



Smoke Signals: The Misinformation Behind FDA's Proposed Regulation Of E-Cigarettes

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The U.S. Food and Drug Administration recently proposed new rules targeting electronic cigarettes. By its authority under the Food, Drug, and Cosmetic Act and the Family Smoking Prevention and Tobacco Control Act, FDA now regulates “tobacco products” — cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The proposed regulation would “deem” additional products within the scope of the statutory definition of “tobacco product.” FDA would deem electronic cigarettes to be tobacco products, even though e-cigs don’t contain tobacco leaves. The deeming regulation would give FDA the power to govern e-cigs’ manufacture, sale, and use, implementing age restrictions, mandating additional scientific review of products, and scrutinizing claims made by the makers of e-cigs.

The new regulations would prevent e-cigarette manufacturers from telling consumers that their products are a safer alternative than tobacco cigarettes. The deeming regulations would prohibit claiming that vaporized nicotine “presents a lower risk of tobacco-related disease or is less harmful than one or more commercially marketed tobacco products.” In fact, the new rules would prevent them from even advertising to the public that their “product or its smoke does not contain or is free of a substance,” even though e-cigs do not produce smoke and do not contain tobacco in any common-sense meaning of the word.

Banning this sort of claims is absurd: e-cigs lack the more than 4,000 chemicals, many of them carcinogenic, of combustible tobacco cigarettes. Electronic nicotine vaporizers need not be particularly healthy in order to be less unhealthy than traditional cigarettes.

This regulatory push is poisoned by a bevy of bad arguments. Most of the rhetoric consists of pure emotion on the part of anti-tobacco activists. Certain anti-tobacco and anti-smoking factions grow hysterical at the mere specter of smoking. Unfortunately, a more powerful lobby is also trying to squelch e-cigs

First, consider the common-sense reaction to the idea of deeming e-cigarettes a tobacco product even though they don’t contain obvious tobacco. If anything, e-cigs are essentially nicotine vaporizers. They

consist of a small battery that warms a chamber filled with water, liquid nicotine, a vapor-producing agent, and flavoring.

Propylene glycol or vegetable glycerin produces the vapor. PG is “generally recognized as safe” by the Center for Disease Control when PG is used as a food preservative in products like ice cream and salad dressing. Some e-liquid manufacturers boast that their PG and VG is USP Grade and Kosher Certified. The flavoring used in reputable e-cigs may be artificial or natural, just like you’d expect from other food and beverage flavorings. There are suppliers that offer 100% organic versions.

So, how does a product like this count as a “tobacco product” according to FDA?

In a 2010 decision, [Sottera, Inc. v. FDA](#), the D.C. Circuit ruled that FDA can regulate all products made or derived from tobacco under its “tobacco product” authority in the FDCA except products that are “marketed for therapeutic purposes.” Those latter products are regulated by FDA as drugs or devices.

Nicotine is an alkaloid extracted from plants in the nightshade family, including the tobacco plant. Since the nicotine compound is ultimately derived from tobacco, and e-cigs use liquid nicotine, FDA wants to deem them tobacco products.

Nicotine used in smoking cessation products like patches, gums and lozenges is also extracted from tobacco plants. Since even over-the-counter versions of those products are marketed for the therapeutic purpose of kicking smoking, not mere recreation, FDA regulates them as drugs or devices, not as tobacco products.

Aside from marketing claims, how different are e-cigs from other FDA-approved sources of nicotine?

Nicotine inhalers like Nicotrol are FDA-approved, prescription-only smoking cessation devices that also utilize liquid nicotine. They consist of a mouthpiece and a plastic cartridge of liquid nicotine. Sound familiar? (Incidentally, all of the scary statistics lately about nicotine toxicity related to mishandling of liquid nicotine used to fill e-cig cartridges extends to inhaler cartridges like those used in Nicotrol therapy.) [Nicotrol’s website](#) touts that inhalers “supply you with nicotine in controlled amounts while sparing you from other chemicals found in tobacco products.” If that’s so awesome for inhalers made by Pfizer, why is it not a compelling argument in favor of e-cigs?

If FDA regulates e-cigs under its “tobacco authority,” then manufacturers may not claim that their products might help someone to stop smoking tobacco cigarettes. If they wanted to make such claims, they would fall under FDA’s therapeutic drug/device provision. This classification would allow manufacturers to suggest this use of e-cigs to consumers, but it would also subject e-cigs to the enormous bureaucratic burdens of FDA’s drug/device approval process. FDA regulation of e-cigs as drug-delivery devices would almost certainly stymie efforts of e-cig manufacturers to bring their products to market in the long term.

For an entertaining and informative refresher on why that process sucks, watch this recent Intelligence Squared debate, [“The FDA’s Caution is Hazardous to Our Health.”](#) Arguing in favor of the motion is [Peter Huber](#) — Manhattan Institute fellow, partner at litigation boutique [Kellogg Huber](#), former MIT

mechanical engineering professor, and former clerk for now-Justices Ruth Bader Ginsburg and Sandra Day O'Connor. Huber argues persuasively (albeit spastically) that FDA stifles innovation and relies on bad scientific methods.

Instead of acknowledging the potential of e-cigs to reduce exposure to the harms of tobacco, e-cig opponents argue that the products may actually *lead to smoking*. Yet, most people use e-cigs to replace tobacco cigarettes. They either wean themselves off of tobacco with vaporizers, or they substitute vaporizers for tobacco cigarettes when smoking would be impermissible or inconvenient. *Does drinking Diet Coke lead to consumption of regular Coke?*

So who is behind the drive to bury e-cigs?

Some activists think we ought to have zero tolerance for any behavior that resembles or reminds us of smoking. Purveyors of this militant stance are unrealistic, unpragmatic, and intolerant. This attitude is typical of abstinence-only zealots, whether the evil they perceive is smoking, premarital sex, or anything else. The zealots draft blue laws. They reduce sex ed to a joke. They call in regulators. They traffic in histrionics and paternalism.

More notably, the pharmaceutical industry [strongly opposes e-cigs](#). Why? Drug companies like GlaxoSmithKline, producer of Nicorette, Johnson & Johnson, producer of nicotine patches, and Pfizer producer of the ([potentially crazy-making](#)) prescription drug Chantix, have been fighting hard to get the government to crack down. They compete with e-cigarette manufacturers for the business of helping people quit smoking.

Is smoking tobacco cigarettes an unhealthy habit? Yes. Is it possible that vaporizing liquid nicotine is an unhealthy habit? Maybe. So is a cheeseburger-laden lunch, a margarita-sloshed happy hour, and a tendency to be a pompous ass who tells other grown-ups which vices they may prioritize over some aspect of physical well-being. Claiming that vaporizing nicotine is *less safe than burning tobacco* is an absurdity born of moralizing over-regulation and the economic motivations of a competing industry.

The FDA allows public comment on its proposed rule until July 9, 2014.