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October 7, 2013

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
The Hubert H. Humphrey Building
200 Independence Ave. SW
Washington, DC 20201

The Honorable Richard Durbin
Senior Senator from Illinois
United States Senate
711 Hart Senate Bldg.
Washington, DC 20510

Dear Secretary Sebelius and Senator Durbin:

I write to you as a public health physician self-employed as a policy consultant. I have been a local health director, state health director, and president of two national public health associations. I have been involved in tobacco control for more than 30 years. Responding to what I perceive to be dysfunctional federal tobacco control policy, I have partnered with the R Street Institute, a Washington-based think tank that respects the role of government in regulating industry, but is deeply concerned about governmental overreach not justified in terms of the desired public health objectives.

This letter is in response to two pieces of recent correspondence. The first is a letter to President Obama from the American Academy of Pediatrics (AAP) and fifteen other non-governmental health-related organizations.[1] The second is a letter from Sen. Durbin to Craig Weiss, president and CEO of NJOY, and others.[2]

While I support, in principle, extending FDA authority over e-cigarettes and all other non-prescription tobacco/nicotine products, I am concerned about the possibility of FDA doing this in a way that will do more harm than good from a public health perspective.

[1] American Academy of Pediatrics, et al, "Deeming Letter to the President," Sept. 19, 2013. http://www.acscan.org/content/wp-content/uploads/2013/09/Deeming-Letter-to-the-President.pdf

[2] Richard Durbin, "Durbin, Harkin, Rockefeller, Waxman & Members of Congress Call on E-Cigarette Makers to Explain Marketing Tactics Targeting Kids," Sept. 26, 2013. http://www.durbin.senate.gov/public/index.cfm/pressreleases?ID=fafe1d70-0a2c-429c-9372-c5ca201cb261

The problems I see are as follows:

1. E-cigarettes, snus and other smoke-free alternatives to cigarettes have the potential to substantially reduce tobacco-attributable illness and death among current smokers, and do so in a way that would not increase teen initiation of tobacco/nicotine use. Any action by FDA, if it is to benefit the health of the public, must recognize both the hazard presented by unregulated tobacco and nicotine products and the potential benefits they could provide if sensibly regulated in a manner that would promote smokers switching to these much-lower-risk products.
2. The recent correspondence – from both Sen. Durbin and the American Academy of Pediatrics, with 15 other co-signers – grossly misrepresents the recently released CDC data on use of e-cigarettes by middle school and high school students.[3] These data clearly show an increase in use no greater than the increase in use by adults. The data also clearly show the vast majority of the increase in use was in students who were already smokers, and do not show any continuation or consistency in use by non-smoking students. The data as presented neither demonstrate recruitment of non-smoking students to e-cigarettes, nor rule out such recruitment. The CDC data suggest that the vast majority of teens initiating e-cigarette use are teen smokers seeking to use them in a harm reduction mode.
3. The letter from the American Academy of Pediatrics and the other 15 voluntary groups erroneously presents the action taken by FDA to ban candy, fruit and alcohol flavors from cigarettes as a great public health victory, with the implication that this ban should be extended to e-cigarette and other smoke-free products.[4] As noted below, these flavorings were long-gone before FDA took this action, and these flavored products never represented more than 1% of the cigarette market. Taking similar action for e-cigarettes and other smoke-free products is likely to reduce the attractiveness of these products to current smokers, thus eliminating any potential public health benefit of FDA regulation of these products. Also as noted below, other experience suggests that, even with these flavorings, e-cigarettes and the other smoke-free options are unlikely to recruit significant numbers of teens to tobacco use.

At the time of the adoption of the law, such candy flavored cigarettes accounted for less than 1% of cigarette sales, and had already been removed from the market for reasons having nothing to

[3] Centers for Disease Control and Prevention, "Notes from the Field: Electronic Cigarette Use Among Middle and High School Students — United States, 2011–2012," Sept. 6, 2013. www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm

[4] American Academy of Pediatrics, et al, "Deeming Letter to the President," Sept. 19, 2013. http://www.acscan.org/content/wp-content/uploads/2013/09/Deeming-Letter-to-the-President.pdf

do with FDA regulation.[5] The one cigarette flavor that did attract large numbers of teens was menthol. This was exempted in the law and is still not banned by FDA despite years of continuing study of this issue. The AAP letter urges FDA regulation of e-cigarettes on the false premise that candy flavors in tobacco products are intended to attract children to tobacco use. Nicotine containing products in any form have a harsh and irritating taste that requires some form of sweetening or other flavoring to make them palatable to adult users. With tobacco cigarettes, this can sometimes be secured by using tobacco with a high sugar content. This is not easily done with e-cigarettes and other smokeless tobacco products. Such products, and even the pharmaceutical nicotine replacement therapy products approved by FDA, always had fruit and candy flavoring.

