

[More Evidence That The Stop-Smoking Drug Chantix Is Linked To Agitation, Aggression, And Violence](#)

New Medical Journal Article Looks At 78 Adverse Event Reports Made To FDA Involving Chantix / Champix (Varenicline)

(Posted by Tom Lamb at www.DrugInjuryWatch.com on August 3, 2010; see <http://bit.ly/caXdEI>)

We last wrote about the relatively popular smoking cessation drug varenicline -- trade name Chantix in the USA and Champix in Europe and other countries, marketed by Pfizer -- about a year ago, when we reported that it was getting a "[black-box](#)" [warning about the risk of serious neuropsychiatric symptoms including agitation, depression, suicidal thoughts, and attempted suicide](#).

Now, in the September 2010 edition of *The Annals of Pharmacotherapy* there appears an article, "[Thoughts and Acts of Aggression/Violence Toward Others Reported in Association with Varenicline](#)", by Thomas J. Moore, Joseph Glenmullen, and Curt D. Furberg, which provides more evidence that seems to link the use of Chantix / Champix to agitation, aggression, and violence.

The authors of this September 2010 medical journal article looked at information on 78 adverse event (AE) reports involving Chantix that had been received by the FDA as well as four other cases reported in clinical trials and three other Chantix AE case reports from the published literature.

From the July 27, 2010 *WebMD* Health News story, "[Stop-Smoking Aid Chantix Sparks Safety Concerns](#)", we get this overview of what the authors found:

The drug is so potentially dangerous that its use should be restricted to exclude police, military, and similar occupations in which workers carry weapons, says Thomas J. Moore, senior scientist for drug safety and policy at the Institute for Safe Medication Practices....

"My colleagues and I have been concerned about the safety profile of [Chantix] since our first report [warning of adverse events] in 2008," Moore tells WebMD....

The researchers used assessment tools to home in on 26 of the cases to look at more closely. Of these 26:

10 involved assault

9 involved homicidal thoughts

7 cases included other thoughts or acts of aggression or violence

In a sampling of the cases, the researchers reported that:

A 24-year-old woman on the drug woke up her boyfriend and started beating him, then attempted to kill herself.

A 21-year-old woman threatened her mother with a shotgun.

A 46-year-old man reported he had "crazy thoughts" of killing himself and his parents.

A 42-year-old man punched a stranger while at a bowling alley.

The symptoms typically began soon after starting the drug, Moore and his colleagues say, occurring a median of two days after starting.

They found that when the drug was stopped, the symptoms and other adverse effects resolved in most all cases.

But, as reported by this same *WebMD* story, Pfizer "disagreed strongly" with the September 2010 medical journal article by Moore, Glenmullen, and Furberg:

MacKay Jameson, a spokesman for Pfizer, issued this statement: "Pfizer takes the safety of all of its medicines seriously. All post-marketing reports of adverse events are reviewed by Pfizer, and reported to regulators, including FDA. The currently approved Chantix label contains a boxed warning regarding reports of serious neuropsychiatric events reported in some patients. If these neuropsychiatric symptoms are observed by the physician, patient or caregiver, patients should stop taking Chantix and notify their healthcare provider immediately. There is no reliable scientific evidence demonstrating that Chantix causes these events."

Clinical studies are under way, he says, "to help us further characterize the benefit risk profile of Chantix in different smokers. As studies complete, the results will be published."

We will continue to monitor the safety profile of Chantix / Champix. Of course, anyone with knowledge about an adverse event involving these smoking cessation drugs can share that with us by submitting a Comment, below.

Attorney [Tom Lamb](#) represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.

<http://www.DrugInjuryWatch.com>