

Commissioner Martin Makary, MD, MPH  
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

Commissioner Makary,

On behalf of the National Association of County and City Health Officials (NACCHO), I write to urge FDA to finalize the proposed rule that sets the tobacco product standard for nicotine yield of cigarettes at a maximum nicotine level of 0.7 mg/g. NACCHO represents the over 3,300 local health departments across the United States that work every day to prevent disease, promote wellness, and assure the nation’s health security. Local health departments offer tobacco prevention and cessation programs, including free quit smoking classes, nicotine replacement therapies, and education to prevent youth from starting to smoke. NACCHO supported the effort to reduce maximum nicotine levels when it was announced during President Trump’s first administration. NACCHO further urges FDA to expand the rule to apply to all combustible tobacco products, including cigarettes, cigars, and hookah, as well as to heated tobacco products. This proposed rule to reduce nicotine in tobacco products sets an important national standard that will reduce initiation for youth, increase the success of people who attempt to quit, and significantly reduce nicotine dependence.

## Public Health Impact of Reducing Nicotine in Combustible Tobacco Products

As noted in the proposed rule, smoking remains the leading cause of preventable death and disease in the United States, killing more than 490,000 Americans every year—nearly one in every five deaths.<sup>1</sup> Since the original Surgeon General’s report on tobacco in 1964 more than 20 million Americans have died from smoking.<sup>2</sup> Smoking is also a primary driver of chronic disease. Smoking causes 30% of all cancer deaths in the United States (including 80% of all lung cancer deaths),<sup>3</sup> at least 25% of all deaths from cardiovascular disease,<sup>4</sup> and 80% of all deaths from COPD.<sup>5</sup> Approximately half of people who continue to smoke will die prematurely, losing at least a decade of life on average compared to people who do not smoke.<sup>6</sup> As FDA notes (proposed rule, 5040), “Rendering cigarettes and certain other combusted tobacco products minimally addictive or nonaddictive through a nicotine product standard would address the principal reason that people who smoke cigarettes have difficulty quitting smoking.”

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<sup>1</sup> HHS, Eliminating Tobacco-Related Disease and Death: Addressing Disparities, A Report of the Surgeon General, 2024.

<sup>2</sup> U.S. Department of Health and Human Services. (2014). The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.

<sup>3</sup> Islami F, et al. Proportion and number of cancer cases and deaths attributable to potentially modifiable risk factors in the United States, 2019. CA: A Cancer Journal for Clinicians. 2024. American Cancer Society. Cancer Facts & Figures 2024. Atlanta: American Cancer Society; 2024.

<sup>4</sup> CDC, Health Effects of Cigarettes: Cardiovascular Disease, 2025, <https://www.cdc.gov/tobacco/about/cigarettesand-cardiovascular-disease.html>. Accessed April 10, 2025.

<sup>5</sup> HHS, The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General, 2014.

<sup>6</sup> HHS, The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General, 2014.



Changes included in the proposed rule will dramatically reduce the number of adults who smoke, reducing tobacco-related disease, disability, and death. Based on FDA's population health model (proposed rule, 5077-5086), the agency estimates that reducing nicotine levels in combusted tobacco products would prevent more than 48 million youth and young adults from initiating smoking by the year 2100. In addition, within five years, FDA estimates it would cause 19.5 million people to quit smoking, including 12.9 million within just the first year of implementation. The public health results from the prompt and full implementation of the proposed rule would benefit local communities across the nation and prevent many youth from taking up smoking – thereby reducing future chronic disease and premature death.

### **A Nicotine Content Standard Should Apply to All Combustible and Heated Tobacco Products and Should Prohibit Changes in Tobacco Products that Might Counteract the Effect of the Reduction in Nicotine**

To maximize public health benefits of a nicotine product standard, NACCHO supports FDA's proposal to apply the standard to certain combustible tobacco products, including cigars, but urges FDA to consider broadening the scope of the proposed rule to include hookah tobacco and heated tobacco products. Broadening the proposed nicotine reduction policy to all combustible tobacco products and to heated tobacco products, which pose similar public health risks as cigarettes and are often flavored and popular among youth, will prevent youth who experiment from becoming addicted to these and other tobacco products. It will also limit the possibility that people who smoke cigarettes will switch to other harmful products to fulfill their need/dependence.

Historically, when various tobacco products have been taxed or regulated differently, the industry has made substitutions. FDA recognized reclassification as a potential problem in its Final Regulatory Impact Analysis of the final deeming rule when it stated, "Deeming all tobacco products, except accessories of a newly deemed tobacco product, to be subject to chapter IX of the FD&C Act would be the necessary first step to rectify an institutional failure in which tobacco products that are close substitutes are not regulated by FDA in a like manner."<sup>7</sup> It is likely that tobacco companies will promote cigars and other combustible tobacco products as alternatives to cigarettes if the nicotine product standard does not address all other forms of combustible tobacco. FDA's proposal to include other combusted tobacco products in the prohibition greatly strengthens the regulation to best achieve its public health goal.

