AMERICAN ACADEMY OF FAMILY PHYSICIANS

December 22, 2018

Dr. Scott Gottlieb, Commissioner
Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061 Rockville, MD 20852

Dear Dr. Gottlieb:

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 request for comments regarding "Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies" as published by the Food and Drug Administration (FDA) in the November 5, 2018 *Federal Register*. The AAFP applauds the FDA for taking proactive steps to determine whether youth ENDS use is an effective, evidence-based cessation method to address adolescent nicotine addiction.

The AAFP supports evidence-based cessation methods, including over the counter nicotine replacement therapy (OTC NRT), prescription NRT, pharmacological options and counseling in adult populations. **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. The AAFP urges that the same rules regulating traditional tobacco products must be applied to ENDS as soon as possible, including regulations regarding flavors and nicotine content.

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 the FDA to clarify policy regarding Section 2713 of the Public Health Service Act to include both counseling and pharmacotherapy as described in the 2008 Public Health Services guideline. Increasing opportunities for family physicians and other clinicians to counsel patients about tobacco cessation will be beneficial in addressing youth ENDS use.

You should know that the AAFP has called for ICD-10-CM to include immediately codes that allow physicians to accurately record ENDS use in youth and adult populations. Adoption of new codes will also prime physicians to discuss nicotine addiction, the hazards of ENDS, and cessation methods with their patients. Adoption of new codes can also aid in the facilitation of research.

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In 2018, the FDA reported a 77% increase in ENDS use among youth within a 12 month timeframe. This increase is extremely alarming and indicates a need to address cessation among youth, specifically those who use ENDS. However, there is very little evidence regarding youth cessation, specifically cessation with pharmacological methods. There must be robust and ethical research with a corresponding body of evidence to determine if nicotine replacement or other drug therapies are beneficial for youth cessation.

There are many factors to consider when conducting clinical trials regarding youth and cessation. Many barriers to address cessation among youth and adolescents exist, including the fact that FDA-approved smoking cessation medications are only approved for those aged 18 and older. This presents both a scientific and clinical barrier for younger adolescents. Comprehensive tobacco- and smoke-free campus policies may impede the ability to conduct research regarding cessation in youth. Side effects associated with pharmacotherapies may also be different in youth, presenting problematic scientific barriers to continued research. Societal barriers also present unique challenges, including overcoming the belief that ENDS are not addictive, or do not lead to dual- or poly-use of other tobacco products. A key clinical barrier is screening for ENDS use in youth. If youth are not screened, or do not disclose their ENDS use, providers are too often unable to effectively address addiction and cessation.

Overcoming these barriers may be difficult but is essential to conducting research. Engaging youth in interviews and focus group about dissemination of best practices in reaching youth audiences can improve the effectiveness of research efforts. It is essential to document the harms of ENDS and nicotine addiction in conjunction with the effect nicotine has on the development of youth and adolescents. This information can be used to create effective public information campaigns about the dangers of ENDS use to overcome societal barriers. Empowering youth and adolescents to engage in their health and health decisions may also impact societal and clinical barriers, further encouraging research.

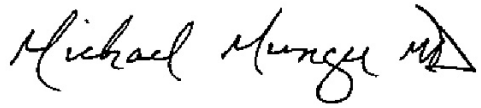
Randomized clinical trials, laboratory studies and cluster randomized trials would be ideal study designs to facilitate research assessing drug therapies for youth ENDS cessation. Within these studies, the control group would be ENDS users who receive a placebo drug therapy compared to ENDS users who receive drug therapy. Endpoints to study could include biological markers of nicotine, self-reporting use, biological markers of lung function, bodily inflammation, carcinogen levels, and volatile organic compound exposure. The research should be designed to account for trends in use among specific populations, accounting for biological, metabolic and social differences between age, race, gender, sexual orientation, flavors of ENDS and dual- and poly-use of tobacco products. Research should also account for social factors, like education attainment, socioeconomic status, exposure to advertising and access to tobacco products. Measuring perception of harm associated with ENDS use among youth and adolescents may also inform intervention strategies for clinicians, facilitating more efficient cessation counseling. Research encompassing effectiveness of the Quitline (1-800-QUIT-NOW), cessation counseling and pharmacologic cessation methods will also inform clinical practice in addressing youth ENDS cessation.

The AAFP calls on the FDA to prioritize youth cessation research, especially using pharmacological methods with ample and consistent funding as soon as possible. An alarming increase in youth ENDS use, which has been shown to lead to traditional cigarette use, is leading to a new generation of tobacco product users addicted to nicotine. Facilitating

cessation research among youth, specifically regarding ENDS addiction, is a crucial component in fulfilling the FDA's mission to protect the health of the public.

We appreciate the opportunity to provide these comments. Please contact Kait Perry, Population Health Strategist, at 913-906-6142 or kperry@aafp.org, with any questions or concerns.

Sincerely,



Michael L. Munger, 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.