August 25, 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 undersigned organizations submit these comments in the above-designated docket regarding the Proposed Rulemaking on a Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products.

Introduction

For decades, researchers have agreed that nicotine is the fundamental addictive agent in tobacco, leading the U.S. Surgeon General to affirmatively conclude in the 1988 report, *The Health Consequences of Smoking: Nicotine Addiction,* that, "nicotine is the drug in tobacco that causes addiction."[1] Now, strong scientific evidence also demonstrates that reducing the nicotine content to a very low level can reduce smoking and nicotine addiction. Reducing nicotine levels in combustible tobacco products provides enormous potential to accelerate progress in preventing and reducing smoking and the death and disease it causes. We urge you to finalize a comprehensive rule that will have the intended public health impact as quickly as possible.

Section 907 of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or TCA) authorizes the Food and Drug Administration (FDA) to adopt product standards if shown to be appropriate for the protection of the public health.[2] In making this determination, FDA must consider the risks and benefits to the population as a whole, including

[1] U.S. Department of Health and Human Services (HHS). *The Health Consequences of Smoking: Nicotine Addiction. A Report of the Surgeon General*. 1988.
[2] 21 U.S.C. §387g(a)(3)(A).

the increased or decreased likelihood that existing users of tobacco products will stop using such products, and the increased or decreased likelihood that those who do not use tobacco products will start using such products.[3] As detailed in these comments, FDA's proposed rule to reduce the nicotine in cigarettes and certain other combustible tobacco products without question meets this statutory standard.

As noted in the proposed rule (at 5041), the FDA is proposing this standard to: "(1) reduce the risk of progression to regular use and nicotine dependence for those who experiment with such tobacco products, especially youth and (2) make it easier for people who are addicted to cigarettes and certain other combusted tobacco products and who are interested in quitting to quit by reducing the nicotine in these products to minimally addictive or nonaddictive levels." Making cigarettes and other combusted tobacco products minimally or non-addictive will prevent most young people from ever engaging in regular smoking behavior and will increase the number of people who smoke who make a quit attempt and successfully quit. As detailed in the Proposed Rule (5077—5086), the FDA estimates that this proposal would prevent more than 48 million youth and young adults from initiating smoking by 2100, prompt 12.9 million people who smoke to quit within one year (rising to 19.5 million in five years) and save 4.3 million lives by the end of the century. The impact of this policy would be historic. There are few actions FDA could take that would be as impactful when it comes to protecting kids, reducing chronic disease and saving lives. Indeed, the overwhelming majority of Americans support this proposal. A 2023 survey found that 80% of adults support reducing nicotine levels in cigarettes and cigars, including about 70% of adults who smoke and about 80% of adults who have tried to quit smoking in the last year.[4]

There is, and will continue to be, a need for FDA to exercise its full authority to reduce the use of all tobacco products and pursue public education campaigns directed at informing the public of the adverse health risks of all tobacco products, including those subject to the nicotine reduction proposal. Such a comprehensive regulatory approach is critical because reducing nicotine in combustible products to minimally or non-addictive levels will not make those products "safe,"[5] and the public, particularly young people, need to understand that any use of these products will continue to carry substantial health risks.

I. Public Health Impact of Reducing Nicotine in Combustible Tobacco Products

Despite great progress in curbing smoking prevalence over the past several decades, approximately one in ten adults still smoke cigarettes and every day more than 1,300 kids try

---

[3] 21 U.S.C. §387g(a)(3)(B)(i).

[4] Mahoney, M. et al., "Support among adults for a policy to lower nicotine levels in cigarettes and cigars–USA, 2023." *Tobacco Control,* 2025.

[5] Thus, it will remain important for FDA to implement the statutory mandate for large, graphic health warning for cigarettes. *See* 15 U.S.C. §1333(a); *Tobacco Products; Required Warnings for Cigarette Packages and Advertisements,* 85 Fed. Reg. 15,638 (March 18, 2020) (to be codified at 21 C.F.R. pt. 1141).

their first cigarette.[6] 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.[7] Smoking is also a primary driver of chronic disease—for every person who dies from smoking, at least 30 people are living with a serious illness caused by smoking, including cancer, heart disease, stroke, COPD, and diabetes.[8] Smoking causes 30% of all cancer deaths in the United States (including 80% of all lung cancer deaths), at least 25% of all deaths from cardiovascular disease, and 80% of all deaths from COPD.[9] Approximately half of people who continue to smoke will die prematurely as a result of their addiction, losing at least a decade of life on average compared to people who do not smoke.[10]

Smoking exacts an enormous economic toll on our country. Each year, smoking-caused health care costs amount to $241.4 billion, with a $72.7 billion burden on the Medicaid program.[11] On top of that, work productivity losses due to smoking-caused illness and premature death costs an additional $364.8 billion per year.[12]

Reducing the nicotine content in cigarettes to minimally or non-addictive levels will prevent young people who experiment with smoking from becoming addicted. Reducing the level of nicotine dependence in adults who smoke, to enable them to quit, will benefit children who bear the consequences of second- and third-hand smoke exposure.[13] Ultimately, the

---

[6] National Center for Health Statistics (NCHS). Percentage of current cigarette smoking for adults aged 18 and over, United States, 2023. National Health Interview Survey. Generated interactively from https://wwwn.cdc.gov/NHISDataQueryTool/SHS_adult/index. Substance Abuse and Mental Health Services Administration (SAMHSA), HHS, *Results from the 2023 National Survey on Drug Use and Health, NSDUH: Detailed Tables,* 2024. https://www.samhsa.gov/data/report/2023-nsduh-detailed-tables.

[7] HHS, *Eliminating Tobacco-Related Disease and Death: Addressing Disparities, A Report of the Surgeon General*, 2024.

[8] *Id.*

[9] 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. https://www.cancer.org/research/cancer-facts-statistics/allcancer-facts-figures/2024-cancer-facts-figures.html. CDC, Health Effects of Cigarettes: Cardiovascular Disease,2025, https://www.cdc.gov/tobacco/about/cigarettesand-cardiovascular-disease.html, Accessed April 10, 2025. HHS, *The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General*, 2014.

[10] HHS, *The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General*, 2014.

[11] Shrestha, S. S., Ghimire, R., Wang, X., Trivers, K. F., Homa, D. M., & Armour, B. S. (2022). Cost of Cigarette Smoking–Attributable Productivity Losses, U.S., 2018. *American journal of preventive medicine*, *63*(4), 478–485. https://doi.org/10.1016/j.amepre.2022.04.032. Xu, X., Shrestha, S. S., Trivers, K. F., Neff, L., Armour, B. S., & King, B. A. (2021). U.S. healthcare spending attributable to cigarette smoking in 2014. *Preventive medicine*, *150*, 106529. https://doi.org/10.1016/j.ypmed.2021.106529.

[12] Shrestha, S. S., Ghimire, R., Wang, X., Trivers, K. F., Homa, D. M., & Armour, B. S. (2022). Cost of Cigarette Smoking–Attributable Productivity Losses, U.S., 2018. *American journal of preventive medicine*, *63*(4), 478–485. https://doi.org/10.1016/j.amepre.2022.04.032. HHS, *The Health Consequences of Smoking – 50 Years of Progress A Report of the Surgeon General,* 2014.

[13] It should be noted, however, that with the continued availability of high nicotine content e-cigarettes, the most commonly used tobacco product among youth, young people will still remain at risk for the consequences of nicotine use, including direct effects on the brain and addiction. The long-term effects of these products remain unknown.

proposed rule will dramatically reduce the number of adults who smoke, reducing tobacco-related disease, disability and death. In the proposed rule (5077—5086), the FDA estimates that reducing nicotine levels in combusted tobacco products would prevent more than 48 million youth and young adults from initiating smoking by 2100. In addition, within five years, the FDA estimates it would cause 19.5 million people to quit smoking, including 12.9 million within just the first year of implementation. Ultimately, more than 4 million lives would be saved by the end of the century, an extraordinary public health achievement.

These declines in smoking would also significantly reduce smoking-caused health care costs over the long- and short-term. In particular, the FDA determined in the proposed rule (5037) that the benefits far outweigh the costs from this rule. Over a 40-year period, the estimated annualized benefits would amount to $1.1 trillion compared to estimated annualized costs of $2.07 billion. Because of the mechanisms of smoking though, some savings would accrue even in the short-term, since quitting smoking has some rapid benefits to the body and reduces the risk of variety of health outcomes. For instance, within just the first year or two of quitting smoking, the risk of coronary heart disease, including having a heart attack, declines dramatically,[14] which, in turn, reduces the associated health care costs.

A. Reducing the Nicotine Content of Cigarettes and Other Combustibles Will Reduce Dependence and Help People Quit Smoking

As stated by a Philip Morris researcher in 1972, "***No one has ever become a cigarette smoker by smoking cigarettes without nicotine.***"[15] Nicotine is the primary addictive agent in cigarettes and other tobacco products.[16] According to the U.S. Surgeon General, "the addiction caused by the nicotine in tobacco smoke is critical in the transition of smokers from experimentation to sustained smoking and, subsequently, in the maintenance of smoking for the majority of smokers who want to quit."[17] Most adults who smoke want to quit (nearly 70 percent) and wish they had never started (about 90 percent), but overcoming an addiction to nicotine is difficult and people who smoke often need to make multiple quit attempts before succeeding.[18]

---

[14] HHS, *Smoking Cessation: A Report of the Surgeon General,* 2020.

[15] Philip Morris, Dunn,W Jr., "Motives And Incentives In Cigarette Smoking"; R107. 1972. https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/jspf0085. For additional industry quotes on nicotine, see Campaign for Tobacco-Free Kids fact sheet, "Tobacco Company Quotes: Nicotine as a Drug," https://www.tobaccofreekids.org/research/factsheets/pdf/0009.pdf.

[16] HHS, *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General,* 2010.

[17] HHS, *The Health Consequences of Smoking—50 Years of Progress, A Report of the Surgeon General,* 2014. See also, HHS, *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General,* 2010, http://www.ncbi.nlm.nih.gov/books/NBK53017/.

[18] VanFrank, B., et al., "Adult Smoking Cessation — United States, 2022," *MMWR* 73(29):633-641, 2024. Fong, G., et al., "The Near-Universal Experience of Regret Among Smokers in Four Countries: Findings from the International Tobacco Control Policy Evaluation Survey," *Nicotine & Tobacco Research*, Vol. 6, Supplement 3, December 2004.

As FDA notes in the Proposed Rule (at 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." Research demonstrates that significantly reducing nicotine levels holds great promise for accelerating progress in reducing smoking. Based on a comprehensive review of the evidence, the World Health Organization Study Group on Tobacco Product Regulation concluded that reducing nicotine content in cigarettes could:[19]

- Reduce smoking acquisition and progression to addiction;
- Increase cessation and reduce relapse; and, ultimately,
- Reduce smoking prevalence.

The first large scale clinical trial of very low nicotine content (VLNC) cigarettes in the U.S., conducted in 2013-2014, randomly assigned over 800 people who smoke to use their usual brand of cigarettes or cigarettes with varying levels of nicotine for six weeks. Participants assigned to smoke cigarettes with lower nicotine content smoked fewer cigarettes, reduced their exposure to and dependence on nicotine, and reduced cravings, compared to the control group. The same study also found that those smoking cigarettes with the lowest nicotine content (0.4 mg/g) were twice as likely to report trying to quit in the 30 days after the study ended compared to those smoking cigarettes with normal nicotine content (34% vs. 17%). Participants assigned to smoke cigarettes with 2.4 mg/g nicotine or less smoked between 23 and 30 percent fewer cigarettes per day at six-week follow-up compared to participants assigned to smoke cigarettes with 15.8 mg/g nicotine. [20] The largest clinical trial to date enrolled 1,250 participants randomized to receive normal nicotine content cigarettes, cigarettes with 0.4 mg/g nicotine cigarette, or cigarettes with gradually reduced nicotine levels over a 20-week period. Those assigned to 0.4 mg/g nicotine cigarettes in the immediate reduction condition had a significant reduction in biomarkers of smoke exposure, smoked significantly fewer cigarettes per day, and had significantly lower dependence scores.[21] Other smaller studies have shown that use of reduced nicotine cigarettes leads to reductions in smoking, nicotine dependence, and biomarkers of exposure to nicotine and other toxins.[22] While most clinical trials with VLNC cigarettes have

---

19 WHO, *Global Nicotine Reduction Strategy*, 2015.

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

21 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.

