



## HOW SAFE ARE NOVEL NICOTINE PRODUCTS?

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During the past several years, there has been a steady stream of unusual, bizarre and potentially unsafe products, foods and beverages containing nicotine being sold to consumers. While these products are indeed novel and make for amusing stories, they pose some very real and serious health concerns. Unlike their medicinal counterparts (e.g., nicotine gum, patch, lozenge) that have been tested and approved for safety and effectiveness by the Food and Drug Administration (FDA), these products have not been tested and yet they are readily available to consumers with no independent assessment of their potential health risks. In a medicinal form that has been approved by FDA for use as a cessation aid, nicotine is safe. However, in these new forms and products, safety (let alone effectiveness) is completely unknown and there is a very real potential for nicotine poisoning and toxicity (or other harmful side effects unrelated to nicotine but due to other ingredients, and their dosage, in these products).

While some of these products may be safe and might even be effective at helping tobacco users quit smoking or chewing, none of them have undergone the rigorous scrutiny of similar nicotine-containing cessation products approved by the FDA. Until these products undergo the necessary clinical trials and are deemed by the FDA as safe and effective as tobacco cessation products, they should be viewed with caution due to the potential health risks and with skepticism due to the unverified claims about the product's effectiveness.

### What is Nicotine?

- "Nicotine ... is a naturally occurring colorless liquid that turns brown when burned and acquires the odor of tobacco when exposed to air. There are many species of tobacco plants; the tabacum species serves as the major source of tobacco products today. Since nicotine was first identified in the early 1800s, it has been studied extensively and shown to have a number of complex and sometimes unpredictable effects on the brain and the body."<sup>1</sup>
- The chemical formula for nicotine is C<sub>10</sub>H<sub>14</sub>N<sub>2</sub>. In proper nomenclature, nicotine is 3-(1-Methyl-2-pyrrolidinyl)pyridine.<sup>2</sup>

### Nicotine Safety and Toxicity

- "[T]he safety of nicotine depends very much on the dose, pattern, and duration of exposure."<sup>3</sup>
- "The rapidity of nicotine dosing is important in that rapid dosing results in much higher arterial concentrations and high concentrations at the sites of nicotine effects, including the brain and the heart."<sup>4</sup>

### Symptoms of Nicotine Overdose<sup>5</sup>

- Body as a whole: muscular twitching; weakness; convulsions; coma ; and collapse.
- Respiratory system: difficulty breathing; rapid breathing; and no breathing.
- Eyes: dilated pupils
- Gastrointestinal system: abdominal cramps, vomiting, drooling, burning in mouth causing mouth lesions.
- Cardiovascular system: rapid and pounding heartbeat followed by slow heart rate, elevated blood pressure followed by decreased blood pressure.

- Nervous system : confusion, excitement, depression, headache, agitation, restlessness.

Overdose may cause seizures. Recovery depends on the dose, time to treatment, and severity of seizures. Overdose is potentially fatal. Recovery is usually gradual, following a period of weakness.

### New Nicotine-based Products, Foods, and Beverages



**Nicotinis** – Several newspaper stories have recently been published in New York City, Boston, and Florida about bars and restaurants developing strange and novel food and beverage products containing tobacco in the aftermath of comprehensive smoke-free workplace laws taking effect.<sup>6</sup> Of these strange novelties, the one that appears to be garnering the most curiosity amongst the media and among some bar owners and their clients, is the nicotini – a martini flavored with tobacco juice. According to news reports, these drinks contain various flavored vodkas and the juices of tobacco leaves (that have been marinated/steeped in vodka and then drained for the juice). The drive behind these products, according to bar owners, is to cater to their smoking clients who need a nicotine fix but don't want them to leave the bar. The concern with a product like a nicotini, or any other food or beverage containing nicotine, is that depending on the amount of tobacco used, the length of steeping/marinating, the size/physical stature of the customer, and the amount and frequency of the product consumed, there is a very real risk for nicotine poisoning/toxicity. Nicotine, in the absence of strict controls over its use, is a poison. What if suddenly, the price of a gallon of gas tripled? Would bars start serving Gasolini's in protest? While novel and interesting, these products are potentially hazardous (even deadly) to unsuspecting customers.



**Nicotine Lollipops** – Lollipops laced with nicotine have appeared and disappeared from pharmacies and the Internet several times in recent years. Manufactured by compounding pharmacists, several internet/online pharmacies were ordered by FDA to stop selling these products last year due to concerns over product safety, risk to children, and use of an unapproved form of nicotine.<sup>7</sup> However, despite this order from FDA, some compounding pharmacies have continued to sell their own versions of these products. While novel, they pose serious questions of safety (not just to children but to the intended user) as well as effectiveness. In addition, several pharmacies selling these lollipops did not provide any directions for use, warnings about contra-indications to use, ingredients, or anything else that would be helpful to a user in terms how to use the product and when not to use the product. While this is an interesting concept for a possible cessation aid, its safety and effectiveness are unknown and, unlike some of the other novel nicotine products, nicotine lollipops raise particular concerns about the attractiveness of this product to children.



