on released drugs is highlighted by this current controversy.

The extent to which Chantix has been linked to such a variety of effects, including seizures, heart problems, and psychosis, makes the drug the perfect example of the need for better adverse event reporting – the system currently is voluntary and not well publicized – and the need for physicians to fully discuss the risk-benefit analysis of all drugs with their patients, particularly for conditions like smoking cessation for which there are a variety of alternative approaches.

Many will undoubtedly call for Chantix to be taken off the market as more information comes forward about side effects, but those making such calls are missing the point. The issue here is not that Chantix had side effects but that the side effects went largely unreported and unacknowledged even after FDA had collected the reports. Physicians were prescribing Chantix without realizing that it was linked to suicidal behavior and traffic accidents, and patients were taking the drug without considering whether a smoking cessation aid with less potential impact on their behavior and health might be available.

As we become more reliant on – if not obsessed with – prescription drugs to solve our health and lifestyle concerns, we must have a better avenue of information on what side effects prescription drugs may have. The notion that a prescription drug is the right answer for any problem may seem even more ludicrous when the potential price is known.

*Health Law Perspectives* (May 2008), available at:  
<http://www.law.uh.edu/healthlaw/perspectives/homepage.asp>

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<sup>11</sup> Ricardo Alonso-Zaldivar, *Drug taken to stop smoking is linked to traffic mishaps*, LOS ANGELES TIMES, May 25, 2008, available at: <http://www.latimes.com/news/nationworld/washingtondc/la-na-smokedrug25-2008may25,0,2037520,full.story> (last accessed May 27, 2008).