FOR IMMEDIATE FREE RELEASE
Thursday, January 6, 2011
PDF Copy of Article

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

Chantix / Champix Worth Questioned

by John R. Polito

An Australian University of Newcastle professor's letter in the Journal Addiction questions whether or not Pfizer's controversial quit smoking pill varenicline is worth it.

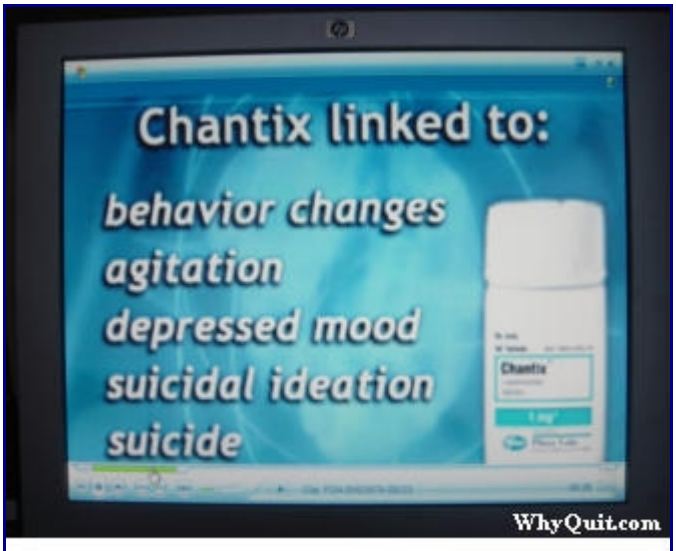
Marketed in Australia and the rest of the world as Champix and in the United States as Chantix, according to Professor Raoul A. Walsh, during 2008 the Australian government paid for 368,924 prescriptions of varenicline (252,618 4-week initiation and 116,306 8-week continuing), yet to this day it has absolutely no idea how many smokers actually quit.

Professor Walsh is concerned that the $93 million the Australian government paid for varenicline between January 2008 and October 2009 is 58% more than the $59 million that the government has budgeted for youth smoking prevention over the four year period ending in 2013.

His letter notes that when results from varenicline's five drug approval studies are combined and averaged that the absolute difference between varenicline and placebo quitting rates at one year was only 10.8%, a rate similar to rates seen among over-the-counter nicotine replacement product users (the nicotine gum, patch and lozenge).

A 2008 study (Aubin) pitted varenicline against the nicotine patch. Although not cited by Professor Walsh, it backs his assertion. In examining the actual percentage of successful quitters at two different time points, the study found "no significant differences" between Chantix and nicotine patch quitting rates at either 6 months (varenicline 38.6% vs. patch 34.1%) or one year (varenicline 34.8% vs. patch 31.4%).

The obvious question becomes, since the Food and Drug Administration (FDA) has already linked Chantix to thousands of serious adverse events, including suicide, if your chances of quitting with Chantix are no better than with the nicotine patch or gum, why take the risk?



Click to view FDA video linking Chantix to suicide

Smokers visiting Pfizer's Chantix website are hit with the assertion that, "Chantix is proven to work. In studies, 44% of Chantix users were quit during weeks 9 to 12 of treatment (compared to 18% on sugar pill)."

According to Professor Walsh, "there are a number of reasons why varenicline may be less effective under 'real world' conditions than in

research trials." He notes that Chantix clinical trials excluded all smokers having major medical conditions, that their varenicline was free, and that participants were paid for their time and travel.

Does Pfizer's unqualified boast of a 44% Chantix quitting rate constitute an unfair and deceptive bait and switch marketing tactic? I ask because it fails to mention that the biggest difference between clinical trials and real-world use is the record number of counseling and support sessions received by participants in Pfizer's clinical trials. As Professor Walsh notes, they were "much higher than in most primary care settings."

"For example," says Professor Walsh, "in the influential Jorenby et al. trial, subjects had a total of 28 contacts (eight telephone, 20 personal) with study personnel, of which 18 involved some counselling. Another typical trial involved 24 contacts including counselling on 13 occasions."