**NICOTINEWAFER.COM**  
**NO SMOKING? NO PROBLEM!**

**Nicotine Wafers** – This product, along with NicoWater, is the most recent entrant in a market that appears to be growing to take advantage of the recent upswing in smokefree workplace laws. The manufacturer is targeting smokers who can't smoke due to workplace or other regulations on smoking ("The NicotineWafer is used primarily when you're not allowed to smoke by regulation or choose not to smoke.") The manufacturers claim that their product is not a cessation aid but

a short-term withdrawal suppressant. This tactic is similar to claims being used by several smokeless tobacco companies for products such as Ariva (“When You Can’t Smoke”), Revel (“Anytime. Anywhere.”), and Exalt (“No Smoking? No Problem”). However, closer scrutiny of information available on the manufacturer’s website reveals that this product is also intended for cessation – “If you’re quitting, use the Nicotine Wafer to make it easy.” The website also provides reasons to use the product even if you’re not a current tobacco user– “Nicotine improves concentration, energy and mood, and is the reason many people choose to smoke. The wafer delivers the same amount of nicotine as a cigarette.” These claims make it clear that this product, like NicoWater, is an unapproved cessation drug and needs FDA approval prior to being made available to consumers. In the absence of this approval, there are serious, unanswered concerns about its safety and effectiveness.



**Nicotine Water** – Bottled water with nicotine (yes, you read this right). Nicowater is a product being sold that looks like most bottled waters, except that it claims to contain 4mg of nicotine per bottle – or the equivalent of two cigarettes. Last year the Food and Drug Administration ruled that Nicowater was an unapproved drug and was being sold as a cessation aid without first being tested for safety and effectiveness like other nicotine-based products used as quit smoking aids such as nicotine gum and the patch.<sup>8</sup> NicoWater, despite this ruling from FDA, has, according to the manufacturer, reformulated its product to be a homeopathic remedy thus circumventing FDA regulation and claims that it is intended only for short-term withdrawal suppression (“NICOWater™ is a homeopathic formula developed for adult smokers who suffer from the symptoms of tobacco cravings and find themselves in situations and/or environments where smoking is prohibited or discouraged.”). However, according to the makers of NicoWater, this product still contains 4mg of nicotine per bottle – which is contrary to the very core of what constitutes a homeopathic product. While this product may have potential as a smoking cessation aid, we will not know the answer to that question until the manufacturer submits a new drug application to FDA and starts the clinical trial process necessary to evaluate the product’s safety and effectiveness. Until that process is completed and this product is approved by FDA, we have to question its safety and effectiveness and recommend FDA-approved cessation aids to tobacco users interested in quitting.

### **If you REALLY Want To Quit, Follow the Advice of the Experts**

In June 2000, the U.S. Public Health Service issued comprehensive clinical treatment guidelines for tobacco cessation<sup>9</sup> (*Treating Tobacco Use and Dependence*). These guidelines, which were subjected to a rigorous peer-reviewed process and developed by the leading experts in cessation in the United States, discuss in detail the most effective and proven strategies to help tobacco users quit smoking and chewing tobacco. If you want to know what works and what does not work in cessation, this is the document to turn to for guidance.

**Individual Level Interventions – Counseling.** The PHS Guidelines confirm the fact that the more frequent a tobacco user talks to and interacts with his/her doctor, dentist, pharmacist, nurse, psychologist (or other health care professional involved his/her quit attempt), the greater the chances he/she has of successfully quitting and remaining abstinent. The clinical guidelines concluded that four specific types of counseling and behavioral therapy categories yield statistically significant increases in abstinence (in relation to no intervention), including:

1. providing practical counseling such as problem solving skills, training/relapse prevention, and stress management;
2. providing support during a smoker’s direct contact with a clinician;
3. intervening to increase social support in the smoker’s environment; and,
4. using aversive smoking procedures (rapid smoking, rapid puffing, other smoking exposure).

