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University of Wisconsin: World's Pharm Nicotine Sales Center

Nicotine patch plus lozenge study findings reflect Professor GlaxoSmithKline's latest sales pitch

by [John R. Polito](#), founder of [WhyQuit](#)

After millions in University of Wisconsin (UW) study funding since 1992, the smoking cessation arm of the pharmaceutical industry expects its money's worth. Welcome to pay day!

Last week a University of Wisconsin quit smoking study [press release](#) told smokers that they need to purchase and suck on a nicotine lozenge while at the same time wearing a nicotine patch. The spin by Professor GlaxoSmithKline (Dr. Michael C. Fiore) and his staff at UW's Center for Tobacco Research and Intervention (UW-CTRI) was masterful.



The University's press release claims to announce key findings from a [UW-CTRI study](#) published in the November 2009 issue of Archives of General Psychiatry entitled, "[A Randomized Placebo-Controlled Clinical Trial of 5 Smoking Cessation Pharmacotherapies.](#)"

Even the title suggests puffing. The placebo controlled study only involved 3 quitting products, the nicotine patch, nicotine lozenge and Zyban (bupropion), and two combinations, the lozenge plus patch and the lozenge plus Zyban. The original study title - "[Efficacy of Three Single and Two Combination Pharmacotherapies Among Daily Smokers: A Randomized Placebo-Controlled Clinical Trial](#)" - was a bit more accurate (see

page 2).

Used in three of five active group study arms, the nicotine lozenge was clearly the study's focus. GlaxoSmithKline's [Commit nicotine lozenge](#) was the only lozenge sold when the study was commenced in [September 2004](#).

Professor GlaxoSmithKline

Aside from the Commit lozenge, GlaxoSmithKline sells the Nicoderm CQ line of nicotine patches and the prescription quitting pill Zyban (bupropion). According to the study, "Medication was provided to patients at no cost under a research agreement with GlaxoSmithKline."

Arguably, no man on earth has done more to promote use of replacement nicotine products (NRT) than Dr. Michael C. Fiore. In 1992 he was lead author of a [nicotine patch review](#) published in the Journal of the American Medical Association (JAMA). He subtitled his paper "[Clinical Guidelines for Effective Use](#)." It foretold his future in serving as lead author and panel chairman in coining official U.S. quit smoking policy in [1996](#), [2000](#) and [2008](#). It's called the PHS "[Clinical Practice Guideline](#)," and each time was written and updated by expert panels [drowning](#) in pharmaceutical industry financial influence.

Dr. Michael C. Fiore founded and has served as [director](#) of UW-CTRI since its creation in 1992. He co-authored this new study along with six UW-CTRI staff members.

In 1998, GlaxoSmithKline (then Glaxo Wellcome) spent \$1 million to establish a [University of Wisconsin Foundation](#) "named chair" for Dr. Fiore to occupy. According to Dr. Fiore's sworn testimony, the endowed chair made available to him unrestricted grants of up to [\\$50,000](#) per year (see PDF page 15).

Dr. Fiore's financial disclosure in the new study states in part:

"In 1998, the University of Wisconsin appointed Dr. Fiore to a named chair funded by an unrestricted gift to University of Wisconsin from Glaxo Wellcome."

It's the exact disclosure language Dr. Fiore has used in a number of studies. Is it fair to say that he wants readers to believe that the University, not Glaxo, picked him to pocket Glaxo's annual \$50,000 gift? It's critical as [Federal regulations](#) protect the integrity of Public Health Service funded research by declaring that accepting more than \$10,000 creates a "significant financial interest."

But according to language from an actual copy of the October 15, 1997 "[Memorandum of Agreement](#)" obtained by WhyQuit under the Freedom of Information Act, Glaxo required that the money be used to "assist the Director of Center for Tobacco Research and Intervention as indicated ..." And Dr. Fiore was the Center's Director on October 15, 1997, and at all times before and since.

Dr. Fiore testified in 2005 that prior to Glaxo committing \$1,000,000 to establish the annual

grant, that he had conversations with Glaxo about "how they might support the sorts of work we're doing in Wisconsin" (see [PDF page 33](#)).