22 See e.g., Donny EC, et al. Smoking in the absence of nicotine: behavioral, subjective and physiological effects over 11 days. *Addiction* 2007; 102: 324-34. Benowitz NL, et al., Nicotine and carcinogen exposure with smoking of progressively reduced nicotine content cigarette. *Cancer Epidemiol Biomarkers Prev* 2007; 16: 2479-85. Benowitz NL, et al., Urine nicotine metabolite concentrations in relation to plasma cotinine during low-level nicotine exposure. *Nicotine & Tobacco Research* 2009; 11: 954-60. Benowitz NL, et al. Smoking behavior and exposure to tobacco toxicants during 6 months of smoking progressively reduced nicotine content cigarettes. *Cancer*

enrolled adults who are not interested in quitting, research also shows that reduced nicotine cigarettes increase abstinence among those who are trying to quit, suggesting that VLNC cigarettes can help people who smoke who are making a quit attempt.[23]

B. Reducing the Nicotine Content of Cigarettes and Other Combustibles Will Prevent Youth from Becoming Addicted

In the proposed rule (at 5047), the FDA described the powerful addictiveness of nicotine, particularly on the adolescent brain. Tobacco use almost always begins during adolescence and adolescents are particularly vulnerable to the addictive effects of nicotine because the brain continues to develop until about age 25.[24] Because adolescence and young adulthood are critical periods of growth and development, exposure to nicotine may have lasting, adverse consequences on brain development.[25] The parts of the brain most responsible for decision making, impulse control, sensation seeking, and susceptibility to peer pressure continue to develop and change through young adulthood.[26] As a result, nicotine exposure during adolescence may result in impaired attention and memory, problems with learning, reduced self-control and anxiety.[27] Nicotine not only harms the adolescent brain, but is critical to the progression to regular smoking behavior, reinforcing a behavior that exposes people who smoke to the harmful chemicals responsible for tobacco-related death and disease. As FDA notes in the Proposed Rule (at 5098—5099), the proposed standard will, "…decrease the likelihood that people who do not smoke cigarettes and/or use certain other combusted tobacco products—particularly youth and young adults—who experiment with combusted tobacco products will become addicted to these products, thereby decreasing progression to regular use, resulting in

---

Epidemiol Biomarkers Prev 2012; 21: 761-9. Hatsukami DK, et al. Reduced nicotine content cigarettes: effects on toxicant exposure, dependence and cessation. *Addiction* 2010; 105: 343-55.

[23] See e.g., Walker, N, et al., "The combined effect of very low nicotine content cigarettes, used as an adjunct to usual Quitine care (nicotine replacement therapy and behavioural support), on smoking cessation: a randomized controlled trial," *Addiction*, 107(10): 1857-1867, 2012. McRobbie, H, et al., "Complementing the standard multicomponent treatment for smokers with denicotinized cigarettes: a randomized controlled trial," *Nicotine & Tobacco Research*, 18(5): 1134-1141, 2016. Becker, K., et al., . A randomized trial of nicotine replacement therapy in combination with reduced-nicotine cigarettes for smoking cessation. *Nicotine & Tobacco Research, 10* (7), 1139–1148, 2008. Hatsukami, D. K., et al., "Nicotine reduction revisited: Science and future directions." *Tobacco Control, 19* (5), 2010.

[24] HHS, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*. 2012. HHS, *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General*, 2016.

[25] HHS. *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General* , 2014; Institute of Medicine, *Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products*, Washington, DC: The National Academies Press, 2015.

[26] Institute of Medicine, *Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products*, Washington, DC: The National Academies Press, 2015.

[27] England, LJ, et al., "Nicotine and the Developing Human: A Neglected Element in the Electronic Cigarette Debate." *American Journal of Preventive Medicine*, 2015; Goriounova NA, Mansvelder HD, "Short-and Long-Term Consequences of Nicotine Exposure During Adolescence for Prefrontal Cortex Neuronal Network Function," *Cold Spring Harbor Perspectives in Medicine*, 2012; Steinberg, Laurence, "Should the Science of Adolescent Brain Development Inform Public Policy?," Issues in Science and Technology, Volume XXVIII, Issue 3, Spring 2012.

reduced tobacco-related morbidity and mortality associated with combusted tobacco product use."

Ethically, it is not possible to conduct studies on non-smoking youth, but research suggests that VLNC cigarettes may have even lower abuse liability for adolescents than adults.[28] In the absence of data among non-smoking youth, preclinical research and trials among youth and young adults who already smoke provides the best evidence of the potential impacts of the proposed rule on non-smoking youth. Preclinical research demonstrates that adolescent rats self-administer nicotine less than adult rats at low doses.[29] Studies with adolescents who smoke find that VLNC cigarettes reduce cravings and cigarette consumption, without evidence of compensation.[30] A secondary analysis of data from the randomized controlled trial described earlier (Donny et al., 2015), found that young adults smoked fewer VLNC cigarettes per day than older adults after two weeks in the trial, suggesting that younger populations may be more sensitive and responsive to a nicotine reduction policy.[31] While there is no known safe level of exposure to nicotine for youth, together, these findings demonstrate that the proposed maximum nicotine level would reduce abuse liability among youth as much, if not more, than it would among adults.

C. A Nicotine Reduction Rule Can Reduce Tobacco-Related Health Disparities

Reducing the nicotine content of combustible tobacco products is a critical component of a comprehensive plan to address tobacco-related health disparities. According to the Surgeon General, "Reducing nicotine in cigarettes and other combustible tobacco products to minimally addictive or nonaddictive levels should reduce tobacco use among many population groups experiencing tobacco-related disparities."[32]

As smoking rates have declined nationally, smoking remains higher among certain populations, especially those with mental health and substance use disorders. According to data from the 2023 National Survey on Drug Use and Health (NSDUH), 26.2% of adults (age 26+)

---

[28] Colby, SMM., et al. "Anticipated effects of nicotine reduction on youth smoking initiation and maintenance." Nicotine and Tobacco Research 21.Supplement_1 (2019): S46-S48. Schassburger RL, et al. Adolescent rats self-administer less nicotine than adults at low doses. *Nicotine Tob Res.* 2016;18(9):1861–1868. Shram MJ, Li Z, Lê AD. Age differences in the spontaneous acquisition of nicotine self-administration in male Wistar and Long-Evans rats. *Psychopharmacology (Berl).* 2008;197(1):45–58.

[29] Schassburger, RL, et al., "Adolescent rates self-administer less nicotine than adults at low doses," *Nicotine & Tobacco Research*, 15: 1003-1013, 2016. Smith, TT, et al., "Animal research on nicotine reduction: current evidence and research gaps," *Nicotine & Tobacco Research*, published online April 4, 2017.

[30] Cassidy RN, et al. Adolescent smokers' response to reducing the nicotine content of cigarettes: Acute effects on withdrawal symptoms and subjective evaluations. *Drug Alcohol Depend.* 2018;188:153–160. Cassidy, R.N., et al. "The impact of reducing nicotine content on adolescent cigarette smoking and nicotine exposure: results from a randomized controlled trial." *Nicotine and Tobacco Research* 25.5 (2023): 918-927.

[31] Cassidy, RN, et al., "Age moderates smokers' subjective response to very low nicotine content cigarettes: evidence from a randomized controlled trial," *Nicotine & Tobacco Research*, published online April 28, 2018.

[32] HHS, *Eliminating Tobacco-Related Disease and Death: Addressing Disparities, A Report of the Surgeon General*, 2024.

with any mental illness currently (past month) smoke, compared to 16.4% of adults with no mental illness.[33] According to the 2019 NSDUH survey, more than one-third (35.8%) of adults with a substance use disorder (alcohol, cannabis, cocaine, or heroin use disorder) reported current (past-month) smoking in 2019.[34] Research shows that these populations are likely to benefit from the proposed nicotine standard. A 2022 review of the evidence on the impact of a nicotine reduction standard on disparately impacted populations concluded that, "a reduced-nicotine standard has the potential to reduce smoking and tobacco toxicant exposure in people with mental health conditions, with minimal mood disruption."[35] Specifically, multiple trials enrolling participants with mental health conditions, including depression, schizophrenia, schizoaffective disorder, and bipolar disorder, have shown reductions in smoking and toxicant exposure among participants assigned to use VLNC cigarettes, with no significant evidence of worsening psychiatric symptoms.[36] Additionally, VLNC trials enrolling those with established substance use have not found increases in alcohol, marijuana or opioid consumption.[37] In fact,

---

[33] SAMHSA, HHS, *Results from the 2023 National Survey on Drug Use and Health, NSDUH: Detailed Tables,* 2024. https://www.samhsa.gov/data/report/2023-nsduh-detailed-tables.

[34] Han B., et al. "Trends in Prevalence of Cigarette Smoking Among US Adults With Major Depression or Substance Use Disorders," 2006-2019. *JAMA.* 2022;327(16):1566–1576.

[35] Tidey, J. W., et al., "Effects of very low nicotine content cigarettes on smoking across vulnerable populations. *Preventive medicine*, *165*, 107099, 2022.

[36] See e.g., 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 (11):e0275522. Tidey, JW, et al., "Effects of 6-week use of reduced-nicotine content cigarettes in smokers with and without elevated depressive symptoms," *Nicotine & Tobacco Research*, 19(1): 59-67, 2017. Tidey, JW, et al., "Smoking topography characteristics of very low nicotine content cigarettes, with and without nicotine replacement, in smokers with schizophrenia and controls," *Nicotine & Tobacco Research*, 18(9): 1807-1812, 2016. Tidey, JW, et al., "Separate and combined effects of very low nicotine cigarettes and nicotine replacement in smokers with schizophrenia and controls," *Nicotine & Tobacco Research*, 15(1): 121-129, 2013. Higgins, ST, et al., "Addiction potential of cigarettes with reduced nicotine in populations with psychiatric disorders and other vulnerabilities to tobacco addiction," *JAMA Psychiatry*, 74(1): 1056-1064, 2017. Higgins, S. T., et al. Changes in cigarette consumption with reduced nicotine content cigarettes among smokers with psychiatric conditions or socioeconomic disadvantage: 3 Randomized clinical trials. *JAMA Network Open, 3* (10), e2019311, 2020. Denlinger- Apte RL, Donny EC, Lindgren BR, et al. Smoking topography characteristics during a 6- week trial of very low nicotine content cigarettes in smokers with serious mental illness. *Nicotine & Tobacco Research* 2020;22:1414–8

[37] Dermody, S.S., et al.. The impact of smoking very low nicotine content cigarettes on alcohol use. *Alcoholism: Clinical and Experimental Research, 40* (3), 606–615, 2016. Dermody, S.S., et al., "An evaluation of potential unintended consequences of a nicotine product standard: A focus on drinking history and outcomes." *Nicotine & Tobacco Research*, 23 (7), 1168–1175, 2020. Pacek, L. R., et al., "Evaluation of a reduced nicotine product standard: Moderating effects of and impact on cannabis use." *Drug and Alcohol Dependence, 167*, 228–232, 2016. Higgins, ST, et al., "Addiction potential of cigarettes with reduced nicotine in populations with psychiatric disorders and other vulnerabilities to tobacco addiction," *JAMA Psychiatry*, 74(1): 1056-1064, 2017. Higgins, S. T., et al. Changes in cigarette consumption with reduced nicotine content cigarettes among smokers with psychiatric conditions or socioeconomic disadvantage: 3 Randomized clinical trials. *JAMA Network Open, 3* (10), e2019311, 2020. Streck, J. M., et al.,. "Investigating tobacco withdrawal in response to reduced nicotine cigarettes among smokers with opioid use disorder and other vulnerabilities." *Experimental and Clinical Psychopharmacology, 28* (6), 714–723, 202.

one study found a reduction in binge drinking among participants assigned to use VLNC cigarettes for 20 weeks.[38]

Research has also demonstrated reduced addiction potential for VLNC cigarettes in other populations with high smoking rates, including socioeconomically disadvantaged populations. According to the 2023 NHIS, the smoking rate among adults with the lowest reported income is nearly twice the overall adult smoking rate of (19.4% vs. 10.8%).[39] Trials that have included participants with low socioeconomic status have found that these participants show reduced smoking and biomarkers of smoke exposure.[40]

II. A Nicotine Content Standard Should Apply to All Combustible and Heated Tobacco Products

To realize maximal potential public health benefits of a nicotine product standard, we support FDA's proposal to apply the standard to certain combustible tobacco products, including cigars, but we urge 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 abuse liability as cigarettes and are often flavored and popular among youth, will prevent youth experimenters from becoming addicted to these and other tobacco products. Furthermore, it will limit the possibility that people who smoke cigarettes will switch to other harmful products to fulfill their addiction. It will also prevent tobacco manufacturers from circumventing a nicotine content standard in cigarettes by marketing and developing non-cigarette substitutes like the small, flavored cigars the industry introduced after flavored cigarettes were removed from the market.

