



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

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 [notice of proposed rulemaking](#) titled, "Regulation of Flavors in Tobacco Products" as published by the Food and Drug Administration (FDA) in the March, 21, 2018 *Federal Register*.

In this regulation, the FDA seeks information related to the role that flavors play in tobacco products and how flavors attract youth to initiate tobacco product use. The AAFP appreciates that the FDA is taking these initial steps since the AAFP calls for strong regulatory action on all nicotine and tobacco-related issues. **The [AAFP believes](#) the FDA should have the 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.**

A robust, evidenced based study clearly indicates [flavored tobacco products](#) of any kind appeal to youth and young adults. 8 out of 10 youth ages 12-17 began using tobacco with [flavored tobacco products](#), and young adult ages 18-24 are [significantly more likely](#) to use flavored tobacco products than older tobacco users. Approximately [9 out of 10](#) people who smoke began using tobacco by age 18, and 98% began using tobacco by age 26. Flavored tobacco products potentially appeal to almost 100% of adults who smoke when they are most likely to initiate tobacco use. Although menthol is the only remaining cigarette flavor, all other tobacco products come in a wide variety of flavors, including, but not limited to ENDS, cigars and little cigars and hookah. These products, especially ENDS, are [increasingly popular among youth](#). Flavored tobacco products are also used at higher rates among [vulnerable populations](#), including women, and [sexual, racial and ethnic](#) minorities.

Regulating flavors in all tobacco products has the potential to decrease youth tobacco initiation rates drastically, improve health outcomes among vulnerable populations, prevent long term addiction to tobacco products, [curb spending](#) due to tobacco-related illnesses, and reduce the overall number of long-term tobacco users. Regulating flavors could also decrease the number of individuals living with chronic illness due to tobacco use and ultimately reduce the thousands of lives lost to tobacco use each year.

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Current evidence does not suggest flavors impact or aid tobacco cessation. [Flavored tobacco products](#), including menthol tobacco products, [decrease cessation and increase tobacco use](#), especially among African Americans. **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](#).

The [AAFP does not support](#) the use of ENDS in any form as a formal cessation option or therapeutic nicotine product. There is mixed evidence regarding the use of ENDS as effective smoking cessation devices. The long-term health consequences of ENDS are unclear. Evidence suggests [youth who use ENDS](#) are more likely to use traditional combustible tobacco products. ENDS are manufactured in a wide spectrum of flavors, only further appealing to youth. The AAFP calls for more robust research around the use of ENDS as tobacco cessation devices and the health effects of ENDS. The AAFP also calls for the same regulations around traditional tobacco products to apply to ENDS in a timely manner, including regulations regarding flavors.

The [AAFP supports](#) the attainment of the highest level of health for all people and urges the FDA to regulate flavored tobacco products, and to specifically include ENDS in these regulations. Further, FDA decisions should be subject to the same standard of review that generally applies under the *Food, Drug and Cosmetic Act*. The tobacco industry should respond to the same regulatory forces that govern other similar industries and should not be able to choose the amount of regulation they accept.

Finally, the AAFP calls on the FDA to closely examine the ENDS marketed under the JUUL® brand. These ENDS are touted as a way to quit smoking; however, as noted earlier, there is only anecdotal evidence supporting successful use of ENDS as cessation devices, and the stronger evidence suggests they are getting more people to start using nicotine than to stop. The AAFP strongly urges the FDA to regulate JUUL devices and pods, other ENDS, and tobacco flavors.

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.