AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

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: Tobacco Product Standard for Nicotine Level of Certain Tobacco Products (FDA–2017–N–6189)

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, "Tobacco Product Standard for Nicotine Level of Combusted Cigarettes" as published by the Food and Drug Administration (FDA) in the March 16, 2018 *Federal Register*.

In this regulation, the FDA seeks information for consideration in developing a tobacco product standard to set the maximum nicotine level for cigarettes. The AAFP applauds the FDA's decision to gather information on how to best implement a regulation that would reduce nicotine levels in cigarettes. This is an important step toward cutting the addictive power of cigarettes and holds the potential for helping smokers quit. With such information from stakeholders in hand, the FDA can move forward with a proposed rule that will limit the amount of nicotine in cigarettes, a move that can make a huge difference in Americans' health.

Tobacco use is the leading preventable cause of death and illness in our nation. Every day, family physicians see the devastating impact that smoking has on our patients. We welcome the FDA's commitment to reducing the number of Americans who smoke, thereby improving their health. Although most tobacco-related diseases are not caused by nicotine, the addictive nature of nicotine reinforces tobacco use, increasing the risk of disease by perpetuating use. Creating a tobacco product standard requiring non-addictive nicotine levels may prevent millions of individuals from suffering from tobacco related illnesses and subsequently impacting the leading cause of preventable death in the United States.

The AAFP believes the FDA should have authority to regulate the manufacturing, sale, labeling, distribution and marketing of all tobacco products including cigars of all sizes and flavors, as well as Electronic Nicotine Delivery Systems (ENDS). The AAFP calls on the FDA to create a non-addictive nicotine level standard for all tobacco products, not just cigarettes. This includes smokeless tobacco, electronic nicotine delivery systems (ENDS), "heat not burn products," and any other tobacco product containing nicotine for recreational use**.** Cigarettes are not the only addictive form of tobacco, and applying this standard across all tobacco products is essential to combating the leading cause of preventable death. The AAFP calls for robust, independent scientific

evidence to determine the non-addictive level of nicotine when determining a standard. It is estimated approximately 5 million people could quit smoking within one year and 13 million within 5 years if a final rule requiring non-addictive levels of nicotine in tobacco products were promulgated immediately. Reducing nicotine to non-addictive levels could reduce smoking rates to 1.4%. Although evidence suggests that reducing the amount of nicotine in cigarettes does not lead to compensatory smoking, tobacco users may switch to different tobacco products if the rule is not applied universally. The tobacco industry may also modify products to meet an exemption, similar to flavored "little cigars," developed after flavored cigarettes were banned, or create products designed to increase the nicotine content of combustible products. Comprehensive and specific regulations are necessary to prevent new products that may circumvent the nicotine level requirement. The FDA must require independent mandatory testing to ensure the nicotine content is indeed non-addictive, and this testing must be conducted in addition to or outside of manufacturer testing.

Clinical studies suggest there is no adverse affect associated with immediate reduction of nicotine to non-addictive levels. However, a gradual reduction in nicotine content may maintain smokers for a longer period of time, continuing to increase the risk for negative health outcomes. A single target approach, in combination with communication and education strategies is the best option to protect the health of the public. Of note, the benefits of quitting can be measured within 20 minutes of the last cigarette and 68% of smokers report the desire to quit.

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. **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 AAFP also calls for the same regulations around traditional tobacco products to apply to ENDS in a timely manner, including regulations regarding flavors and nicotine content.

The AAFP, in partnership with over 35 other health and public health organization, calls on the FDA to issue a proposed rule within 6 months of the ANPRM, and the final rule within one year. Implementation of the final rule should occur no later than March,2020. Swift action regulating nicotine content will prevent millions of Americans from dying prematurely due to tobacco use.

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.