



September 12, 2025

Dockets Management Staff (HFA-305)
Food and Drug Administration
Department of Human and Health Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Comment on Docket No. FDA-2024-N-5471, “Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products.”

To Whom It May Concern:

Trust for America’s Health (TFAH) is a non-profit, non-partisan public health policy, research, and advocacy organization that promotes optimal health for every person and community and makes the prevention of illness and injury a national priority. Our research, such as the *Promoting Health and Cost Control in States (PHACCS)* report, highlights that evidence-based policies that reduce smoking and tobacco consumption promote better health and reduce healthcare costs.¹ TFAH is grateful for the opportunity to comment on the U.S. Food and Drug Administration’s (FDA) proposed rule on “[Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products.](#)”

TFAH supports the FDA’s proposal to establish a maximum nicotine level of 0.7 mg/g in cigarettes and other combusted tobacco products to reduce their addictiveness. Our position is detailed below.

Very low-nicotine content cigarettes reduce nicotine dependence and increase smoking cessation

Research demonstrates that cigarettes with very low nicotine content decrease nicotine

¹ Promoting Health and Cost Control in States: How States Can Improve Community Health & Well-being Through Policy Change (Tobacco Pricing). July 2019. Trust for America’s Health (TFAH). <https://www.tfah.org/wp-content/uploads/2019/12/TFAH-2019-PHACCS-TobaccoPricing-FINAL.pdf>



dependence and increase attempts to quit smoking.^{2, 3, 4, 5} One randomized control trial found that compared to smokers of normal nicotine content, smokers of reduced nicotine content smoked fewer cigarettes, reduced their nicotine dependence, and experienced reduced cravings. Furthermore, smokers of reduced nicotine content were twice as likely to report attempts to quit smoking.⁶ In addition, research shows that an immediate reduction of nicotine content has greater health benefits than a gradual approach, including decreased exposure to carbon monoxide, lower nicotine dependence, and increased duration of smoking abstinence.^{7, 8, 9} Therefore, TFAH supports the FDA's proposal to implement an immediate nicotine reduction standard to maximize the policy's public health benefits for the 28 million adults and 380,000 youth in the U.S. who smoke cigarettes.¹⁰

A nicotine reduction rule can prevent youth from developing a lifelong nicotine addiction

A nicotine reduction standard is particularly crucial for protecting youth, as it can help prevent those who experiment with cigarettes from developing a lifelong addiction. One study found that youth are less sensitive to the addictive effects of cigarettes with very low nicotine content compared to those with higher nicotine content.¹¹

² Higgins, S. T., Sigmon, S. C., Tidey, J. W., Heil, S. H., Gaalema, D. E., Lee, D. C., DeSarno, M. J., Klemperer, E. M., Menson, K. E., Cioe, P. A., Plucinski, S., Wiley, R. C., & Orr, E. (2024). Reduced Nicotine Cigarettes and E-Cigarettes in High-Risk Populations: 3 Randomized Clinical Trials. *JAMA network open*, 7(9), e2431731. <https://doi.org/10.1001/jamanetworkopen.2024.31731>

³ Mercincavage M, Souprountchouk V, Tang KZ, et al. A randomized controlled trial of progressively reduced nicotine content cigarettes on smoking behaviors, biomarkers of exposure, and subjective ratings. *Cancer Epidemiol Biomarkers Prev*. 2016;25(7):1125–1133

⁴ Mercincavage M, Saddleson ML, Gup E, Halstead A, Mays D, Strasser AA. Reduced nicotine content cigarette advertising: how false beliefs and subjective ratings affect smoking behavior. *Drug Alcohol Depend*. 2017;173:99–106

⁵ Hatsukami DK, Hertsgaard LA, Vogel RI, et al. Reduced nicotine content cigarettes and nicotine patch. *Cancer Epidemiol Biomarkers Prev*. 2013;22(6):1015–1024

⁶ Donny EC, Hatsukami DK. Randomized Trial of Reduced-Nicotine Standards for Cigarettes. *N Engl J Med*. 2016 Jan 28;374(4):396–7. doi: 10.1056/NEJMc1513886. PMID: 26816022.

