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July 13, 2018

Scott Gottlieb MD  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

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

Commissioner Gottlieb:

On behalf of the 16,000 members of the American Thoracic Society, I want to thank FDA for the opportunity to comment on the Advanced Notice of Proposal Rule Making regarding Regulation of Premium Cigars (docket number FDA-2017-N-6107). As chair of the ATS Tobacco Action Committee, I appreciate the opportunity to comment on this important public health issue.

As background, the ATS is comprised of over 16,000 physicians, scientists, nurses, respiratory therapists and allied health professionals dedicated to the prevention, detection, treatment, cure and research of pulmonary disease, critical care illness and sleep disordered breathing. Our members seek to improve health through research, education, clinical care and advocacy. As respiratory experts, our members are all too familiar with disease, death and emotional destruction caused by tobacco products, including cigars. As researchers, we are well aware of the extensive scientific evidence base that documents the known adverse health effects of tobacco products – including cigars and exposure to secondhand and third-hand tobacco smoke. It is with this expertise that the ATS offers the following comments:

#### **General Comments:**

The ATS strongly recommends the agency use its full range of authority to regulate all aspects of the cigar industry, including manufacturing, distribution, advertising/marketing, labeling, sales and post-market surveillance. Any action to exempt cigars or a subset of cigars from FDA’s regulatory authority would be a significant failure on the part of the agency to fulfill its public health mission.



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## Known Adverse Health Effects of Cigars

As noted by the National Cancer Institute, cigar use is associated with several serious adverse health effects including a 4- to 10-fold increased risk of cancers of the oral cavity, larynx, esophagus, and lung. It may also cause cancer of the pancreas. Daily cigar smokers, particularly those who inhale, are at increased risk for developing heart disease and chronic obstructive pulmonary disease (COPD).(1)

## Cigar Smoke

Cigar smoke also has known adverse health effects. Cigar smoke contains higher concentrations of toxic and carcinogenic compounds, including cancer-causing tar, than cigarettes and is a major source of fine-particle and carbon monoxide indoor air pollution.(2) In fact, a single large cigar can contain as much tobacco as an entire pack of cigarettes.

## Changing Demographics of Cigar Use

Cigar use is on the rise among youth with the number and percentage of youth using cigars products rising since 2009. Today cigars are the second most frequently used tobacco products (second to unregulated e-cigarettes) among high school age youth, with an estimated 1.13 million cigars users (approximately 8%) of that age. This figure represents an almost 3% increase in cigar use among adolescents from 2013.(3) For middle school aged children, CDC estimates there are 170,000 users and cigars are the third most commonly used tobacco product in that age group.(4) While overall youth tobacco use is down, youth are responding to a changing market place, driven in part by an explosion of flavored cigars, cigarillos, and e-cigarettes. This evolving tobacco market makes it even more imperative that FDA implement and enforce effective regulation of all tobacco products, including cigars, to reduce youth tobacco use.

## Process Delays

The ATS notes with frustration that the agency has delayed action on regulating tobacco products, including cigars. We further note that this is not the first time the agency has sought public input on whether and how to regulate cigars. Many of the questions raised in the current advanced notice of proposed rule-making were asked and answered during the deeming rule notice and comment process that was completed in 2016. By engaging in an advanced notice of proposed rule-making regarding cigars, the agency is deferring essential policy actions that will have a direct and positive impact on public health. In light of the overwhelming evidence on the adverse health effects of cigar use and the known effective policy interventions FDA has authority to implement, FDA's failure to take timely action is inexcusable.

## Effective Regulation of Cigars

As the agency considers how to implement effective regulation of cigars, the ATS urges FDA to implement the following policies:

- **Ban Characterizing Flavors in Cigars**

The ATS notes that since the Family Smoking and Tobacco Control Act explicitly banned flavored cigarettes – with the notable exception of menthol – the tobacco industry has responded by expanding their line of flavored cigar products.



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From “Blueberry Swisher Sweets”, “Mango White Owls”, to “Strawberry Zag Zigs,” introduced since the cigarette flavoring ban, the tobacco industry has dramatically expanded its offering of products that are clearly intended to appeal to youth markets. The use of fruit, candy and sweetened flavors in cigar products is particularly concerning. As noted earlier in our comments, flavoring agents play an important role increasing tobacco initiation. Removing characterizing flavors from cigars will significantly reduce youth and young adult initiation of cigars.

And the industry appears to have been successful in marketing these products to children. Cigar use has increased across nearly all categories of youth use since 2010 and is now the second most commonly used tobacco product (second only to e-cigarettes) among high school aged children.

- **Require Testing of Flavoring Agents for Respiratory Health Effects**

The ATS notes that the majority of flavoring agents used in tobacco products are categorized by FDA as “generally accepted as safe” and that indication was based on historical experience with the flavors as food additives. The majority of the flavoring agents have never been tested for their potential respiratory impacts. FDA should require that all ingredients used as sub-characterizing flavoring agents should be tested for respiratory health effects. We further recommend that testing be conducted by qualified researchers who are not associated with the tobacco industry.

- **Warning Labels**

All cigar products should require warning labels. Warning labels should include graphic images, be prominently displayed on the packaging and consist of at least (50%) of the surface area of the package. The ATS concurs with the warning label messages developed in earlier FDA action, including:

- WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
- WARNING: Cigar smoking can cause lung cancer and heart disease.
- WARNING: Cigars are not a safe alternative to cigarettes.
- WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.
- WARNING: Cigar use while pregnant can harm you and your baby.  
or SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.\*
- WARNING: This product contains nicotine. Nicotine is an addictive chemical.



- **Disclosure of Ingredients**

The industry should be required to disclose all product ingredients. Product ingredients should be required to be disclosed both to FDA staff and on product packaging.

- **Manufacturing Processes**

The FDA should develop and enforce good manufacturing processes for the production of cigars. The manufacturing of cigars varies significantly from highly mechanized mass produced cigars to hand rolled cigars. Manufacturing standards should be developed to reduce product variation (especially nicotine content), and impurities, and ensure worker safety. Further, FDA should develop product tracking requirements, similar to pharmaceutical products, to allow tracking of tobacco products by lot.

- **Ban on Online Sales**

The ATS recommends that FDA ban online sales of all tobacco products, including cigars. The ATS notes online sales of tobacco products are one of the methods by which youth purchase tobacco products. Existing steps to prevent sales of tobacco products are easily defeated and have not been successful at preventing tobacco sales to youth. The ATS strongly recommends that the sale of all tobacco products be in person sales requiring point of purchase age verification with significant penalty for tobacco venders who knowingly or unknowingly sell tobacco products to youth.

- **Universal ID checks at Point of Sale**

As noted above, the ATS supports the requirement of universal age verification at the point of sale. Further, FDA should levy significant penalties on tobacco venders that knowingly or unknowingly sell cigars to minors – or up to age 21 depending on state and local restrictions. Penalties for sales to youth or people under the legal purchase age should be borne primarily by the tobacco vender as it is the tobacco vender's responsibility to ensure they are selling tobacco products to eligible customers only.

I appreciate the opportunity to comment on the advanced notice of proposed rule-making regarding regulation of cigars. The ATS urges FDA to move quickly to implement and enforce effective regulation of all tobacco products, including cigars. Effective regulation of cigars will have positive individual and public health effects for generations to come.



Sincerely,



Harold J. Farber MD, MSPH, ATSF  
Chair  
ATS Tobacco Action Committee



Enid R. Neptune MD  
Vice Chair  
ATS Tobacco Action Committee

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