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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. Docket No. FDA-2017-N-6107 for “Regulation of Premium Cigars”

July 16, 2018

We are writing on behalf of the Association of State and Territorial Health Officials (ASTHO) to provide comments on the proposed rule entitled “Regulation of Premium Cigars.” In the interest of public health, ASTHO encourages FDA to exercise its regulatory authority over all tobacco products, as assumed under its 2016 final deeming rule. ASTHO agrees with FDA’s 2016 conclusion that there is no appropriate public health justification for exempting premium cigars from FDA oversight. FDA’s scientific review found that all cigars pose serious negative health risks, including about 9,000 premature deaths a year, and are potentially addictive. A loosening of restrictions on premium cigars, those that are handmade or fall into the “roll your own” category, would be an action contrary to FDA’s stated responsibility to regulate “the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.”¹

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.

In 2016, the FDA final deeming rule was an important step to protect the public’s health by ensuring that regulations for cigarettes (e.g., minimum purchase age of 18 and warning labels on product packaging and advertisements) were also applied to all tobacco products, including e-cigarettes. Maintaining these restrictions and regulations on all addictive and harmful tobacco products containing nicotine, including premium cigars, is in the best interest of the health and wellbeing for youth and adults alike in across the nation.² Premium cigars are defined as tightly rolled, dried tobacco leaves that is handmade and sells for at least \$2 per cigar. These cigars can be more than 7 inches in length, and typically contain between 5 and 20 grams of tobacco. Some premium cigars contain the tobacco equivalent of an entire pack of cigarettes and can take between 1 and 2 hours to smoke.³

While the composition and patterns of use for cigars may differ from cigarettes, this does not mean that cigars are safe to consume or are deserving of less stringent regulation. The National Cancer Institute (NCI) details how cigar smoke has higher levels of cancer-causing substances, tars, and toxins than cigarette smoke does, and reiterates that cigars are addictive and harmful even if their smoke is not fully inhaled by the user. NCI further elaborates that the larger size of cigars and the resulting increased smoking time generally result in greater exposure to toxic substances such as carbon monoxide and

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ammonia compared to cigarette smoking.³ Since premium cigars are often differentiated from other types of cigars based on their larger size, these findings demonstrate that large cigars can pose greater harm, not lesser harm, to their users.

Because all cigars are addictive and harmful, premium cigars should not be singled out for less restrictive regulations by FDA – to the contrary, FDA should uphold the deeming rule regulations for all cigars to ensure that ingredients and additives of cigars are known to the public, and that appropriate, science-based health warnings are communicated to all cigar consumers.³ Rolling back existing restrictions does nothing to better protect the public’s health and creates an opportunity for manufacturers of other harmful tobacco products to seek similar exemptions.

The deeming rule should include the development and enforcement of a standard definition of premium cigars; without it, state statutes are currently defining premium cigars differently. Maine defines premium cigars based on weight, while Minnesota’s definition includes a minimum price of two dollars.^{4,5} Earlier this year, the Colorado Senate passed a measure to define premium cigars, which emphasizes the handmade nature of premium products.⁶ Invariably, these definitions will not completely exclude all products that appeal to youth or are readily available for purchase at convenience stores. In the interest of protecting the public’s health, ASTHO encourages FDA to ensure that all cigars, and all tobacco products more broadly, are subjected to the same regulations across all states and U.S. territories.

Tobacco use remains the leading preventable cause of death in the United States and is responsible for more than \$170 billion in healthcare costs every year. More than 16 million Americans currently suffer from smoking-related illnesses and more than 480,000 die each year from cigarette smoking and exposure to secondhand smoke. Cigar smoke, like cigarette smoke, contains toxic and cancer-causing chemicals that are harmful to both smokers and nonsmokers. Cigar smoke is possibly more toxic than cigarette smoke because of the increased levels of cancer-causing nitrosamines, tar, and toxins found in the product.⁷ With the effective regulation of premium cigars, FDA will be able to continue its work to reduce the burdens of tobacco use nationwide and promote health and wellness in the U.S. states and territories.

Sincerely,



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Executive Director, ASTHO

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¹ FDA. "FDA Mission." Available at <https://www.fda.gov/AboutFDA/WhatWeDo/default.htm#mission>. Accessed 4-11-2018.

² FDA. "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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products." Available at <https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the>. Accessed 4-11-2018.

³ National Cancer Institute. "Cigar Smoking and Cancer." Available at <https://www.cancer.gov/about-cancer/causes-prevention/risk/tobacco/cigars-fact-sheet>. Accessed 4-11-2018.

⁴ Maine Legislature. "Maine Revised Statutes." Available at <http://www.mainelegislature.org/legis/statutes/22/title22sec1551.html>. Accessed 4-11-2018.

⁵ The Office of the Revisor of Statutes. "2017 Minnesota Statutes." Available at <https://www.revisor.mn.gov/statutes/?id=297f.01>. Accessed 4-11-2018.

⁶ Colorado General Assembly. "Traditional And Large Premium Cigars Tax Definition." Available at <http://leg.colorado.gov/bills/SB18-126>. Accessed 4-11-2018.

⁷ National Cancer Institute. *Monograph 9: Cigars: Health Effects and Trends*. Bethesda, MD: National Cancer Institute. 2012. Tobacco Control Monograph Series, No. 9.