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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-6565 for “Regulation of Flavors in Tobacco Products”

July 16, 2018

The Association of State and Territorial Health Officials (ASTHO) is pleased to submit comments on the notice of proposed rulemaking entitled, “Regulation of Flavors in Tobacco Products.” ASTHO strongly supports the notice of proposed rulemaking to regulate flavoring in all tobacco products. FDA’s action to limit tobacco flavorings should include public educational campaigns so that youth and young adults are aware of the consequences that accompany flavored tobacco use in both combustible and noncombustible products. ASTHO would like to provide information regarding the following sections:

- B2. The role of flavors (other than tobacco) in initiation and/or patterns of use of combustible tobacco products, particularly among youth and young adults.
- B3. The role of flavors (other than tobacco) in initiation and/or patterns of use of noncombustible tobacco products, particularly among youth and young adults.
- D.11. Consumer perceptions of the health risks of tobacco products with flavors (other than tobacco) when compared to other tobacco products, both with and without flavors. Include information from, and define, all populations: Youth, young adults, and adults (and any subgroup thereof, if applicable).
- E.14. If FDA were to establish a tobacco product standard prohibiting or restricting flavors, to which types of tobacco products should the standard apply (*e.g.*, combusted, noncombustible, both), and why?

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.

Flavored tobacco products threaten and undermine the progress made to prevent youth from smoking combustible tobacco. Some of the products include e-cigarettes, menthol in regular cigarettes, hookah, and cigars. Examples of such flavorings besides menthol consist of candy, fruit, dessert, and cocktail flavors with colorful packaging sold at cheap prices. Marketing for flavored tobacco products, including e-cigarettes is geared towards attracting youth consumers. These marketing strategies have proven to be successful, as nearly 73 percent of high school students and 57 percent of middle school students currently using tobacco products reported using flavored tobacco products.¹

A study conducted by Burnett et al. looked at youth e-cigarette utilization and concluded that found e-cigarettes to be appealing in this population, even amongst those who never smoked e-cigarettes. The

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same participants also perceived flavored e-cigarettes use as “cool” and believed flavored e-cigarettes would encourage initiation and social acceptance among peers. In addition to flavoring products, flavorings play a role in the initiation of noncombustible and combustible tobacco use among youth. Evidence suggests that youth e-cigarette use increases the risk for subsequent cigarette smoking.² National Youth Tobacco Survey data indicate that between 2011 and 2013, the intention to smoke cigarettes was approximately 43.9 percent among youth e-cigarette users. Among those who did not smoke e-cigarettes, only 21.5 percent reported that they had intentions of trying cigarettes.³

Menthol is a type of tobacco flavoring, menthol that has been legally allowed to persist in cigarettes following the 2009 Family Smoking Prevention and Tobacco Control Act. Menthol cigarette use is a key contributor to health disparities stemming from tobacco use, as 88 percent of African American cigarette smokers ages 12 and older prefer menthol cigarettes as a result of decades of targeted advertising.^{4,5} Menthol cigarettes are also more popular among young adults aged 18-25 than in the general population, indicating that menthol in cigarettes encourages nicotine addiction in America’s young people.⁶ Menthol makes cigarettes more harmful by making smoke less irritating to inhale deeply and more addictive by changing how nicotine impacts the brain.⁷ There is no public health interest in allowing menthol cigarettes to be produced and sold in the United States, and restricting menthol cigarettes would have the net effect of discouraging African Americans and young people from cigarette smoking in the first place.

This perceived appeal of flavored tobacco continues into young adulthood. The National Cancer Institute assessed hookah use among young adults and concluded that initiation of hookah use has strong ties to the personalization of flavoring. Smoking hookah is also perceived as a recreational and social activity, as 90.7 percent of young adults who smoke hookah prefer to do so with friends as opposed to alone.⁵ The appeal of convenience was noted among college populations as well.⁸

Flavoring has also increased the marketing of cigars in the tobacco industry. Many smaller types of flavored cigars are being sold for cheaper prices aimed at attracting youth and young adults. This is apparent in looking at the vast increased of unique flavoring brands which have doubled since 2008, from 108 flavor options to 250.⁹ Subsequently, sales of flavored cigars have also increased by nearly 50 percent since 2008. Additionally, the cigar brands that are most often purchased among 12 to 17-year-old are all flavored cigars. Flavored cigar use also decreases with age, indicating that flavored cigars appeal almost exclusively to younger consumers.¹⁰ Flavored cigar use among youth is another key contributor to tobacco product initiation and nicotine addiction.

