AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

April 10, 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 Associate Commissioner Kux:

On behalf of the American Academy of Family Physicians (AAFP), which represents 129,000 family physicians, residents and medical students across the country, I write in response to the request for comments titled, "Nicotine Steering Committee; Establishment of a Public Docket; Request for Comments" as published by the Food and Drug Administration (FDA) in the Tuesday, February 20, 2018 *Federal Register*.

The AAFP calls for strong regulatory action on all nicotine and tobacco-related issues. Tobacco use is the leading cause of preventable death in the United States. Nicotine is the leading cause for addiction to tobacco products, further propagating the public health crisis.

Though not explicitly addressed in this FDA request for comments, the AAFP 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 the FDA 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. In its 2015 update regarding tobacco cessation, the U.S. Preventive Services Task Force (USPSTF) reinforces its "A" recommendation for these services, and states:

> "The USPSTF recommends that clinicians ask all adults about tobacco use, advise them to stop using tobacco, and provide behavioral interventions and FDA approved pharmacotherapy for cessation to adults who use tobacco."

Insurance companies and health plans do not provide uniform coverage of tobacco cessation services across the country because both counseling and pharmacotherapy were not specifically mentioned in previous rules on tobacco cessation treatment. The AAFP strongly encourages the FDA to work with other federal agencies through existing collaborations such as the Surgeon General's Interagency Committee on Smoking and Health to discuss these issues.

The AAFP supports the use of over the counter nicotine replacement therapy (OTC NRT). OTC NRT is a safe and effective form of therapeutic nicotine used for combustible tobacco product cessation. OTC NRT includes products like lozenges, patches, gums and nasal sprays. These products are

more effective when partnered with counseling, highlighting the need for reimbursement for uniform coverage of tobacco cessation services, including counseling and pharmacotherapy. Combination therapy, combines a passive, long-acting patch with a "rescue" OTC NRT to help quell acute craving. Strong evidence in peer-reviewed literature supports the effectiveness of Combination OTC NRT for tobacco cessation, combustible tobacco products. The AAFP acknowledges that no level of tobacco use is safe and OTC NRT use should be used with the end goal of complete cessation, not smoking reduction.

The AAFP does not support the use of Electronic Nicotine Delivery Systems (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 and the relatively new nature of ENDS does allow for the development of evidence regarding long-term health outcomes of ENDS use. ENDS are toxic to pregnant women and children, effecting fetal and child development. ENDS vapors and aerosols are not harmless and contain substances and toxins that can be harmful to the body. There are several unintentional injuries associated with ENDS, including fires caused by charging the batteries and poisoning from acute nicotine exposure at toxic levels. Regardless of ENDS regulation by the FDA per the Deeming Rule, many manufactures are still not currently required to submit the ingredients list to the FDA. Lack of enforcement around manufacturing could result in unsafe and inconsistent levels of nicotine and other chemicals within each cartridge, which is not conducive to cessation. The unknown efficacy of ENDS as cessation devices in combination with the known negative health outcomes and lack of regulation enforcement renders ENDS a non-option therapeutic nicotine for combustible tobacco product cessation. 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.

Given that nicotine is an addictive drug, the FDA must have full jurisdiction over all tobacco products and nicotine delivery devices, such as ENDS. 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. Further, the FDA should have authority to regulate the manufacture, sale, labeling, distribution and marketing of tobacco products and nicotine delivery devices including products such as nicotine water. The AAFP supports the use of OTC NRT and combination therapy as therapeutic nicotine for combustible tobacco product cessation and reimbursement for cessation counseling. The AAFP does not support the use of ENDS as a cessation option for combustible tobacco product cessation.

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.