



FOR IMMEDIATE FREE RELEASE  
Wednesday, December 2, 2009

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

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## Petition for Honest Quit Smoking Studies

Did you try to stop smoking by using replacement nicotine (NRT), Zyban (bupropion) or Chantix (varenicline)? Did broken "double your chances" promises leave you feeling defeated, different, hopeless and alone?

But what if these products were shams? What if users were not quitting because of these products but in spite of them? What if defective studies robbed you of money, time and priceless periods of quitting confidence? Would it stir you to action? Would you join the call for honest quit smoking studies?

### [Petition Link](#)

- Please share the petition link with family and friends -

The above link is to petition drive demanding honest quit smoking studies. It explains how smokers have been deceived and demands that studies be driven by honesty, integrity and science, not frustrations, profits and greed.

The World Health Organization estimates that smoking will claim five million lives during 2010. How many will die because they trusted one of the greatest perversions of science the world has ever known?

Whether hooked, free or simply a concerned onlooker, I hope you'll try to understand how smokers have been tricked and consider signing the [Petition](#). Together we can make a difference!

So how does the sham work? Here's a brief overview. It centers upon placebos.

- A placebo is an inert product that contains no active ingredient. Nearly all stop smoking studies randomly assigned quitters to receive either an identical look-alike placebo product, or a real quit smoking product such as the nicotine gum, patch, lozenge, Zyban or Chantix.

- Placebo controls are the gold standard in most study areas for measuring a new medicine's value or worth. For example, if we assign half of a study's participants to receive a new blood pressure or cholesterol medication and half to receive placebo sugar pills, we would be able to determine the new medicine's relative worth as compared to placebo, at lowering blood pressure or cholesterol.
- The fact that participants are blind as to which pill they received diminishes subjective influences and roots study findings in objective performance and science. Unfortunately, that is exactly what makes placebo-controlled quit smoking studies a sham and worthless. Smokers with lengthy quitting histories know exactly what withdrawal feels like. They have become experts at recognizing it.
- Participants are often recruited into quit smoking studies by advertisements promising a chance of receiving weeks or months of free "medicine," medicine they hope will reduce withdrawal anxieties and make quitting easier.
- When signing up for the study, informed consent requires that participants be told that instead of receiving real "medication" that they may be randomly assigned to receive an inert placebo product having no known value in helping smokers quit.
- Interestingly, drug addiction is the only study area where the condition researchers seek to treat (withdrawal) does not exist until researchers command its onset ("Ok, now stop smoking.")
- When those assigned to receive placebo obey the command to stop smoking, users with lengthy quitting histories recognize the onset of nicotine fits and soon find themselves in full-blown withdrawal. Would you be able to tell if the gum you were chewing contained nicotine? So could they.
- Their hopes that "medicine" would diminish withdrawal anxieties are dashed. Frustrations grow. They realize they have been assigned to the study's placebo group. They give up, throw in the towel and relapse to smoking. The stop smoking product being tested is thus handed an unearned, default frustrations victory.
- It wasn't that the product was good but that the placebo group's anxiety beating was contrary to expectations. Aside from drug addiction, there is no other medical condition where when researchers assign participants to placebo, that escalating anxieties make them vastly worse than the moment the study commenced.
- It is impossible to blind experienced quitters as to the presence or absence of chemical withdrawal. The pharmaceutical industry knows this. More than 100 new placebo-controlled quit smoking studies are now being conducted. The industry relies heavily upon placebo quitter frustrations to create study headlines, headlines it knows will make billions in profits selling products that are worthless as quitting aids.
- How do we make stop smoking studies honest? Stop using placebos. Make quitting products compete against quitting methods with proven effectiveness such as

counseling and support.

- Placebo is not a real quitting method and it is not cold turkey. Those who join studies seeking "medicine" expect to diminish withdrawal anxieties. Real cold turkey quitters expect to endure and move beyond them.

What would happen if quitting products were forced to compete against real cold turkey quitters, who received quality counseling and support? Real-world quitting method surveys suggest that health headlines would read, "Cold turkey again defeats nicotine patch."

Please join in demanding honesty in smoking cessation research and policy. Help spread the word. Ask family and friends to consider signing the [Petition](#) too. Email them the link. You can also print or send a [PDF copy](#) of the petition. It contains links that will aid readers in better understanding the issues. Below is a full copy of the Petition filled with links to additional reading.

This is our chance. One billion smokers are worth fighting to save! Together we can make a difference!

## **Request for Honest Smoking Cessation Research and Policy**

### **Petition Summary:**

The world's smokers are trapped in a vicious cycle of attempting to quit, repeatedly failing and then dying prematurely. Stop smoking findings from placebo-controlled NRT, Zyban and Chantix clinical trials are not being realized in real-world use. Randomized trials were not blind as claimed. Experienced quitters are experienced at recognizing withdrawal. World Medical Association study ethics forbid placebo use when a proven intervention exists. There is consensus that counseling is a proven intervention. Although the vast majority of quit smoking studies are conducted in the U.S. their influence is felt worldwide. This petition is directed at the senior U.S. health official, the Secretary of Health and Human Services. It asks her to restore honesty, integrity and science to studies and policy by prohibiting use of placebo controls in government-backed studies, to replace it with counseling, to suspend current quitting policy requiring all quitters to buy and use pharmacology products, and to begin offering counseling and support to smokers attempting to quit without pharmacology products.