The October 15, 1997 "[Memorandum of Agreement](#)" spelled out in significant detail what Glaxo expected from Dr. Fiore. Among other things, his assignments included "Dissemination of the AHCPR Guidelines to clinicians nationwide with updates to reflect newly available smoking cessation pharmacotherapeutic and counseling treatments. A key component of this dissemination effort will be to implement AHCPR's guidelines as the new national standard of care. These recommendations stipulate that every patient visiting a health care setting is asked if they use tobacco ... and provided ... pharmacotherapy ..."

Dr. Fiore had worked as a paid consultant to Glaxo in early 1997 in helping gain FDA approval of Zyban, and in helping [market](#) it once approved.

On March 12, 1998, Dr. Fiore spoke before the U.S. Senate Judiciary Committee. According to his [testimony transcript](#), Dr. Fiore's told the Committee that the reason smokers are not quitting is because they are not using effective treatment.

"New and effective clinical treatments exist and these would have an enormous impact if they could achieve greater implementation," Fiore testified. "Every patient who wants to quit should be offered effective treatments including ... pharmacotherapies ... nicotine replacement therapies ... as well as the new non-nicotine medicine, Zyban."

"Think about the potential public health impact if clinicians nationwide provided the brief, effective treatments outlined in the AHCPR Guidelines. The rates of quitting among those who try would increase from the background 'cold turkey' rate of 7% to at least 15% each year. This would result in more than one million additional ex-smokers per year," Fiore testified.

"Both counseling and medications are terribly underutilized." "What can be done?" "Establish an evidence-based Guideline, such as the AHCPR Guideline, updated with the new FDA-approved medications, as the standard of care for reimbursable smoking cessation treatment," he testified.

The June 2000 U.S. Guideline was chaired by Dr. Fiore and a panel on which [11 of 18 members](#) disclosed pharmaceutical industry financial ties. As requested by Glaxo in its October 15, 1997 "[Memorandum of Agreement](#)" creating the endowed Chair in which Fiore sat, the panel made the bold step of making government recommendations for use of FDA approved quitting products mandatory. Guideline [Recommendation 7](#)) reads:

"Numerous effective pharmacotherapies for smoking cessation now exist. Except in the presence of contraindications, these should be used with all patients attempting to quit smoking."

Recommendation 7 effectively forbid health officials from encouraging, educating and supporting cold turkey quitters, pharmacology's only real competitor, and the method responsible for generating [80-90%](#) of all long-term successful quitters.

Dr. Fiore's financial ethics were openly challenged in a February 8, 2007 front-page Wall Street Journal article entitled, "[Nicotine Fix – Behind Antismoking Policy, Influence of Drug Industry](#)". According to the article:

"As the federal government weighs the data in making new recommendations, many of its advisers are receiving money from companies with a stake in the outcome. Dr. Fiore holds a chair at Wisconsin that is funded by GlaxoSmithKline. He directs a tobacco research center that received nearly \$1 million in funding from makers of quit-smoking medicine in 2004 and \$400,000 in 2005. Between 1999 and 2004, Dr. Fiore personally pocketed \$10,000 to \$40,000 a year from the quitting-aid industry for honorariums and consulting work. He says he stopped such work in 2005."

"In at least two medical-journal articles that Dr. Fiore wrote or co-wrote promoting the use of stop-smoking medicine, no mention was made of his financial ties to the makers of those treatments."

Still, it wasn't sufficient to motivate him to resign as chairman of the U.S. Guideline panel, or in 2008 from announcing release of [revised Guidelines](#) that added Pfizer's [controversial](#) quitting pill Chantix to the list of products satisfying the Guideline's mandatory pharmacology use recommendation.

Interestingly, on [September 5, 2006](#), Dr. Fiore certified to the U.S. Government as part of his Guideline panel disclosure statement that "Dr. Fiore does not accept honorarium or do consultancy work for the pharmaceutical industry." By the time the revised Guideline was released in May 2008, Dr. Fiore had revised that assertion to state, "in 2005 received compensation from one pharmaceutical company" (see [page 225](#)). A portion of his financial disclosure in last week's study declares, "Dr. Fiore has received honoraria from Pfizer." When and how much honoraria? Those are well kept secrets.

