



FOR IMMEDIATE FREE RELEASE
Friday, January 28, 2011
[PDF Copy of Article](#)

Contact: John R. Polito
john@whyquit.com
(843) 797-3234

Chantix serious injuries exceed 8,500

Health officials know that cold turkey quitting is safe. What they refuse to examine is whether or not Chantix is more effective than cold turkey under real-world conditions.

by [John R. Polito](#)

Pfizer's controversial quit smoking pill varenicline has been marketed here in the U.S. since 2006 as Chantix, and as Champix in the rest of the world. A [report released yesterday](#) by the [Institute for Safe Medication Practices](#) (ISMP), a consumer medication safety watchdog, reveals that varenicline has "now triggered reports of more than 8500 serious injuries" to the U.S. Food and Drug Administration (FDA).

On April 1, 2008, the FDA released [a video clip](#) warning that Chantix use had been linked to "behavior changes, agitation, depressed mood, suicidal ideation and suicide." On July 1, 2009 the FDA required Pfizer to add the FDA's highest level of product warning alert - a black boxed warning label - advising patients and healthcare providers as to risks of hostility, agitation, depressed mood, and suicidal thoughts or actions (FDA [podcast](#) and [press release](#)).

According to the ISMP's January 27, 2011 report, "despite the safety measures enacted to date, an unacceptable toll continues of reported serious injuries associated with this drug."

"Varenicline (CHANTIX) continued to account for large numbers of reported serious psychiatric side effects," wrote the ISMP. "In the second quarter the drug was suspect in more possible cases of hostility-aggression, depression and psychosis than any other monitored drug."

The report notes that the FDA logged 378 serious Chantix adverse drug events during the 2nd quarter of 2010, which included "130 possible cases of clinical depression, 112 possible cases of hostility aggression, and 70 cases of psychosis or losing touch with reality."

"Case reports of these serious side effects outstripped those from the most powerful antipsychotic and antidepressant drugs which are used more directly in vulnerable patient populations with mental disorders," wrote the ISMP.

On a positive note, the ISMP report states that "we have seen possible improvement for one psychiatric side effect - suicidal and self injurious behavior. In the second quarter of 2010, the 45 possible cases of suicidal behaviors were fewer than the other categories and did not outnumber all other monitored drugs. This may reflect some benefit of the FDA warnings which focused primarily on this adverse effect."

Pfizer's army of paid consultants had argued that Chantix FDA adverse event reporting had likely been inflated by media publicity about violence and suicides among Chantix users. The ISMP report presents charts comparing the number of Chantix prescriptions written since 2008 to the number of serious adverse events reported. Contrary to such assertions, the data suggests that over this 2 ½ year period "the flow of reported serious injuries has largely tracked the number of prescriptions dispensed."

UK Data Suggests Chantix Effectiveness Claims Vastly Overstated

On January 6, 2011, I [documented](#) how Stop Smoking Services data from England's National Health Service (NHS) suggests that Pfizer's initial clinical trials had vastly inflated Chantix's worth. While 4-week point prevalence quit smoking rates in Pfizer's Gonzales clinical trial (2006 JAMA) were approximately 48% for varenicline versus only 23% for placebo, 4-week NHS Stop Smoking Services rates were 60% for varenicline versus a whopping 49% for those quitting without using any medications.

This decline of varenicline's 4-week victory margin from 25 percentage points over placebo to just 11 percentage points over real-world non-medication quitters raises serious doubts as to whether Chantix would prevail long-term (6 months or one year) over real-world cold turkey quitters.

Keep in mind that at 4 weeks brain dopamine pathway receptors of NHS non-medication quitters had already re-sensitized, down-regulated receptor numbers and adjusted to natural stimulation, while varenicline users still had at least one more month of treatment prior to attempting to adjust to natural stimulation.

The FDA could have demanded a quick and inexpensive real-world quitting method survey to determine Chantix's relative worth as compared to other far less dangerous quitting methods. It has not.

The FDA also could have required Pfizer to conduct an over-the-pharmacy-counter study to determine Chantix's real-world quitting rate when used as a stand-alone quitting product without any formal counseling or support, how real-world quitters are use it. This would have allowed the FDA to tell smokers Chantix's actual worth when unaccompanied by the record 25 counseling /support sessions received by clinical trial participants during drug approval studies.

Why is the pharmaceutical industry so afraid to pit smokers wanting to quit cold turkey against those wanting medications? Why isn't the FDA demanding such studies? Oddly, it's as if the FDA does not want to know whether or not quitting without Chantix is more effective long-term than quitting with it. But why?