What isn't mentioned by Professor Walsh is that according to June 2000 U.S. Guideline evidence Tables 13 and 14, the number and duration of counseling sessions and support contacts employed in Pfizer's Chantix trials could account for nearly all successful quitting seen among Chantix users at long-term follow-up.

Table 13. Meta-analysis: Efficacy of and estimated abstinence rates for total amount of contact time (n = 35 studies)

Total amount of contact time	Number of arms	Estimated odds ratio (95% C.I.)	Estimated abstinence rate (95% C.I.)
No minutes	16	1.0	11.0
1-3 minutes	12	1.4 (1.1, 1.8)	14.4 (11.3, 17.5)
4-30 minutes	20	1.9 (1.5, 2.3)	18.8 (15.6, 22.0)
31-90 minutes	16	3.0 (2.3, 3.8)	26.5 (21.5, 31.4)
91-300 minutes	16	3.2 (2.3, 4.6)	28.4 (21.3, 35.5)
>300 minutes	15	2.8 (2.0, 3.9)	25.5 (19.2, 31.7)

Source: June 2000 Clinical Practice Guideline, Treating Tobacco Use and Dependence, Chapter 5, Evidence. Stop smoking rates from long-term studies of at least 5 months. Chantix studies involved up to 25 counseling sessions, each a maximum of 10 minutes in length, or 250 minutes maximum.

Table 14. Meta-analysis: Efficacy of and estimated abstinence rates for number of person-to-person treatment sessions (n = 45 studies)

Number of sessions	Number of arms	Estimated odds ratio (95% C.I.)	Estimated abstinence rate (95% C.I.)
0-1 session	43	1.0	12.4
2-3 sessions	17	1.4 (1.1, 1.7)	16.3 (13.7, 19.0)
4-8 sessions	23	1.9 (1.6, 2.2)	20.9 (18.1, 23.6)
> 8 sessions	51	2.3 (2.1, 3.0)	24.7 (21.0, 28.4)

Source: June 2000 U.S. Clinical Practice Guideline, Treating Tobacco Use and Dependence, Chapter 5, Evidence. Stop smoking rates from long-term studies of at least 5 months. Chantix studies had approximately 25 counseling sessions, with 12-13 face to face and the balance via telephone.

For example, participants received 25 counseling sessions of up to 10 minutes each in the 2008 Aubin

Chantix versus nicotine patch study, which found "no significant differences" in long-term point prevalence quitting rates, yet both groups exceeded 30% at 6 months (38.6% vs. 34.1% respectively). According to Table 6.30 of the 2008 U.S. Guideline Update, the average 6 month point prevalence quitting rate for the nicotine patch when used as a stand-alone quitting aid without counseling or support is three times lower at 11.8%.

Table 6.30. Meta-analysis (2000): Effectiveness of and estimated abstinence rates for OTC nicotine patch therapy (n = 3 studies)[a]

OTC therapy	Number of arms	Odds Ratio (95% C.I.)	Estimated abstinence rate (95% C.I.)
Placebo	3	1.0	6.7
OTC nicotine patch therapy	3	1.8 (1.2–2.8)	11.8 (7.5–16.0)

[a] Go to *www.surgeongeneral.gov/tobacco/gdlnrefs.htm* for the articles used in this meta-analysis.
Source: Clinical Practice Guideline, Treating Tobacco Use and Dependence: 2008 Update, Page 129

The billion dollar question is why the U.S. Food and Drug Administration (FDA) approved allowing Pfizer to design its drug approval studies so as to include a record number of counseling/support sessions, when prescription NRT and Zyban use history should have taught the FDA that relatively few quitters would seek or use counseling or support.

Shockingly, to this day, with thousands of varenicline users worldwide reporting serious adverse events, no person on earth knows Chantix or Champix's real-world effectiveness as a stand-alone quitting product. It isn't being studied. But why?

As noted by Professor Walsh, "in Australia, the [government's subsidized medication] guidelines state that varenicline should be restricted to patients entering a comprehensive counselling programme," but no data is being collected to determine whether or not that's happening.

