September 15, 2025

Dockets Management Staff [HFA-305]
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA–2024–N–5471, Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products

The American Academy of Pediatrics, American Lung Association and American Thoracic Society submit these comments in the above-mentioned docket on the proposed rule that would reduce nicotine levels in cigarettes and certain other combusted tobacco products.

The Proposed Rule Should Be Expanded to Include All Tobacco Products, including E-Cigarettes and Nicotine Pouches

As leading medical and public health organizations in the U.S., our organizations appreciate the U.S. Food and Drug Administration (FDA) issuing this proposed rule to reduce nicotine levels in cigarettes and certain other combusted tobacco products. Lowering nicotine content in the tobacco products covered by this proposed rule would lead to considerable public health benefits by reducing smoking rates across the overall population. In addition to the impact that reductions in smoking will have on individuals, the product standard also promises to reduce children's exposure to secondhand and thirdhand smoke by facilitating cessation in parents and other caregivers. According to nationally representative data collected between 2013 and 2014, 37.9% of children 3 to 11 years of age showed signs of secondhand smoke inhalation. Furthermore, parents and caregivers who smoke are important sources of children's secondhand smoke exposure, and the home is the place where children are most exposed to secondhand smoke.[1] As such, the child health benefit of this rule could be significant. We appreciate the FDA's commitment to addressing these issues.

However, we strongly recommend that FDA broaden its rule to include all tobacco products, including hookah/waterpipe tobacco, heated tobacco products, e-cigarettes and nicotine pouches, so that the nicotine in all tobacco products is reduced to non-addictive or minimally addictive levels. We are especially concerned about the potential impact reduced nicotine levels in just cigarettes and some combusted tobacco products could have on youth tobacco product initiation with tobacco products not included in this tobacco product standard, particularly e-cigarettes and nicotine pouches. Our organizations are also concerned about potential increases in use of two or more tobacco

products (dual or poly use of tobacco products) or potential switching in lieu of complete cessation to other tobacco products with higher nicotine levels in existing users if the proposed rule is not expanded.

Applying a low-nicotine standard to all tobacco products, including e-cigarettes, will have even more significant public health benefits, including reduced youth initiation, reduced adult tobacco use and increased success at tobacco cessation attempts. Implementing a well-crafted low-nicotine tobacco product standard will save lives. In order to protect individuals in the U.S. from the dangers of all tobacco products, as is the responsibility of FDA, it is necessary for the proposed rule to include all tobacco products.

Two of our organizations, the American Academy of Pediatrics and the American Lung Association, signed on to comments led by the Campaign for Tobacco-Free Kids that include extensive discussions of why hookah tobacco and heated tobacco products should be included in the proposed rule, which our organizations will not repeat in these separate comments. Unfortunately, because e-cigarettes and nicotine pouches are relatively new to the U.S. market, there is limited research on the effects of nicotine levels in these products. To better understand their public health impact, the FDA – in collaboration with the National Institutes of Health (NIH) – should conduct studies focused on reducing nicotine levels in emerging tobacco products, including e-cigarettes and nicotine pouches.

In addition, there is increasing evidence showing harms from e-cigarettes, including actual disease risks that we think FDA needs to take into account as part of this proposed rule. A 2024 study published in the New England Journal of Medicine, which examined and combined results from over 100 studies about e-cigarette disease risks, found that for cardiovascular disease, stroke and metabolic disease, e-cigarettes have similar risks to cigarettes. There were lower, but still substantial risks for respiratory and oral disease compared to cigarettes. Using both e-cigarettes and cigarettes together was riskier than cigarette smoking for all outcomes.[2] Another study of nearly 120,000 people showed that those who currently use e-cigarettes had a 17% greater risk of ending up in the emergency room, and 84% greater risk of death, compared to those who don't use e-cigarettes.[3] In light of these studies, our organizations believe that leaving nicotine levels in e-cigarettes at the same levels they are now present greater risks than was understood even several years ago.

A low-nicotine product standard that applies only to cigarettes and some combusted tobacco products will also leave our youth vulnerable to the lure of tobacco addiction. As noted by several recent National Youth Tobacco Surveys, although e-cigarette use among middle and high school students has declined, it remains the most used tobacco product and one of the main nicotine gateway products of choice for youth. Nicotine pouch use among middle and high school students has also seen an increase from 2021 to 2024, although there was no statistically significant increase from 2023 to 2024. Perhaps even more alarming is the levels of addiction seen among existing youth users of these products.

In 2024, frequent use (20 out of the past 30 days) was 38.4% for e-cigarettes and 29.3% for nicotine pouches; daily use was 26.3% for e-cigarettes and 22.4% for nicotine pouches.[4]

Implementation Concerns with a Proposed Rule that Does Not Include All Tobacco Products

If the scope of the proposed rule remains the same or is expanded to include some additional but not all tobacco products, our organizations do want to point out some implementation concerns with the proposed rule that FDA should take into consideration.

While the proposed specific nicotine level of 0.7 milligrams/gram (mg/g) may be appropriate for adults, we do have concerns about whether the level is low enough to prevent initiation by children. Generally speaking, there is no safe level of nicotine exposure for children. Acknowledging that FDA is prohibited from reducing nicotine levels in tobacco products to zero under the Tobacco Control Act, we encourage FDA to set the nicotine level at the lowest level feasible with the current 0.7 mg/g as the ceiling. Setting the nicotine level at the lowest possible level will also create a margin of safety that could act to discourage initiation.

