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

On behalf of the American College of Chest Physicians (CHEST), we would like to thank the Food and Drug Administration (FDA) for initiating Docket No. FDA–2024–N–5471, Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products. CHEST supports the prevention of tobacco addiction and advocates for the protection of communities and individuals from the detrimental impact of tobacco addiction. CHEST recognizes this rule as a necessary step in FDA regulatory policy toward achieving these goals. In addition, we offer evidence-based and clinically grounded recommendations that are crucial to ensuring the rule results in the intended progress toward the goal of protecting youth and reducing tobacco-related disease and death, as stated by the Center for Tobacco Products (CTP).

Representing more than 18,000 pulmonary, critical care, and sleep medicine professionals, CHEST has maintained a decades-long leadership role in advancing clinical and public health efforts to reduce tobacco-related harm. From the early identification of smoking as a cause of lung cancer in the 1960s to surgeon general warnings and banning of smoking on airplanes, CHEST has consistently supported national policy change and efforts to raise awareness to reduce tobacco-related disease. CHEST appreciates the opportunity to continue to offer FDA evidence-based data and relevant direct clinical perspectives to strengthen this proposed rule and advance tobacco-related policy.

CHEST acknowledges the importance of several elements in the current rule, which represent meaningful steps toward reducing the devastating burden of tobacco-related disease:

- The reduction of nicotine content in cigarettes, which is expected to reduce the addictive potential of these products and support higher cessation rates, thus increasing cessation and reducing relapse, and reducing smoking prevalence.[1,2]
- The evidence-based approach to immediate (non-gradual) reduction to the target nicotine level, which will result in greater decreases in nicotine dependence, higher rates of abstinence, and reduce the delay in the public health benefits of nicotine reduction.[3,4]

The projected public health and economic benefits of this rule, while emphasizing that robust implementation, enforcement, and expansion to additional products will be necessary to fully realize these gains.

CHEST recommends the following measures to strengthen the rule and its positive impact:

- Expand nicotine standards to apply to all heated tobacco products and addictive elements
- Emphasize and ensure flavored cigarettes, cigars, and vapes are not considered safe cessation tools.
    - Ensure these products are not marketed without FDA authorization, which often is targeted toward young people, putting them at risk for significant health harms
    - Support or research the impact of nicotine reduction in e-cigarettes and other nicotine products
- Immediate implementation of the finalized rule instead of the current two-year delay
- Provide public funding for the implementation and monitoring of surveillance and enforcement of the new standards to ensure success and achieve outcomes.
    - Obtain post-implementation surveillance data that is as close to "real-time" as possible and make data available for independent analysis
    - Recommend organizations be offered incentives for promoting cessation, such as receiving higher marks (e.g. CMS Five-Star Quality Rating System) and increased reimbursement

CHEST recommends the following actions for consideration in future rules:

- Close the synthetic nicotine loophole and take action to regulate these products[5]
- Ensure equitable access to tobacco cessation products
- Expand public funding for tobacco cessation services and provide education about existing services available to the public
- Develop and implement a strategic action plan to expand coverage of comprehensive tobacco treatment and promote utilization, maximizing the number of people who will quit smoking instead of switching to alternative, but still harmful, tobacco products
- Encourage innovation in tobacco cessation products by expanding patient-important end points beyond total abstinence[6]

CHEST has historically championed evidence-based tobacco control policies and views nicotine reduction as a necessary but incomplete evolution in FDA's regulatory framework, one that must be paired with broader product standards, enforcement, and cessation support. In alignment with CHEST's mission to advance lung health, we emphasize that lowering nicotine content is a critical step in helping individuals quit and avoiding addiction in vulnerable populations, including youth and those with limited access to cessation support. CHEST also urges the FDA to prioritize explicit commitments to comprehensive implementation and patient support strategies, including robust public education campaigns, which are imperative to mitigate potential unintended consequences and maximize successful patient outcomes. CHEST stands prepared to offer our support and expertise to aid the FDA with the implementation of this rule to improve respiratory health outcomes nationwide.

[1] WHO, *Global Nicotine Reduction Strategy*, 2015.

[2] Hatsukami, DK, et al., "Reduced nicotine content cigarettes: effects on toxicant exposure, dependence and cessation," *Addiction*, 105: 343-355, 2010

[3] Hatsukami, D. K., et al. Effect of immediate vs gradual reduction in nicotine content of cigarettes on biomarkers of smoke exposure: A randomized clinical trial. *Journal of the American Medical Association, 320* (9), 880, 2018.

[4] Donny, EC, et al., "Randomized trial of reduced-nicotine standards for cigarettes," *New England Journal of Medicine*, 373: 1340-1349, 2015.

[5] https://www.chestnet.org/newsroom/chest-news/2021/12/chest-signs-letter-to-fda-urging-swift-action-to-close-the-synthetic-nicotine-loophole

[6] Warraich HJ, King BA, Compton WM, Herrmann ES, Hai MT, Califf RM, Bertagnolli MM. Opportunities for Innovation in Smoking Cessation Therapies: A Perspective From the National Institutes of Health and U.S. Food and Drug Administration. Ann Intern Med. 2025 Jan;178(1):122-125. doi: 10.7326/ANNALS-24-02318. Epub 2024 Oct 15. PMID: 39401434.