

*Via Courier
and Overnight Mail*

Todd A. Harrison

T 202.344.4724
F 202.344.8300
TAHarrison@venable.com

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Howard Shelanski, Esq., Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
The White House
Washington, DC 20500

**Re: Request for Meeting Regarding FDA's Proposed Electronic Cigarettes
"Deeming" Regulation**

Dear Mr. Shelanski:

We write on behalf of the Smoke Free Alternatives Trade Association (SFATA), a trade association of United States companies engaged in the electronic cigarette ("e-cigarette") industry. SFATA members represent a significant percentage of the U.S. domestic sales of e-cigarettes and, accordingly, have a substantial interest in the regulatory status of e-cigarettes.

In December 2012, SFATA met with OIRA's then-Acting Administrator, Boris Bershteyn, to discuss the association's concerns regarding a potential U.S. Food and Drug Administration (FDA or "the agency") "tobacco product deeming regulation." Such a regulation would "deem" e-cigarettes as "tobacco products" and thus subject them to the full panoply of regulations and obligations under the Family Smoking Prevention and Tobacco Control Act ("Tobacco Act"). It is now our understanding that these deeming regulations have been forwarded to OIRA for assessment pursuant to Executive Orders 12866 and 13563.

In exercising its agency oversight authority, we beseech OIRA to rigorously evaluate the scientific, technical, economic, and other information proffered by FDA in support of this regulation when quantifying its costs and benefits. In doing so, you will find that the likely effects of these deeming regulations will devastate the e-cigarette industry and FDA has indisputably failed to consider multiple alternatives.

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An E-Cigarette Is Not A Tobacco Product

SFATA's position is that an e-cigarette is not a "tobacco product," as defined in Section 101(a)(rr)(1) of the Tobacco Act.¹ The Tobacco Act is not the appropriate vehicle to regulate e-cigarettes because there are substantial differences between e-cigarettes and traditional "tobacco products." Most fundamentally, e-cigarettes involve no burning or combustion and generally contain a rechargeable lithium battery, vaporization chamber, and cartridge (usually containing nicotine and propylene glycol). Some e-cigarettes do not even contain nicotine. As a result of these and other considerable differences, there is no evidence of which we are aware (and certainly none which FDA has published) which would suggest that the risk/safety profile of e-cigarettes is in any way comparable to that of true tobacco products. The same point applies to good manufacturing practices ("GMP"). The differences between e-cigarettes and tobacco cigarettes are so great that the GMP standards appropriate for one are plainly not appropriate for the other.²

Furthermore, it is no answer to the above argument to say that the *Sottera, Inc. v. FDA*³ decision itself stands for the proposition that e-cigarettes are "tobacco products" because the case did not present the question of whether e-cigarettes are (or are not) "tobacco products." Instead, the question presented in *Sottera* was simply whether e-cigarettes were "drugs" or "devices."

Congress Never Intended for the Tobacco Act to Apply to E-Cigarettes

Of additional significance, Congress never intended for the Tobacco Act to apply to e-cigarettes. The Tobacco Act was enacted to regulate tobacco and the smoking of tobacco because of the serious adverse health consequences of tobacco smoking. Proof of this is found throughout the Tobacco Act, but is most explicitly acknowledged in the congressional factual findings which provide the predicate to the Act.⁴ For example, Finding No. 13 states that tobacco use "causes over 400,000 deaths in the United States each year, and approximately 8,600,000 Americans have chronic illnesses related to smoking" and Finding No. 14 indicates that a 50% reduction in youth smoking would "result in approximately \$75,000,000,000 in savings attributable to reduced health care costs."⁵

¹ See SFATA's comments submitted in Federal Register Dockets FDA-2012-D0071 and FDA-2012-D-0049.

² For your convenience, we have enclosed draft legislation that effectively addresses the unique characteristics of vaporizing products, like e-cigarettes.

³ 627 F.3d 891 (D.C. Cir. 2010).

⁴ See Tobacco Act § 2.

⁵ *Id.*

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Recent studies suggest that there is no comparison between tobacco smoke and e-cigarette vapor when it comes to serious adverse health effects. In fact, researchers have found that secondhand vapor from e-cigarettes poses no discernible risk to the public health. In October 2012, CHANGE, LLC at the Center for Air Resources Engineering and Science at Clarkson University in Potsdam, NY published an indoor air quality study.⁶ The study compared harmful by-products commonly found in tobacco smoke to the levels of those same compounds found in several popular brands of vaporized e-cigarette liquid. The study concluded, “For all byproducts measured, electronic cigarettes produce very small exposures relative to tobacco cigarettes. The study indicates no apparent risk to human health from e-cigarette emissions based on the compounds analyzed.”