"Clearly, there is a need for high-quality research to evaluate the probable population impact of this cessation intervention," wrote Professor Walsh. He recommends using a "tiny proportion of varenicline prescription spending" to fund data collection so that valid estimates of the long-term effects of varenicline on cessation rates can be determined.

U.S. Sticking Its Head in the Sand

U.S. health officials appear to be going out of their way to not analyze available data so as to discover whether or not FDA approved quitting products such as Chantix are effective in real-world use. An August 2010 Freedom of Information Act Request (FOIA) sought all survey results in which smokers were asked how they quit smoking.

The National Institute of Health (NIH) responded to the FOIA request on September 28, 2010. It noted that the National Cancer Institute does sponsor three surveys that "include questions asking smokers how they quit smoking," but that the NIH search "did not produce any hard-copy records or 'short-summary report'" of findings.

The NIH FOIA office's assertion that no reports exist stands in stark contrast to a February 8, 2007 front-page Wall Street Journal article which featured a non-published National Cancer Institute survey in which those quitting without medications actually did slightly better, long-term, than those using them.

The Office of the Assistant Secretary of Health (ASH) responded to the FOIA request on October 12, 2010 stating that it had "conducted a search along with the Office of the Surgeon General and could not

locate records responsive to your request."

England's 4 Week Blinders

More varenicline quitting data is generated by England's National Health Service (NHS) Stop Smoking Services than any other nation. The problem is that it's almost worthless.

A pharm industry dream come true, the NHS declares total quitting success and ends follow-up of stop smoking program participants at 4 weeks. It does so knowing that the brain dopmaine pathways of NRT, Zyban and Champix users have another 4 to 8 weeks of stimulation by quitting products before attempting to end product use and adjust to natural stimulation.

Before looking at the most recent four-week NHS 2009-2010 quitting method data, reflect on Pfizer's website assertion that "44% of Chantix users were quit during weeks 9 to 12 of treatment (compared to 18% on sugar pill)." With that in mind, attempt to predict both the the 4 week quitting rate for both NHS varenicline users and for those quitting without use of any quitting product, cold turkey quitters.

Four Week Quitting Rates for NHS Stop Smokiing Services

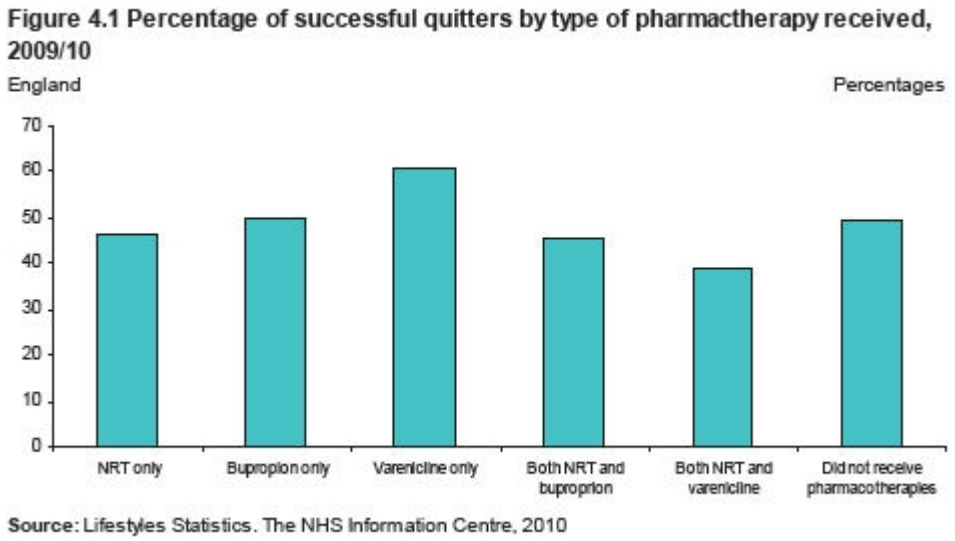


Figure 4.1, Statistics on NHS Stop Smoking Services: England, April 2009 – March 2010,Page 54

While Pfizer's website suggests quitters can expect 2.4 times better odds at 12 weeks than among those taking sugar pills, as shown by the above graph, last year NHS varenicline users performed only about 20% better than non-medication quittters at 4 weeks.

