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June 11, 2015

Mitchell Zeller
Director, Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Mr. Zeller:

It has now been over a year since the FDA issued its proposed regulations, “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” (Docket No. FDA–2014–N–0189) (the “deeming regulations”). We are concerned that, although the period for public comment closed in August 2014, the products covered by the proposed deeming regulations, particularly electronic cigarettes,¹ remain outside the FDA’s authority under the Tobacco Control Act. Our concerns are heightened by the fact that, in the year since the deeming regulations were first proposed, several reports have come out regarding the potential for harm to the public health that these products pose.

Youth usage of e-cigarettes is increasing at an alarming rate. In 2013, more than a quarter million youth who had never smoked a cigarette used electronic cigarettes.² In 2014, more teens used e-cigarettes than any other tobacco product.³ We fear that these trends may result in increased teen addiction to nicotine, in turn causing increased use of combustible cigarettes and reversing hard-won declines in youth smoking. Moreover, e-cigarettes are now widely available to minors on the Internet: One recent study has shown that minors can easily purchase e-cigarettes online despite state laws requiring online sellers of e-cigarettes to verify their customers’ ages and identities using a government-record database.⁴ There are also concerns regarding the

¹ We use “electronic cigarette” and “e-cigarette” broadly to encompass the variety of electronic nicotine delivery methods currently on the market.

² Bunnell, R.E., *et al.*, *Intentions to Smoke Cigarettes Among Never-Smoking US Middle and High School Electronic Cigarette Users: National Youth Tobacco Survey, 2011-2013*, Nicotine & Tobacco Research, e-published Aug. 20, 2014, available at <http://www.ncbi.nlm.nih.gov/pubmed/25143298>.

³ University of Michigan, Institute for Social Research, *E-cigarettes Surpass Tobacco Cigarettes Among Teens*, (posted Dec. 16, 2014), available at <http://home.isr.umich.edu/releases/ecigarettes-surpass-tobacco-cigarettes-among-teens/>.

⁴ Williams, R.S., *et al.*, *Electronic Cigarette Sales to Minors via the Internet*, JAMA Pediatrics, 2015; 169(3): e1563. doi:10.1001/jamapediatrics.2015.63.

toxicity of e-cigarettes: In 2014, there were nearly four thousand calls to poison control centers due to exposure to e-cigarettes, more than double the calls made in 2013.⁵ Last year also saw the first reported death from ingesting liquid nicotine, that of a one-year-old child.⁶

As you know, attorneys general have been very active with respect to the regulation of e-cigarettes on both the federal and state level. In October 2013, the National Association of Attorneys General (NAAG) sent a letter to then-commissioner Margaret Hamburg, signed by 41 attorneys general, asking that the FDA issue proposed rules and begin regulating e-cigarettes. After the proposed deeming regulations were issued, 29 attorneys general filed comments on August 8, 2014, recommending that the regulations be strengthened in several respects. Our concerns remain. There can be no question that regulating e-cigarettes is appropriate for the protection of the public health. E-cigarettes should be subject to the same advertising and marketing restrictions as combustible cigarettes, and should be part of the ban on characterizing flavors. Stronger health warnings are also needed – nicotine is a harmful and addictive product and e-cigarettes contain potentially harmful chemicals. And, as evidenced by the ease with which youth have been able to purchase e-cigarettes on the Internet, the FDA should prohibit all non-face-to-face sales of tobacco products.

While waiting for the deeming regulations to take effect, states have continued to take a variety of actions to address our concerns relating to electronic cigarettes. We recently sent letters to several manufacturers of electronic cigarettes inquiring about their policies and practices to ensure that their products are not being marketed or advertised towards youth. In addition, Ohio Attorney General Mike DeWine has sent letters to two electronic cigarette companies on behalf of a group of states, urging the companies to age-restrict their promotional videos on YouTube. Many states have introduced a variety of legislative proposals attempting to fill the void left by the federal government with regard to regulation of e-cigarettes.

Some companies have expressed a willingness to work with the states regarding preventing sales to minors, but several have instead taken the position that it is up to the FDA to implement a “comprehensive regulatory framework” to address the states’ concerns relating to electronic cigarettes. Moreover, while states want to address these concerns, their doing so may create a patchwork approach to regulation at the state level, and could result in some state laws or regulations being preempted under Section 916 of the Food, Drug and Cosmetic Act once the FDA finalizes the deeming regulations and eventually issues any subsequent regulations relating to the deemed products. The FDA needs to implement comprehensive nationwide regulations promptly to avoid these potential pitfalls.

⁵ <http://www.aapcc.org/alerts/e-cigarettes/>.

⁶ <http://abcnews.go.com/Health/childs-death-liquid-nicotine-reported-vaping-gains-popularity/story?id=27563788>.

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We urge you to finalize the proposed regulations as soon as possible to ensure that these products are properly regulated to prevent harm to the public health and to ensure that they are not marketed to our nation's youth.

Very truly yours,



Greg Zoeller
Attorney General of Indiana
Chair, NAAG Tobacco Committee



Janet Mills
Attorney General of Maine
Vice-Chair, NAAG Tobacco Committee

c.c. Howard Shelanski, Administrator
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