United States Senate
WASHINGTON, DC 20510

March 10, 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 are writing to urge you to strengthen and finalize the long overdue proposed deeming regulations that would give the Food and Drug Administration (FDA) regulatory authority over all tobacco products, including e-cigarettes. The release of the proposed deeming rule for the Family Smoking Prevention and Tobacco Control Act last April was an important step to achieve more appropriate and comprehensive regulation of tobacco products. This rule has been delayed and these delays have consequences. We urge you to finalize this rule quickly – ideally before Commissioner Hamburg's pending departure, and no later than one year from the release date of the proposed rule.

As it stands, e-cigarettes are being aggressively marketed to children and the use of e-cigarettes by minors has skyrocketed in recent years. Teen use of e-cigarettes now surpasses use of regular cigarettes according to recent data from the government-sponsored Monitoring the Future survey, with over 16 percent of tenth graders and over 17 percent of twelfth graders reporting use of e-cigarettes during the past month. Last April, a report released by Members of the House and Senate demonstrated that many e-cigarette companies are using the same marketing tactics that cigarette companies used for decades to market to children. The report showed that e-cigarette makers are dedicating extensive resources to reaching young people through social media, sponsorship of youth oriented events, and television and radio advertisements that reach substantial youth audiences. Children are responding to this outreach while regulation on the federal level awaits final action.

In light of these troubling developments, the agency should strengthen the proposed deeming regulation. E-cigarettes and refill liquids come in thousands of different flavors, including candy and fruit flavorings. A recent study in the *New England Journal of Medicine* found that the use of candy flavors in tobacco products exploits the association children have between these familiar flavors and the candies that they enjoy.[1] These kid-appealing flavorings and associated marketing are driving the significant increase in youth use of e-cigarettes. Additionally, a recent study revealed that teens were able to purchase e-cigarettes online in 94 percent of attempts, and none of the teens were required to show proof of age when the e-cigarettes were delivered. The final rule must recognize these methods for attracting children to tobacco products and ensure that sales of these products to minors are restricted.

As poisoning incidents involving e-cigarettes and nicotine liquids continue to increase, the final deeming rule should also require that manufacturers use child-proof packaging. The American Association of Poison Control Centers reported 3,957 calls to poison control centers in 2014 involving exposures to e-cigarette devices and nicotine liquids, with most of the calls involving the poisoning of small children.

[1] Brown, Jessica E., BS, Wentai Luo, PhD, Lorne M. Isabelle, MS, and James F. Pankow, PhD. "Candy Flavorings in Tobacco — NEJM." *New England Journal of Medicine*. The New England Journal of Medicine, 5 June 2014. Web. 09 Feb. 2015. <http://www.nejm.org/doi/full/10.1056/NEJMc1403015>

Finally, we urge you to not weaken the new product provisions of the Tobacco Control Act for e-cigarettes and other products that FDA has proposed to regulate. In comments on FDA's proposed deeming rule, some have urged FDA to change the "grandfather date" in Section 910 of the statute from February 15, 2007, to the date of the proposed or final deeming rule. We urge you to reject this request, both because FDA has no statutory authority to alter the grandfather date and because doing so would expose children and others to a host of new tobacco products that have not been subject to agency review.

Altering this grandfather date would exempt a wide range of e-cigarettes and related products from any premarket review to determine whether they constitute threats to public health. Because of FDA's delay in asserting its jurisdiction over other tobacco products, there are likely hundreds of e-cigarette products on the market today without any regulatory review of their consequences for public health. Grandfathering of these products would mean these products would never be subject to a review by FDA to determine whether they are appropriate to be sold, and essentially undermine consumer protections.

We urge you to strengthen and quickly finalize the proposed deeming regulations and also firmly adhere to the new product provisions of the Tobacco Control Act.

Sincerely,

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United States Senate

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