⁷ Hatsukami, DH, et al., “Effect of Immediate vs. Gradual Reduction in Nicotine Content of Cigarettes on Biomarkers of Smoke Exposure: A Randomized Clinical Trial,” *JAMA*, 320(9): 880-891, 2018.

⁸ Meier, E., Rubin, N., Dermody, S. S., Tessier, K. M., Hecht, S. S., Murphy, S., Jensen, J., Donny, E. C., al'Absi, M., Drobos, D., Koopmeiners, J., Denlinger-Apte, R., Tidey, J. W., Vandrey, R., Thorne, C., & Hatsukami, D. (2023). Immediate Switching to Reduced Nicotine Cigarettes in a U.S.-Based Sample: The Impact on Cannabis Use and Related Variables at 20 Weeks. *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco*, 25(5), 867–874. <https://doi.org/10.1093/ntr/ntz231>

⁹ Piper, M. E., Drobos, D. J., & Walker, N. (2019). Behavioral and Subjective Effects of Reducing Nicotine in Cigarettes: A Cessation Commentary. *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco*, 21(Suppl 1), S19–S21. <https://doi.org/10.1093/ntr/ntz100>

¹⁰ Jamal, A., E. Park-Lee, J. Birdsey, et al. “Tobacco Product Use among Middle and High School Students—National Youth Tobacco Survey, United States, 2024.” *MMWR Morbidity and Mortality Weekly Report*, 73(41):917–924, 2024. Available at [10.15585/mmwr.mm7341a2](https://doi.org/10.15585/mmwr.mm7341a2).

¹¹ Colby, S. M., Cassidy, R. N., Denlinger-Apte, R., Smith, T. T., Pacek, L. R., McClernon, F. J., & Tidey, J. W. (2019). Anticipated Effects of Nicotine Reduction on Youth Smoking Initiation and Maintenance. *Nicotine & tobacco research: official journal of the Society for Research on Nicotine and Tobacco*, 21(Suppl 1), S46–S48. <https://doi.org/10.1093/ntr/ntz101>

While combustible tobacco products are largely responsible for tobacco-related illness and death, we urge the FDA to consider research on expanding the scope of the product standard to electronic nicotine products, such as e-cigarettes. Vaping has emerged as the most popular form of nicotine use among youth, impacting 1 in 10 high school students as of 2023.¹² This can lead to acute cardiovascular events, increased exposure to carcinogens, respiratory disease, and impaired brain development from early nicotine use.^{13, 14, 15} Given that vaping poses significant health risks to youth whether or not they use other recreational tobacco products, reducing use in this population is a critical public health priority.¹⁶ Therefore, the FDA should prioritize research into nicotine reduction strategies tailored to e-cigarettes, accounting for their distinct use patterns and diverse device characteristics.¹⁷

A nicotine reduction rule can reduce tobacco-related health disparities

People with lower socioeconomic status, people with co-occurring psychiatric or substance use disorders,^{18 19} and certain populations of color are disproportionately impacted by tobacco use or exposure.²⁰ Research shows that low-income neighborhoods have a higher concentration of tobacco retailers and are disproportionately located near schools.²¹ Tobacco-related morbidity and mortality disproportionately impact Black and American Indian/Alaska Native (AI/AN)

¹² Birdsey J, Cornelius M, Jamal A, et al. Tobacco product use among U.S. middle and high school students—National Youth Tobacco Survey, 2023. *MMWR Morb Mortal Wkly Rep.* 2023;72(44):1173–1182. doi:10.15585/mmwr.mm7244a1

¹³ National Center for Chronic Disease Prevention and Health Promotion, (US) Office on Smoking and Health. E-cigarette use among youth and young adults: a report of the surgeon general. Centers for Disease Control and Prevention. 2016. https://archive.cdc.gov/www_cdc_gov/tobacco/sgr/e-cigarettes/index.htm

