

# United States Senate

WASHINGTON, DC 20510

May 8, 2014

The Honorable Margaret Hamburg  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Commissioner Hamburg:

We write to bring to your attention two new studies, recently reported in *The New York Times*,<sup>1</sup> describing the harmful chemicals, including formaldehyde, that are sometimes released in the plume of vapor from certain high powered e-cigarettes. As you review comments submitted to the record in response to the Food and Drug Administration's (FDA) newly proposed rules that for the first time extend authority to e-cigarettes, it is important that the agency recognize the potential health impacts associated not only with the direct inhalation of liquid nicotine through e-cigarettes, but also the impacts that the emitting "vapor" or "plume" may have both to the user and any secondhand inhalers. Given both what is unknown about these new products, as well emerging information about the health risks that they pose, it is critical that the agency's regulatory oversight keep pace with these new nicotine delivery products and the way in which they are commonly utilized.

The lack of rules and regulations has allowed the emergence of new nicotine products, such as e-cigarettes, hookah pens, and liquid nicotine products, also called e-liquids. In the absence of federal oversight, makers of these products have taken advantage of a regulatory black hole by marketing these new nicotine delivery products directly to youth, including through use of bright colors, cartoons, and flavors, including cotton candy and bubble gum. In many ways these techniques have worked; in only one year, use of e-cigarettes among high school students has doubled, as have sales of these products every year since 2010.<sup>2,3</sup> However, in many ways, this data underestimates the prevalence of new nicotine products in the marketplace, since the technologies and their terminology continue to change in ways that are not captured by these studies. Because many of the same limitations on smoking in public spaces do not apply universally to e-cigarettes and other advanced nicotine delivery products, these products put at risk not only adults and youth who use these devices, but potentially also those who are involuntary exposed to secondhand vapors.

In the FDA's April 25, 2014 request for comments regarding the regulation of e-cigarettes, the FDA acknowledges that while all tobacco products are potentially harmful and addictive, "there are distinctions in the hazards presented by various nicotine-delivering products" and that "certain new tobacco products that are noncombustible (such as e-cigarettes)

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<sup>1</sup> The New York Times. *Some E-Cigarettes Deliver a Puff of Carcinogens*, Matt Richtel. May 3, 2014

<sup>2</sup> Centers for Disease Control and Prevention, *MMWR*, Vol.62 No.35 (Sept. 6, 2013), pp.729-528.

<sup>3</sup> Legacy Foundation, *E-cigarette policy: the FDA should promptly exercise regulatory authority over e-cigarettes* (Jan. 2014).

may be less hazardous than combustible products given the carcinogens in smoke and the dangers of secondhand smoke from combustible products.”<sup>4</sup> While it is true that e-cigarettes do not generally create combustion like traditional cigarettes, the recent *New York Times* report suggests that the heating of the liquid materials used in e-cigarettes can, under the right circumstances, produce vapors that contain a number of toxins, some of which, like formaldehyde, are produced as a result of other ingredients being heated to high temperatures. Additionally, in an effort to obtain a more potent nicotine high, some sellers and users of e-cigarettes and other advanced nicotine delivery products, manipulate these devices so that the nicotine liquid can be applied directly onto the heating element, a process called “dripping”, which heats the liquid nicotine intensely and rapidly, producing not only a rapid nicotine rush, but also changing the chemical reactions of the ingredients present in these liquid nicotine products. The resulting “emissions” can create levels of carcinogens, such as formaldehyde, that are similar to those present in traditional cigarette smoke.

It is now well established that secondhand smoke from traditional cigarettes, cigars, and pipes causes premature death and disease in youth and in adults who do not smoke. Additionally, secondhand smoke has immediate adverse effects on the cardiovascular system and can lead to lung cancer and coronary heart disease. However, it took several years after the first Surgeon General report alerted the public to the dangers of smoking tobacco for a subsequent acknowledgement to be made on the significant health impacts of involuntarily inhaled secondhand smoke. As the FDA works to protect the public, especially children, from the health impacts associated with e-cigarettes, we simply cannot afford to lag behind in our complete understanding of the health consequences to the user and bystander of these and other advanced nicotine delivery products. We urge the FDA, as it finalizes its regulations governing e-cigarettes and other advanced nicotine delivery products, to take this new information into consideration and move quickly to develop a regulatory structure to minimize the harm to public health from the rapidly evolving market of nicotine products.

Sincerely,



Edward J. Markey  
United States Senator



Tom Harkin  
United States Senator



Richard J. Blumenthal  
United States Senator



Sherrod Brown  
United States Senator

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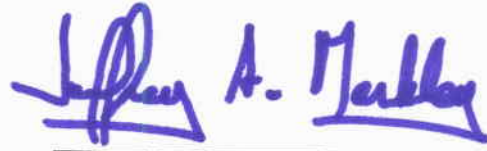
<sup>4</sup> Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products. Published April 25, 2014 RIN 0910-AG38





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Barbara Boxer  
United States Senator



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Jeff Merkley  
United States Senator



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Jack Reed  
United States Senator



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Richard J. Durbin  
United States Senator