## **Petition:**

The Honorable Kathleen Sebelius  
Secretary of Health and Human Services  
200 Independence Avenue, S.W.  
Room 615-F  
Washington, DC 20201

Telephone: (202) 690-7000  
Fax: (202) 690-7203  
Email: [Kathleen.Sebelius@hhs.gov](mailto:Kathleen.Sebelius@hhs.gov)

Re: Request for honest smoking cessation research and policy

Dear Secretary Sebelius:

Six million Americans filled 12 million prescriptions for the stop smoking pill Chantix since its release in May 2006. Pfizer boasts a 44% Chantix success rate. According to the Centers for Disease Control (CDC), there were 36.3 million daily smokers in 2006. The CDC reported in November 2009 that there were 36.7 million daily smokers in 2008, and that the adult smoking rate actually increased from 20% to 21% over the prior year.

This is despite 45% of current smokers making a serious quitting attempt of at least one day during the prior year, significant increases in the cost of cigarettes, fewer lawful places to smoke, and despite the CDC's assertion of smoking "killing more than 443,000 people every year." Also factor in those quitters who believed in nicotine replacement therapy (NRT) and its unkept marketing promise to "double" their chances.

U.S. stop smoking policy is utter chaos. Flawed and profits driven smoking cessation research is primarily to blame for the quitter's current cycle of trying, failing and dying. The U.S. Department of Health and Human Services (HHS) shares culpability for making sham and defective research the cornerstone of national quitting policy.

As you know, 70% of stop smoking studies are conducted in the U.S and their influence is felt worldwide. Madam Secretary, I join in asking that you make honesty, integrity and science the hallmarks of HHS cessation research and policy.

Since 2000, decline in U.S. smoking has remained [stalled](#) at 46 million smokers. It was then that HHS allowed pharmaceutical industry [influence](#) to write official U.S.

cessation policy. One policy provision swallows all others. "[Recommendation 6](#)" reads, "Numerous effective medications are available for tobacco dependence, and clinicians should encourage their use by all patients attempting to quit smoking."

A stroke of corporate genius, it effectively destroyed the credibility and funding of all stop smoking programs designed to help quitters end nicotine use. Programs were instead compelled to recommend use of replacement nicotine or other chemicals that mimic nicotine's dopamine stimulating effects. It forced thousands of HHS employees to turn their backs on the [80-90%](#) of quitters who trusted their natural instincts and attempted to end nicotine use, instead of replace it.

"Recommendation 6" effectively buried the most critical quitting lesson of all, that any nicotine use when quitting, even one puff, [almost always](#) results in relapse. It muddied natural learning with the false lessons that nicotine is "medicine," its use "therapy," and that few succeed in quitting without it. Still, more than two decades later, roughly [90%](#) of long-term ex-smokers quit and remain quit without using pharmacology products.

The quitter's trying, failing and dying cycle is happening during an era when pharmacology quitting products routinely double placebo performance inside randomized clinical trials, yet [fall flat on their face](#) in real-world competition against real cold turkey quitters (most recently: [2009 GlaxoSmithKline survey](#); a [2007 UK NHS survey](#), see Table 6; a [2006 National Cancer Institute survey](#); a [2006 general practice patient survey](#); and a [2005 study of UK NHS quitters](#), see Table 6). But how?

More than [300](#) placebo-controlled quitting trials reflect the most deadly science sham ever. Placebo is not a real quitting method and is [not cold turkey](#). There is consensus that placebo-controlled quitting trials were [not blind](#) as claimed. Common sense screams that it is [impossible](#) to hide the onset or absence of full-blown withdrawal from nicotine addicts with significant quitting histories. They know exactly how it feels.

How bad is it? A [2009 nicotine patch study](#) by the patch's co-inventor found that "of 165 subjects receiving placebo patches, 27 believed they had received active patches, 112 believed they had not, and 26 were unsure."

Researchers entice smokers to join studies by dangling the prospect of receiving weeks or months of free "medicine." If within 24 to 48 hours of quitting, four times as many participants can correctly determine their randomized assignment as cannot, then clinical trials measure frustrations, not product effectiveness or efficacy.

Official U.S. quitting policy openly [acknowledges](#) that placebo blinding failures "should be borne in mind when appraising" study evidence. But a just released [patch plus lozenge study](#), co-authored by the chairman and father of U.S. policy, doesn't once comment on the study's blinding integrity. If pharmacology studies are not rooted in science then why pretend they are?

Madam Secretary, Principle 32 of the World Medical Association's Declaration of Helsinki, on the "[Ethical Principles for Medical Research Involving Human Subjects](#)" states: "The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances: The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists."

Following Principle 32 would save lives and compel honest study competition. Guideline "Recommendation 5" identifies counseling as a proven intervention. It states, "Two components of counseling are especially effective and clinicians should use these when counseling patients making a quit attempt: practical counseling (problem-solving/skills training) and social support."

The problem is that counseling "Recommendation 5" is totally consumed by pharmacology "Recommendation 6."

Quitting product performance must not be measured against placebo but against effective counseling and support. Counseling's timing, intensity and objective should be to enable quitters to navigate the first three critical days of nicotine cessation, and move beyond peak withdrawal anxieties to the gradually increasing calmness beyond.

Secretary Sebelius, use of placebo controls in drug addiction studies is license to rob, defeat and kill. I encourage HHS to suspend "Recommendation 6" and immediately offer non-pharmacology quitters quality counseling and support. I encourage HHS to adopt the World Medical Association's research ethics principles, to require pharmacology to prove itself against counseling and support, and when doing so to carefully monitor and scrutinize counseling's substantive content within clinical trials to ensure that it is tailored to support successful nicotine cessation, not defeat it.

Madam Secretary, it will take courage and leadership to stand up to pharmaceutical industry financial influence and put the freedom, health and life expectancy of smokers first. I have every confidence that you are up to the task.

Sincerely,

(Your Name)

Sign the Petition at <http://globalink.org/petitions/polito>

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**December 2, 2009. Last updated December 3, 2009.**  
**John R. Polito is solely responsible for the content of this article.**