¹⁴ Rose, J. J., Krishnan-Sarin, S., Exil, V. J., Hamburg, N. M., Fetterman, J. L., Ichinose, F., Perez-Pinzon, M. A., Rezk-Hanna, M., Williamson, E., & American Heart Association Council on Cardiopulmonary, Critical Care, Perioperative and Resuscitation; Council on Epidemiology and Prevention; Council on Cardiovascular Radiology and Intervention; Council on Lifestyle and Cardiometabolic Health; Council on Peripheral Vascular Disease; Stroke Council; and Council on Arteriosclerosis, Thrombosis and Vascular Biology (2023). Cardiopulmonary Impact of Electronic Cigarettes and Vaping Products: A Scientific Statement From the American Heart Association. *Circulation*, 148(8), 703–728. <https://doi.org/10.1161/CIR.0000000000001160>

¹⁵ Hamberger, E. S., & Halpern-Felsher, B. (2020). Vaping in adolescents: epidemiology and respiratory harm. *Current opinion in pediatrics*, 32(3), 378–383. <https://doi.org/10.1097/MOP.0000000000000896>

¹⁶ Winickoff, J. P., Evins, A. E., & Levy, S. (2024). Vaping in Youth. *JAMA*, 332(9), 749–750. <https://doi.org/10.1001/jama.2024.13403>

¹⁷ Vander Weg MW. Lowering Nicotine Levels to Reduce Dependence on E-Cigarettes—Promising yet Complicated. *JAMA Netw Open.* 2024;7(7):e2423336. doi:10.1001/jamanetworkopen.2024.23336

¹⁸ Loretan CG, Wang TW, Watson CV, Jamal A. “Disparities in Current Cigarette Smoking Among US Adults With Mental Health Conditions.” *Preventing Chronic Disease* 2022;19:220184. Available at <http://dx.doi.org/10.5888/pcd19.220184>.

¹⁹ NIDA. 2023, February 24. “Do people with mental illness and substance use disorders use tobacco more often?” Available from: <https://nida.nih.gov/publications/research-reports/tobacco-nicotine-e-cigarettes/do-people-mental-illness-substance-use-disorders-use-tobacco-more-often>.

²⁰ Promoting Health and Cost Control in States: How States Can Improve Community Health & Well-being Through Policy Change (Tobacco Pricing). July 2019. Trust for America’s Health (TFAH). <https://www.tfah.org/wp-content/uploads/2019/12/TFAH-2019-PHACCS-TobaccoPricing-FINAL.pdf>

²¹ D’Angelo H, Ammerman A, Gordon-Larsen P, et al. “Sociodemographic Disparities in Proximity of Schools to Tobacco Outlets and Fast-Food Restaurants.” *American Journal of Public Health*, 106(9): 1556–1562, September 2016. <https://www.ncbi.nlm.nih.gov/pubmed/27459453>

populations, who experience higher rates of lung and bronchus cancer, head and neck cancers, hypertension, heart disease, and stroke.^{22,23,24}

A 2024 U.S. Surgeon General’s report found that reducing nicotine in cigarettes and other combustible tobacco products to minimally addictive levels can reduce tobacco use among populations experiencing tobacco-related disparities.^{25, 26} Furthermore, one study found that cigarettes with very low nicotine content can reduce smoking rates for people with mental health conditions and concurrent substance use disorders.²⁷ Therefore, TFAH supports the establishment of a maximum nicotine level to mitigate disparities in tobacco-related illness and death.

There is concern that a nicotine reduction standard could disproportionately drive individuals to the black market to purchase high-nicotine content products. However, an experimental study investigating the regulatory effects of a reduced-nicotine policy on behavior found that nicotine content levels are *not* a driver of purchasing tobacco products. Researchers found that cigarette purchases were highest when other combustible tobacco products were unavailable, and lowest when alternative products were available.²⁸ Therefore, TFAH supports the FDA’s proposal to apply the maximum nicotine limit to multiple combustible tobacco products, including cigarette tobacco, roll-your-own (RYO) tobacco, cigars, and pipe tobacco, to prevent the availability of combustible, high-nicotine content products from undermining the policy’s public health impacts.