What we do know is that a [2009 study financial disclosure](#) states, "Michael C. Fiore has received honoraria or consulting fees from pharmaceutical companies. He has served as an investigator on research studies at the University of Wisconsin that were funded by Pfizer, Sanofi-Synthelabo and Nabi Biopharmaceuticals. In 1998, the University of Wisconsin (UW) appointed Dr. Fiore to a named Chair funded by an unrestricted gift to UW from Glaxo Wellcome."

Turning "No Significant Differences" into \$\$ Millions \$\$

Newspaper health headlines around the globe echoed the University of Minnesota [press release](#) announcement that "combining an over-the-counter nicotine-replacement patch with the nicotine-replacement lozenge is the best bet for smokers trying to quit." A [London](#) headline read "Using two nicotine products works best to quit smoking," in [Canada](#) it was the "Nicotine patch plus lozenge best for quitting smoking," in [India](#) "Nicotine patch, lozenge combo helps kick the butt" and in [Australia](#), "Nicotine lozenge and patch combined help to quit smoking faster."

"If you combine these different types of nicotine replacement you're going to get the best bang for your buck," the Australian story quotes UW-CTRI assistant professor and co-author Megan E. Piper as saying.

The problem with the University's "bang for the buck" sales pitch is that it's contrary to the study's findings. According to the [full-text](#):

"Finally, while there was substantial evidence that the patch plus lozenge was highly efficacious relative to the placebo condition, it is important to note that its 6-month outcome **did not differ significantly from the other active cessation treatments in head-to-head comparisons."**

Although not mentioned in the study's more widely circulated official summary (known as the [study abstract](#)), this finding was important enough to mention twice in the study's full-text. The other reference reads:

"It should be noted that there were **no significant differences either between the 2 combination conditions or among the monotherapy conditions at any of the time points using the Bonferroni-corrected P values."**

If the study found "no significant differences" between using the patch or lozenge alone than when using them at the same time, isn't the University of Wisconsin press release highly misleading? If "important to note," then why did the press release and study summary fail to note this critical finding? Why the headlines? Why, during hard economic times, encourage smokers to hand GlaxoSmithKline twice as much money to purchase its [Commit lozenge](#) and [Nicoderm CQ patch](#) when the study expressly found no "bang for the buck"?

Although we cannot undo the worldwide lozenge plus patch message broadcast by the University of Wisconsin, hopefully responsible journalists, health advocates and researchers will help shine light on what's happened here.

But the study is plagued by far more than NRT sales spin contrary to study findings. UW-CTRI Director Michael C. Fiore and staff co-authored a double-dose nicotine paper that either failed to investigate the percentage of patch-lozenge users who found themselves hooked on the cure at study's end, or failed to share those findings.

Missing data also includes continuous smoking cessation rates, missing one-year cessation rates, and failure to include a study blinding integrity assessment.

No NRT Chronic Use Findings

If GlaxoSmithKline Commit nicotine lozenge dosing recommendations were followed, study lozenge users were provided [20 lozenges per day](#), giving each a total of 1,680 lozenges over the study's 3 months lozenge use period (12 weeks). The paper contends that the study's duration and last follow-up was at 6 months. While participants were encouraged to return all unused lozenges, each was supplied a quantity sufficient to allow

9.3 lozenges per day for 6 full months.

Unlike a 2 mg or 4 mg piece of nicotine gum which traps nicotine, a 2mg or 4mg nicotine lozenge fully dissolves within 20-30 minutes. It releases up to 25% more nicotine than gum. There is still no public data on the percentage of lozenge quitters who experience long-term lozenge dependency. A [2003 study](#) found that up to 7% of nicotine gum quitters and 37% of all current gum users remain persistent long-term users for at least 6 months. Additionally, up to 2% of patch quitters are still using at 6 months.

The obvious question becomes, does the combination of wearing the patch while sucking lozenges produce significant long-term NRT dependency concerns? The authors acknowledge that "the nicotine patch plus nicotine lozenge has not been previously evaluated." Should UW-CTRI be telling smokers that the patch plus lozenge provides the most "bang for the buck" when UW-CTRI failed to evaluate and factor in the risk of long-term NRT dependency, and the thousands of extra bucks getting hooked could cost?

How difficult would it have been to request a urine sample when participants arrived for their six-month follow-up session, and test for nicotine's key use marker, cotinine? How many freedom seeking quitters did Dr. Fiore and his team leave [hooked on the cure](#)? What about that white coat oath to "first do no harm?"

