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U.S. Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2017-N-6189 for “Tobacco Product Standard for Nicotine Level of Certain Tobacco Products”

July 16, 2018

The Association of State and Territorial Health Officials (ASTHO) provides comments on the Advanced Notice of Proposed Rulemaking for tobacco product standards for nicotine levels of certain tobacco products. ASTHO strongly supports FDA’s consideration to reduce the level of nicotine in tobacco products so that they are minimally addictive or nonaddictive, while using the best available science to determine a level that is appropriate for the protection of the public’s health.

ASTHO is the national nonprofit organization representing the state and territorial public health agencies of the United States, U.S. territories, and Washington, D.C. ASTHO’s members, the chief health officials of these jurisdictions, are dedicated to formulating and influencing sound public health policy and assuring excellence in state-based public health practice. ASTHO supports public health policies that reduce disparities and makes the healthiest choice the easy choice for all.

Tobacco use remains the leading preventable cause of death in the United States, accounting for approximately 480,000 deaths annually.¹ Tobacco use also results in \$157 billion in direct and indirect medical costs each year.² CDC reports that between 2011 and 2013, smoking prevalence among adults in the United States decreased in 26 states.³ The use of emerging tobacco products, such as e-cigarettes, is on the rise, with e-cigarette use among U.S. adults increasing from 3.3 percent in 2010 to 8.5 percent in 2013.⁴ Regulations for nicotine levels could have a positive impact on addiction and second and third hand smoke exposure.

With sound, scientific insight, reducing nicotine in all tobacco products (including e-cigarette liquids, dissolvable products, lotions, and gels) to non-addictive levels could give addicted users the choice and ability to quit more easily, and potentially prevent social smokers and impressionable youth from initiating regular use and becoming regular smokers. A simulation model published by FDA researchers in the *New England Journal of Medicine* projects that a median of 13 million smokers would stop smoking combustible cigarettes within five years of them becoming non-addictive and, that by 2060, approximately 1.6 percent of American adults would smoke combustible cigarettes if no other policies were changed from the present. This projection represents a significantly reduced death, disease, and economic burden resulting from all tobacco use in the United States.⁵

The scope of a regulation that limits the nicotine content of tobacco products could improve smoking rates among vulnerable populations where more than 25.3 percent of low-income populations, 31.8 percent of Native Americans, 20.5 percent of LGBT, and 35.8 percent of those with serious psychological

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distress still smoke at much higher rates than the national average.⁶ Achieving health equity nationwide requires valuing everyone equally with focused and ongoing societal efforts to address avoidable inequalities, historical and contemporary injustices, and the elimination of health disparities.⁷

The lack of regulation over current levels of nicotine in tobacco products puts youth at risk of nicotine overdose and makes quit attempts difficult. ASTHO urges FDA to use its authority to investigate comprehensive interventions and conclusive scientific evidence to reduce nicotine levels across all tobacco products.

Liquid nicotine poisoning is an emerging public health issue given that liquid nicotine containers are appealing to youth. Nicotine is an acute toxin that can cause nausea, vomiting, bradycardia, trouble breathing, and death when swallowed or absorbed through the skin.⁸ Some e-cigarette liquid manufactures report nicotine concentrations up to 5.4 percent.⁹ Just a teaspoon of 1.8 percent nicotine liquid can be fatal, even for an individual weighing 200 pounds.¹⁰ The American Association of Poison Control Centers (AAPCC) reported 3,783 liquid nicotine poisoning cases in 2014, an increase of approximately 1,300 percent since 2011, when there were only 271 reported cases.¹¹ According to AAPCC, more than half of these liquid nicotine exposures involved children under the age of 6.¹² E-cigarette use among high school students increased from 660,000 students in 2013 to 2 million students in 2014, and use among middle school students increased from 120,000 students in 2013 to 450,000 students in 2014¹³ as the youth-targeted advertisements and colorful packaging continuing to increase making these products more appealing to minors.

The growing body of evidence about the dangers of nicotine products warrants providing pregnant women and adolescents with warnings about using smokeless tobacco and dissolvable and e-cigarette products.¹⁴ Safety requirements for products containing liquid nicotine have the potential to prevent accidental liquid nicotine poisoning. Children and pregnant women are particularly vulnerable to nicotine because even in small concentrations nicotine exposure during developmental years impairs brain and lung development.¹⁵ Effective labeling policies should require products to display safety warnings, nicotine concentration, and an ingredient list.¹⁶

ASTHO strongly supports comprehensive policy approaches requiring that all tobacco products, including e-cigarette liquids, dissolvable products, lotions, and gels, are sold at non-addictive nicotine levels. Comprehensive policies that include the reduction of both nicotine levels and increased support for cessation are necessary to prevent unintended consequences of this regulatory provision. FDA's ability to assert jurisdiction over products currently on the market and emerging tobacco products will improve the health of the nation and reduce addiction to harmful products containing nicotine at dangerous levels.

Sincerely,

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¹ U.S. Department of Health and Human Services. "The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General." Available at http://www.cdc.gov/tobacco/data_statistics/sgr/50th-anniversary/index.htm#fact-sheets. Accessed 4-11-2018.

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⁸ England LJ, Bunnell RE, Pechacek TF, et al. "Nicotine and the Developing Human: A Neglected Element of the E-Cigarette Debate." *American Journal of Preventive Medicine*. 2015. 49(2):286-293. Available at [http://www.ajpmonline.org/article/S0749-3797\(15\)00035-5/abstract?cc=y](http://www.ajpmonline.org/article/S0749-3797(15)00035-5/abstract?cc=y). Accessed 4-11-2018.

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¹² Ibid.

¹³ Arrazola RA, Singh T, Corey CG, et al. "Tobacco Use Among Middle and High School Students — United States, 2011–2014." *Morbidity and Mortality Weekly Report*. 2015. 64(14):381-38. Available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6414a3.htm>. Accessed 4-11-2018.

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¹⁵ England LJ, Bunnell RE, Pechacek TF, et al. "Nicotine and the Developing Human: A Neglected Element of the E-Cigarette Debate." *American Journal of Preventive Medicine*. 2015. 49(2):286-293. Available at [http://www.ajpmonline.org/article/S0749-3797\(15\)00035-5/abstract?cc=y](http://www.ajpmonline.org/article/S0749-3797(15)00035-5/abstract?cc=y). Accessed 4-11-2018.

¹⁶ Tobacco Control Legal Consortium. "Policy Approaches to Prevent Liquid Nicotine Poisonings." Available at <http://publichealthlawcenter.org/resources/policy-approaches-prevent-liquid-nicotine-poisonings>. Accessed 4-11-2018.