XXX

No Copyright - This Article is Public Domain

John R. Polito is solely responsible for the content of this article.
Any factual error will be immediately corrected upon receipt of credible authority
in support of the writer's contention. E-mail comments to john@whyquit.com

Share this Chantix article with others

[Tweet](#)



[Share](#)

[PDF copy of this article for printing and sharing](#)

Related Links and Articles

- [Chantix/Champix worth questioned](#) - John R. Polito, 12/29/09
- [Five facts Chantix ads keep hidden](#) - John R. Polito, 12/29/09
- [Pfizer's Chantix Continues Killing Quitters](#) - John R. Polito, 10/22/08
- [Chantix and Champix mental health safety assurances contrary to evidence](#) - John R. Polito, 06/12/08
- [Strong Safety Signal Seen for New Varenicline Risks](#) - ISMP, 05/21/08
- [U.S. quit smoking policy integrity drowns in pharmaceutical influence](#) - John R. Polito, 05/13/08
- [FDA pulls video clip admitting Chantix suicide link](#) - John R. Polito, 04/03/08
- [New FDA Chantix suicide risk video clip raises concerns](#) - John R. Polito, 04/02/08
- [FDA Chantix Handling Betrayed Public Health](#) - John R. Polito, 02/08
- Windows media clip of WhyQuit's candid views on Chantix & Champix: [18mb video for dial-up users](#) | [high res 53mb format](#) | and [7mb audio only format](#), length 48 minutes, recorded 10/19/07 by Joel Spitzer
- [Flawed research equates placebo to cold turkey](#) - John R. Polito, 03/07
- [Nicotine Fix - Behind Antismoking Policy, Influence of Drug Industry](#) - Kevin Helliker, 02/07
- [Evidence of Collusion: Pharma-Govt Smoking Guidelines](#) - AHRP, 02/07
- [WSJ Highlights Financial Conflicts of Chair of Federal Guidelines Panel](#) - Michael

- Siegel, MD 02/07
- [Nixing the Patch: Smokers quit cold turkey](#) - Ken Millstone, 02/07
 - [New Study Challenges Thinking on Use of NRT During Pregnancy](#) - Michael Siegel, MD, 02/07
 - [Nicotine for the Fetus, the Infant and Adolescent](#) - H.K. Ginzel, MD, 02/07
 - [The secret to quitting smoking](#) - John R. Polito, 01/07
 - [Financial Ties Between Guideline Panels and Big Pharma Run Deep](#) - Michael Siegel, MD, 01/07
 - [Chantix - an 8 in 10 failure rate or worse?](#) - John R. Polito, 12/06
 - [Do physician's have a legal duty to ignore Guideline Recommendation 7?](#) - John R. Polito, 12/06
 - [Chantix likely as ineffective as NRT](#) - John R. Polito, 11/06
 - [Is the U.S. government's quitting policy killing smokers?](#) - John R. Polito, 10/06
 - [Will Chantix really help me quit smoking?](#) - John R. Polito, 08/06
 - [It's unlikely this NRT study was blind](#) - John R. Polito, 08/06
 - [Conference Sponsorship by Pharma Precludes Objective Symposium](#) - Michael Siegel, MD 07/06
 - [13th World Conference on Tobacco or Health Drenched in Nicotine](#) - John R. Polito, 07/06
 - [Cold Turkey Twice as Effective as NRT or Zyban](#) - John R. Polito, 05/06
 - [Nicotine Not Medicine, Its Use Not Therapy](#) - John R. Polito, 04/06
 - [How to use behavioral findings to sell NRT](#) - John R. Polito, 01/06
 - [GlaxoSmithKline Attacks Cold Turkey Quitting](#) - John R. Polito, 12/05
 - [UK Guidance for NRT use in pregnancy and by children](#) - ASH London, 12/05
 - [June 2000 Guideline Chairman Michael Fiore's Testimony - see PDF pages 14 & 15](#), 05/05
 - [The Nicotine Patch, Gum and Lozenge - Mounting Evidence of a Sham](#) - John R. Polito, 04/05
 - [40 Years of Progress?](#) - Joel Spitzer, 10/04
 - [Widespread Blinding Failures Put NRT Studies in Serious Question](#) - John R. Polito, 06/04
 - [Nicotine Gum Maker's Concern Raises Concerns](#) - John R. Polito, 05/04
 - [A Quitter's Dilemma: Hooked on the Cure](#) - New York Times, 05/04
 - [Quebec CT Quitters Disprove "Double Your Chances" NRT Assertion](#) - John R. Polito, 04/04
 - [Are nicotine weaning products a bad joke?](#) - John R. Polito, 10/03
 - [Is CT Quitting More Productive & Effective than NRT?](#) - John R. Polito, 07/03
 - [Are Teens Getting Hooked on NRT?](#) - John R. Polito, 06/03
 - [March 2003 OTC NRT Meta-Analysis Finds 93% Midyear Relapse Rate](#) - John R. Polito, 03/03
 - [Quitting Methods - Who to Believe?](#) - Joel Spitzer, 2003
 - [JAMA Study Concludes NRT is Ineffective](#) - John R. Polito, 09/02
 - [Real-World Nicotine Patch and Gum Rates](#) - John R. Polito, 06/02
 - [Does the OTC Nicotine Patch Really Double Your Chances of Quitting?](#) - John R. Polito, 04/02
 - [Is Nicotine Replacement Therapy The Smoker's Last Best Hope?](#) - John R. Polito, 11/00
 - [Financial Disclosures for June 2000 Guideline Panel](#) - U.S. Public Health Service, 06/00

- [June 2000 Guideline Recommendation 7 - pharmacotherapy use by all quitters](#) - 06/00



[WhyQuit.Com](#) | [Joel's Library](#) | [About Us](#) | [Contact Us](#) | [Link to Us](#) | [What's New?](#)

Written January 28, 2011 and last updated January 28 2011 at 1130 EST