Cigars should also be included in this proposed standard because cigars contain many of the toxins and carcinogens found in cigarettes and many other harmful ingredients, and to dispel the common misconception about the addictiveness of cigars. In its proposed Deeming Rule, FDA highlighted research indicating existing misperceptions that cigars were less addictive than cigarettes or not addictive at all, further noting that some youth did not realize that cigars even contained nicotine.<sup>8</sup> FDA has also asserted that it should not exempt premium cigars from regulation under the Tobacco Control Act because doing so, "could mislead consumers to believe that premium cigars are safe, which contradicts the available evidence that all cigars are harmful and potentially addictive."<sup>9</sup>

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<sup>7</sup> FDA, Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements, Final Regulatory Impact Analysis; Final Regulatory Flexibility Analysis; Unfunded Mandates Reform Act Analysis, May 2016, at 60-61, <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM500254.pdf>.

<sup>8</sup> 81 Fed. Reg. at 29063, citing 79 Fed. Reg. at 23158, 23166.

<sup>9</sup> 81 Fed. Reg. at 29021. While FDA's application of the Deeming Rule to premium cigars was vacated in *Cigar Association of America, et al. v. FDA*, 132 F.4th 535 (D.C. Cir. 2025), the definition of "premium cigars" for purposes of that holding is still a matter of pending litigation in the District Court. For purposes of the proposed rule limiting nicotine in cigarettes and cigars, FDA should determine that the rule should apply to all cigars determined to be within FDA's regulatory authority.



Hookah should also be included in this proposed standard because hookah tobacco smoking is harmful and studies have shown that hookah smoke contains many of the toxins and carcinogens found in cigarettes.<sup>10</sup> FDA is not proposing to include hookah (waterpipe) tobacco within the scope of the nicotine reduction standard due to the agency's expectation that "there is little risk of switching under the proposed product standard" (proposed rule, 5034). In this aspect, FDA has not sufficiently considered how patterns of use may change in a marketplace where hookah is among the only available combustible tobacco product with addictive levels of nicotine. Further, the agency does not demonstrate evidence of a low-level of risk of switching or an increase in initiation, particularly among youth. The proposed rule does not sufficiently consider how regulating hookah tobacco differently than other combustible tobacco products may also exacerbate widespread misperceptions about the health harms of hookah tobacco, particularly among young people. FDA should consider the potential public health benefits of including hookah in the proposed rule, examine the evidence based on associations between cigarette and hookah tobacco use, and consider the likely increase in hookah tobacco use in a marketplace where it is the only available combusted product with addictive levels of nicotine.

Heated tobacco products (HTPs) also should be included in this proposed standard. There is a substantial public health risk from excluding HTPs from the rule. HTPs can deliver addictive levels of nicotine, just like cigarettes, and are often used with cigarettes. HTPs have not been on the market long enough to accumulate long-term data on health risks, but FDA has failed to sufficiently consider how patterns of use may change in a marketplace where HTPs are among the only available products with addictive levels of nicotine. FDA should consider the potential public health benefits on initiation and cessation of including heated tobacco products in the proposed rule, examine the evidence base on associations between cigarette and heated tobacco product use, and consider the likely increase in use in a marketplace devoid of addictive cigarettes and other combustible tobacco products, particularly among youth.

In addition to nicotine, other substances contained in tobacco products might also have the potential to produce dependence and be addictive. It is important for FDA to establish a rule that prohibits any change in products subject to the rule that has the effect of diluting or offsetting the effect produced by the reduction in nicotine. Section 910 of the Tobacco Control Act prohibits tobacco product manufacturers from modifying tobacco products in the absence of a marketing order from FDA. Any product standard establishing a maximum level of nicotine in tobacco products should explicitly prohibit manufacturers from making other changes in a tobacco product with the effect of diluting or offsetting the reduction in dependence produced by reducing the nicotine content of such product. FDA must also recognize that the emergence of nicotine analogs, or compounds that are structurally similar to nicotine and include nicotine derivatives and metabolites, poses a substantial threat to the efficacy of a nicotine product standard.<sup>11</sup>

### **Implementation Considerations**

NACCHO affirms FDA's assessment (proposed rule, 5070-5072) that the evidence demonstrates a greater public health benefit from an immediate reduction rather than a gradual reduction in nicotine content. The most robust evidence to support an immediate reduction approach comes from a 20-week randomized controlled trial of 1200 adults that assigned people who smoke to normal nicotine content cigarettes, reduced nicotine content cigarettes (0.4 mg/g), or cigarettes with the nicotine content gradually reduced over the course of the study (from 15.8 mg/g

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<sup>10</sup> HHS, Prevention Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General, 2012.

