



May 1, 2014

The Honorable Margaret Hamburg, Commissioner  
United States Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

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SEATTLE (KING COUNTY)  
DISTRICT OF COLUMBIA

Re: FDA Regulation of Electronic Cigarettes

Dear Commissioner Hamburg,

On behalf of eleven of the largest metropolitan health departments, representing more than 33 million Americans, we would like to congratulate you on addressing the sale and labeling of tobacco products, which include electronic cigarettes or e-cigarettes, through the proposed deeming regulations issued last week. Although this is an important first step, there are gaps in the proposed regulations that must be addressed to protect and promote the public's health such as the marketing, flavoring, and manufacturing of e-cigarettes.

Local health departments have a responsibility to protect the health and well-being of residents within their jurisdictions. We have extensive experience regulating tobacco products at the local level and are proud of the sustained decrease we have seen in the number of Americans who report regular use of cigarettes. However, in the ever-evolving tobacco market, we must remain vigilant for new products, especially when those products, such as e-cigarettes, are being marketed in ways that appeal to youth and could undermine existing tobacco regulations. While many local health departments have taken steps to curb the sale and use of e-cigarettes, not all localities have this regulatory authority. There are also areas, such as marketing and manufacturing, where the Food and Drug Administration (FDA) should act to fill existing regulatory gaps and to create uniform nationwide regulations.

**E-cigarettes pose a potential risk to public health.** E-cigarettes are battery-powered devices that vaporize a liquid mixture usually containing nicotine derived from tobacco. They pose a potential public health risk both because nicotine is a highly addictive substance and because e-cigarettes have not been found to be safe for human use by the FDA. On the contrary, the FDA and other independent scientists have found numerous potentially dangerous chemicals and carcinogens as well as varying levels of nicotine that are inconsistent with the amount indicated on the labels of e-cigarette solutions. Furthermore, because e-cigarettes are unregulated, we do not know the full range of chemicals being produced by the large number of different e-cigarettes currently on the market.



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**E-cigarettes are both appealing and very accessible to youth.** The proposed deeming regulation begin to curb youth access by setting a minimum age requirement to purchase e-cigarettes but do not extend the current prohibition on characterizing flavors for combustible cigarettes to e-cigarettes or other covered tobacco products. While e-cigarettes have been available for sale through online retailers for the better part of a decade, only in the last five years have they become widely available in traditional retail outlets, coinciding with substantial decreases in price. What began as a sliver of the tobacco market is now predicted to eclipse traditional tobacco sales by mid-century. Indeed, tobacco industry analysts have projected that e-cigarette sales will exceed \$10 billion in retail sales by 2017<sup>1</sup>. This exponential growth may be in part due to their growing popularity among younger people, who often perceive e-cigarettes as a safer, less expensive and more appealing alternative to traditional cigarettes. The CDC’s National Youth Tobacco Survey, released in September 2013, found that e-cigarette use among young people is rapidly increasing, having doubled from 2011 to 2012. In the survey, ten percent of high school students reported having used e-cigarettes at least once.<sup>2</sup>

**Ads for e-cigarettes are increasing in volume and prominence.** The proposed deeming regulations do not propose any advertising or marketing restrictions that would regulate e-cigarettes even though the FDA has the authority to do so. Big tobacco companies such as Lorillard, Reynolds and Altria have made significant financial commitments to their own e-cigarette brands in recent years and are steadily increasing their advertising budgets to promote them. By one estimate, e-cigarette companies spent more than \$15 million in the first quarter of 2013 promoting e-cigarettes, compared to \$2 million during the same period the year before.<sup>3</sup> The lion’s share of advertising dollars is being spent in the television market, where ads for most conventional tobacco products have been banned since the early 1970s. Further, e-cigarette advertisements regularly employ youth-oriented marketing strategies that the tobacco industry used decades ago such as celebrity endorsements and messages that associate smoking e-cigarettes with themes like freedom, rebelliousness, and glamour. In addition, some e-cigarette marketing campaigns, such as Blu’s “Why Quit?” campaign, clearly discourage smoking cessation. This threatens to undermine our efforts to get smokers to quit, and it may entice former smokers to relapse.

**E-cigarettes have been marketed using unsubstantiated claims regarding health and safety.** Such advertising is misleading, because existing scientific research shows

<sup>1</sup> Goodman, A. E-Cigarette Sales Are Smoking Hot – Four Ways to Invest In Them. December 5, 2013. Available at: <http://www.forbes.com/sites/agoodman/2013/12/05/e-cigarettes-are-smoking-hot-4-ways-to-approach-them/>.

<sup>2</sup> Catherine Corey, Notes from the Field: Electronic Cigarette Use Among Middle and High School Students – United States, 2011-2012, Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report, September 6, 2013, available at [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm?s\\_cid=mm6235a6\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm?s_cid=mm6235a6_w).

<sup>3</sup> Elliot, S. E-Cigarette Makers’ Ads Echo Tobacco’s Heyday, New York Times, August 29, 2013. Available at: [http://www.nytimes.com/2013/08/30/business/media/e-cigarette-makers-ads-echo-tobaccos-heyday.html?\\_r=0](http://www.nytimes.com/2013/08/30/business/media/e-cigarette-makers-ads-echo-tobaccos-heyday.html?_r=0).



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that e-cigarettes can still pose health problems and such claims have not been reviewed or approved by the FDA or any regulatory agency. Some cartridges are labeled as containing no nicotine yet have been found to contain nicotine. Beyond the FDA's testing, little research exists relative to the contents of e-cigarette cartridges. In addition, the few tests that have been conducted found levels of nicotine that differed from their labeled strength.

**E-cigarettes are not required to display any health warnings.** Cigarettes and smokeless tobacco products are required to carry health warnings. Even nicotine replacement therapy (NRT) is required to carry warnings. With the proposed deeming regulation, e-cigarettes will be required to display health warnings, although with significant delays. The delay has the potential to continue to foster the perception, particularly on the part of youth, that e-cigarettes are safe, or the misunderstanding that they have been found to be safe and effective cessation devices. The marketing of these products as a smoking alternative perpetuates this confusion.

We urge you to act boldly and swiftly, especially given the lengthy delay in issuing your first proposed regulations. As many of our major metropolitan areas continue to act on the local level, we urge you follow our lead and use your full authority to apply all current tobacco regulations to e-cigarettes. The FDA must move quickly to address the growing concern about youth use beyond setting a minimum age requirement to purchase e-cigarettes.

The Big Cities Health Coalition intends to submit more detailed comments specifically addressing your deeming regulation. If you have questions, please contact Dr. Shelley Hearne, DrPH at [shearne@naccho.org](mailto:shearne@naccho.org) and (202) 463-8156.

Sincerely,

Dr. Oxiris Barbot, MD  
Commissioner of Health  
Baltimore City Health Department  
Baltimore, MD

Dr. Barbara Ferrer, PhD, MPH, MEd  
Executive Director  
Boston Public Health Commission  
Boston, MA



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Dr. Bechara Couchair, MD  
Former Commissioner  
Chicago Department of Public Health  
Chicago, IL

Mr. Stephen Williams, MEd, MPA  
Director  
Houston Department of Health and Human Services  
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