Has UW-CTRI reflected on the array of [harms](#) flowing from long-term NRT addiction, including risk of seeing spikes in urine of the carcinogen NNN that may be [700 times greater](#) than seen in smokers, or nicotine's ability in [mice studies](#) to triple cancer tumor growth rates and accelerate cancer's spread rate by nine-fold?

How can informed consent ever evolve into becoming truly informed if researchers fail to evaluate and document known risks? Sadly, the first study to combine patch plus lozenge use cannot claim that any study participant successfully arrested their chemical dependency upon nicotine.

Missing Continuous Cessation Rates

Participant smoking status was checked at 1 week, the end of treatment (treatment ended at 8 weeks except for lozenge, which was used 12 weeks) and at 6 months. The study analyzed quitting using two different quitting definitions. According to the study:

"Smoking status was assessed both as 7-day point prevalence abstinence ('Have you smoked at all, even a puff in the last 7 days?') and continuous abstinence (smoking at all since the target quit day)."

The problem is that the study fails to disclose continuous abstinence rates. UW-CTRI registered this study with the government at [ClinicalTrials.gov](#) on June 1, 2006 but did not specify which quitting definition would be used, as is normally the case. Such built in flexibility allowed UW-CTRI to select and feature the outcome that most closely aligned with researcher biases.

Continuous abstinence quitting rates would be expected to be lower than point prevalence.

But how much lower? We don't know. It often takes NRT users a bit of time to adjust to transferring nicotine delivery from cigarettes to NRT. Cigarettes stimulate brain dopamine pathways within seconds while NRT stimulation requires minutes. It's rather easy for a participant who relapsed to smoking under a continuous abstinence standard to defeat carbon monoxide breath tests used to determine smoking status at follow-up visits.

Carbon monoxide has a four hour half-life. NRT cigarette substitution for a single day preceding a follow-up visit is likely to result in a relapsed smoker being classified as a successful quitter. Participant incentive to pass a breath test cannot be evaluated as the study fails to disclose follow-up attendance incentives or participant awareness of how the breath tests outcome impacts payment.

Point-prevalence quitting also does not account for a study participant who changed their quitting method. The duration of participant use of nicotine replacement therapy has never been an outcome determining factor in NRT clinical trials. For example, if a nicotine patch and lozenge user in this study decided to stop using both at the end of their first day of quitting, and successfully continued on cold turkey, this study counted them as having successfully completed nicotine replacement "therapy."

Given UW's multi-million dollar history of conducting pharmaceutical industry research, UW-CTRI should at a minimum have assured readers that there were no statistically significant differences between continuous cessation and point-prevalence outcomes. It didn't.

Missing One Year Cessation Rates

When UW-CTRI registered this clinical trial with the National Institute of Health's ClinicalTrials.gov study tracker on June 1, 2006, it stated that the primary outcome would be smoking cessation at 6 and 12 months as verified by expired carbon monoxide findings. Twelve months? Funded by the National Institute on Drug Abuse, the full-text of the study tells readers that final follow-up occurred at 6 months (26 weeks).

Did the study obtain one-year follow-up data? If so, where is it? Did UW-CTRI obtain one-year continuous and point-prevalence cessation rates? If so, what were those findings and are they consistent with the selected data featured by UW-CTRI?

It is not an acceptable excuse to claim that medical journal editors limited the length or word count of an article. Nearly all journals now allow additional unpublished supplemental research data to be shared online at the journal's website. But even if they don't, UW-CTRI has its own website.

Missing Blinding Integrity Assessment

A key boast of both the UW-CTRI study summary and press release is that the "nicotine patch plus nicotine lozenge produced significantly higher abstinence rates at 6-month postquit than did placebo" (odds ratio 2.34). But if either group was able to quickly determine their randomized assignment then the study was not blind as claimed. If not blind, assignment frustrations or satisfaction may have determined outcome instead of

product performance and worth.

The study randomly assigned 189 study participants to receive and use inert placebo products (37 to patch, 36 to lozenge, 41 lozenge plus patch, 37 lozenge plus Zyban, and 38 to Zyban) and 1,315 users to the true quitting product (262 to patch, 260 to lozenge, 267 lozenge plus patch, 262 lozenge plus Zyban, and 264 to Zyban).

