

# United States Senate

WASHINGTON, DC 20510

April 24, 2015

The Honorable Sylvia Mathews Burwell  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Secretary Burwell:

We write today on the one year anniversary of the Food and Drug Administration's (FDA) proposed e-cigarette and other tobacco products deeming rule to urge you to strengthen and finalize this rule without further delay.

This proposed rule is an important first step to allow FDA to exercise its authority to regulate e-cigarettes under the Family Smoking Prevention and Tobacco Control Act of 2009. We were pleased to see that the rule proposes prohibiting e-cigarette sales to minors, as well as prohibiting vending machine sales and free samples, to further prevent sales and use by minors. In addition, the proposed rule requires manufacturers to list product ingredients, tobacco products containing nicotine to carry an addiction warning label, and new or changed tobacco products to be approved by FDA before going to market. While we commend FDA on proposing these important steps, we believe the proposed rule must be improved to address the marketing of these products to children and e-cigarette flavorings and be finalized as soon as possible.

Until this rule is finalized, e-cigarettes will continue to operate completely unregulated, with an increasing number of children taking up this addictive habit every day. In fact, the CDC's 2014 National Youth Tobacco Survey<sup>1</sup> just released last week found that e-cigarette use among high school students tripled in the last year from 4.5 percent in 2013 to 13.4 percent in 2014, and the University of Michigan's annual Monitoring the Future survey<sup>2</sup> shows that more teenagers reported using e-cigarettes than traditional tobacco products in 2014. This demonstrates the need for FDA to regulate these products to ensure that the positive strides we have made in reducing smoking rates are not reversed.

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<sup>1</sup> Centers for Disease Control and Prevention, Tobacco Use Among Middle and High School Students — United States, 2011–2014, Morbidity and Mortality Weekly Report (April 17, 2015). (online at <http://www.cdc.gov/mmwr/pdf/wk/mm6414.pdf>): 381-385.

<sup>2</sup> University of Michigan, Monitoring The Future. Institute for Social Research (2014). (online at <http://www.monitoringthefuture.org/>).

First, we are disappointed that FDA did not propose stronger rules to prevent companies from marketing e-cigarette products to children. E-cigarette companies are taking a page out of the Big Tobacco playbook, using celebrity endorsements of their products, cartoons, and advertising in magazines with youth readership and at music festivals and sports events targeted at children. According to a 2014 study in the journal *Pediatrics*<sup>3</sup>, exposure to e-cigarette marketing by children aged 12 to 17 increased by 256 percent between 2011 and 2013, exposing 24 million children to e-cigarette advertisements. In this context, it is unsurprising that youth use of e-cigarettes has skyrocketed during the same timeframe. It is well known that tobacco advertising influences consumer behavior, especially that of children, and we urge you to apply the same marketing regulations to e-cigarettes that already exist for traditional cigarettes.

Second, we are concerned that the proposed rule does not address the use of flavorings, like candy, soft drink, and fruit flavors, in e-cigarettes. FDA itself acknowledged in the proposed rule that children are the most likely to use flavored tobacco products. The Family Smoking Prevention and Tobacco Control Act prohibits these kinds of flavorings from being used in traditional cigarettes and we believe the same scrutiny should be applied to e-cigarettes and refill liquids so that children are not attracted to these products. Therefore, we urge you to similarly ban candy, soft drink, and fruit-flavored e-cigarettes and refill liquids that appeal to children.

Additionally, we believe FDA must explicitly ban online sales of e-cigarettes due to the ease with which minors are able to purchase these products, undermining any bans on purchases by minors. In fact, a study published this year by the University of North Carolina Lineberger Comprehensive Cancer Center<sup>4</sup> found that only 5 out of 98 attempts by teens to purchase e-cigarettes online were blocked by age verification requirements. We urge you to ban online sales outright to better ensure that children do not have easy access to these products.

Lastly, we are encouraged that FDA's proposed rule requires pre-market approval for products that were not on the market as of February 15, 2007, as set forth in the Family Smoking Prevention and Tobacco Control Act of 2009. As a result, nearly every e-cigarette product on the market will be subject to review by FDA, as intended by the law. We understand that e-cigarette manufacturers are lobbying to change the grandfather date for products subject to FDA regulations, so as to exempt more of their products. We support FDA's position that this grandfather date is unchangeable and urge you to finalize the rule with this policy to better protect more consumers, including children.

Last year, FDA took an important initial step by proposing to regulate e-cigarettes, but more must be done to strengthen this rule and ensure that the same practices used by Big Tobacco for years to promote smoking are not used by e-cigarette companies to create a new generation of smokers. We urge you to work swiftly to finalize the proposed rule and improve it by barring e-cigarette marketing to minors, preventing the sale of candy flavored products, and

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<sup>3</sup> Duke, Jennifer, Youn O. Lee, Annice E. Kim, et al. *Exposure to Electronic Cigarette Television Advertisements Among Youth and Young Adults*. *Pediatrics*. June 2014; 134 (1): 1-8.

<sup>4</sup> University of North Carolina, Lineberger, *Few Online E-Cigarette Vendors Block Sales To Minors, UNC Lineberger Study Finds*. UNC Lineberger Comprehensive Cancer Center (March 2, 2015).

eliminating online sales. These changes, in addition to FDA's existing proposal, will better align e-cigarette regulation to traditional cigarettes and ensure that our children are protected from these harmful nicotine products. We look forward to continuing to work closely with FDA and HHS on this and other issues essential to protecting the public health.

Sincerely,



Jack Reed  
U.S. Senator



Sherrod Brown  
U.S. Senator



Richard J. Durbin  
U.S. Senator



Edward J. Markey  
U.S. Senator



Richard Blumenthal  
U.S. Senator



Barbara Boxer  
U.S. Senator



Charles E. Schumer  
U.S. Senator



Patty Murray  
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Dianne Feinstein  
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Jeffrey A. Merkley  
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