Cold turkey quitters become nicotine-free and move beyond peak withdwrawal within 72 hours of ending all nicotine use. It's then that the brain is able to begin restoring a4b2-type nicotinic receptor sensitivities and down-regulating receptor numbers to levels seen in non-smokers.

NRT, bupropion and varenicline each stimulate, desensitize and keep dopamine pathway receptors un-regulated. It isn't until treatment stops and stimulation ends that medication users are compelled to adapt to the changes already navigated by successful cold turkey quitters.

While the U.S. government suppresses and hides almost all real-world quitting method data - findings it knows conflict with official cessation policy which mandates quitting products use by all quitters - the U.K. pretends the fiction that those still undergoing medication treatment have already successfully

quit.

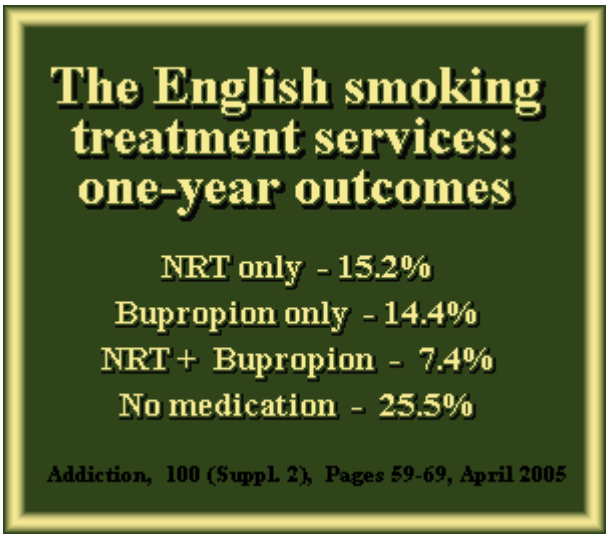
Table 4.1 People setting a quit date and successful quitters[1], by type of pharmacotherapy received[2,3,4], April 2009 to March 2010

England — Numbers / *Percentages*

	Number setting a quit date	Number of successful quitters	*Percentage who successfully quit*
Numbers			
England	**757,537**	**373,954**	***49***
Number who received NRT only	493,459	229,587	*47*
Number who received Bupropion (Zyban) only	9,509	4,761	*50*
Number who received Varenicline (Champix) only	175,380	105,925	*60*
Number who received both NRT and Bupropion (Zyban)	852	387	*45*
Number who received both NRT and Varenicline (Champix)	8,022	3,119	*39*
Number who did not receive pharmacotherapies	39,222	19,376	*49*
Number where treatment option not known[5]	31,093	10,799	*35*

NHS Stop Smoking Services 4 week quitting method data for 20009-2010

Look closely at the above NHS 2009-2010 quitting data, while keeping in mind that in the Aubin study, Chantix and NRT point prevalence quitting rates were nearly the same at both 6 months and one year. Now contrast that to the only study to examine long-term NHS Stop Smoking Services rates, the 2005 Ferguson study (see bottom of Table 6). There, non-medication quitters did substantially better than medication quitters. Varenicline use wasn't seen in the Ferguson study as it did not arrive on the market until May 2006.



Will Pfizer's financial muscle and influence permit real-world evaluation of questions as fundamental as whether or not Chantix and Champix are more effective than unassisted cold turkey quitting?

Aside from the obvious problem of motivating entrenched health bureaucrats to care whether these quitting products actually work, the primary problem is finding truly independent cessation researchers who are not already financially beholden to the quitting product industry. Stay tuned.

XXX

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 Share

PDF copy of this article for printing and sharing

Related Links and Articles

- 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 behavorial 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

Written January 6, 2011 and last updated January 10 2011 at 0924 EST