A. The Tobacco Industry Manipulates Loopholes in Product Regulation

History shows that the tobacco industry is adept at manipulating loopholes in tobacco control regulations to their advantage. Time and time again, tobacco companies have skillfully modified their products to circumvent regulation and minimize the effectiveness of policies designed to reduce tobacco use:

---

[38] Dermody, S.S., et al., "An evaluation of potential unintended consequences of a nicotine product standard: A focus on drinking history and outcomes." *Nicotine & Tobacco Research,* 23 (7), 1168–1175, 2020.

[39] National Center for Health Statistics (NCHS). Percentage of current cigarette smoking for adults over the aged 18 and over, 2023. National Health Interview Survey. Generated interactively from https://wwwn.cdc.gov/NHISDataQueryTool/SHS_adult/index.html.

[40] Higgins, ST, et al., "Addiction potential of cigarettes with reduced nicotine in populations with psychiatric disorders and other vulnerabilities to tobacco addiction," *JAMA Psychiatry*, 74(1): 1056-1064, 2017. Tidey JW, et al. Reducing the nicotine content of cigarettes: effects in smokers with mental health conditions and socioeconomic disadvantages. *Nicotine & Tobacco Research* 2019;21:S26–8. Higgins, S. T., et al. (2020). Changes in cigarette consumption with reduced nicotine content cigarettes among smokers with psychiatric conditions or socioeconomic disadvantage: 3 Randomized clinical trials. *JAMA Network Open, 3* (10), Article e2019311.

- In the 1960s and 1970s, companies developed "little cigars" that look like cigarettes to avoid federal cigarette regulations and taxes.[41]
- Manufacturers modified their products to be classified as cigars rather than cigarettes to evade the TCA's prohibition of characterizing flavors in cigarettes[42] and the use of misleading cigarette descriptors such as "light" and "low."[43]
- Tobacco companies have also added weight to filters to allow for reclassification of their cigarettes or "little cigars" as "large cigars" subject to lower federal excise taxes.[44]
- Tobacco companies intentionally designed and marketed little cigars as similar products to cigarettes to appeal to people who smoke cigarettes.[45]

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. …Historically, when products have been taxed or regulated differently, substitutions have occurred."[46]

There is little doubt 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 and limits the industry's ability to circumvent this regulation.

---

41 Delnevo, CD & Hrywna, M, "A Whole 'Nother Smoke' or a Cigarette in Disguise: How RJ Reynolds Reframed the Image of Little Cigars," *American Journal of Public Health* 97(8):1368-75, August 2007.

42 Delnevo, CD, et al., "Close, but no cigar: certain cigars are pseudo-cigarettes designed to evade regulation," *Tobacco Control* 26(3):349-354, May 2017. Delnevo, CD & Hrywna, M, "Clove cigar sales following the US flavoured cigarette ban," *Tobacco Control* 24(e4):e246-50, December 2015.

43 *See* descriptions and references in comments of Campaign for Tobacco-Free Kids and other health groups in Docket No. FDA-2017-N-6189, Tobacco Product Standard for Nicotine Level of Combusted Cigarettes (July 16, 2018), at 7-8 (Public Health ANPRM Comments). https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/2018_07_16_Nicotine_Standard_ANPRM.pdf.

44 Delnevo, CD, et al., "Close, but no cigar: certain cigars are pseudo-cigarettes designed to evade regulation," *Tobacco Control* 26(3):349-354, May 2017. Campaign for Tobacco-Free Kids, *Not Your Grandfather's Cigar: Cheap & sweet cigars lure America's kids*, 2023 Update, October 4, 2023, https://assets.tobaccofreekids.org/content/what_we_do/industry_watch/cigar_report/2023_Cigar-Report.pdf, at 19.

45 Delnevo, CD, et al., "Close, but no cigar: certain cigars are pseudo-cigarettes designed to evade regulation," *Tobacco Control* 26(3):349-354, May 2017.

46 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.

B. Cigars Are a Harmful and Addictive Substitute for Cigarettes

As FDA recognized in its proposed rule, there is no rational basis for reducing nicotine levels in cigarettes without including cigars, stating, "if the product standard were only to cover cigarettes, it would likely be less effective."[47] In addition, FDA determined "that the non-cigarette combusted products within the proposed scope of this rule (i.e., RYO tobacco, cigars, pipe tobacco) could function as acceptable substitutes for many people who smoke cigarettes while exposing them to similar risks and toxicity as cigarettes."[48]

A recent study measuring support for a policy to reduce nicotine levels in cigarettes and cigars found broad support, including among those who smoke cigars. In fact, 70.3% of adults who currently smoked cigars support this policy even when it included cigars.[49]

Because of the addictiveness of cigars, common co-use (dual use) between cigarettes and cigars among youth and adults, and the pervasive misperception that cigars are less addictive than cigarettes, we strongly support FDA's decision to include cigars in this proposed rule.

a. Cigars can deliver addictive levels of nicotine and are harmful to health

As decades of research shows, cigars pose an increased risk of disease and addiction. FDA referenced much of this supportive research in its proposed rule as well.[50] Cigar smoke contains many of the same harmful constituents as cigarette smoke and may have higher levels of several harmful compounds. Cigar smoking causes cancer of the oral cavity, larynx, esophagus and lung and some people who smoke cigars are at increased risk for heart disease, chronic obstructive pulmonary disease (COPD) and an aortic aneurysm.[51]

Furthermore, cigars contain nicotine and can deliver nicotine at levels high enough to produce dependence among those who smoke cigars.[52] One full-size cigar may contain as much

---

47 90 Fed. Reg. at 5055.

48 90 Fed. Reg. at 5055.

49 Mahoney, M. et al., "Support among adults for a policy to lower nicotine levels in cigarettes and cigars–USA, 2023." *Tobacco Control,* 2025.

50 90 Fed. Reg. at 5057-8.

51 National Cancer Institute (NCI)*, Cigars: Health Effects and Trends. Smoking and Tobacco Control Monograph No. 9*, 1998, http://cancercontrol.cancer.gov/Brp/tcrb/monographs/9/m9_complete.pdf.

52 Henningfield, JE, et al., "Nicotine concentration, smoke pH and whole tobacco aqueous pH of some cigar brands and types popular in the United States," *Nicotine & Tobacco Research* 1(2):163-168, 1999, at 166. NCI Monograph 9, at 186, 191. Baker, F, et al., "Health Risks Associated With Cigar Smoking," *Journal of the American Medical Association* 284(6):735-740, 2000, at 737. Fabian, LA, et al., "*Ad lib* Smoking of Black & Mild Cigarillos and Cigarettes," *Nicotine & Tobacco Research* 14(3):368-371, March 2012, at 370. Goel, R, et al., "A Survey of Nicotine Yields in Small Cigar Smoke: Influence of Cigar Design and Smoking Regimens," *Nicotine & Tobacco Research*, published online September 15, 2017. Pickworth, WB, et al., "Dual Use of Cigarettes, Little Cigars, Cigarillos, and Large Cigars: Smoking Topography and Toxicant Exposure," *Tobacco Regulatory Science* 3(Suppl 1):S72-S83, April 2017, at S79. Claus, ED, "Use Behaviors, Dependence, and Nicotine Exposure Associated with Ad Libitum Cigar Smoking," *Tobacco Regulatory Science* 4(1):548-561, 2018, at 558.

tobacco as a whole pack of cigarettes and thus contains much more nicotine than one cigarette. Cigarettes contain an average of about 10-15 mg of nicotine;[53] many popular brands of larger cigars contain between 100 and 200 mg.[54]

Nicotine levels in cigars vary by product and the type of tobacco used, but it is not always associated with the size of the cigar. One study found that some cigarillos had higher levels of free nicotine per mass compared to large cigars, leading the authors to state, "consumers smoking the same brand of cigar may unintentionally be exposed to varying doses of nicotine and potentially other smoke constituents."[55]

The amount of nicotine delivered to someone who smokes cigars depends on various factors, such as how the cigar is smoked, the number of puffs taken, and the degree of inhalation.[56] The high pH of cigar smoke means that the nicotine is in its free, unprotonated form, making it easily absorbed through the oral mucosa, even if the users do not fully inhale the smoke.[57] A leading review of the science of cigar smoking concluded that, "[c]igars are capable of providing high levels of nicotine at a sufficiently rapid rate to produce clear physiological and psychological effects that lead to dependence, even if the smoke is not inhaled."[58] More recent data are also showing that more people who smoke large and premium cigars do inhale the smoke.[59] Authors of a study looking at a variety of cigar products noted, "it is clear that all cigar products delivered significant and addictive quantities of nicotine and CO – findings that support the rationale for their regulation."[60]

b. Transitions between cigarettes and cigar smoking are common among adults and youth

Cigars must be included in the reduced nicotine standard because, as FDA recognized, "[i]f the proposed product standard covered only cigarettes, some number of people who smoke

---

[53] Benowitz, N and Henningfield, J.,"Reducing the nicotine content to make cigarettes less addictive," Tobacco Control, 22:i14-i17, 2013.

[54] American Cancer Society, "Is Any Type of Smoking Safe?" March 6, 2018, https://www.cancer.org/cancer/cancer-causes/tobacco-and-cancer/is-any-type-of-smoking-safe.html.

[55] Koszowski, B, et al., "Nicotine Content and Physical Properties of Large Cigars and Cigarillos in the United States," *Nicotine & Tobacco Research* 20(3):393-398, 2018, at 395, 397.

[55] American Cancer Society, "Is Any Type of Smoking Safe?" March 6, 2018, https://www.cancer.org/cancer/cancer-causes/tobacco-and-cancer/is-any-type-of-smoking-safe.html.

[56] Henningfield, JE, et al., "Nicotine concentration, smoke pH and whole tobacco aqueous pH of some cigar brands and types popular in the United States," *Nicotine & Tobacco Research* 1(2):163-168, 1999, at 165. NCI Monograph 9, at 186.

[57] NCI Monograph 9, at ii, 4, 11, 97, 183, 191.

[58] Baker, F., et al., "Health Risks Associated With Cigar Smoking," *Journal of the American Medical Association,* 284(6): 735-740, 2000, at 737.

[59] Smith, C., Hiteman, K., Triplett, C., & Pickworth, W. B. (2023). Survey of Premium Versus Large Manufactured Cigars Use in U.S. Consumers. *Nicotine & Tobacco Research*, *25*(Suppl_1), S39-S43. https://doi.org/10.1093/ntr/ntad009, at S42.

[60] Pickworth, WB, et al., "Dual Use of Cigarettes, Little Cigars, Cigarillos, and Large Cigars: Smoking Topography and Toxicant Exposure," *Tobacco Regulatory Science* 3(Suppl 1):S72-S83, April 2017, at S79.

cigarettes and are addicted to nicotine would likely migrate to similar combusted tobacco products to maintain their nicotine exposure (or engage in dual use with other similar combusted tobacco products), thus reducing the positive public health impact of this proposed product standard."[61]

As detailed in comments previously submitted by public health groups to the ANPRM, it is not uncommon for people who smoke cigarettes to replace them with cigars.[62] In addition, those who smoked cigarettes before smoking cigars (secondary cigar smoking) can smoke more and inhale more nicotine, thus showing higher scores of nicotine dependence, than those who smoke cigars without prior experience with cigarettes (primary cigar smoking). Dual use of both cigars and cigarettes is also fairly common and can lead to greater nicotine intake and indications of dependence compared to people who smoke cigars exclusively.[63] Even more concerning is that adolescents who have smoked cigars also reported more frequent cigarette smoking in the past month, more daily smoking in the past month, and, notably, higher levels of nicotine dependence compared to adolescents who did not use cigar products.[64]

Newer data about dual use and transitional patterns of use between cigarettes and cigars only reinforce the importance of including cigars in this proposed standard. Analysis of more recent data from the Population Assessment of Tobacco and Health (PATH) study show that at least half of adults who smoke non-premium cigars also smoke cigarettes, while more than 20% of those who smoke premium cigars concurrently smoke cigarettes.[65] Data from the Tobacco Use Supplement to the Current Population Survey (TUS-CPS) show that women and people who

---

61 90 Fed. Reg. at 5056.