<sup>11</sup> Vagg, R., & Chapman, S. (2005). Nicotine analogues: A review of tobacco industry research interests. *Addiction* (Abingdon, England), 100(5), 701–712. <https://doi.org/10.1111/j.1360-0443.2005.01014.x>

to 0.4 mg/g).<sup>12</sup> Those in the immediate nicotine reduction group showed greater reduction in cigarettes per day, greater decreases in measures of dependence, higher rates and duration of abstinence, and greater reductions in biomarkers of smoke exposure compared to the gradual reduction group, while no significant differences were found between the gradual reduction group and control group.<sup>13</sup>

The important public health benefits that would result from adoption of this rule should not be postponed. FDA's proposal of an effective date two years from publication of the final rule (proposed rule, 5111) is unnecessarily lengthy. The effective date should be no longer than one year after final publication, an implementation period consistent with the one-year period generally provided for in the Tobacco Control Act.<sup>14</sup> Postponing the effective date of the rule will place the hundreds of thousands of people who smoke and people—including youth—who will initiate smoking at unnecessary risk for increased smoking-related illness and shortened lifespans. The public health benefits far outweigh the compliance costs. Given the stronger evidence for reduction in smoking and dependence from an immediate reduction approach and the greater implementation challenges of a gradual approach, the evidence clearly supports FDA's proposal to use an immediate reduction approach.

Reducing nicotine in combustible tobacco products is technologically feasible. As FDA describes in the proposed rule, "more than 96 percent of nicotine can be successfully extracted from tobacco while retaining 'a strong characteristic aroma...not different from the unextracted blend,' achieving a product that 'was subjectively rated as average in nicotine characteristics.'"<sup>15</sup> FDA correctly concludes that producing reduced-nicotine tobacco for other combusted tobacco products should be no more difficult than producing it for cigarettes. "Given the similarities between the tobacco used in cigarettes and in other combusted tobacco products that FDA proposes to include within the scope of this product standard, FDA expects that it is similarly technically feasible for noncigarette tobacco products to comply with the proposed maximum nicotine level." (proposed rule, 5075).

Products currently on the market are both deadly and highly addictive. FDA correctly determined (proposed rule, 5111) that the public health imperatives that provide the foundations for replacing these products with very-low nicotine content (VLNC) cigarettes are inconsistent with permitting the continued sale of non-conforming inventories beyond the effective date of the rule. The presence of non-conforming product on the market after the effective date of the rule will only dilute the effectiveness of the rule and cause confusion in the marketplace.

To gain public support for these regulatory activities, FDA and its partners should emphasize that the intent is to protect the health of individuals and that the target for regulatory activities is not individual smokers. There is no evidence to suggest that this change to product standards would increase any illicit activity and the public health benefits far exceed any costs.

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<sup>12</sup> Hatsukami DK, et al. Reduced nicotine content cigarettes: effects on toxicant exposure, dependence and cessation. *Addiction* 2010; 105: 343-55.

<sup>13</sup> Philip Morris, "Our Manifesto: Designing a Smoke-Free Future." <https://www.pmi.com/who-we-are/designing-a-smoke-free-future>. Accessed August 7, 2025

<sup>14</sup> 21 U.S.C. 387g(d)(2).

<sup>15</sup> 90 Fed. Reg. at 5074, citing Grubbs, H.J., R. Prasad, and T.M. Howell, inventors; Philip Morris USA Inc., assignee. Selective Basic Component Removal from Material Esp. Nicotine from Tobacco, by Solvent Followed by Selective Removal of Desired Component by Extn., Esp. With Acid Not Soluble in Solvent. U.S. Patent No. 5,018,540. U.S. 1991. Roselius, W., O. Vitzthum, and P. Hubert, inventors; Studiengesellschaft Kohle gGmbH, assignee. Process for the Extraction of Nicotine from Tobacco. U.S. Patent No. 4,153,063. U.S. 1979.

FDA must carefully regulate the marketing of nicotine products and precede with a nicotine reduction policy and public education campaign to ensure adequate communication to help deter people who do not already smoke, especially youth, from initiating.

It is important to note that the Administration's proposal to eliminate the Centers for Disease Control and Prevention's (CDC) Office of Smoking and Health coupled with cuts to public health funding, would constrain local prevention efforts, such as quit lines. Working directly with local and tribal public health is particularly essential because successful tobacco prevention and cessation programs require relationship building in communities and trusted messengers to ensure programs and interventions are relevant to those who are intended to benefit. The hyperlocal nature of prevention and cessation efforts requires distribution of resources based on need and potential reach. The rule, if finalized, will be most successful in protecting health and reducing unnecessary suffering and health care costs if coupled by a reinvestment in CDC's joint efforts with local and state health departments to stop youth initiation and provide avenues to help current smokers quit.

NACCHO urges FDA to promptly finalize a comprehensive rule to reduce the maximum nicotine level for tobacco products as soon as possible. If you have any questions or require additional information, please contact Adriane Casalotti, Chief of Government and Public Affairs, at [acasalotti@naccho.org](mailto:acasalotti@naccho.org).

Sincerely,



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