



May 8, 2019

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

Dear Associate Commissioner Kux:

On behalf of the American Academy of Family Physicians (AAFP), which represents 134,600 family physicians and medical students across the country, I write to further clarify the AAFP's position on nicotine level standards in tobacco products.

First, the AAFP continues to welcome the FDA's commitment to reducing the number of Americans who smoke and use tobacco products. [Tobacco use](#) is the leading cause of preventable death in the United States, including deaths related to secondhand smoke. Americans are [addicted to nicotine](#) more than any other drug, and research indicates nicotine is as addictive as drugs like cocaine and heroin. **The AAFP affirms that there is no safe level of nicotine and does not endorse or support the use of any tobacco or nicotine product, aside from current FDA approved cessation medications.**

The AAFP acknowledges that due to the *Tobacco Control Act*, the FDA is prohibited from requiring that the reduction of nicotine yields of a tobacco product be zero. [The AAFP encourages](#) increased funding for innovative approaches to identify those at risk for tobacco and nicotine use. We acknowledge the FDA's study forecasted potential public health benefits, which seems promising, but we urge additional studies on this topic. This should include funding to help people quit, including providing medications, counseling, and improvements in primary care clinic systems. This research should include comprehensive studies to determine if low-nicotine products reduce harm and determine if a non-addictive nicotine threshold exists. This research should be utilized to determine appropriate regulation strategies. **The AAFP opposes efforts of the FDA to work with the tobacco industry to approve low-nicotine products; the FDA should make this determination based on robust evidence.**

The [AAFP supports](#) evidence-based cessation methods, including over the counter nicotine replacement therapy (OTC NRT), prescription NRT, pharmacological options, and counseling. 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

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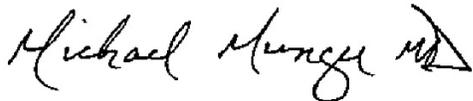
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around traditional tobacco products to apply to ENDS in a timely manner, including regulations regarding flavors and nicotine content.

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

Sincerely,

A handwritten signature in black ink that reads "Michael Munger MD". The signature is written in a cursive style with a stylized "M" and "D".

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.