AMERICAN ACADEMY of FAMILY PHYSICIANS

April 29, 2025

The Honorable Robert F. Kennedy Jr.
Secretary
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

The Honorable Marty Makary, M.D.
Commissioner
U.S. Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Ave
Silver Spring, MD 20993

Submitted electronically via regulations.gov

Re: FDA-2024-N-5471; Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products

Dear Dr. Makary,

On behalf of the American Academy of Family Physicians (AAFP), which represents more than 128,300 family physicians and medical students across the country, I write in response to the proposed rule published in the Federal Register on January 16, 2025, regarding the establishment of a tobacco product standard to reduce nicotine yield in cigarettes and certain other combusted tobacco products.

On behalf of frontline family physicians regularly combating tobacco-related chronic diseases and deaths, **the AAFP supports the FDA's proposed rule to cap nicotine levels at 0.7 milligrams per gram of total tobacco in cigarettes and other combusted tobacco products.** This measure represents a critical step in addressing smoking-related health issues, with the potential to significantly reduce the 48 million preventable deaths attributed to smoking-related diseases. By reducing nicotine levels and extending these protections to Electronic Nicotine Delivery Systems (ENDS), the FDA can prevent new generations from becoming addicted to nicotine, help current smokers quit more effectively, and take a meaningful step toward Making America Healthy Again.

The AAFP recommends the FDA:

- Finalize the proposed tobacco product standard establishing a maximum nicotine yield of 0.7 milligrams per gram of total tobacco in cigarettes and other combusted tobacco products.
- Extend the tobacco product standard to ENDs, including e-cigarettes and vapes, to protect children and support quitting.

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In 2018, cigarette smoking cost the United States over $600 billion, including $185 billion spent treating preventable, smoking-related illnesses and chronic health conditions.[i] And in 2020 alone, the U.S. lost an estimated $436.7 billion due to cigarette smoking-related impacts on personal income and productivity losses, including absenteeism and the inability to work.[ii] Yet, this staggering financial toll is overshadowed by its devastating impact on human life. Smoking causes more than 480,000 deaths annually and reduces life expectancy by 10 years. **For every American who dies of smoking, at least 30 others are living with a serious smoking-related illness**: that's more than 16 million Americans currently living with cancer, heart disease, type 2 diabetes, chronic obstructive pulmonary disease (COPD), and other diseases caused by tobacco use. The evidence is clear: the cost of smoking is not just measured in dollars, but in lives diminished and lost.

Nicotine addiction lies at the core of the tobacco epidemic, trapping millions of working-class Americans in cycles of dependence and chronic disease. Family physicians play a crucial role in influencing tobacco use behaviors, with evidence highlighting the positive impact primary care physicians can have by encouraging smoking cessation among their patients.[iii]

Further, rural communities are disproportionately harmed by tobacco use. In 2023, adults and young adults living in Arkansas, Indiana, Kentucky, Louisiana, Michigan, Mississippi, Missouri, Ohio, Oklahoma, Tennessee, and West Virginia had a 50% higher smoking prevalence and smoked more cigarettes, averaging 53 packs, per capita annually than people in other states.[iv] This translates to nearly 15 or more cigarettes per day, or 500 more cigarettes per year, than the average smoker in the rest of the U.S.[v] As a result, rural populations suffer higher rates of tobacco-related disease in death. For instance, lung cancer mortality is 18-20% higher in rural areas than in urban areas, largely due to higher smoking rates.[vi],[vii] Family physicians in rural and underserved areas witness firsthand how tobacco addiction perpetuates poor health outcomes. With a higher per capita presence in rural regions compared to urban areas; family physicians are well-versed in the devastating effects of smoking and play a crucial role in implementing tobacco cessation methods.[viii]

<u>Establishing a maximum nicotine yield is a vital step towards curbing nationwide tobacco dependence.</u>

The FDA's proposed rule would establish a tobacco product standard that sets a maximum nicotine yield in cigarettes and certain other combusted tobacco products to minimally or non-addictive levels of 0.7mg of nicotine per gram of total tobacco. The rule applies to products such as traditional cigarettes, cigarette tobacco, roll-your-own tobacco, and heated tobacco products. The stated goals are to prevent initiation, promote cessation, and reduce overall nicotine dependance across the U.S.

On behalf of family physicians providing frontline tobacco cessation support across America, the AAFP urges the FDA to set a maximum nicotine yield in most combustible tobacco products. The AAFP's position on Tobacco Prevention consistently calls for an immediate reduction in the nicotine content of tobacco products to non-addictive levels, and robust and comprehensive regulation of all tobacco and nicotine products by the FDA. By mandating lower nicotine levels, the FDA can make America healthy again, and reduce one of the most significant contributors to preventable death and chronic disease in the U.S.