We are now a little more than four years into the implementation of the FDA tobacco law by the FDA Center for Tobacco Products (CTP). Cigarettes, roll-your-own cigarette tobacco and traditional smokeless tobacco products have been "grandfathered in" and limitations on age-related marketing and on labeling have been implemented. While FDA has the authority to regulate the quality and consistency of manufacturing, it has not done so to date, even for the products under its jurisdiction.

I offer the scientific basis for proposing that FDA and other federal and public health authorities consider working with at least certain parties within the tobacco industry in pursuit of public health goals in a forthcoming R Street policy study titled "The Promise of E-cigarettes for Tobacco Harm Reduction."[6] The greatest irony of the FDA tobacco law is that it grandfathers in cigarettes, the most hazardous of tobacco products and the product that is both most addictive and most attractive to teens. As written, the law inhibits introduction into the market of an array of smoke-free alternative products that promise to be far less hazardous than cigarettes. These same products, more likely than not, should prove less addictive and less attractive to teen non-smokers. One must question the public health benefit of a law that has the practical effect of protecting cigarettes from competition from these other products.

A more rational approach would be to bring all tobacco and nicotine products under the same regulatory umbrella, on equal footing. FDA could then proceed to implement provisions of the law governing quality of manufacture, labeling and marketing needed to prevent contamination from what the law refers to as "filth and adulteration"; eliminate predatory marketing; and enforce age restrictions on product sales. Once those measures are in place, FDA could address warning labels for the newly regulated products and issues related to the differences in risk posed by each type of product.

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[5] Michael Siegel, "FDA Commissioner Falsely Asserts that Flavored Cigarettes are a Gateway for Teen Smoking; Representative Waxman Also Makes the Same False Claim," *Tobacco Analysis*, June 24, 2010. http://tobaccoanalysis.blogspot.com/2010/06/fda-commissioner-false-asserts-that.html

[6] Dr. Joel Nitzkin, "The Promise of E-cigarettes for Tobacco Harm Reduction," R Street Institute, October 2013. http://www.rstreet.org/wp-content/uploads/2013/10/R-Street-Policy-Study-No-11.pdf

At each step, FDA would need to address both benefits and risks associated with each product. Potential benefits include reducing tobacco-attributable illness and death among smokers and those exposed to environmental tobacco smoke. One set of risks relates to the potential for tobacco-attributable illness by users of each product. The other set of risks relates to the possibility of raising the rates of nicotine addiction among teens and others in the non-user population.

A bold, simple approach is the most beneficial course of action if our collective goal is reduction and eventual near-elimination of tobacco-related addiction, illness and death. This would consist of deeming all currently not-covered tobacco/nicotine products and product components (such as e-cigarette parts and fluids) as covered by the FDA tobacco law, and waiving or resetting the "new product" cut-off date to the date when the deeming action would be fully in effect for the newly deemed products. This would eliminate the need for FDA to try to remove from the market newly deemed products that have been developed or substantially modified in the last six years. There would be no public health downside to this action, but there would be potential public health benefits to regulating the quality of manufacturing, marketing and prohibition of sales to minors.

Respectfully Submitted

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Cc: Margaret Hamburg, Commissioner, Food and Drug Administration
Mitch Zeller, Director, Center for Tobacco Products, Food and Drug Administration
American Academy of Pediatrics, American Lung Association, American Academy of Family Physicians, American Cancer Society Cancer Action Network, American College of Obstetricians and Gynecologists, American College of Physicians, American College of Preventive Medicine, American Heart Association, American Public Health Association, American Thoracic Society, Campaign for Tobacco-Free Kids, Legacy, National Association of County and City Health Officials, Oncology Nursing Society, Partnership for Prevention, Society for Adolescent Health and Medicine