Flavoring of tobacco products can skew notions of the perceived health risks associated with both combustible and non-combustible use of such products. When looking at perceptions of e-cigarettes among youth, one study conducted in 2018 by Camenga et al. found that most of the participants assumed that e-cigarettes were less dangerous than cigarettes because of the flavoring.² Among young adults using hookah, there was a strong sense of perceived control as well as a notion that smoking hookah products is more beneficial than smoking cigarettes.⁸

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If FDA were to establish a tobacco product standard prohibiting or restricting flavors, it should apply to both combustible and noncombustible tobacco products. Evidence shows that both combustible and noncombustible products appeal to youth and young adult populations due to the flavoring.¹ Flavored tobacco products are socially accepted and appealing to youth and young adults.

Scientific evidence supporting FDA's initial and correct conclusion that flavors in tobacco products appeal to youth and young adults and may contribute to initiation and continuation of tobacco use continues to grow and is well documented. FDA should prohibit the use of all flavors unless manufacturers submit scientific evidence demonstrating that a particular flavored tobacco product appropriately protects the public health, considering its health impacts on current users, non-users, and former users, as the law requires. ASTHO supports a rule that would extend to all tobacco products and flavors, including menthol in cigarettes and smokeless tobacco, as well as all forms of e-cigarettes currently on the market and those coming to market.

Sincerely,



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Executive Director, ASTHO



Marcus Plescia, MD, MPH
Chief Medical Officer, ASTHO



Rahul Gupta, MD, MPH, MBA, FACP
ASTHO Tobacco Issues Forum, Chair
ASTHO Prevention Policy Committee Chair
Commissioner of Health, West Virginia Department of Health & Human Resources Bureau for Public Health

¹ Truth Initiative. "Flavored tobacco use among youth and young adults." Available at: <https://truthinitiative.org/sites/default/files/Truth-Flavors-Fact-Sheet.pdf>. Accessed: 4-11-18.

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- ² Camenga D, Fiellin L, Pendergrass T, *et al.* "Adolescents' perceptions of flavored tobacco products, including e-cigarettes: A qualitative study to inform fda tobacco education efforts through videogames." *Addictive Behaviors*. 2018. 82:189-194. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/29573891>. Accessed: 4-11-18.
- ³ Bunnell RE, Agaku IT, Arrazola RA, *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: official journal of the Society for Research on Nicotine and Tobacco*. 2015;17(2):228235. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/25143298>. doi: 10.1093/ntr/ntu166. Accessed: 4-11-18.
- ⁴ Giovino GA, Villanti AC, Mowery PD, *et al.* "Differential trends in cigarette smoking in the USA: is menthol slowing progress?" *Tobacco Control*. 2013. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/23997070>. Accessed: 4-11-18.
- ⁵ National Cancer Institute. "The Role of the Media in Promoting and Reducing Tobacco Use." *Tobacco Control* 1998.07-6242. Available at: https://cancercontrol.cancer.gov/brp/tcrb/monographs/19/m19_complete.pdf. Accessed: 4-11-18.
- ⁶ Villanti AC, Mowery PD, Delnevo CD, *et al.* "Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004–2014." *Tobacco Control*. 2016. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/27729565>. Accessed: 4-11-18.
- ⁷ Ton HT, Smart AE, Aguilar BL, *et al.* "Menthol Enhances the Desensitization of Human $\alpha 3\beta 4$ Nicotinic Acetylcholine Receptors. *Molecular Pharmacology*." 2015. Aug;88(2):256-64. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4518085/>. Accessed: 4-11-18.
- ⁸ Castaneda G, Barnett TE, Soule EK, Young ME. "Hookah smoking behavior initiation in the context of Millennials." *Public Health*. 2016. 137:124-130. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/27003670>. Accessed: 4-11-18.
- ⁹ Reveles CC, Segri NJ, Botelho C. "Factors associated with hookah use initiation among adolescents." *Journal de pediatria*. 2013. 89(6):583. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/24035875>. Accessed: 4-11-18.
- ¹⁰ Center for Tobacco Free Kids. "Flavored tobacco products attract kids." <https://www.tobaccofreekids.org/assets/factsheets/0383.pdf>. Updated 2017. Accessed: 4-11-18.