This study commenced in [September 2004](#). Just three months earlier, a study jolted the University of Wisconsin's NRT empire. A [June 2004 study](#) found that placebo controlled NRT trials were generally not blind as claimed, that participants correctly determined group assignment at rates significantly above chance. The study warned researchers that:

"Clinical trials of NRT should uniformly test the integrity of study blinds. Moreover, if blindness failure is observed, subsequent efforts should be made to determine if blindness failure is related to study outcome and, if so, to provide an estimate of treatment outcome adjusted for blindness bias. Without these methods and analyses, the **validity of NRT clinical trial results could be questioned."**

The average quitter in the UW-CTRI study had 6 prior quitting attempts. Experienced quitters become skilled at recognizing the onset of full-blown withdrawal. Most join clinical trials in hopes of receiving free medication, a study advertising enticement tactic relied upon by UW-CTRI in recruiting study participants.

Among the UW-CTRI study's 189 placebo users, 58 (30.6%) failed to quit for an entire day and by week's end 145 of 189 (76.7%) had relapsed to smoking. Did frustrations over placebo assignment awareness contribute to relapse? We don't know. UW-CTRI either ignored the June study's "validity" warning or failed to disclose the study's blinding assessment results.

Researchers are awakening to the realization that it's probably [impossible](#) to blind experienced drug addicts to the presence or absence of full-blown withdrawal. It's common sense. Drug addiction is the only study area where the condition sought to be treated (withdrawal) does not exist until researchers command its onset. Drug addiction may be the only pharmacology research area where use of placebo controls is a license to steal.

How bad can blinding failures be? A [June 2009 nicotine patch study](#) by the the patch's co-inventor found that four times as many participants assigned to wear the placebo patch correctly determined their assignment as guessed wrong.

Did those assigned to use the active patch plus lozenge experience periodic over-stimulation of brain dopamine pathways by significantly greater quantities of nicotine than normal? If so, what role did awareness of nicotine's presence and satisfied stimulation expectations play in motivating them to continue on and receive the proven benefits of additional one-on-one counseling sessions? Were they eventually able to free themselves from external chemical stimulation? Again, we don't know.

Press Release Misrepresents Cold Turkey Effectiveness

When the University of Wisconsin press release caused "best bet" headlines to circle the globe, 70-90% of quitters were then and there engaged in cold turkey quitting attempts. Cold turkey quitters were not recruited or present in UW-CTRI study. It was not necessary for the UW-CTRI press release to bash and undermine cold turkey quitter confidence. But it did.

"We know that most smokers want to quit. Many have tried," declared the press release. "Many of the smokers who try, though, try 'cold turkey'; the least effective way to go about it with only a five percent or less success rate. Our findings offer a scientifically validated option. Forty percent of smokers who received the combination of the nicotine patch and the nicotine lozenge were able to achieve long-term abstinence. This treatment provided a two-fold better outcome for quitting success than did the placebo."

The above paragraph is highly misleading. UW-CTRI knowingly contrasts the generally accepted 12-month rate for uneducated, un-counseled and unsupported cold turkey quitters, 5%, to the lozenge plus patch's 40% 6-month rate after intense one-on-one counseling (an apples to oranges comparison). Including the "two-fold" placebo assertion within the same paragraph effectively suggests that placebo is four times as effective as cold turkey.

Even GlaxoSmithKline doesn't reach as far as UW-CTRI in implying a 5% six-month cold turkey quitting rate. For example, its [online marketing](#) for the Commit lozenge asserts that cold turkey quitters experience a 10% 6-month quitting rate.

Nor does the press release paragraph award any credit to what the study calls one-on-one "intensive counseling." The US Guideline evidence tables compiled by Dr. Fiore scream the independent effectiveness of counseling. The press release's assault on pharmacology's primary competitor ignores counseling's massive contribution in producing a rather impressive 6-month point-prevalence quitting rate of 40 percent.

What's fascinating about Professor GlaxoSmithKline is his attempts to change the definition of cold turkey quitting. He can't allow cold turkey to be defined as simply "abrupt nicotine cessation." Why? Because clinical NRT trials don't evaluate whether or not participants successfully arrest their underlying chemical dependency. It would leave him and his team out in the cold. Instead, his world revolves around a single method of nicotine delivery, smoking it.