62 Public Health ANPRM Comments, at 9-11.

63 See discussion and references in Public Health ANPRM Comments, at 10-11.

64 Schuster, R. M., Hertel, A. W., & Mermelstein, R. (2013). Cigar, cigarillo, and little cigar use among current cigarette-smoking adolescents. *Nicotine & Tobacco Research, 15*(5), 925–931. https://doi.org/10.1093/ntr/nts222, at 927-928.

65 The National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on Patterns of Use and Health Effects of "Premium Cigars" and Priority Research ("NASEM Report"), Mead, A. M., Geller, A. B., & Teutsch, S. M. (Eds.). (2022). *Premium Cigars: Patterns of Use, Marketing, and Health Effects*. National Academies Press (US), at 422. Jeon, J., Mok, Y., & Meza, R. (2023). Cross-sectional Patterns and Longitudinal Transitions of Premium and Non-Premium Cigar Use in the United States. *Nicotine & Tobacco Research*, *25*(Suppl_1), S16-S23. https://doi.org/10.1093/ntr/ntad031, at S19. Edwards, K. C., Halenar, M. J., Delnevo, C. D., Villanti, A. C., Bansal-Travers, M., O'Connor, R., Del Valle-Pinero, A. Y., Creamer, M. R., Donaldson, E. A., Hammad, H. T., Lagasse, L., Anesetti-Rothermel, A., Taylor, K. A., Kimmel, H. L., Compton, W., Cheng, Y. C., Ambrose, B. K., & Hyland, A. (2023). Patterns of Premium and Nonpremium Cigar Use in the United States: Findings from Wave 6 (2021) of the Population Assessment of Tobacco and Health Study. *Nicotine & Tobacco Research 25*(Suppl_1), S5-S15. https://doi.org/10.1093/ntr/ntad010, at S9.

smoke cigarettes and cigars are using cigars more frequently than before.[66] Research also indicates that dual use of cigars and cigarettes may lower quitting success.[67]

Patterns of dual use can differ by race, ethnicity and product. Non-Hispanic Black adults have higher odds of smoking both cigarillos and cigarettes compared to other races and ethnicities, while non-Hispanic Black and Hispanic adults had lower odds of smoking both cigarettes and filtered cigars compared to non-Hispanic White adults, who also used both cigarettes and filtered cigars in higher quantities per day compared to other races and ethnicities.[68]

Transitions from cigarette smoking to cigar smoking continues to be significant, with PATH data from 2021 showing that 21.8-25.4% of adults who smoke non-premium cigars reporting that they formerly smoked cigarettes and 45.2% of those who smoke premium cigars indicating that they formerly smoked cigarettes.[69] Data from the National Survey on Drug Use and Health and other studies show similar ranges of dual use and transitions from cigarettes to cigars.[70]

In 2024, cigar smoking among high school boys (2.1%) was nearly as high as cigarette smoking (2.2%).[71] Historically, cigar use among non-Hispanic Black high school students has surpassed cigarette smoking in that population. For instance, the 2020 NYTS showed that cigar smoking among Black high school youth was more than three times higher than cigarette

---

[66] Azagba, S., & Shan, L. (2022). Trends in the frequency of cigar use among US adults, 1998/99-2018/19. *Addictive behaviors*, *131*, 107331. https://doi.org/10.1016/j.addbeh.2022.107331, at 3-4.

[67] Li, L., Borland, R., Cummings, K. M., Hyland, A., Le Grande, M., Fong, G. T., & McNeill, A. (2023). Non-cigarette combustible tobacco use and its associations with subsequent cessation of smoking among daily cigarette smokers: findings from the International Tobacco Control Four Country Smoking and Vaping Surveys (2016-20). *Addiction (Abingdon, England)*, *118*(1), 140–148. https://doi.org/10.1111/add.16023, at 146.

[68] Hirschtick, J. L., Mukerjee, R., Mistry, R., Mattingly, D., & Fleischer, N. L. (2022). Short communication: Racial/ethnic disparities in cigar and cigarette exclusive, dual, and polyuse among adults. *Addictive behaviors reports*, *15*, 100412. https://doi.org/10.1016/j.abrep.2022.100412, at 3.

[69] Edwards, K. C., Halenar, M. J., Delnevo, C. D., Villanti, A. C., Bansal-Travers, M., O'Connor, R., Del Valle-Pinero, A. Y., Creamer, M. R., Donaldson, E. A., Hammad, H. T., Lagasse, L., Anesetti-Rothermel, A., Taylor, K. A., Kimmel, H. L., Compton, W., Cheng, Y. C., Ambrose, B. K., & Hyland, A. (2023). Patterns of Premium and Nonpremium Cigar Use in the United States: Findings from Wave 6 (2021) of the Population Assessment of Tobacco and Health Study. *Nicotine & Tobacco Research 25*(Suppl_1), S5-S15. https://doi.org/10.1093/ntr/ntad010, at S9.

[70] Chen-Sankey, J., Bover Manderski, M. T., Ganz, O., Schroth, K. R. J., Villanti, A. C., & Delnevo, C. D. (2023). Cross-sectional Use Patterns and Characteristics of Premium Versus Non-Premium Cigar Smokers in the United States, 2010-2019. *Nicotine & Tobacco Research*, *25*(Suppl_1), S24-S32. https://doi.org/10.1093/ntr/ntad012, at S29. Smith, C., Hiteman, K., Triplett, C., & Pickworth, W. B. (2023). Survey of Premium Versus Large Manufactured Cigars Use in U.S. Consumers. *Nicotine & Tobacco Research*, *25*(Suppl_1), S39-S43. https://doi.org/10.1093/ntr/ntad009, at S41.

[71] Jamal, A., Park-Lee, E., Birdsey, J., West, A., Cornelius, M., Cooper, M. R., Cowan, H., Wang, J., Sawdey, M. D., Cullen, K. A., & Navon, L. (2024). 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. https://doi.org/10.15585/mmwr.mm7341a2.

smoking (9.2% cigar use vs. 2.8% cigarette smoking).[72] Among youth and young adults, research has found that current cigarette smoking increases the odds of cigar initiates transitioning to current cigar use within six months and is also associated with smoking cigars more frequently.[73]

c. Misperceptions about the addictiveness of cigars persist

Cigars should be included in this proposed standard to dispel the common misconception about the addictiveness of cigars. In FDA's proposed Deeming Rule, the agency highlighted research indicating existing misperceptions that cigars were less addictive than cigarettes or not addictive at all, including that some youth did not realize that cigars even contained nicotine.[74] FDA also previously argued 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."[75]

Researchers interviewing Black young adults who smoke cigars found that, although almost all participants generally believed that people could become addicted to cigars, nearly half of them did not identify as being addicted to cigars.[76] Another focus group study similarly found that young people do not always understand that all cigars contain nicotine, nor did participants identify themselves as being addicted to cigars.[77] A recent study of youth who smoked cigars or were susceptible to smoking cigars found that half of respondents did not know or were unsure that blunts (marijuana wrapped in a hollowed-out cigar or cigar wrapper)

---

72 Gentzke, A. S., Wang, T. W., Jamal, A., Park-Lee, E., Ren, C., Cullen, K. A., & Neff, L. (2020). Tobacco Product Use Among Middle and High School Students - United States, 2020. *MMWR. Morbidity and mortality weekly report*, *69*(50), 1881–1888. https://doi.org/10.15585/mmwr.mm6950a1. Data from the 2020 NYTS are the most recent available for these demographic breakdowns.

73 Cantrell, J., Xu, S., Kreslake, J., Liu, M., & Hair, E. (2022). Cigar Use Progression Among New Cigar Initiators: A Two-Part Growth Curve Analysis Among a Youth and Young Adult Cohort. *Nicotine & Tobacco Research*, *24*(1), 28–36. https://doi.org/10.1093/ntr/ntab143, at 34.

74 81 Fed. Reg. at 29063, citing 79 Fed. Reg. at 23158, 23166.

75 81 Fed. Reg. at 29021. We recognize that 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). However, 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.

76 Elhabashy, M., Phan, L., Hamilton-Moseley, K. R., Broun, A., Duarte, D. A., Ajith, A., Jewett, B., Mead-Morse, E. L., Choi, K., & Chen-Sankey, J. (2022). Exploring the Experiences and Perceptions of Cigar Craving and Addiction among Young Adult Black Cigar Smokers. *International journal of environmental research and public health*, *19*(11), 6680. https://doi.org/10.3390/ijerph19116680, at 8.

77 Hackworth, E. E., Ntansah, C. A., Henderson, K. C., Pei, D., Reynolds, R. M., Duong, H. T., Yang, B., Ashley, D. L., Thrasher, J. F., & Popova, L. (2023). "I Crave a Blunt, I Don't Crave a Cigarillo": A Focus Group Study on Perceptions of Nicotine and Addiction among US Adults Who Currently Smoke Little Cigars or Cigarillos. *International journal of environmental research and public health*, *20*(6), 5086. https://doi.org/10.3390/ijerph20065086, at 4-5.

contained nicotine, and half of respondents thought that blunts were less harmful or less addictive than tobacco-only cigars.[78]

The 2022 report on premium cigars from National Academies of Sciences, Engineering, and Medicine noted that these misperceptions had real consequences: "evidence indicates that lower perceived risks of cigars, which likely includes premium cigars, is associated with subsequent use,"[79] and that there is "strongly suggestive evidence . . . that lower perceived harm and addictiveness of cigars in general is associated with cigar use behavior, including current use in adults and initiation in youth."[80]

This general misunderstanding could impact the effectiveness of a policy to lower the nicotine content in cigars because if people do not realize that cigars are addictive, they may not understand the implications of this policy. However, these misperceptions could be addressed with educational campaigns about the addictiveness of cigars leading up to the policy implementation.[81] It is still vitally important to include cigars in this standard. If not, it could perpetuate these misperceptions and send the wrong message that these products are not addictive or less addictive than cigarettes.

C. Hookah (Waterpipe) Tobacco Should be Subject to the Nicotine Standard

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" (at 5034). We disagree with the FDA's determination, and believe FDA has failed to demonstrate there is not a risk of switching or an increase in initiation, particularly among youth, under the conditions of a nicotine product standard in which hookah tobacco is exempt. We urge the FDA to consider the potential public health benefits of including hookah in the proposed rule, examine the evidence base 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.

---

78 Kowitt, S. D., Jetsupphasuk, M., Clark, S. A., Jarman, K. L., Goldstein, A. O., Thrasher, J. F., Jebai, R., Ranney, L. M., & Cornacchione Ross, J. (2024). Knowledge and beliefs about blunts among youth in the United States. *Preventive medicine reports*, *47*, 102884. https://doi.org/10.1016/j.pmedr.2024.102884, at 4.

79 NASEM Report, at 188.

80 NASEM Report, at 190.

81 Hackworth, E. E., Ntansah, C. A., Henderson, K. C., Pei, D., Reynolds, R. M., Duong, H. T., Yang, B., Ashley, D. L., Thrasher, J. F., & Popova, L. (2023). "I Crave a Blunt, I Don't Crave a Cigarillo": A Focus Group Study on Perceptions of Nicotine and Addiction among US Adults Who Currently Smoke Little Cigars or Cigarillos. *International journal of environmental research and public health*, *20*(6), 5086. https://doi.org/10.3390/ijerph20065086, at 4-5. Ntansah, C. A., Hackworth, E. E., Henderson, K. C., Reynolds, R. M., Yang, B., Ashley, D. L., Duong, H. T., Thrasher, J. F., & Popova, L. (2024). Reactions to Messages About a Nicotine Reduction Policy: A Focus Group Study Among People Who Use Little Cigars and Cigarillos. *Nicotine & Tobacco Research*, *26*(1), 87-93. https://doi.org/10.1093/ntr/ntad155, at 91.