To the extent that the agency presents OMB with scientific data to support that e-cigarettes are a particular danger to children, this research is severely limited. In fact, the only information we are aware of at this time is a set of misleading statistics released by the Centers for Disease Control and Prevention (CDC) in early September 2013.⁷ The CDC reports nothing about e-cigarette *use* in its survey; the report statistics only reflect the number of adolescents who have *tried*, perhaps only once, an e-cigarette. The statistics reported are for “ever having tried” and “tried at least once in the last 30 days.” In sum, the statistics misidentify anyone who has tried an e-cigarette within the last month as a current user. We also reiterate that not all e-cigarettes have nicotine in them, and the CDC report does not make this vital distinction. How many of the subjects ever tried e-cigarettes with nicotine? Based on its report, CDC does not know.

Moreover, the study’s CDC press release title, “E-Cigarette Use More Than Doubles Among U.S. Middle and High School Students from 2011-2012,” grossly misrepresents the data collected. The number that doubled was those subjects who had ever tried e-cigarettes. What the CDC fails to point out is that the study population is $\frac{3}{4}$ of the same people from one observation to the next (i.e., students in high school from 2011 compared to those in 2012). Further, e-cigarette technology is novel enough that most of the “trying” is recent. Of course the study demonstrates an increase, and, strikingly, if the exact same number of subjects tried an e-cigarette for the first time in 2011 and 2012, this would double the number of those who had ever tried the product. For example, based on the study design, an 11th grader in 2011 who tried an e-cigarette in 10th grade is still part of the “ever tried” group when he is a 12th grader in 2012. If an additional classmate tried an e-cigarette for the first time in 11th grade, he also joins the “ever tried” group in 2012.

⁶ T.R. McAuley, P.K. Hopke, J. Zhao & S. Babaian, *Comparison of the Effects of E-cigarette Vapor and Cigarette Smoke on Indoor Air Quality*, 24 INHAL TOXICOL 850 (2012).

⁷ See Centers for Disease Control and Prevention, *Notes From the Field: Electronic Cigarette Use Among Middle and High School Students – United States, 2011-2012*, 62 MORBIDITY & MORTALITY WEEKLY REPORT 729 (Sept. 6, 2013), <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm> (last visited Oct. 14, 2013).

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The findings of Action on Smoking and Health (ASH), a campaigning public health charity in the United Kingdom established by the Royal College of Physicians, also contradict those alleged by CDC.⁸ Among 2,178 children (aged 11 to 18), ASH found that regular use of e-cigarettes is extremely rare. The study also found that only 1 in 10 16-18 year olds who had heard of e-cigarettes (and 1 in 20 11-15 year olds) has “tried e-cigarettes once or twice.” Moreover, 1 in 100 16 -18 year olds (and 0% 11-15 year olds) uses e-cigarettes more than once a week. Among subjects who have never smoked, only 1% have “tried e-cigarettes once or twice,” and 0% report continued e-cigarette use. Further, among children who have heard of e-cigarettes, sustained use is rare and confined to children who currently or have previously smoked. In short, ASH found no evidence of regular e-cigarette use among children who have never smoked or who have only tried smoking once.

The Tobacco Act was aimed at one industry – the tobacco industry: “It is in the public interest for Congress to adopt legislation to *address the public health crisis created by the actions of the tobacco industry.*”⁹ Before FDA is allowed to expand its “tobacco product” jurisdiction to include e-cigarettes within that jurisdiction, the agency should be required to shoulder the burden of proof to demonstrate that it has a credible scientific basis for concluding that the health and safety risks of e-cigarettes, whatever FDA perceives them to be, are comparable to the well-known and thoroughly documented health and safety risks of tobacco smoking. FDA cannot, at this time, meet this burden, as a solid body of evidence on both the safety risks associated with e-cigarette use and the benefits of regulating these vapor products as “tobacco products” does not exist.

Aside from the small amount of research previously discussed, the e-cigarette research currently being conducted by the agency is still in its infancy, hardly a solid foundation for promulgating deeming regulations. In fact, less than one month ago, FDA and NIH announced the “first-of-kind” Tobacco Centers of Regulatory Science (TCORS), awarding \$53 million to fund tobacco-related research in fiscal year 2013.¹⁰ One of the projects announced for the Yale TCORS is “Flavors and E-cigarette Effects in Adolescent Smokers.” This announcement is a clear indication that FDA is still in the information-gathering stage. Again, no place it should be while establishing deeming regulations that have the potential to, in effect, destroy an entire industry.