Under Dr. Fiore's squinted definition, a cold turkey quitter who becomes educated by reading a cold turkey quitting book, or who receives quality support, can no longer be classified as a cold turkey quitter. In his mind, they have to quit in ignorance, alone and in darkness.

Dr. Fiore lives a double standard. In his world, a nicotine replacement user receiving "intense counseling" is held up as a successful NRT quitter, while the same counseling given to an abrupt nicotine cessation quitter strips them of their cold turkey status, while awarding full credit to counseling.

Dr. Fiore normally asks us to believe that a smoker joining a clinical trial in hopes of obtaining free "medication" has the same expectations as real-world cold turkey quitters, who expect to encounter and navigate full-blown withdrawal. This UW-CTRI press release may be the first occasion where his team has implied that cold turkey is not only inferior to NRT, but inferior to placebo too.

Professor GlaxoSmithKline has had sixteen years as UW-CTRI director to design a quality study that pits real cold turkey quitters against pharmacology quitters. He has yet to do so. Why?

UW-CTRI already knows the outcome. It knows that while pharmacology consistently crushes frustrated placebo quitters inside clinical trials, it falls flat on its face in head-to-head real-world competition against real cold turkey quitters. Most recently: a [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).

The press release fails to warn readers that clinical trial outcomes are often vastly different than seen under real-world conditions. Contrary to the press release, real-world [evidence](#) crowns cold turkey king.

Significantly Lower Milwaukee Rates Not Shared or Adequately Explained

The UW-CTRI study was apparently conducted at two different cities, Madison, Wisconsin and Milwaukee, Wisconsin. The study notes that:

"There was a significant main effect for the study site, such that, relative to Madison, Milwaukee had significantly lower 7-day point-prevalence abstinence rates at all 3 follow-up points."

The study fails to share how much lower the Milwaukee rates were. Nor is there any analysis as to how there could be so much variance between sites. Did counseling's substantive content, mode of delivery, or actual counseling time vary between sites? Did the lozenge plus patch provide the "most bang for the buck" in Milwaukee? If not in Milwaukee, then in what cities worldwide will it do so? Any? We don't know.

University of Wisconsin Violates Placebo Group's Human Rights

We're told that smoking claims half of adult smokers, with females losing an average of 14 years of life expectancy while males lose 13. The average smoker in this study was 44 years of age, smoked a pack-a-day and had 6 prior quitting attempts. For many, this study was their last chance for survival, as they'd run out of time and a smoking induced cancer, heart attack or stroke would soon claim them. As the study noted, they had a "high level of motivation."

If true, why would the University of Wisconsin rob them of their final period of cessation confidence? Why randomly assign participants to the least effective smoking cessation

intervention on earth, placebo? The [University of Wisconsin Health Sciences Institutional Review Boards](#) had responsibility for standing up to Professor GlaxoSmithKline and his team. It failed.

The University of Wisconsin review boards reference yet ignore the World Medical Association's Declaration of Helsinki on the "[Ethical Principles for Medical Research Involving Human Subjects](#)." Principle 32 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."**

Thousands of commercials and magazine advertisements have shouted existence of proven interventions since the U.S. Food and Drug Administration first approved nicotine gum in 1984. The U.S. National Library of Medicine's www.PubMed.gov search engine puts intervention findings from hundreds of smoking cessation studies at the fingertips of institutional review board members.

It isn't just the University of Wisconsin violating the UMA's Declaration of Helsinki. Search results at www.ClinicalTrial.gov identify more than [100 new smoking cessation studies](#) involving placebo controls.

Study Misrepresents Patch as Most Popular NRT

The authors devote three paragraphs to explaining why the lozenge, patch and Zyban were selected for study. Referencing 1995, 2000 and 2001 sources, the authors wrote:

"The nicotine patch was included in this study because it is the **most commonly used pharmacotherapy for smoking cessation."**

But according to a 2006 Mintel Report, nicotine gum held a 58% share of the U.S. NRT market in 2005 (\$288 million in sales), more than twice the nicotine patch's 28% share (\$138 million in sales).

Why did UW-CTRI misrepresent the patch as being the most commonly used NRT product? How can a University of Wisconsin press release twice anoint the lozenge + patch as "best" when the nicotine delivery device holding nearly a 60% share of the market wasn't evaluated?