The FDA's proposed tobacco product standard can reduce the burden of smoking-related disease for all Americans in three significant ways:

1. **Support the Americans disproportionately impacted by tobacco and nicotine dependence.** According to the FDA's population health model, by 2100, approximately 48 million youth and young adults who would have otherwise started smoking will not do so due to the proposed product standard. Additionally, the model projects that more than 12.9 million current smokers will quit smoking (including those who switch to non-combusted tobacco products) within one year of implementation, increasing to 19.5 million former smokers within five years.
2. **Protect American children and young adults from nicotine addiction.** If the proposed rule is finalized, the FDA estimates that over 47 million youth and young adults who would have otherwise initiated smoking will not start by the year 2100.[ix]
3. **Enable Americans to sustainably reduce smoking with limited withdrawal symptoms.** By decreasing nicotine exposure through a nicotine yield cap, this rule will help mitigate withdrawal symptoms that deter smokers from quitting, ultimately improving cessation success rates.[x] Robust clinical trial data supports this method, showing that very low nicotine content (VLNC) cigarettes can reduce daily consumption, dependence, and increase quit attempts.[xi]

If finalized, the tobacco product standard would complement tobacco cessation interventions, significantly reducing the cost and severity of tobacco-related diseases for all Americans. Robust scientific evidence supports the efficacy of nicotine reduction strategies in shrinking the risk of premature death, adding up to 10 years to life expectancy, and reducing the risk of developing or exacerbating adverse health effects and smoking-related chronic diseases. In fact, quitting smoking before the age of 40 reduces the risk of dying from smoking-related disease by about 90%.[xii]

Further, in 2022, the US Preventive Services Task Force (USPSTF) conducted a systematic review that concluded that tobacco control policies combined with primary care-based cessation support generate significant cost savings within just a few years, largely due to reductions in smoking-related hospitalizations and chronic disease management costs.[xiii] These cost-savings and improved health outcomes can ease the financial strain on public

programs like Medicare and Medicaid, reduce costs for American taxpayers, and improve the quality of life for millions of Americans. Thus, the nicotine yield standard is not only a public health intervention; it is also a strategic investment in the long-term sustainability of our nation's healthcare system.

Sustained funding for Medicaid programs that support smoking cessation is also crucial to supplement the FDA's efforts and improve health outcomes. Medicaid plays a critical role in helping low-income individuals quit tobacco by offering coverage for cessation counseling and medications in nearly every state. Given that smoking rates among Medicaid enrollees are nearly twice as high as those with private insurance, ensuring access to cessation services through Medicaid is both a cost-saving and life-saving imperative.[xiv] Studies show that comprehensive Medicaid tobacco cessation coverage can reduce expensive hospital admissions, Medicaid expenditures, and smoking prevalence, especially when paired with outreach and primary care provider engagement. Family physicians, who regularly serve Medicaid patients, are uniquely equipped to deliver these interventions. Therefore, sustained investments in Medicaid cessation programs are essential to the success of the FDA's nicotine reduction strategy.

Immediate implementation and manufacturing regulation will ensure the success of this rule.

The AAFP supports the FDA's proposal to immediately require a reduction of nicotine levels in combustible tobacco products rather than a gradual step-down approach. An immediate reduction has proven to be more effective in decreasing cigarette consumption and smoking dependence over time, without compensatory smoking behaviors.[xv] Further, we agree with the FDA, that this immediate nicotine reduction approach would reduce manufacturing costs for products covered by the proposed standard, as manufacturers would not have to spend excess time and resources to formulate multiple products, submit each for premarket review, secure approval, and repeat this process for each iteration of the tobacco product at each stage of the gradual reduction approach.

To further bolster the success of this product standard for the FDA and manufacturers, the AAFP also recommends FDA to finalize the proposed rule that would establish the use of a manufacturing code to serve as a common identifier for tobacco production and distribution records. Currently, there is no requirement for the use of a manufacturing code for tobacco products. This manufacturing code would allow manufacturers and the FDA to ID production batch of finished products and help monitor/investigate any nonconforming products. This would help both manufacturers and the FDA appropriately regulate the implementation of the product standard.

Also, we acknowledge the FDA's concerns that reducing nicotine levels may lead to the emergence of illicit markets. However, evidence suggests that the risk of a substantial illicit market for VLNC cigarettes is minimal. In fact, a comprehensive international review by the National Academies of Science, Engineering and Medicine in 2015 found no significant illicit market formation following similar reduction policies in other countries.[xvi]

Regulate all tobacco products, including e-cigarettes, equally to protect children and encourage quitting.