Because hookah tobacco smoking is inherently harmful, reducing hookah tobacco use and its associated health harms is sufficient justification on its own to merit including hookah tobacco use in the proposed product standard, regardless of the likelihood that people who smoke cigarettes will switch to hookah under the proposed rule. Studies have shown that hookah smoke contains many of the toxins and carcinogens found in cigarettes.[82] Some of these harmful components are in gaseous form and others are particulates. At least 82 toxicants and carcinogens have been identified in waterpipe tobacco smoke, including tobacco-specific nitrosamines (TSNAs), polycyclic aromatic hydrocarbons (PAHs), and heavy metals.[83] In addition, hookah smoke contains the toxins and carcinogens from the burning of the charcoal, including carbon monoxide. A meta-analysis that analyzed 17 studies of waterpipe tobacco smoking found that a single waterpipe tobacco smoking session was associated with carbon monoxide exposure equivalent to more than half a pack of cigarettes and exposure to tar equivalent to more than two full packs of cigarettes.[84] None of these harmful components are eliminated by the passage of the smoke through the water and many of these harmful substances are delivered to the user's lungs. In addition to these harmful chemicals, hookah tobacco also contains nicotine. Research shows that in a typical waterpipe session, users are subjected to up to more than twice the nicotine exposure from smoking a single cigarette.[85] Research shows that waterpipe tobacco use is associated with nicotine dependence, including experiences of withdrawal and difficulty quitting, at least among some users.[86]

According to the CDC, using a waterpipe to smoke tobacco poses serious health risks to users and others exposed to the smoke from the waterpipe tobacco.[87] Waterpipe tobacco use is linked to many of the same adverse health effects as cigarette smoking, such as lung, bladder and oral cancers and heart disease.[88] Other documented long-term effects include impaired

---

82 HHS, *Prevention Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General*, 2012.

83 Ward, KD, et al., "The waterpipe: an emerging epidemic in need of action," *Tobacco Control,* 24(S1): i1-i2, 2015. Sepetdijian, E, et al., "Measurement of 16 Polycyclic Aromatic Hydrocarbons in Narghile Waterpipe Tobacco Smoke," *Food and Chemical Toxicology*, 46: 1582-1590, 2008. Schubert, J., et al., "Mainstream Smoke of the Waterpipe: Does this Environmental Matrix Reveal as Significant Source of Toxic Compounds?" *Toxicology Letters*, 205(3): 279-284, 2011. Jacob, P., et al. "Nicotine, Carbon Monoxide and Carcinogen Exposure After a Single Use of a Water Pipe," *Cancer Epidemiology, Biomarkers, & Prevention*, 20: 2345-2353, 2011.

84 Primack B, et al. Systematic review and meta-analysis of inhaled toxicants from waterpipe and cigarette smoking. *Public Health Reports,* 131(1), 76-85, 2016.. See also, HHS, Prevention Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General, 2012. Eissenberg, T and Shihadeh, A. "Waterpipe tobacco and cigarette smoking: direct comparison of toxicant exposure," *American Journal of Preventive Medicine*, 37(6): 518-523, 2009. Maziak, W, et al., "CO exposure, puff topography, and subjective effects in waterpipe tobacco smokers," *Nicotine & Tobacco Research*, 11(7): 806-811.

85 Primack B, et al. 2016. HHS, *Prevention Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General*, 2012. Eissenberg, T and Shihadeh, A., 2009. Maziak, W, et al., "CO exposure, puff topography, and subjective effects in waterpipe tobacco smokers," *Nicotine & Tobacco Research*, 11(7): 806-811, 2006.

86 Aboaziza, E and Eissenberg, T., "Waterpipe tobacco smoking: what is the evidence that it supports nicotine/tobacco dependence?" *Tobacco Control*, published online December 9, 2014.

87 Centers for Disease Control and Prevention. "Hookahs." Available at https://www.cdc.gov/tobacco/other-tobacco-products/hookahs.html. Accessed June 3, 2025.

88 HHS, *Prevention Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General*, 2012. Knishkowy B, Amitai, Y. "Waterpipe (narghile) smoking: an emerging health risk behavior," *Pediatrics* 2005.

pulmonary function, chronic obstructive pulmonary disease, esophageal cancer and gastric cancer.[89] As a result of exposure to the dangerous chemicals in waterpipe tobacco smoke, research shows that even short-term waterpipe tobacco use is associated with acute health effects, including increased heart rate, blood pressure, reduced pulmonary function and carbon monoxide intoxication.[90] In a 2015 report, the World Health Organization Study group on tobacco product regulation surveyed the research to date and corroborated these findings.[91] Given the health harms and addiction potential of hookah tobacco smoking, FDA should revise the scope of the proposed rule to include hookah tobacco.

The proposed rule does not sufficiently consider how patterns of use may change in a marketplace where hookah is the only available combustible tobacco product with addictive levels of nicotine. While fewer than 1% of high school students reported current hookah use in 2024, only a decade ago hookah was the second most popular tobacco product among youth, with 9.4% of high schoolers reporting current use.[92] Indeed, the Surgeon General has described how patterns of youth tobacco use have shifted in the past, finding that, "decreases in cigarette and cigar smoking during 2011–2016 were offset by increases in hookah and e-cigarette use, resulting in no significant change in any tobacco use."[93] History clearly shows that youth tobacco preferences can rapidly shift to less regulated products, such as when the FDA exempted flavored disposables from its 2020 enforcement guidance. Similarly, these youth use trends and patterns of use can easily change if hookah tobacco is exempt from the proposed rule.

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. For example, the 2013-2014 wave of the FDA's PATH study found that 60.6% of current youth (ages 12-17) hookah users use hookah because they think it might be less harmful than cigarettes.[94] Longitudinal data from the PATH study has also shown that youth who perceive hookah to be less harmful than cigarettes are more likely to initiate use and increase their frequency of hookah tobacco use over time.[95] Leaving hookah tobacco as the only available

---

89 El-Zaatari, ZM, et al., "Health effects associated with waterpipe smoking," *Tobacco Control*, 24(S1): i31-i43, 2015.

90 *Id.*

91 World Health Organization, Study Group on Tobacco Product Regulation ("TobReg"), 2015.

92 Ahmed, J., et al., "Tobacco Product Use Among Middle and High School Students — National Youth Tobacco Survey, United States, 2024," *MMWR* 73(41):917-924, 2024. Arrazola, R.A., et al., "Tobacco Use Among Middle and High School Students — United States, 2011–2014," *MMWR* 64(14):381-385, 2015.

93 HHS, *Smoking Cessation: A Report of the Surgeon General,* 2020.

94 Ambrose, BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014," *JAMA*, published online October 26, 2015.

95 Gautum, P., et al., "Prevalence and Predictors of Waterpipe Smoking Initiation and Progression Among Adolescents and Young Adults in Waves 1–4 (2013–2018) of the Population Assessment of Tobacco and Health (PATH) Study," *Nicotine & Tobacco Research*, 24(8): 1281-1290, 2022. Kuk AE, et al., "The Effect of Perceptions of Hookah Harmfulness and Addictiveness on the Age of Initiation of Hookah Use among Population Assessment of

addictive combustible tobacco product threatens to reverse the tremendous public health gains that have been made in reducing hookah tobacco use in the past decade.

The proposed rule also does not duly examine the existing research on co-use and transitions in use among hookah tobacco and cigarettes, particularly among youth and young adults. Research suggests that hookah use may play a role in cigarette initiation by exposing youth and young adults to addictive nicotine . Research studies have found that hookah use is associated with susceptibility to cigarette smoking, subsequent cigarette initiation, increased intensity of cigarette smoking, and reduced cessation success.[96] A meta-analysis of prospective cohort studies examining the association between hookah use and subsequent cigarette smoking initiation among youth and young adults found that hookah use is associated with more than doubling of the odds of later initiation of cigarette smoking.[97] The meta-analysis includes data from the first two waves of the FDA's PATH study which found that among youth who had never smoked a cigarette at baseline, odds of any cigarette use initiation and odds of past 30-day cigarette use at one year follow up were approximately double for ever users of hookah tobacco, compared with never users.[98] Research also shows that most hookah users are polytobacco users.[99] For example, in the 2013-2014 wave of the FDA's PATH study, 73% of youth and 81.6% of adult past-year hookah users were poly-tobacco users, with 75.3% of poly-tobacco use

Tobacco and Health (PATH) Youth." *International Journal of Environmental Research and Public Health*. 2022; 19(9):5034

[96] Al Oweini D. et al., "The association of waterpipe tobacco smoking with later initiation of cigarette smoking: a systematic review and meta-analysis exploring the gateway theory," *Tobacco Control* 2020;29:577-584. Bahelah, R. "Curiosity and susceptibility to cigarette smoking among cigarette-naïve, waterpipe smoking US youth: National Youth Tobacco Survey, 2014." *Tobacco Prevention & Cessation*, *3*, 132, 2017.
Soneji, S, et al., "Associations between initial water pipe tobacco smoking and snus use and subsequent cigarette smoking: Results from a longitudinal study of US adolescents and young adults," *JAMA Pediatrics*, published online December 8, 2014. Doran, N, et al., "Hookah use predicts cigarette smoking progression among college smokers," *Nicotine & Tobacco Research*, 17(11): 1347-1353, 2015. Salloum, RG, et al., "Waterpipe Tobacco Smoking and Susceptibility to Cigarette Smoking Among Young Adults in the United States, 2012-2013, *Preventing Chronic Disease*, 13, 2016. Thomas, JL, et al., "Abstinence rates among college cigarette smokers enrolled in a randomized clinical trial evaluating Quit and Win contests: The impact of concurrent hookah use," *Preventive Medicine*, 76: 20-25, 2015. Watkins SL, Glantz SA, Chaffee BW. Association of noncigarette tobacco product use with future cigarette smoking among youth in the Population Assessment of Tobacco and Health (PATH) study, 2013-2015. *JAMA Pediatrics* 2018;172:181

[97] Al Oweini D. et al., "The association of waterpipe tobacco smoking with later initiation of cigarette smoking: a systematic review and meta-analysis exploring the gateway theory," *Tobacco Control* 2020;29:577-584.

[98] Watkins SL, Glantz SA, Chaffee BW. Association of noncigarette tobacco product use with future cigarette smoking among youth in the Population Assessment of Tobacco and Health (PATH) study, 2013-2015. *JAMA Pediatrics* 2018;172:181.

[99] See e.g., Sterling, KL, et al., "Examining Hookah Smoking Among a Cohort of Adolescent Ever Smokers," *Nicotine & Tobacco Research*, 113(12): 1202-1209, 2011. Rath, JM, et al., "Patterns of Tobacco Use and Dual Use in US Young Adults: The Missing Link between Youth Prevention and Adult Cessation," *Journal of Environmental and Public Health*, 2012.

among adult past-year hookah users including cigarettes. Rates of poly-tobacco use were similar for past-month hookah users.[100]

Finally, FDA did not consider the possibility that exempting hookah tobacco would create a loophole that other combustible tobacco product manufacturers may try to manipulate by rebranding their products as hookah tobacco—which they have a long history of doing, as described in the previous section on cigars. FDA also did not consider alternative mechanisms for smoking hookah tobacco that might be employed by users that could undermine the impact of the proposed rule.

D. Heated Tobacco Products Should be Subject to a Nicotine Standard

We disagree with FDA's decision to exclude heated tobacco products (HTPs) from the proposed rule. There is a substantial public health risk from excluding HTPs from the rule that the agency has failed to recognize. HTPs can deliver addictive levels of nicotine, just like cigarettes, and are often used with cigarettes. While they have not been on the market long enough to accumulate long-term data on health risks, available independent data show that these products are not harmless. We urge FDA to 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.

Significantly, in its decision authorizing the sale of Philip Morris International's (PMI) IQOS heated tobacco products, FDA stated that these products had similar abuse liability to cigarettes. "The data indicate that THS 2.2 [IQOS] has addictive potential and abuse liability similar to CC [conventional cigarettes]. "[101] If a nicotine standard were applied only to conventional cigarettes and not HTPs, then tobacco use patterns, including initiation and cessation, could easily change, perpetuating the tobacco burden rather than reducing it..

FDA's authorization for IQOS to make reduced exposure claims in its marketing is not a reason to exclude HTPs and IQOS from this proposed rule. The marketing orders are specific to IQOS, and not for all HTPs, which have not been evaluated by FDA. A whole category of product should not be excluded from this rule because of findings related to one product.

Moreover, FDA's finding about reduced exposure to certain harmful and potential harmful constituents (HPHCs) in smoke released from IQOS products does not translate into

---

[100] Soneji, S., et al., "Transitions in frequency of hookah smoking among youth and adults: findings from waves 1 and 2 of the Population Assessment of Tobacco and Health (PATH) study," 2013–15. *Addiction*, 116(4), 936-948, 2021.

[101] FDA, Decision Summary for IQOS Tobacco Heating System (THS), Marlboro Heatsticks, Smooth Menthol Heatsticks, and Fresh Menthol Heatsticks from Philip Morris Products S.A., April 30, 2019, https://www.fda.gov/media/124247/download, at 49.

reducing one's health risk. FDA *denied* PMI's request to market IQOS as a "reduced risk" product, finding there was not enough evidence that switching completely to IQOS would present less risk than continuing to smoke cigarettes.[102] Consumers already misinterpret messages about reduced exposure as meaning reduced risk.[103] Excluding HTPs from the proposed rule could reinforce that misunderstanding, leading to consumers believing that HTPs expose them to less nicotine, lower risk of addiction and lower risk of disease.