Study Fails to Disclose It's Also a Psychiatric Study

After first reading the UW-CTRI study I was nagged by the fact that while 5,269 smokers were screened for participation that only 1,504 were included. Had the study cherry-picked participants? Although readers are told that 3,149 passed telephone screening, the study provides no explanation as to why the final 1,504 were chosen.

I soon stumbled upon an unpublished UW-CTRI study summary entitled "[Psychiatric](#)

[Disorders in Smokers Seeking Treatment: Differences in Dependence and Outcomes.](#)" It had been presented at a nicotine researcher's convention in Dublin in April 2009. The study involved an identical 1,504 participants and referenced the same NIDA study grant listed in the lozenge + patch study (P50 DA019760).

What the patch + lozenge paper fails to tell readers is that at least 1,080 of the study's 1,504 participants had a history of an [Axis I psychiatric disorder](#). The psychiatric disorders [study summary](#) notes that 205 participants suffered from a current Axis I anxiety disorder, 579 had a history of anxiety disorder, and 71 suffered from a current mood disorder. The summary proclaims that these participants "were less likely to achieve abstinence by the end of treatment than smokers without these disorders, regardless of treatment condition."

Overall, the unpublished study asserts that of the 1,470 participants who underwent mental health screening that 73.5% had at least one Axis I psychiatric disorder. What we don't know is how many were assigned to each pharmacology treatment group or the placebo group, how they performed, and how their performance affected that study arm's outcome.

If primarily a mental health quitting study, should UW-CTRI have disclosed that fact in both the lozenge + patch study and its press release? Were the 1,504 quitters chosen for the lozenge + patch study fairly typical smokers, or were they hand-picked based upon mental health issues? If not typical, has UW-CTRI mislead the world in assuming they were?

Missing Findings from Companion Primary Care Study

Interestingly, this clinical trial has an almost identical UW-CTRI primary care [companion trial](#). It does not involve placebo controls and substitutes the Wisconsin Telephone Quit Line for one-on-one face-to-face counseling sessions. According to ClinicalTrials.gov, the trial was completed more than a year ago, on July 24, 2008. I cannot locate any report or abstract from the study.

A portion of the companion study's description states:

"Randomized clinical trials may not accurately reflect the public health benefit of tobacco dependence pharmacotherapies when used in real-world clinical settings due to differences in patient selection, motivation, and adherence."

Clearly, this primary care companion study reflects conditions far closer to what's seen in real-world use. Why didn't UW-CTRI use results from the companion study to proclaim to the world the expected outcome after combining lozenge and patch use? What were those results? Were they not newsworthy? We don't know. If primary care findings were not consistent with clinical trial findings, are University of Wisconsin researchers free to issue press releases that fail to disclose inconsistent or contrary findings?

Suppressed Study Finding: Counseling Highly Effective

The biggest news from this study is the value of one-on-one pre-quitting counseling. It's highly unusual for any pharmacology study to afford participants, including the placebo

group, three one-on-one counseling sessions prior to experiencing peak withdrawal (between 24 and 72 hours), and another three afterwards. Even with a massive 77% placebo group smoking relapse rate after just one week, counseling roughly doubled the placebo group's expected six-month quitting rate to 22.2 percent.

But placebo isn't really a quitting method, is it? The ultimate question remains, what will the six-month quitting rate be for lozenge plus patch users under real-world use conditions, when they don't receive three hours of intense, one-on-one counseling?

A [2003 study review](#) by GlaxoSmithKline consultants found that when the nicotine patch was used under over-the-counter (O-T-C) conditions it produced a six-month rate of 7 percent. What if that finding was relative to this study where "intense counseling" plus patch use generated a 34.4% rate, and the patch plus lozenge generated a 40.1% rate? Wouldn't we expect O-T-C conditions to result in a six-month lozenge plus patch quitting rate in the neighborhood of 8 percent? Now, compare that to GlaxoSmithKline's [online assertion](#) that cold turkey generates a 10% six-month rate. See the problem?

But the pharmaceutical industry isn't selling counseling or trying to inspire quitters to trust their natural instincts. It sells products. It's why it isn't exactly fair to expect the industry or Professor GlaxoSmithKline to invest time and money working to refine and improve the substantive content of quality counseling and support.

