June 20, 2018

Leslie Kux, Associate Commissioner for Policy
Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Regulation of Premium Cigars (FDA–2017–N–6107)

Dear Commissioner Kux:

On behalf of the American Academy of Family Physicians (AAFP), which represents 131,400 family physicians and medical students across the country, I write in response to the advance notice of proposed rulemaking titled, "Regulation of Premium Cigars" as published by the Food and Drug Administration (FDA) in the March 26, 2018 *Federal Register* (ANPRM), in which the FDA seeks information related to the regulation of premium cigars and the sale and distribution of tobacco products.

The AAFP applauds the FDA for taking this initial step since the AAFP calls for strong regulatory action on all nicotine and tobacco-related issues, including premium cigars, and applauds FDA for the ANPRM. **We strongly urge the FDA to not revise the 2016 Deeming Rule that placed cigars under the agency's regulatory authority.** Since the FDA has already considered and rejected the claim that the frequency of use and lack of inhalation of premium cigars avoids negative health effects, there is no reason for the FDA to reverse its 2016 decision. T**he AAFP believes the FDA should have authority to regulate the manufacture, sale, labeling, distribution and marketing of all tobacco products including cigars of all sizes and flavors, as well as Electronic Nicotine Delivery Systems (ENDS). All regulations around flavors should apply to all tobacco and nicotine products.**

Cigars of all sizes (large cigars, cigarillos and little cigars) are associated with increased risk of negative health effects. These include increased risk of several cancers, gum disease, tooth loss, and lung disease. Cigars contain high concentrations of cancer causing chemicals which are released when smoked. In some cases, cigars may contain 20 times more tobacco than traditional cigarettes. Cigars contain nicotine and are still addictive, regardless of inhalation. Cigar use of all sizes and flavors impacts the health of the public by causing addiction and contributing to the tobacco epidemic.

Cigar use is popular among youth, particularly little cigars and cigarillos. In the 2009 *Family Smoking Prevention and Tobacco Control Act* (FSPTCA), the FDA banned flavors in cigarettes, except for menthol. The FSPTCA does not apply to cigars, which are still widely produced in flavors appealing to children, like fruit and candy flavors. Flavored tobacco products of any kind are known to appeal to youth and young adults; over 80% of youth between 12 and 17 used flavored tobacco products when

using tobacco for the first time. Cigars are also often less expensive than cigarettes, can be sold in smaller quantities and have colorful packaging, continuing to appeal to youth, as well as both adult tobacco users and non-users. Continuing to include cigars of all sizes and flavors under the FDA's regulatory authority will provide public health benefits.

The AAFP believes there is no public health benefit or justification to exclude any tobacco products from the 2016 Deeming Rule. The FDA should continue to prioritize addressing the leading cause of preventable death by regulating cigars of all sizes and flavors. Furthermore, exemptions for products incentivize product modification to meet the exemptions. This strategy, especially in tobacco products, has proven to be harmful to public health. The AAFP calls on the FDA to include cigars of all sizes and flavors under the agency's regulatory authority. The AAFP also urges the FDA to consider promulgating additional regulations beyond the 2016 Deeming Rule to protect the health of the public.

The AAFP supports evidence-based cessation methods, including over the counter nicotine replacement therapy (OTC NRT), prescription NRT, pharmacological options, and counseling. Though not explicitly addressed in this FDA request for comments, the AAFP also calls on the FDA to work with the Centers for Medicare & Medicaid Services to increase opportunities for family physicians and other healthcare professionals to counsel patients about tobacco cessation. We call on HHS to clarify the interim final rule titled, "Coverage of Certain Preventive Services Under the Affordable Care Act" which implements Section 2713 of the Public Health Service Act to include both counseling and pharmacotherapy as described in the 2008 Public Health Services guideline.

We appreciate the opportunity to provide these comments. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org with any questions or concerns.

Sincerely,

John Meigs, Jr., MD, FAAFP
Board Chair

About Family Medicine
Family physicians conduct approximately one in five of the total medical office visits in the United States per year – more than any other specialty. Family physicians provide comprehensive, evidence-based, and cost-effective care dedicated to improving the health of patients, families and communities. Family medicine's cornerstone is an ongoing and personal patient-physician relationship where the family physician serves as the hub of each patient's integrated care team. More Americans depend on family physicians than on any other medical specialty.