Nicotine analogs and nicotinic alkaloids such as methyl-6 nicotine pose a significant threat to the effectiveness of a nicotine product standard if they are used to circumvent the requirements of the rule. These are nicotine-like chemicals that have similar addictive properties but are chemically different enough to avoid being classified as nicotine. FDA should strongly consider regulating these other nicotine-like chemicals as part of this rule to prevent a loophole that manufacturers affected by the rule could exploit.

To properly enforce the proposed rule, FDA needs to have a consistent and appropriate way to measure nicotine content in tobacco products. More importantly, the monitoring and reporting of nicotine levels should not be left solely to tobacco companies. Given that tobacco manufacturers manipulated products and nicotine measurement methods in the past, e.g. by introduction of ventilation holes in cigarettes, nicotine levels in all manufactured batches need to be independently verified, either by the FDA Tobacco Products Laboratory or the Tobacco Laboratory of the CDC Division of Laboratory Sciences, using a standardized method. Nicotine smoke yields also need to be determined, using the WHO Intense Method to detect potential manipulations of the nicotine distribution along the cigarette. Manufacturers should not be allowed to shorten the cigarette length and compress tobacco content, a potential strategy to increase smoke nicotine concentration, or distribute nicotine content unevenly along the cigarette to create puffs with higher nicotine levels.

The proposed rule should not only apply to products marketed in the United States, but to all products manufactured in the United States. Continued manufacturing of products with “regular” nicotine content, such as for export, raises the risk of diversion to illegal markets either locally or by re-importation from neighboring countries. The rule also needs to prohibit manufacturing and sales of any devices and methods capable of increasing the

nicotine contents of a low nicotine product after manufacturing, e.g. by adding concentrated nicotine available for mixing of e-cigarette liquids.

More Tobacco Cessation Options for Youth Needed

We also note with concern, and significant frustration, that there are still no FDA-approved nicotine cessation medications for youth. The e-cigarette epidemic has created a new generation of youth nicotine users for which clinicians have no highly effective pharmaceutical interventions that can be prescribed on-label. Physicians are treating young patients who want to quit, who know why they should quit, and have parents desperate to help them quit but are struggling due to the powerful hold of nicotine addiction, in many cases due to e-cigarettes with extremely high levels of nicotine. The addiction levels seen in the National Youth Tobacco Survey noted earlier in our comments support this. FDA needs to take a more proactive approach to getting medications into the pipeline that could help with youth nicotine addiction.

Conclusion

Tobacco use continues to be the leading cause of preventable death and disability in the U.S and kills more than 490,000 Americans each year.[5] In 2023, 27 million individuals in the U.S. currently smoked cigarettes[6] and an estimated 2.25 million middle and high school students use at least one tobacco product, including e-cigarettes.[7] The U.S. spends more than $240 billion annually on tobacco-related medical care for adults.[8]

A nicotine product standard that includes all tobacco products is essential to maximize the benefit to public health. We thank you for your time and attention to this issue and urge you to keep these comments in mind as FDA moves forward with this proposal to reduce nicotine levels in tobacco products.

Sincerely,

American Academy of Pediatrics
American Lung Association
American Thoracic Society

---

[1] Brian P. Jenssen, Susan C. Walley, Rachel Boykan, Alice Little Caldwell, Deepa Camenga, Section on Nicotine and Tobacco Prevention and Treatment, Committee on Substance Use and Prevention, Section on Nicotine and Tobacco Prevention and Treatment, Committee on Substance Use and Prevention; Protecting Children and Adolescents From Tobacco and Nicotine. Pediatrics May 2023; 151 (5): e2023061806. 10.1542/peds.2023-061806.

[2] Glantz SA, Nguyen N, Oliveira da Silva AL. Population-Based Disease Odds for E-Cigarettes and Dual Use versus Cigarettes. NEJM Evidence 2024; 3(3): DOI: 10.1056/EVIDoa2300229.

[3] Goldberg Scott S, Feigelson HS, Powers JD, Clennin MN, Lyons JA, Gray MT, Vachani A, Burnett-Hartman AN. Demographic, Clinical, and Behavioral Factors Associated with Electronic Nicotine Delivery Systems Use in a Large Cohort in the United States. Tob Use Insights. 2023 Jan 5; 16:1179173X221134855.

[4] Park-Lee E, Jamal A, Cowan H, et al. *Notes from the Field:* E-Cigarette and Nicotine Pouch Use Among Middle and High School Students — United States, 2024. MMWR Morb Mortal Wkly Rep 2024; 73:774–778. DOI: http://dx.doi.org/10.15585/mmwr.mm7335a3

[5] U.S. Department of Health and Human Services. Eliminating Tobacco-Related Disease and Death: Addressing Disparities—A Report of the Surgeon General. Atlanta, GA; 2024.

[6] Centers for Disease Control and Prevention. National Center for Health Statistics. National Health Interview Survey, 2023. Analysis by the American Lung Association Epidemiology and Statistics Unit using SPSS software.

[7] Jamal A, Park-Lee E, Birdsey J, et al. Tobacco Product Use Among Middle and High School Students — National Youth Tobacco Survey, United States, 2024. MMWR Morb Mortal Wkly Rep 2024; 73:917–924. DOI: http://dx.doi.org/10.15585/mmwr.mm7341a2

[8] U.S. Department of Health and Human Services. The Health Consequences of Smoking — 50 Years of Progress: A Report of the Surgeon General. U.S. Department of Health and Human Services; 2014.