University of Wisconsin Responsible for UW Studies & Press Releases

Perversion of science by pharmaceutical industry appropriation of a university's reputation, judgment and integrity isn't just a University of Wisconsin concern. College campuses around the world are being transformed into product sales control centers.

When universities refuse to exercise health research oversight it isn't just their reputations at risk. Here, millions of smokers worldwide trusted in the University of Wisconsin's institutional integrity.

The World Health Organization asserts that during the next year smoking will claim five million worldwide. This University of Wisconsin press release has infected the entire world with the insane message that the answer to smoking nicotine is to purchase and introduce as much pharmaceutical grade nicotine into your bloodstream as possible.

Like a house of cards, hundreds of default efficacy victories born of unblinded frustrations are destined to fall. Real science is beginning to expose the most deadly medical research sham the world has ever known. We can only hope that all who knowingly participated eventually face accountability.

I, [John R. Polito](#), am solely responsible for the content of this article. Any errors brought to my attention will be immediately corrected.

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Related Links and Articles

- Polito, JR [The Surgeon General's Reports: 50 years of cessation ignorance](#), January 20, 2014
- Polito, JR [Australia's half-baked quit smoking campaign](#), November 30, 2013
- Polito, JR [The Great American quit smoking sham](#), November 18, 2013
- Polito JR [BMJ's non-publication policy should extend to pharma's nicotine](#), BMJ, October 19, 2013
- Gallup [Gallup Poll: cold turkey 48 times smarter than Nicorette](#), August 26, 2013
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Learn More About Smart Turkey Quitting

- WhyQuit.com - WhyQuit is the Internet's oldest forum devoted to the art, science and psychology of cold turkey quitting, the stop smoking method used by the vast majority of all successful long-term ex-smokers. Left to



right, WhyQuit is organized under three headings: (1) Motivation, (2) Education and (3) Support.

- **"Never Take Another Puff"** - Imagine a free 149 page stop smoking ebook that's registered more than 4 million downloads and was written by a man who has devoted 40 years, full-time to helping smokers quit. Never Take Another Puff (NTAP) was authored by Joel Spitzer, the Internet's leading authority on how to stop smoking cold turkey. It is an insightful collection of almost 100 articles on every cessation topic imaginable.
- **"Freedom from Nicotine - The Journey Home"** - Written by John R. Polito, a former 30-year heavy smoker and WhyQuit's 1999 founder, Freedom from Nicotine (FFN) is a free nicotine dependency recovery book that documents the science underlying nicotine dependency and successful cessation. Whether hooked on cigarettes, e-cigarettes (e-cigs), bidis, kreteks, a pipe, hookah or cigars, on dip, chew, snuff or snus, or on the nicotine gum, lozenge, spray, inhaler or patch, FFN provides a comprehensive yet easy to follow road-map to freedom from nicotine.
- **Turkeyville** - Visit Turkeyville, Facebook's most popular quit smoking support group. The group's primary focus is the first few days and helping new quitters get started. Yes you can!
- **Joel's Library** - Joel's Library is home to Joel Spitzer's "Daily Quitting Lesson Guide." The Guide walks new quitters through the first two weeks of smoking cessation, recommending daily videos to watch and articles to read. Joel's Library is also home to more than 100 original short stop smoking articles, to his free ebook Never Take Another Puff, and to his collection of more than 200 video stop smoking lessons.
- **Nicotine Addiction 101** - WhyQuit's guide to understanding nicotine dependency.
- **Freedom** - Looking for a deadly serious and highly focused education oriented support group? Home to Joel Spitzer, Freedom is the Internet's only 100% nicotine-free peer messageboard support forum. Explore Freedom's hundreds of thousands of archived member posts on how to quit smoking.
- **Nicotine Cessation Topic Index** - An alphabetical subject matter index to hundreds of nicotine cessation support group discussions, article and videos.
- **40 Quitting Tips** - Key cold turkey nicotine cessation tips on how to stop smoking, vaping, chewing or sucking nicotine into your body and bloodstream.



Knowledge is a Quitting Method!



<u>WhyQuit</u>	<u>Law of Addiction</u>	<u>Joel's Library</u>	<u>Freedom</u>	<u>Turkeyville</u>	<u>How to Quit</u>
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