July 17, 2014

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

RE: Proposed rule, “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 ID: FDA-2014-N-0189)

The Association of State and Territorial Health Officials (ASTHO) is the national nonprofit organization representing public health agencies in the United States, the U.S. Territories, and the District of Columbia. ASTHO members, the chief health officials of these jurisdictions, formulate and influence sound public health policy and ensure excellence in state-based public health practice. ASTHO members have a strong history of supporting programs that improve tobacco prevention and control efforts in their states. ASTHO, through its Tobacco Prevention and Control project, serves as a resource to state health agencies and national and federal partners on perspectives, capacities, challenges, and opportunities to implement state-based tobacco prevention initiatives. ASTHO members, along with our key public health partners and 20 affiliate organizations, represent the leaders in state, territorial, and local health departments. ASTHO works with national partners in tobacco prevention and control, including the National Association of Chronic Disease Directors (NACDD), the Directors of Health Promotion and Education (DHPE), the Association of Maternal and Child Health Programs (AMCHP), and National Association of County and City Health Officials (NACCHO), and the Tobacco Control Network (TCN), through the ASTHO Tobacco Issues Forum chaired by Edward Ehlinger, MD, MSPH, Minnesota Commissioner of Health.

Tobacco use remains the leading preventable cause of death in the United States, accounting for approximately one of every five deaths (438,000) each year. Each year, tobacco use results in $157 billion in direct and indirect medical costs. The U.S. has made tremendous progress in reducing tobacco use, but there is much work still to be done. The lack of regulation for tobacco products like e-cigarettes threatens to undermine the progress that has been made by the public health community in the past 50 years. In the absence of federal regulation, states have attempted to address these tobacco products in various ways, including imposing age restrictions, taxes, and restrictions on use of other tobacco products in public spaces and workplaces.

ASTHO and its members are pleased that the Food and Drug Administration (FDA) has proposed new rules to regulate e-cigarettes, cigars, pipe tobacco, hookahs (water pipes), nicotine gels, and certain dissolvables. This marks an important step in the process of regulating tobacco products and nicotine delivery devices currently free of restrictions, and we applaud the FDA for asserting jurisdiction over these new tobacco products and applying new provisions to regulate them. We appreciate the opportunity to provide feedback on the proposed rules, and encourage the FDA to conduct a careful review of the ideas, suggestions, and comments that the public health community provides to these proposed rules. In particular, ASTHO is providing comments on several components in the proposed rule
that deserve special consideration, including: (1) the regulation of premium cigars under FDA authority; (2) age verification requirements for internet sales of tobacco products; (3) safety requirements for packaging to prevent child poisonings; and (4) the use of characterizing flavors in newly-deemed products.

First, the proposed rule includes the option to exempt “premium cigars” from the FDA’s tobacco product authorities. While cigars may have different patterns of use than conventional cigarettes, cigar smoke is composed of the same toxic and carcinogenic constituents found in cigarette smoke. According to the National Cancer Institute, cigars generate more smoke per unit and higher concentrations of some chemicals (including carbon monoxide, nitrogen oxides, and carcinogenic N-nitrosamines and ammonia).\(^1\) In fact, the tar of cigar smoke may be more carcinogenic than cigarette smoke tar.\(^1\) Most of the cancers caused by cigarette smoking occur at increased rates among regular cigar smokers, and regular cigar smokers who inhale deeply have increased rates of coronary heart disease and chronic obstructive pulmonary disease.\(^1\) Cigar smoking is also the second most common form of tobacco use among youth. According to the 2011 Youth Risk Behavior Surveillance System, 17.8 percent of high school boys currently smoke cigars,\(^2\) and each day more than 2,700 youths under 18 years old try cigar smoking for the first time.\(^3\) Young adults are also much more likely to be cigar smokers than older adults (15.9 percent of 18 to 24 year olds, compared to 4.9 percent of 45 to 64 year olds).\(^4\) In light of the high use of cigars among youth, and the serious health risks associated with cigar use, ASTHO urges the FDA to include all cigars, including premium cigars, as tobacco products under FDA’s regulatory authorities.

Second, the availability of e-cigarettes to youth is an issue that state health agencies have struggled with. Although many states have already passed legislation banning the sale of e-cigarettes to minors, several states currently have no age restrictions on e-cigarette sales.\(^5\) FDA’s proposed rule includes provisions for age verification and banning vending machine sales for newly-deemed products to prevent youth access, but the rule also states “this prohibition on sales from electronic or mechanical devices is not intended to impact the sale of any tobacco product via the Internet.” Currently, electronic smoking devices are readily available online through a completely unregulated market. The internet provides an easy channel through which youth can potentially purchase these products, and the final deeming rule should address this by requiring age verification for mail-order and/or internet sales of tobacco products. ASTHO recommends that the FDA develop a plan to enforce age-verification for online sales of tobacco products to prevent youth access.

Third, the proposed rule does not mention safety requirements for packaging that could prevent child poisonings. The level of nicotine and other toxins can vary widely between electronic inhalation products,\(^6\) and some devices contain nicotine levels that approach fatal doses.\(^7\) E-cigarette liquids thus pose a poisoning threat to young children. The number of poison center calls for e-cigarette exposures increased rapidly from 2010 to 2014 (from 0.3% in September 2010 to 41.7% in February 2014, as a proportion of combined monthly e-cigarette and cigarette exposure calls), and 51.1 percent of e-cigarette poison exposures occurred among children ages 5 and under.\(^8\) The Tobacco Products Directive formally approved by the European Parliament in 2014 includes language to ensure “electronic cigarettes and refill containers are child- and tamper-proof, are protected against breakage and leakage and have a mechanism that ensures refilling without leakage.”\(^9\) ASTHO recommends that the final FDA rule impose similar safety measures for packing of tobacco products to prevent unintentional poisonings.
Fourth, the rule does not propose to regulate characterizing flavors for deemed products. The 2009 Family Smoking Prevention and Tobacco Control Act banned cigarettes that contain flavors other than tobacco or menthol. Products like e-cigarettes and “little cigars” are not currently subject to this law, and many companies market these products in flavors that appeal to youth and could facilitate youth uptake of tobacco use. For example, a congressional report released in April 2014 highlighted the tactics e-cigarette manufacturers currently use to appeal to youth including: sponsoring youth-oriented events, providing free samples at youth-oriented events, using celebrities to glamorize e-cigarettes, advertising via non-age-restricted social media sites, airing television commercials during programs with youth viewership, and marketing e-cigarettes in youth-appealing flavors including “Cherry Crush, Chocolate Treat, Peachy Keen, and Grape Mint.”\textsuperscript{11} ASTOP encourages the FDA to impose regulations for flavoring and marketing of newly-deemed tobacco products once the rule is finalized. To expedite the regulation of characterizing flavors of these other tobacco products, ASTOP urges the FDA to begin the investigation and regulation process now, while the deeming rule is being finalized, so that rules for flavoring and marketing are ready to propose as soon as the new deeming regulations go into effect.

ASTHO appreciates the opportunity to offer comments on this proposed rule, and supports the FDA’s decision to assert jurisdiction over additional tobacco products. We are confident that taking this important step to further regulate tobacco products will ultimately improve the health of the nation. ASTOP encourages the FDA to finalize the deeming rule as soon as possible to close the regulatory gaps that currently exist. In addition, ASTOP encourages the FDA to make a plan to rapidly review new applications for substantial equivalence or modified risk claims so that products are not available on the market longer than necessary before being rigorously reviewed by the FDA.

Sincerely,

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