Newer research continues to accumulate on the health risks from using HTPs. A recent systematic review and meta-analysis of studies raises some questions about the relative risk of using HTPs compared to cigarettes, stating, "Overall, the findings are so mixed that these data provide no clear indication of the relative risks or benefits of HTPs, including insufficient evidence to indicate any certain benefits over cigarettes."[104] In a related commentary, one of the authors stated, "…the evidence we reviewed was inconclusive. Though most studies suggested that heated tobacco products might reduce risks of disease compared with smoking, other studies found no difference, or even the potential of increased risk."[105]

As with hookah, FDA's decision of whether to include HTPs in the proposed rule must look beyond current use rates and consider possible changes in HTP use in a marketplace where addictive combustible products are not available. Excluding HTPs from this rule could shift current patterns of use in ways that do not protect the public's health.

E. The Rule Should Prohibit Other Changes in Tobacco Products That Might Counteract the Effect of the Reduction in Nicotine

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

---

[102] FDA, "FDA Authorizes Marketing of IQOS Tobacco Heating System with 'Reduced Exposure' Information," Press Release, July 7, 2020, https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-iqos-tobacco-heating-system-reduced-exposure-information.

[103] Popova, L., Lempert, L. K., & Glantz, S. A. (2018). Light and mild redux: heated tobacco products' reduced exposure claims are likely to be misunderstood as reduced risk claims. *Tobacco control*, *27*(Suppl 1), s87-s95. https://doi.org/10.1136/tobaccocontrol-2018-054324, at S91-s92. FDA, TPSAC, January 24 and January 25, 2018 Webcast, accessed June 9, 2025 at https://web.archive.org/web/20230201131319/https://www.fda.gov/advisory-committees/tobacco-products-scientific-advisory-committee/january-24-25-2018-webcast.

[104] Braznell, S., Dance, S., Hartmann-Boyce, J., & Gilmore, A. (2025). Impact of heated tobacco products on biomarkers of potential harm and adverse events: a systematic review and meta-analysis. *Tobacco control*, tc-2024-059000. Advance online publication. https://doi.org/10.1136/tc-2024-059000, at 8.

[105] Hartmann-Boyce, J. (2025, May 1) As heated tobacco products reenter the US market, evidence on their safety remains sparse – new study. *The Conversation*. https://theconversation.com/as-heated-tobacco-products-reenter-the-us-market-evidence-on-their-safety-remains-sparse-new-study-254278.

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 poses a substantial threat to the efficacy of a nicotine product standard. Nicotine analogs are compounds that are structurally similar to nicotine and include nicotine derivatives and metabolites.[106] Internal industry documents reveal that tobacco manufacturers previously studied the potential for analogs to "replace nicotine in order to create more 'desirable' products and to circumvent anticipated nicotine regulation."[107] In recent years, several products have been marketed with nicotine analogs intended to mimic the pharmacological effects of nicotine.[108] It is imperative that FDA determine whether products with nicotine analogs can be regulated as "tobacco products" under the Tobacco Control Act. If they are not "tobacco products," then they must be regulated as "drugs" under the Food, Drug and Cosmetic Act.[109] The failure of FDA to assert regulatory authority over products with nicotine analogs would seriously undermine a nicotine product standard for combustible and heated tobacco products.

III. Implementation Considerations

A. FDA's Proposed Maximum Nicotine Level

We agree that FDA's proposed maximum nicotine level of 0.7 mg/g is appropriate for the protection of public health. As described previously, the largest clinical trials of VLNC cigarettes (Donny, et al., 2015 & Hatsukami, et al., 2018) find the greatest benefit on reductions in smoking and biomarkers of smoke exposure among individuals assigned to smoke cigarettes with a nicotine level of 0.4 mg/g. As described in the proposed rule (at 5062), 22nd Century reports that testing of the cigarettes they supply for these trials has found variations in the nicotine content of these cigarettes in the range of 0.4 to 0.7 mg/g. Thus, it is reasonable to assume that the benefits found in research studies that use these cigarettes also translate to cigarettes that contain 0.7mg/g. Setting a maximum nicotine level of 0.7 mg/g also allows for sufficient flexibility for manufacturers to meet the standard while allowing for potential variabilities in tobacco growing practices and product testing. To minimize the risk of abuse liability or compensation on a population-wide basis, FDA should not compromise in setting the nicotine level any higher than

---

106 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

107 *Id.* at 701.

108 *See generally,* Letter from ACS CAN, et al. to FDA Commissioner Robert Califf re "urgent public health imperative to regulate nicotine analog products," May 29, 2024. https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/2024_05_29_Coalition-letter-to-FDA-on-nicotine-analog-products.pdf

109 *Id.*

0.7 mg/g, as such a level is not supported by the scientific evidence that underpins the FDA proposal.

Importantly, contrary to assertions from the tobacco industry, we agree with the FDA's conclusion that the proposed standard is not equivalent to limiting nicotine to zero.[110] As the FDA describes in the proposed rule (at 5076), the research shows that, "nicotine is measurable in both the tobacco filler and the smoke yield of VLNC cigarettes and therefore does not equal zero. After using VLNC cigarettes, nicotine exposure has been shown to occur as evidenced by studies measuring biomarkers of nicotine exposure and neurological receptor occupancy."

B. An Immediate Nicotine Content Reduction Will Have a Larger Public Health Impact than a Gradual Reduction

We agree with FDA's assessment (at 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 the previously described 20-week randomized controlled trial of 1200 adults (Hatsukami et al., 2018) 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 to 0.4 mg/g). Those in the immediate nicotine reduction condition 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 condition, while no significant differences were found between the gradual reduction condition and control condition.[111] Other smaller trials have found similar findings.[112] While trials like these have limitations, including the fact that participants are given cigarettes for free and may compensate with normal nicotine content cigarettes that are readily available in the marketplace, residential and in-patient trials, where participants only have access to study cigarettes, also show no evidence of compensation.[113] A gradual reduction approach would delay the tremendous public health benefits from a nicotine

---

110 Under the Tobacco Control Act, FDA lacks the authority to reduce the nicotine in a tobacco product to zero. 21 U.S.C. §387g(d)(3)(B). Nothing in the statute precludes limiting nicotine to the level specified in the proposed rule.

111 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.

112 Benowitz NL, et al. "Smoking behavior and exposure to tobacco toxicants during 6 months of smoking progressively reduced nicotine content cigarettes." *Cancer Epidemiol Biomarkers Prev*. 2012;21(5):761-769. Mercincavage M, 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.

113 Donny, E. C., et al., "Smoking in the absence of nicotine: Behavioral, subjective and physiological effects over 11 days." *Addiction, 102* (2), 324–334, 2007. Smith, T. T., et al. "The impact of exclusive use of very low nicotine cigarettes on compensatory smoking: An inpatient crossover clinical trial." *Cancer Epidemiology Biomarkers & Prevention, 29* (4), 880–886, 2020.

reduction standard, leading more young people to start smoking and more people to die from smoking.

As described in greater detail in the following section, an immediate nicotine content reduction is also preferable because it reduces the possibility of compensatory smoking, whereas evidence suggests that a gradual approach could create opportunities for people who smoke to compensate by smoking more cigarettes. While VLNC cigarettes do not contain enough nicotine for compensation to be feasible, people who smoke may be able to compensate with intermediate-level nicotine cigarettes, smoking these products more intensely and exposing themselves to more toxicants. Some studies have found increases in biomarkers of smoke exposure and cigarettes per day among participants assigned to smoke cigarettes with moderate levels of nicotine.[114]

A gradual approach is also disadvantageous because it prolongs the implementation process and is more burdensome on farmers and manufacturers who will have to adjust to multiple nicotine content standards. It would also create more opportunities for consumers to stockpile cigarettes. 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.

C. The Proposed Nicotine Standard Will Not Lead to Compensatory Smoking

As FDA summarizes in the proposed rule (at 5070 – 5072), the research does not support concerns that reducing the nicotine level in cigarettes to very low levels would lead those who smoke to smoke more cigarettes or inhale smoke more deeply in order to obtain the nicotine fix they are accustomed to ("compensatory smoking"), which would have the unintended consequence of exposing them to even more harmful constituents. Substantially reducing nicotine in tobacco makes it almost impossible for those who smoke to compensate for the lower nicotine level by smoking more cigarettes, taking more puffs on the cigarette, or inhaling more deeply. Researchers estimate that someone who typically smokes ten cigarettes per day would need to consume at least one hundred VLNC cigarettes per day to achieve compensation. [115]

---

[114] Hatsukami DK, et al., "Reduced nicotine content cigarettes: effects on toxicant exposure, dependence and cessation." *Addiction*. 2010;105(2):343-355. Benowitz NL, et al. "Smoking behavior and exposure to tobacco toxicants during 6 months of smoking progressively reduced nicotine content cigarettes." *Cancer Epidemiol Biomarkers Prev*. 2012;21(5):761-769. Mercincavage M, 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.

[115] Benowitz, NL, et al., "The Role of Compensation in Nicotine Reduction," *Nicotine & Tobacco Research*, 2019, S16-S19.

Indeed, research shows that people who smoke in fact do not compensate when nicotine content is reduced to very low levels.[116] For example, one study that examined the number of cigarettes smoked per day (CPD), carbon monoxide exposure and cotinine levels among participants while they smoked reduced nicotine content cigarettes, found significant decreases in CPD and cotinine levels and a decrease (non-significant) in carbon monoxide exposure compared to when they smoked their usual brand, which suggests minimal, if any, compensatory smoking.[117] Similarly, the randomized clinical trial described earlier (Donny, et al., 2015) found that participants assigned to use VLNC cigarettes inhaled less smoke per cigarette, smoked fewer cigarettes and did not have a significant increase in the level of expired carbon monoxide, indicating that participants did not compensate for the reduction in nicotine by increasing their smoking behavior.[118]

D. FDA Must Counter Misperceptions about the Harms of Reduced Nicotine Products

Reducing the nicotine content of tobacco products will not render them harmless; in fact, products with lower nicotine levels will remain harmful and deadly. While nicotine is the primary addictive agent in cigarettes and is not benign, the overwhelming health consequences of smoking come from the more than 7,000 chemicals and 69 cancer-causing agents produced from combusted cigarettes.[119] As the FDA described in the proposed rule (at 5052), while the public demonstrates high levels of correct perceptions about the addictiveness of nicotine, misperceptions about the health harms of nicotine are widespread, particularly the misperception that nicotine causes cancer. For example, 2015 data from FDA's nationally representative Health Information National Trends Survey (HINTS) found that three-quarters of people either did not know the relationship between nicotine and cancer (24%) or incorrectly believed that nicotine causes cancer (49%).[120] Data from Wave 4 (2016-2018) of the FDA's Population Assessment on

---

[116] See e.g., Donny, EC, et al., "Randomized trial of reduced-nicotine standards for cigarettes," *New England Journal of Medicine*, 373: 1340-1349, 2015. Hatsukami, DK, et al., "Compensatory smoking from gradual and immediate reduction in cigarette nicotine content," *Cancer Epidemiology, Biomarkers & Prevention*, 24: 472-476, 2015. Benowitz, NL, et al., "Smoking behavior and exposure to tobacco toxicants during 6 months of smoking progressively reduced nicotine content cigarettes," *Cancer Epidemiology, Biomarkers & Prevention* , 21: 761-769, 2012.Hatsukami, DK, et al., "Nicotine reduction revisited: science and future directions," *Tobacco Control*, 19: e1-10, 2010. Hatsukami, DK, et al., "Reduced nicotine content cigarettes: effects on toxicant exposure, dependence and cessation," *Addiction*, 105: 343-355, 2010.

[117] Hatsukami, DK, et al., "Compensatory smoking from gradual and immediate reduction in cigarette nicotine content," *Cancer Epidemiology, Biomarkers & Prevention*, 24: 472-476, 2015.

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

[119] HHS, *The Health Consequences of Smoking—50 Years of Progress, A Report of the Surgeon General*, 2014, http://www.surgeongeneral.gov/library/reports/50-years-of-progress/.

[120] O'Brien, E.K., et al., "U.S. adults' addiction and harm beliefs about nicotine and low nicotine cigarettes," *Preventive Medicine*, 96: 94-100, 2017.

