August 8, 2014

**Re: The Food and Drug Administration Deems 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 Restricting the Sale and Distribution of Tobacco Products and Required Warnings for Tobacco Product Packages and Advertisements;**

**Docket No. FDA-2014-N-0189**

Dear Commissioner Hamburg:

On behalf of the Public Health Advocacy Institute at Northeastern University School of Law (PHAI), I am writing in response to the agency's request for comment on the proposed tobacco "deeming" rule as published in the *Federal Register* on April 25, 2014.

The mission of PHAI is to advocate for public health and enhance a commitment to public health in individuals and institutes who shape public health policy. Our goal in offering this comment is to advise the FDA Center for Tobacco Products about how electronic cigarettes should be regulated to maximize any potential public health benefit they may provide and minimize potential negative impact on public health under the Family Smoking Prevention and Tobacco Control Act.

## The Public Overwhelmingly Believes that Electronic Cigarettes are Reduced Risk Products

When polled, electronic cigarette users frequently cite perceived health benefits of using electronic cigarettes as opposed to conventional cigarettes.[1]

In one study, more than 80% of current smokers who used electronic cigarettes indicated that they used them because they believed these products were less toxic than conventional cigarettes.[2] In a recent study using data from Health Information National Trends Survey (HINTS 4 Cycle 2), 65% of current smokers believed electronic cigarettes were less harmful than conventional cigarettes.[3] This was the lowest measure of the belief that electronic cigarettes were reduced risk products that we could find.

In yet another recent study, 70.3% of U.S. respondents in the International Tobacco Control Four Country Survey who were aware of electronic cigarette believed that they were reduced risk products as compared with combustible cigarettes.[4]

There is no evidence that suggests anything but the overwhelmingly dominant public perception that electronic cigarettes are a reduced risk product. After thoroughly reviewing the available public health literature, we are unaware of any study that has

found that a majority of people aware of electronic cigarettes, whether never, current or former smokers or never, ever or current electronic cigarette users, do not believe that they are reduced risk or modified risk tobacco products. This is the prevailing perception. It is one that has been a key marketing point by manufacturers[5] and by retailers.[6] Even if the manufacturers do not make such overt safety claims anymore, the public perception is set and it would appear unlikely to change.

## Electronic Cigarettes Should Only be Permitted into the Marketplace as Modified Risk Tobacco Products

If electronic cigarettes are to be approved by the Center for Tobacco Products to be marketed, they should only be approved to meet the predominant expectations of consumers. Were the CTP to grant premarket approval of any other type of application, e.g., "New Tobacco Product," it would have the effect of approving electronic cigarettes as safer products because that is what most everyone has come to believe. Manufacturers would wrongfully benefit from this belief without meeting the requirements of the modified risk premarket application to ensure that such FDA-approved products represent, in fact, a reduced risk of disease or injury.

To regulate electronic cigarettes as "modified risk" products would require applicants to demonstrate that the product, as it is actually used by consumers, will "significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products." [7] Such a showing would need to account for the possibility of dual use that impedes or delays smoking cessation and the potential role of these products as a pathway to new use of conventional cigarettes because these are important factors in determining the public health impact of these products.

Applicants seeking to introduce a product deemed to be a "modified risk" as opposed to a "new tobacco product" face an appropriately higher burden of proof that their product complies with any regulations set regarding the health properties of the product.

Current public perceptions render any non-modified risk-based sales as false and misleading because consumers already believe and anticipate that these products provide the benefit of an MRTP. Based on a fair review of all the material facts, including public perception of electronic cigarettes as a reduced risk product and the industry's role in creating that perception, this should be a basis for rejection of a New Tobacco Product Application under sec 910c2c of the Food Drug and Cosmetic Act because the, "proposed labeling is false or misleading."

Furthermore, approval as a new tobacco product would prohibit manufacturers from marketing electronic cigarettes based on reduced risk appeal and they would, therefore, continue to rely on sex appeals and other marketing techniques, some of which

may appeal to youth, that many public health leaders, as well as several members of Congress, have expressed great concerns about.[8] [9]

The proposed rule would allow for a 24-month compliance period for the submission for premarket tobacco applications.[10] During that time, and until or unless the application is denied, sales and marketing would be allowed to continue as it currently functions. This lenient 24-month compliance period should provide electronic cigarette manufacturers with enough time to compile the necessary application for electronic cigarette products as "modified risk" products.

**Electronic Cigarettes Should Be Advertised Primarily to Promote Their Harm Reduction Propensities, Provided Manufactures Can Demonstrate Harm Reduction**

Alternatively, if electronic cigarettes applications as "new tobacco products" were to be approved, an elimination of attractive advertising, which tends to influence young and/or never-smokers, would deter these demographics from using electronic cigarettes as an introduction to tobacco products that are not risk-free or as a pathway for usage of conventional cigarettes and their well-known acute risks.

One possible approach would be to issue a rule to require electronic cigarette advertising to include modified risk language (e.g., "The US Food and Drug Administration has approved this product as a Modified Risk Tobacco Product"). This would have the effect of eliminating attractive marketing for products that do not meet modified risk criteria. If all electronic cigarette advertising must include such a statement but only approved MRTPs are permitted by law to make such a statement, then non-MRTP electronic cigarettes would fail to meet the requirements to advertise as they do today. This would create an important incentive for manufacturers to submit MRTP applications rather than seeking approval only as "new tobacco products." Making harm reduction a required element in any marketing could help to fulfill the purported harm reduction potential of electronic cigarettes.[11]

**Include Premium Cigars in Deeming Rule and Comprehensively Regulate Flavors of Newly Deemed Tobacco Products.**

PHAI wishes to make two short additional points:

1) Option one, including premium cigars, should be pursued rather than option two for the simple reason that merely deeming premium cigars as tobacco products (which they undeniably are) does not require CTP to do anything with that authority unless and until evidence suggests that further action is appropriate. But setting up another 2-step process should such further regulation ever become necessary is needlessly burdensome, time-consuming, and would not benefit public health.

2) A comprehensive regulatory approach to flavors in all newly deemed products including electronic cigarettes and little cigars should be an immediate priority for further regulation. It is difficult to imagine any public health benefit that could be derived from the presence of flavors, particularly the candy-like or alcoholic beverage-like flavors often used in these products. Such flavors clearly have no role to play other than to make products more attractive to new users and vulnerable populations, whether or not that is the intention of the manufacturers. Remaining flavors should only be permitted upon an adequate and scientifically valid showing by manufacturers that such flavors serve the purpose of improving public health.

Respectfully submitted,
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[5] In this archived capture of the NJOY website, the first testimonial on the screen shows a smiling person, Dale Gertrhat from Nebraska, with the caption, "It's safer than my cigarettes." http://web.archive.org/web/20080820130018/http://www.njoy.com/

[6] See, e.g., retailer website, http://www.safervapors.com/ , and http://greatcigarettesmokeless.com/wp-content/uploads/2013/04/532.jpg

[7] Deeming Regulation, *supra* note 24, at 7.

[8] Debbie Elliot, "E-Cigarette Critics Worry New Ads Will Make 'Vaping' Cool For Kids." NATIONAL PUBLIC RADIO (May 3, 2014). Available at: http://www.npr.org/templates/transcript/transcript.php?storyId=284006424

[9] Office of Senator Dick Durbin (IL), "Members of Congress: More and More Children Being Exposed to E-Cigarette Marketing Are Picking Up Habit." (August 4, 2014). Available at: http://www.durbin.senate.gov/public/index.cfm/pressreleases?ID=30fd7173-e0e9-45ed-87e4-3974bff21b0b

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