The absence of a credible scientific basis for establishing deeming regulations goes directly to the question of congressional intent/FDA jurisdiction. Congress gave FDA jurisdiction over “tobacco

⁸ See ASH, *Fact Sheet: Use of E-Cigarettes in Great Britain Among Adults and Young People* (May 2013), http://www.ash.org.uk/files/documents/ASH_891.pdf (last visited Oct. 14, 2013).

⁹ Tobacco Act § 2 (Finding No. 29) (emphasis added).

¹⁰ FDA, News Release, *FDA and NIH Create First-of-Kind Tobacco Centers of Regulatory Science* (Sept. 19, 2013), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm368992.htm> (last visited Oct. 14, 2013).

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products” because of the known health risks/costs of “tobacco products.” FDA should not be allowed to regulate e-cigarettes as “tobacco products” without first demonstrating that e-cigarettes have “tobacco product” risks. The idea that FDA should regulate first and ask questions later does not just fly in the face of its legal obligations, but also sound judgment. Vaporizing devices such as e-cigarettes are so drastically different from tobacco products that even Matthew L. Myers, president of Campaign for Tobacco-Free Kids, concedes that “e-cigarettes have potentially positive value.”¹¹

Fairness Principles Strongly Disfavor An E-Cigarette Deeming Regulation

In addition to the above paramount reasons, fairness principles strongly disfavor the inclusion of e-cigarettes in a “tobacco products deeming regulation.” There are critical small business and economic arguments for not including e-cigarettes in such a proposed regulation. The e-cigarette industry, quite unlike the tobacco industry, is comprised of a number of new, small, and fledgling companies. These companies, which are located in various parts of the United States, are providing jobs and economic opportunity for hundreds of workers. The burden of a deeming regulation applicable to e-cigarettes will crush these businesses and destroy the jobs of current employees. For these reasons, OIRA should be particularly vigilant when appraising those arguments made by “Big Tobacco” in favor of the deeming regulation. Aside from their already questionable integrity (as evidenced throughout the 1990s), Big Tobacco recognizes that an e-cigarette deeming regulation means the destruction of most competitors. In short, only Big Tobacco has the capital to meet the heavy financial burdens that will undoubtedly accompany a deeming regulation.

There are also two core regulatory principles at stake here. The first principle is the fairness principle that “like-products should be treated alike” for regulatory purposes. E-cigarettes are not analogous to tobacco cigarettes and, therefore, they should not be regulated in the same manner. The second principle is that identifiable benefits of a deeming regulation should outweigh (perhaps significantly outweigh) the identifiable costs or burdens of such regulation. Here, the cost-benefit calculation overwhelmingly disfavors regulating e-cigarettes as “tobacco products.”

In the last five to six years, the e-cigarette industry has grown to over \$2 billion globally, and inapt regulations will no doubt have drastic economic consequences. Regulation of e-cigarettes is a serious issue that deserves comprehensive consideration, which clearly FDA has not afforded by prematurely promulgating the deeming regulations without adequate scientific support or review of alternative approaches.

¹¹ Andrew Higgins & Matt Richtel, *European Lawmakers Reject Tight Restrictions on E-Cigarettes*, N.Y. TIMES B1 (Oct. 9, 2013), http://www.nytimes.com/2013/10/09/business/international/european-lawmakers-reject-tight-restrictions-on-e-cigarettes.html?ref=todayspaper&pagewanted=all&_r=0 (last visited Oct. 14, 2013).

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OIRA has been charged with the responsibility of protecting the integrity and legitimacy of regulatory review. We, therefore, implore that you hold FDA up to the required standard that it “use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.”¹² Due to FDA’s obvious failure to meet this standard, OIRA should reject the proposed deeming regulation and, at most, have the agency issue an Advanced Notice of Proposed Rule Making (“ANPRM”).¹³

At the aforementioned December 2012 meeting, Mr. Bershteyn encouraged SFATA to request a meeting with OIRA once the e-cigarette deeming regulations arrived at OMB. Accordingly, we would appreciate the opportunity to meet with you further to discuss the issues related to our letter. In the meantime, thank you for considering SFATA’s views.

Respectfully,



Todd A. Harrison
Ralph S. Tyler
Counsel to SFATA

cc: Smoke Free Alternatives Trade Association (SFATA)

Enclosure

¹² Ex. Order 13563, 3 C.F.R. § 13563 (Jan. 18, 2011).

¹³ Second to taking no action at this time, an ANPRM is the appropriate way to proceed where, as here, a technology or product is new, the legal and policy implications of a particular regulatory approach are highly ambiguous, and much of the relevant evidence regarding, for example, safety and use of the product has been neither collected nor reviewed.