Tobacco or Health (PATH) study similarly found that nearly three-quarters (74.7%) of youth (ages 12-17) believed that nicotine is the main substance that causes smoking-related cancer.[121]

Some studies of adults who smoke have shown that they perceive VLNC cigarettes to be less harmful than normal nicotine content cigarettes, incorrectly linking nicotine content with risk for smoking-related disease. For example, a 2015-2016 nationally representative survey found that nearly half (47.1%) of adults who smoke thought that smoking VLNC cigarettes would be less likely to cause cancer than smoking regular cigarettes. Those with this misperception were also less likely to report that they would quit if the government required tobacco companies to remove most of the nicotine from cigarettes.[122] In research trials, participants assigned to use VLNC cigarettes also perceive them to be less harmful.[123] Studies submitted as part of 22nd Century's Modified Risk Tobacco Product (MRTP) application for its VLN™ cigarettes also demonstrated misperceptions about the health risks of their products. For example, themes identified in their qualitative research included, "There were misperceptions voiced regarding the health effects of nicotine use, as many were unsure about its impact relative to the other compounds found in tobacco smoke."[124] The company's quantitative consumer perception study also showed that participants who currently smoked ranked the VLN™ pack with the proposed modified risk claims as having lower risk of critical disease, mortality, and general health issues than the VLN™ pack without claims and lower risk than a comparator Marlboro Gold pack. As the study notes, "The results also suggest that Current Smokers associate reduced consumption of nicotine with lower health risk."[125]

It is critical for the FDA to carefully regulate the marketing of these products,and precede a nicotine reduction policy with an extensively-tested public education campaign to ensure adequate communication about the health risks of these products so as to not encourage people who don't already smoke—especially youth—to experiment. People who smoke should be encouraged to quit completely and be educated about the most effective ways to quit successfully.

While it is important to correct misperceptions about the health effects of nicotine, FDA also needs to be careful not to go too far in the other direction and create perceptions that

---

121 O'Brien, E. K., et al., "Youths' perceptions of nicotine harm and associations with product use." *Nicotine and Tobacco Research*, *25*(7), 1302-1309, 2023.

122 Byron, M.J., et al., "Public misperception that very low nicotine cigarettes are less carcinogenic," *Tobacco Control*, 27:712-714, 2018.

123 Denlinger-Apte, RL, et al., "Low nicotine content descriptors reduce perceived health risks and positive cigarette ratings in participants using very low nicotine content cigarettes," *Nicotine & Tobacco Research*, published online January 18, 2017. Pacek, LR, et al., "Perceived nicotine content of reduced nicotine content cigarettes is a correlate of perceived health risks," *Tobacco Control*, published online July 22, 2017. 2017.

124 M/A/R/C® Research, "Qualitative Study to Develop PARE / VLN™ Hypothetical Claims Among U.S. Adult Cigarette Smokers, Adult Former Cigarette Smokers and Adult Never Cigarette Users Phases 1, 2, 3, and 4," at 16.

125 M/A/R/C® Research, "Quantitative Study to Evaluate VLN Hypothetical Product Messages Among U.S. Adult Cigarette Smokers, Adult Former Cigarette Smokers and Adult Never Cigarette Users," at 123.

nicotine is safe. This could encourage people who smoke to continue using other tobacco products rather than completely quitting or encourage uptake of alternative tobacco products among young people. As described earlier, nicotine is a highly addictive drug and can have lasting impacts on adolescent brain development, particularly the parts of the adolescent brain responsible for attention, learning, mood and impulse control.[126] According to the Surgeon General, "The use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe."[127] Public health education campaigns on the health harms of reduced nicotine products should be carefully designed and tested to ensure that they do not exacerbate the current public health crisis of youth tobacco use. Over 2.2 million middle and high school students are current tobacco users and many are using these products frequently or daily, an indicator of addiction. [128]

IV. Technical Achievability

A. Reducing Nicotine in Cigarettes is Technologically Feasible

Research demonstrates that reducing nicotine content in cigarettes to minimally or non-addictive levels is technologically feasible. The FDA presented ample evidence in the proposed rule (at 5073-5075) that there are a wide range of techniques available to reduce nicotine content. One option is genetic engineering, which as FDA notes, "has resulted in up to a 98 percent reduction in nicotine levels."[129] A second option is chemical extraction. 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.'"[130] Other options exist to manipulate nicotine levels, including tobacco farming practices, tobacco blending or crossbreeding, and tobacco curing processes.

---

126 HHS, *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General,* CDC, Office of Smoking and Health (OSH), 2014.

127 HHS, *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General*. Atlanta, GA: 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, 2016.

128 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

129 90 Fed. Reg. at 5074, citing Dunsby, J., and L. Bero. ''A Nicotine Delivery Device without the Nicotine? Tobacco Industry Development of Low Nicotine Cigarettes.'' *Tobacco Control,* 13(4):362–9, 2004.

130 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.

Indeed, for decades the tobacco companies have demonstrated their proficiency in manipulating the nicotine level of cigarettes.[131] In the 1980s-1990s, Philip Morris produced three brands of low-nicotine cigarettes: Merit De-Nic, Benson & Hedges De-Nic and Next. Vector Tobacco introduced Quest, a low-nicotine cigarette, in 2003. The tobacco manufacturer 22nd Century currently produces Spectrum, a very low nicotine U.S.-grown tobacco cigarette, which is currently used in government-funded clinical research studies and VLN™, an MRTP-authorized cigarette available to the public. Reducing nicotine content in cigarettes to minimally or non-addictive levels is also consistent with several tobacco companies' purported missions of shifting away from combustible tobacco products by "transforming tobacco" (R.J. Reynolds)[132] and investing in a "smoke-free future" (Philip Morris).[133]

The tobacco industry's own documents also show that the industry has a long history of manipulating nicotine levels in cigarettes to make them *more* addictive. Internal company documents from as far back as the 1950s expose the tobacco industry's extensive research on the importance of nicotine and how best to deliver nicotine to people who smoke and optimize its effects.[134] The documents demonstrate that they have known for decades that the key to their business is creating and sustaining dependence on nicotine, and they have purposely designed their products to do this effectively and efficiently. As U.S. District Judge Gladys Kessler concluded in her landmark 2006 civil racketeering judgment against the major cigarette manufacturers, *U.S. v. Philip Morris U.S.A., Inc.*,

> ". . . [C]igarette company defendants researched, developed, and implemented many different methods and processes to control the delivery and absorption of the optimum amount of nicotine which would create and sustain smokers' addiction. These methods and processes included, but were not limited to: altering the physical and chemical make-up of tobacco leaf blends and filler; maintaining or increasing the nicotine to tar ratio by changing filter design, ventilation and air dilution processes, and the porosity and composition of filter paper; altering smoke pH by adding ammonia to speed nicotine absorption by the central nervous system; and using other additives to increase the potency of nicotine."[135]

Thus, it is clear that, if required by law, tobacco manufacturers could adjust nicotine levels in their products.

---

131 Cigarettes with reduced nicotine are often referred to as reduced-nicotine cigarettes, very low nicotine content (VLNC) cigarettes, and de-nicotinized cigarettes.

132 RJ Reynolds, "Our vision: We will achieve market leadership by transforming the tobacco industry," accessed August 8, 2017, http://www.rjrt.com/transforming-tobacco/our-mission-and-vision/.

133 Philip Morris, "Our Manifesto: Designing a Smoke-Free Future," Accessed August 8, 2017, https://www.pmi.com/who-we-are/designing-a-smoke-free-future.

134 Wayne, GF & Carpenter, CM, "Tobacco Industry Manipulation of Nicotine Dosing," *Handbook of Experimental Psychology* (192):457-85, 2009.

135 U.S. v. Philip Morris, USA, Inc., 449 F. Supp. 2d 1, 383-84 (D.D.C. 2006), *aff'd in relevant part,* 566 F.3d 1095 (D.C. Cir 2009), *cert. denied,* 130 S.Ct. 3501 (2010).

Finally, we agree with FDA's conclusion that producing reduced-nicotine tobacco for other combusted tobacco products should be no more difficult than producing it for cigarettes. FDA concludes in the proposed rule (at 5075) that, "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."

B. FDA Should Make the Effective Date of the Rule as Early as Possible

The enormous public health benefits that would result from this rule should not be postponed any longer than absolutely necessary. Postponing the effective date of the rule only means that many hundreds of thousands of people who smoke and people who will initiate smoking will unnecessarily have their lives shortened by an addiction that this rule could have prevented. We believe that the FDA's proposal of an effective date two years from the final rule publication (at 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.[136]

As indicated above, tobacco product manufacturers are already capable of extracting nicotine from tobacco and producing VLNC cigarettes. Growing low-nicotine tobacco is only one of several methods of complying with the standard. A tobacco product standard calling for a nicotine level to be set at non-addictive levels does not necessarily require "substantial changes to the methods of farming domestically grown tobacco;"[137] thus, the statute does not require FDA to postpone the effective date of such a standard until two years after promulgation of the rule. Moreover, industry participants will have been on notice for a significant period of time before such a requirement would be imposed, and prudent companies would have been making plans to comply with such a standard.

Tobacco product manufacturers will no doubt make self-serving claims about how difficult, expensive, and time-consuming it would be to implement such a standard. FDA should view such claims skeptically given the clear economic interest the industry has in resisting or postponing measures designed to shrink the market for a highly profitable product. The public health benefits that will be gained from implementing the rule, however, make it imperative to make the rule effective as soon as possible. These benefits far outweigh the compliance costs the industry will experience.

---

136 21 U.S.C. 387g(d)(2).

137 *Id.*

In considering the appropriate implementation period, it is important to consider the likelihood that companies seeking to market products in conformance with the product standard will be able to use the substantial equivalence (SE) pathway to market. In the proposed rule, FDA constructively suggested (at 5100) the possibility of a "streamlined" SE Report in which applicants could demonstrate how the modification of the product was made to conform to the standard, provide test data to show that the standard was met and did not cause the product to raise different questions of public health and certify that no other changes were made.

It is also important for the rule to be applied simultaneously to all manufacturers. The continued availability of combusted products containing conventional levels of nicotine would undermine the effectiveness of the regulatory strategy and would create an opportunity for exempted manufacturers to earn windfall profits by continuing to supply high-nicotine level cigarettes. Manufacturers should not be enabled to undercut the effectiveness of important public health initiatives merely because they are small.

C. Manufacturers, Distributors, and Retailers Should Not Be Allowed to Sell Off Existing Nonconforming Inventories after the Effective Date

Products currently on the market are both deadly and highly addictive. We agree with FDA's determination (at 5111) that the public health imperatives that provide the foundations for replacing these products with 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 provide a wholly unjustified windfall to companies that have stockpiled an inventory in anticipation of its promulgation. Indeed, permitting industry participants to sell off existing non-conforming inventories would creative a massive incentive for companies to accumulate large inventories in anticipation that they would be able to extract additional profits from the sale of such products after the rule becomes effective. As noted above, all industry participants will have had a substantial period of prior notice of the promulgation of such a rule and will have had many opportunities to make arrangements to comply.

D. FDA Should Require a Rigorous Method of Product Testing to Analyze Nicotine Levels

The proposed nicotine product standard will produce the anticipated public health benefits only if the rule is enforced through rigorous product testing to analyze and validate nicotine levels. The preamble to the proposed rule sets out the necessary elements of a sufficient product testing system that manufacturers must implement (at 5106-5111):

- Manufacturers must analyze the nicotine levels of cigarettes and other products covered by the rule using an analytical test method validated in an analytical test laboratory;

- Manufacturers must design and implement a sampling plan covering each batch of finished tobacco products they manufacture;
- Manufacturers must establish procedures for the control and disposition of non-conforming tobacco products;
- Manufacturers must use a manufacturing code as a common identifier to identify the production batch of a particular finished product released for distribution to assist manufacturers and FDA in the event of a nonconforming product investigation; and
- Manufacturers must establish and maintain records showing the results of product testing on each batch to determine conformance with the standard.

Rigorous implementation of each of these elements must be a prerequisite for the introduction of very low nicotine tobacco products into commerce and continued manufacture and sale of such products.

V. E-Cigarettes and Nicotine Pouches

A. Research Needed on Nicotine Levels in E-Cigarettes and Nicotine Pouches

There is little research examining how nicotine reduction in cigarettes and other combustible products will affect the use of non-combustible products.[138] People who smoke combustible products may completely or partially switch to non-combustible products.