**Individual Level Interventions – Pharmacotherapy.** In addition to counseling, the PHS Guidelines strongly recommend the use of FDA-approved drug treatment (where clinically appropriate) in conjunction with counseling, to increase the likelihood of a successful quit attempt. The types of drugs recommended break down into two main categories – those that are nicotine-based (nicotine replacement therapies) and those that treat other symptoms experienced by individuals attempting to quit (e.g., depression). The treatments recommended include:

- Nicotine Gum (commercially available as<sup>10</sup>: Nicorette, Nicorette Mint, Nicorette Orange, generic) – Nicotine gum has an established record of clinical efficacy and increases long-term abstinence rates (over placebo – no drug treatment) by 30 to 80 percent. It is available only as an over-the-counter product.
- Nicotine Patch (commercially available as: Nicoderm CQ, Nicotrol, Habitrol, generic) – The nicotine patch has an established record of clinical efficacy and approximately doubles long-term abstinence rates (over placebo – no drug treatment). It is available both over-the-counter and as a prescription medication.
- Nicotine Inhaler (commercially available as: Nicotrol Inhaler) – The nicotine inhaler has an established record of clinical efficacy and more than doubles long-term abstinence rates (over placebo – no drug treatment). It is available only as a prescription medication.
- Nicotine Nasal Spray (commercially available as: Nicotrol NS) – Nicotine nasal spray has an established record of clinical efficacy and more than doubles long-term abstinence rates (over placebo – no drug treatment). It is available only as a prescription medication.
- Bupropion SR (commercially available as: Zyban) – Bupropion SR has an established record of clinical efficacy and approximately doubles long-term abstinence rates (over placebo – no drug treatment). This is a non-nicotine medication and is available only in prescription as either a smoking cessation product (Zyban) or an anti-depressant (Wellbutrin).

[Note, a nicotine lozenge, known as Commit, has since been approved by FDA for use as an approved, over-the-counter, nicotine-based cessation aid – but it was not studied as part of the PHS Guideline review.]

**Campaign for Tobacco Free Kids, October 21, 2003 / Ann Boonn**

**Related Campaign for Tobacco-Free Kids Factsheets ([www.tobaccofreekids.org](http://www.tobaccofreekids.org))**

- *Tobacco Cessation: An Overview*
- *Tobacco Cessation Works: An Overview of Best Practices and State Experiences*
- *Benefits from Tobacco Use Cessation*
- *Resources for Quitting Smoking*
- *Key Tobacco-Cessation Findings and Recommendations from the U.S. Public Health Service and U.S. Preventive Services Task Force*
- *State Cessation-Related Statistics & Potential Savings from Reducing Smoking by One Percentage Point*
- *Medicare and Medicaid Costs & Savings From Covering Tobacco Cessation*
- *What Kind of Tobacco Cessation Might Medicare, Medicaid, and Private Health Insurers Cover?*

<sup>1</sup> *NIDA Research Report Series, Nicotine Addiction*, NIH Publication No. 01-4342, <http://www.nida.nih.gov/researchreports/nicotine/nicotine.html>.

<sup>2</sup> [http://www.galaxygoo.org/nicotine/what\\_is\\_nicotine.html](http://www.galaxygoo.org/nicotine/what_is_nicotine.html).

<sup>3</sup> *Nicotine Safety and Toxicity*, edited by Neal L. Benowitz, MD, Oxford University Press, 1998.

<sup>4</sup> *Nicotine Safety and Toxicity*, edited by Neal L. Benowitz, MD, Oxford University Press, 1998.

<sup>5</sup> Wheeler, KG, Department of Emergency Medicine, Boston Medical Center, Boston, MA. Review provided by VeriMed Healthcare Network. <http://www.nlm.nih.gov/medlineplus/ency/article/002510.htm>.

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<sup>6</sup> <http://www.sun-sentinel.com/features/printedition/search/sf-licicotini30jul30.story>;  
[http://gershkuntzman.homestead.com/files/Tobacco\\_in\\_Your\\_Tiramisu.htm](http://gershkuntzman.homestead.com/files/Tobacco_in_Your_Tiramisu.htm);  
<http://www.bebeyond.com/LearnEnglish/BeAD/Readings/CosTrendHealth.html>; <http://discover.npr.org/features/feature.jhtml?wfid=1220315>  
(click on audio link)).

<sup>7</sup> For more information, see <http://www.fda.gov/bbs/topics/ANSWERS/2002/ANS01144.html>.

<sup>8</sup> For more information, see <http://www.fda.gov/bbs/topics/NEWS/2002/NEW00818.html>.

<sup>9</sup> Fiore MC, Bailey WC, Cohen SJ, et al. *Treating Tobacco Use and Dependence*. Clinical Practice Guideline. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. June 2000, [http://www.surgeongeneral.gov/tobacco/treating\\_tobacco\\_use.pdf](http://www.surgeongeneral.gov/tobacco/treating_tobacco_use.pdf).

<sup>10</sup> This is NOT a product endorsement, just a statement of fact about FDA-approved stop smoking aids available to consumers.