The AAFP applauds the FDA's focus on combustible tobacco products and encourages the FDA to expand the proposed product standard to include e-cigarettes and other electronic nicotine delivery systems (ENDS). The AAFP recognizes the increased use of ENDS, especially among youth and young adults, as well as its use by those attempting to quit smoking tobacco. Current research does not support ENDS as a smoking cessation device and there remain significant concerns about ENDS marketing, safety, quality, and its negative health implications to the public. We are deeply concerned that ENDS have become a new on-ramp to nicotine addiction for children and young adults and have consistently advocated for greater regulation of these products.

The AAFP does not support the use of ENDS in any form as a formal cessation option or therapeutic nicotine product. 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. Nicotine exposure is harmful to developing brains in children and youths, disrupting brain development and affecting learning, memory, attention, mood, and impulse control.[xvii] Although some progress has been made since the U.S. Surgeon General declared youth vaping an epidemic in 2018, millions of teenagers continue to use e-cigarettes, drawn by fruit and candy flavors and trapped by high-nicotine formulations. According to the 2024 National Youth Tobacco Survey, approximately 1.63 million high school and middle school students reported current use of e-cigarettes, compared to 760,000 students who reported using any combustible tobacco product.[xviii] Notably in 2018, the AAFP called on the FDA to apply a nicotine standard across the spectrum of tobacco-related products specifically to prevent the tobacco industry from shifting users to nicotine-heavy products. We reiterate that call today.

Further, nicotine yield varies among ENDS due to user experience, nicotine delivery method, lack of industry standardization, and governmental regulation. Since nicotine yield is variable within ENDS, the AAFP urges the FDA to develop a nicotine yield cap for ENDS, because ENDS are a gateway to combustible tobacco products, especially for children and young adults. **While this proposed rule protects Americans of all ages from the consequences of**

nicotine use from combustible tobacco products, the decision to scope out ENDS from the product rule leaves American children and young adults vulnerable to the consequences of nicotine use. Thus, we urge the FDA to complete its commitment to protecting children by extending the tobacco product nicotine yield standard to ENDS, including e-cigarettes and vapes.

Establishing a maximum nicotine yield for ENDS is particularly important to reduce the long-term health consequences of using noncombustible tobacco products and increase the likelihood for smokers to sustainably quit smoking. Across multiple settings, non-smokers who use e-cigarettes are consistently three times more likely than those avoiding e-cigarettes to initiate combustible cigarette smoking and become current smokers. Further, former smokers using e-cigarettes have over twice the odds of relapsing as non-users.[xix] The FDA's population health model within the proposed rule even indicates that an increase in non-combusted product use would occur alongside a reduction in cigarette smoking. Thus, expanding the scope of the proposed rule to include ENDS would also reduce the potential for dual use and compensatory behaviors. Without regulation, smokers may switch to or concurrently use high-nicotine e-cigarettes to compensate for the reduced nicotine in combusted products, undermining the rule's intent.

Including ENDs in the tobacco product standard will best serve the FDA's goal of reducing the epidemic of tobacco dependence for everyone, rather than pushing the problem from one product to another.

<u>Ensure Adequate Staffing to Implement and Enforce current and future regulations.</u>

The AAFP has consistently advocated for robust regulatory measures to combat nicotine addiction, acknowledging the influence of tobacco companies on American consumers. The proposed nicotine cap is a crucial step to help Americans escape this hold. However, its success hinges on the FDA being sufficiently resourced to implement and enforce these standards. We are concerned that recent reductions in the federal tobacco control infrastructure may limit the effectiveness of this rule.

On March 27, HHS announced a major organizational restructuring plan that included significant reductions in FDA staff. While this reorganization is largely focused on streamlining administrative functions, our current understanding is that these reductions have also impacted the Center for Tobacco Products. We emphasize the importance of these Centers and the FDA overall to family physicians, who rely on FDA guidance to support their patients in managing tobacco dependence and cessation. We request that the agency remains equipped to consistently meet these needs.

On behalf of family physicians and their patients, we are prepared to work with you to protect the health of the American public, prevent smoking-related chronic disease, and promote the well-being of all Americans.

We appreciate the opportunity to provide comments on this proposed rule.
Should you have any questions, please contact Sahana Chakravartti, Regulatory Specialist, at schakravartti@aafp.org

Sincerely,

Steve Furr, M.D., FAAFP

Steven Furr, MD, FAAFP
American Academy of Physicians, Board Chai

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