²² Schabath, M.B., W.D. Cress, and T. Muñoz-Antonia. “Racial and Ethnic Differences in the Epidemiology and Genomics of Lung Cancer.” *Cancer Control*, 23(4):338-346, 2016. Available at [10.1177/107327481602300405](https://doi.org/10.1177/107327481602300405).

²³ Siegel, R.L., K.D. Miller, H.E. Fuchs, et al. “Cancer Statistics, 2022.” *CA: A Cancer Journal for Clinicians*, 72(1):7-33, 2022. Available at [10.3322/caac.21708](https://doi.org/10.3322/caac.21708).

²⁴ Odani, S., B.S. Armour, C.M. Graffunder, et al. “Prevalence and Disparities in Tobacco Product Use among American Indians/Alaska Natives—United States, 2010-2015.” *MMWR Morbidity and Mortality Weekly Report*, 66(50):1374-1378, 2017. Available at [10.15585/mmwr.mm6650a2](https://doi.org/10.15585/mmwr.mm6650a2).

²⁵ HHS, Eliminating Tobacco-Related Disease and Death: Addressing Disparities—A Report of the Surgeon General, 2024, at 716. <https://www.hhs.gov/sites/default/files/2024-sgr-tobacco-related-health-disparities-full-report.pdf>

²⁶ Krebs, N. M., Allen, S. I., Veldheer, S., Martinez, D. J., Horn, K., Livelsberger, C., Modesto, J., Kuprewicz, R., Wilhelm, A., Hrabovsky, S., Kazi, A., Fazzi, A., Liao, J., Zhu, J., Wasserman, E., Reilly, S. M., Reinhart, L., Trushin, N., Moyer, R. E., Bascom, R., ... Muscat, J. E. (2017). Reduced nicotine content cigarettes in smokers of low socioeconomic status: study protocol for a randomized control trial. *Trials*, 18(1), 300. <https://doi.org/10.1186/s13063-017-2038-9>

²⁷ Donny EC, White CM. A review of the evidence on cigarettes with reduced addictiveness potential, *Int J Drug Policy*. 2022;99:103436. Foulds J, et al. The effects of reduced nicotine content cigarettes on biomarkers of nicotine and toxicant exposure, smoking behavior and psychiatric symptoms in smokers with mood or anxiety disorders: a double-blind randomized trial. *PLoS One*. 2022;17

²⁸ Kaplan, B. A., Koffarnus, M. N., Franck, C. T., & Bickel, W. K. (2021). Effects of Reduced-Nicotine Cigarettes Across Regulatory Environments in the Experimental Tobacco Marketplace: A Randomized Trial. *Nicotine & tobacco research: official journal of the Society for Research on Nicotine and Tobacco*, 23(7), 1123–1132. <https://doi.org/10.1093/ntr/ntaa226>

Conclusion

TFAH appreciates the opportunity to provide feedback on the FDA's proposed rule on nicotine yield standards for cigarettes and other tobacco products. We support the establishment of a maximum nicotine level policy, recognizing its potential to reduce nicotine dependence, promote smoking cessation, and address health disparities, particularly in communities of color and among individuals of low socioeconomic status. We encourage the FDA to prioritize this initiative as a critical step toward preventing youth addiction and improving public health outcomes.

TFAH remains committed to advancing evidence-based policies that promote health equity and reduce tobacco-related illnesses. We look forward to further engagement on this important issue. For additional questions or information, please contact Dara Lieberman, TFAH's Director of Government Relations, at dlieberman@tfah.org. Thank you for considering our comments.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Nadine Gracia". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

J. Nadine Gracia, MD, MSCE
President and CEO
Trust for America's Health