

Submission to the FDA regarding e-cigarette "deeming regulations"

By ACSH Staff — June 30, 2014

June 27, 2014

To:

Center for Tobacco Products

Docket No. FDA-2014-N-0189

From:

The American Council on Science and Health

Elizabeth M. Whelan, Sc.D., M.P.H., President

Gilbert L. Ross, M.D., Medical Director

Re: Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products

The American Council on Science and Health (ACSH), a public health education and consumer advocacy nonprofit devoted throughout our 35 year history to the promotion of sound science in public health policy, urges the FDA to promote the benefits of electronic cigarettes as a method of Tobacco Harm Reduction (THR) in helping smokers quit, and reconsider the e-cigarette regulations proposed by the FDA. These deeming regulations would make e-cigarettes less accessible, affordable, or attractive to adult consumers who are choosing to use e-cigarettes as a safer alternative to smoking. These proposed regulations on e-cigarettes should be commensurate with health risk and because e-cigarettes are far less harmful than combustible tobacco products, the regulations should take that into account. Although we do agree that e-cigarettes should not be sold to minors and that they should contain health warnings about the potential for addiction to nicotine, the requirement for manufacturers to obtain pre-market approval via a new tobacco product application will limit the availability of e-cigarettes to addicted smokers trying to quit.

The FDA estimates that these applications will require thousands of man-hours of data collection and hundreds of thousands (or millions) of dollars or more, a burden few current e-cigarette companies will be able to survive. Yet, the older, less reliable products entering the market before February 15, 2007 will be grandfathered in under the Family Smoking Prevention and Tobacco Control Act. And still, this applies to only about one percent of all e-cigarettes and vapor products.

The reality is that the only e-cigarette marketers with the wherewithal to play the FDA's regulation game are those manufactured by Big Tobacco. And the truly tragic aspect is that the FDA continues to trumpet its success thanks to the FDA-approved cessation aids in spite of the fact that the smoking rate has fallen only three percentage points over the past seven years, from 21 percent in 2005 to 18 percent in 2012 and the fact that these methods succeed only slightly more often than cold-turkey quitting.

Our own published research on this subject¹ published in a peer-reviewed academic journal, as well as many other studies and epidemiological data, support our assertion that the methodologies comprising THR the substitution of low-risk nicotine-delivery products to replace lethal cigarettes have significant potential benefits in terms of reducing the tragic toll of cigarette smoking by supplying addicted smokers with the substance they crave nicotine but at a much reduced cost in terms of adverse health effects.

Those who support the concept of tobacco harm reduction, including ACSH, urge you to rely on the readily available scientific and empirical evidence to recommend policies promoting THR and e-cigarettes, which is this:

- The benefits from electronic cigarettes for public health are supported by a growing mountain of scientific and empirical evidence, which over the past five years consistently indicates that e-cigarettes:

- are approximately 99% less hazardous than cigarettes
- are consumed almost exclusively (i.e. > 99%) by smokers and former smokers who quit by switching to e-cigs
- have helped several million smokers quit and/or sharply reduce cigarette consumption
- have contributed to the historic declines in sales of cigarettes over the past two years

The most important piece of supporting evidence for the use of e-cigarettes to help smokers quit is this:

While many smokers, the public, and even many physicians, believe that nicotine is a toxic component of cigarette smoke, in fact the toxic chemicals reside amongst the thousands of other chemicals in the tar and the gas phase. The nicotine is the primary (but not the sole) addictive agent ***smokers smoke for the nicotine, but they die from the smoke.***

Furthermore, studies have indicated that levels of the contaminants that e-cigarette users are exposed to are far below any levels that would pose a health risk. And, the exhaled vapor poses no risk to bystanders.^{2,3}

If onerous, needless regulations such as those recently proposed by the FDA are enacted presenting obstacles for desperate smokers trying to quit electronic cigarettes will become black market items or sold almost exclusively by Big Tobacco companies, eager to snap up the currently vibrant small businesses in the e-cigarette stream of commerce.

Even worse is the fact that government agencies continue to misrepresent the findings of studies conducted on the safety and use of e-cigarettes. In September 2013, CDC Director Tom Frieden

and OSH Director Tim McAfee falsely claimed that nicotine (but not Big Pharma's tobacco derived nicotine) damages the brain, that e-cigarettes are addictive, and that e-cigs are gateways to cigarette smoking for teens. They did so by intentionally misrepresenting their own NYTS survey findings by repeating their deceitful talking point that e-cig use by teens had doubled from 1% in 2011 to 2% in 2012. But CDC's survey actually found that past-30-day use of an e-cig by teen smokers increased from 7.6% in 2011 to 15.7% in 2012, while use by nonsmoking teens increased from .36% in 2011 to .7% in 2012, which demonstrates that teen smokers are switching to e-cigs just like adult smokers and that virtually no nonsmoking teens have used an e-cig. Since then, CDC Director Tom Frieden has repeated his false claims over and over again in press releases and on interviews with news media to further confuse, scare and lobby for the FDA deeming regulation.

Making e-cigs inaccessible to desperate smokers by these needless measures will send smokers this message: *Keep on smoking*. While no tobacco product is free of health risks, e-cigarette and vapor products are a noncombustible alternative to traditional cigarettes. Regulations should not create hurdles or discourage cigarette smokers from switching to non-combustible products such as vapor products which these proposed regulations certainly would. The likely outcome, should these regulations be passed, is a severe reduction in consumer (smoker) choice, and thus fewer quitting and more preventable deaths we already have almost one-half million smoking-related deaths each year (as opposed to zero from e-cigarettes).

The World Health Organization predicts **one-billion** prematurely dead from cigarettes this century if current trends continue. That must not be allowed to happen. While some agenda-driven opponents of e-cigarettes warn: We just don't know what might happen with e-cigarettes, we at The American Council on Science and Health respond, We surely do know what will happen with the real ones: e-cigarettes present the best hope for averting this catastrophe if stringent regulations are avoided.

Thank you for your consideration.

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