Nicotine strength in non-combustible tobacco products is highly variable but has been increasing over time in the case of e-cigarettes and has started out alarmingly high in some nicotine pouch products. One study that looked at nicotine strength in e-cigarettes from 2017 to 2022 found that the unit share of products containing greater than or equal 5% nicotine strength increased by nearly 1,500% during the time period and represented over 80% of e-cigarette sales by March 2022.[139] In addition, a study looking at nicotine strength in approximately 45 nicotine pouch products from 20 different manufacturers found that the nicotine content ranged from 1.79 to 47.5 milligrams per pouch, and the labeling of nicotine content was missing on a majority of products.[140]

---

138 Bhatnagar A, Whitsel LP, Blaha MJ, Huffman MD, Krishan-Sarin S, Maa J, Rigotti N, Robertson RM, Warner JJ; on behalf of the American Heart Association. New and emerging tobacco products and the nicotine endgame: the role of robust regulation and comprehensive tobacco control and prevention: a presidential advisory from the American Heart Association. *Circulation.* 2019;139:00–00. DOI: 10.1161/CIR.0000000000000669

139 Ali FRM, Seaman EL, Crane E, Schillo B, King BA. Trends in US E-cigarette Sales and Prices by Nicotine Strength, Overall and by Product and Flavor Type, 2017-2022. Nicotine Tob Res. 2023 Apr 6;25(5):1052-1056. doi: 10.1093/ntr/ntac284. PMID: 36580384; PMCID: PMC10077931.

140 Mallock N, Schulz T, Malke S, Dreiack N, Laux P, Luch A. Levels of nicotine and tobacco-specific nitrosamines in oral nicotine pouches. Tob Control. 2024 Feb 20;33(2):193-199. doi: 10.1136/tc-2022-057280. PMID: 38378209.

Further research is needed to determine whether nicotine should be reduced in non-combustible products. Specifically, FDA, working with federal government partners, should examine the "impact of lowering nicotine levels in noncombustible products in the context of other lower-nicotine combustible products,"[141] determine the effects of high nicotine levels in such non-combustible products on sustaining addiction, and whether reducing nicotine levels in these products would be desirable to protect public health.

B. Monitoring Patterns of Use in E-Cigarettes and Nicotine Pouches

Once this rule is finalized and implemented, it will be important for FDA, working with federal government partners, to monitor patterns of use of non-combustible tobacco products among both adults and youth over time to see if use of these products is increasing and how products are being used and whether, in the case of adults, complete switching from the tobacco products included in the rule is occurring. For example, of particular concern would be dual use of non-combustible tobacco products and tobacco products included in this rule. Dual use of e-cigarettes and cigarettes has historically been significant,[142] is associated with higher toxicant exposure than exclusive e-cigarette use,[143] and, at a minimum, does not reduce the risk of disease from either product.[144] Monitoring patterns of use of all tobacco products will ensure this rule and any future actions on nicotine levels in tobacco products have their intended public health impact.

VI. Enforcement Against, and Prevention of, Illicit Trade

FDA has requested comments on the extent to which the proposed rule would result in illicit trade in high nicotine cigarettes and other combusted products covered by the rule and how such an increase in illicit trade could impact public health (at 5103). For the reasons given below, we agree with the FDA's observation that "[e]stablishing and maintaining illicit markets in relevant tobacco products will be challenging, and to the extent that they emerge, it is unlikely they will be significant enough to outweigh the benefits of the product standard." (at 5102). FDA relied in part on the 2015 report (requested by FDA) of the National Research Council and Institute of Medicine of the National Academy of Sciences (now the National Academies), finding that the demand for illicit cigarettes would be limited if a nicotine reduction standard were implemented "because some people who smoke would quit, and others would use modified

---

141 Bhatnagar, A. 2019.

142 Cornelius ME, Wang TW, Jamal A, Loretan CG, Neff LJ. Tobacco Product Use Among Adults — United States, 2019. MMWR Morb Mortal Wkly Rep 2020;69:1736–1742. DOI: http://dx.doi.org/10.15585/mmwr.mm6946a4

143 Xue, Z., Orr-Souza, E., Nargis, N. Patel, M. & Nighbor, T. Nicotine and Toxicant Exposure among Individuals using both Combustible Cigarettes and E-cigarettes Based on Level of Product Use, Nicotine & Tobacco Research, 2025;, ntaf053, https://doi.org/10.1093/ntr/ntaf053

144 Glantz SA, Nguyen N, Oliveira da Silva AL. Population-Based Disease Odds for E-Cigarettes and Dual Use versus Cigarettes. NEJM Evid. 2024 Mar;3(3):EVIDoa2300229. doi: 10.1056/EVIDoa2300229. Epub 2024 Feb 27. PMID: 38411454; PMCID: PMC11562742.

products (e.g. VLNC cigarettes) or seek legal alternatives."[145] FDA should reject industry arguments that no nicotine limitation should be imposed because it would lead to increased manufacture and sale of nonconforming illicit products.[146]

Additionally, the public health benefit of the proposed rule and prevention of illicit trade will be enhanced if FDA is utilizing all enforcement measures.

A. Impact of Proposed Rule on Illegal Sales to Minors

Reducing the level of nicotine in combusted tobacco products will curb what has long been the most significant illicit trade in tobacco products: the illegal sale of those products to persons too young to legally buy them. The science strongly establishes that making cigarettes and other combustible tobacco products no longer addictive will prevent substantial numbers of young people from moving from experimentation with those products to regular use. By reducing youth demand for combustibles, the proposed rule will shrink the illicit market involving sales to those who have not reached legal age for tobacco product purchases. The market for illicit sales to minors is, in part, a result of the absence of a nicotine product standard. It also is worth noting that, even though all would acknowledge the persistence of illegal sales to youth, even the tobacco companies have not argued that such sales justify repealing existing age restrictions on the sale of tobacco products. The existence of an illegal market in products that harm public health argues for more effective enforcement measures, not for abandoning policies that erect legal barriers to their manufacture and sale to protect public health.

B. Implications of Current Illegal Cigarette Market

The tobacco industry has long argued against proven tobacco control strategies – including higher cigarette taxes, stronger health warnings and stronger regulation – on the grounds that they will lead to an uncontrolled illicit market. These industry arguments, however, focus largely on the illicit market involving the diversion of cigarettes from the legal market to the illegal market in the form of smuggling finished packs of legal cigarettes from low-tax states to high tax states.[147] These arguments fail to account for the substantial, unique barriers to

---

145 90 Fed. Reg. at 5102 (quoting NRC/IOM report *Understanding the U.S. Illicit Tobacco Market: Characteristics, Policy Context, and Lessons from International Experiences* (2015), at 9.

146 The comments of 36 public health, medical and other organizations in Docket No. FDA-2018-N-0529, Draft Concept Paper: Illicit Trade in Tobacco Products After Implementation of a Food and Drug Administration Product Standard (July 18, 2018) are also incorporated by reference. https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/2018_07_16_Illicit_Trade.pdf

147 See e.g., Altria Client Services, Comments in Docket No. FDA-2018-N-0529 (83 Fed. Reg. 11,754, March 16, 2018), "Draft Concept Paper: Illicit Trade in Tobacco Products After Implementation of a Food and Drug Administration Product Standard" (July 16, 2018), https://www.altria.com/-/media/Project/Altria/Altria/aboutaltria/federal-regulation-of-tobacco/regulatory-filings/documents/ALCS-Comments-to-Dkt-No-FDA-2018-N-0529- Draft-Concept-Paper-Illicit-Trad.pdf (Cigarette black markets in United States "due primarily to price differentials driven by state and municipal taxation.").

sustaining a robust underground market for high-nicotine products that do not exist for interstate smuggling.

First, as FDA points out in the preamble to the proposed rule, "[t]he current illicit cigarette trade in the United States is predominately based on tax evasion and is facilitated by ease of access to tobacco products close to where the sales to consumers take place (e.g. across State lines)." (at 5102). In contrast, because the proposed nicotine product standard would apply nationwide, there would be no legal domestic sales of nonconforming products to consumers.

Moreover, even the existence of interstate smuggling of cigarettes to avoid high state taxation has not functioned to substantially undermine public health gains from increased cigarette taxes. Despite interstate smuggling of cigarettes, the general consensus of economic studies is that every 10% increase in the real price of cigarettes reduces overall cigarette consumption by approximately 3-5%, reduces the number of young adults who smoke by 3.5%, and reduces the number of youth who smoke by 6-7%.[148] This is not to deny the existence of illicit markets that function to reduce the effectiveness of tax increases in reducing smoking. Rather, it is to establish that illicit markets do not come close to nullifying the effects of tax increases in reducing cigarette consumption. As CDC found, "Significant increases in state and local tobacco taxes generate reductions in tobacco use and raise tobacco tax revenues for the jurisdiction, despite the tax avoidance and evasion that results from significant tax and price differentials in the United States."[149] In short, nothing in the history and economics of cigarette tax and price increases suggests that an illicit market in high-nicotine cigarettes would be so substantial as to nullify the public health gains from the proposed rule.

Second, whereas interstate smuggling involves the diversion of finished cigarettes into the illegal market, a substantial illicit market in high-nicotine cigarettes likely would involve the large-scale manufacturing of illegal products. The establishment of clandestine manufacturing facilities, involving multiple individuals and capable of producing and shipping a substantial number of nonconforming cigarettes – in violation of a host of federal laws but unknown to federal enforcement authorities – is highly implausible. We agree with the FDA's conclusion that "[i]llicit manufacturing of NNC cigarettes at a scale large enough to diminish the public health benefits of this proposed product standard would be difficult to disguise from Federal, State, and local enforcement authorities." (at 5102). The enactment of the Prevent All-Cigarette Trafficking (PACT) Act, which requires the prepayment of taxes on internet, mail order, and other non-face to face cigarette sales (known as "delivery sales") and prohibits the sending of cigarettes through the U.S. mail, has been a potent tool to prevent tax evasion and likely will play a similarly

---

148 See generally, Chaloupka, FJ, et al., "Macro-Social Influences: The Effects of Prices and Tobacco Control Policies on the Demand for Tobacco Products," Nicotine & Tobacco Research 1(Supp. 1):S105-09, 1999; Campaign for Tobacco-Free Kids, Raising Cigarette Taxes Reduces Smoking, Especially Among Kids (and the Cigarette Companies Know It),2021, and sources cited therein

149 CDC, Preventing and Reducing Illicit Tobacco Trade in the United States, at 6, 2015.

important role in preventing the emergence of a significant illegal market for high-nicotine cigarettes.[150]

Third, for widespread marketing of high-nicotine cigarettes to occur, the cigarettes must be readily identifiable as high-nicotine from their packaging and promotion. Put differently, the illegality of the high-nicotine cigarettes will be clear from the packaging and promotion of the cigarettes themselves. This is in stark contrast to current illicit cigarette markets, in which the illicit market functions to conceal the illegality of the product. Thus, cigarettes smuggled from low-tax to high-tax jurisdictions often have counterfeit tax stamps and thus are not immediately apparent as illegal; even counterfeit cigarettes are disguised as legitimate. In contrast, the manufacture and sale of illicit high-nicotine cigarettes will be inherently difficult to conceal from the authorities.

Therefore, the existence of an illegal market for cigarettes involved in interstate smuggling does not imply that a similarly robust illicit market for high-nicotine cigarettes and other combustible tobacco products will result from the issuance of a nicotine product standard.

C. Maximizing Enforcement Measures

To the extent that greater enforcement tools are needed to prevent the emergence of an illicit market in high-nicotine combustible products, FDA should supply those tools by implementing the mandate in Section 920(b) of the Tobacco Control Act to adopt a "track and trace" system[151] that should include a unique, counterfeit-proof identifier on every pack of legal cigarettes and further require companies to maintain records that would make firms at every level of the supply chain accountable to ensure that each pack gets to its lawful buyer. As noted, illegal high-nicotine products will be inherently difficult to conceal from law enforcement.However, to the extent that their packaging and promotion do not themselves evidence their illegality, the absence of the legally-required identifier would do so. The system of product testing and related record-keeping mandated by the proposed nicotine rule could provide a foundation for implementation of a track and trace system.

In recent years, a vast market for illicit e-cigarette products has emerged consisting of products being marketed without FDA authorization. The public health community has called on FDA and its federal law enforcement partners to use all the enforcement tools at their disposal to clear the market of these unauthorized products, particularly flavored products that put young

---

[150] Moreover, it is not likely that an appreciable number of individuals would respond to implementation of the proposed rule by adding nicotine to a conforming product. It would be difficult for individuals who smoke to find a way to produce a cigarette with a consistently satisfying level of nicotine and an acceptable taste. Moreover, FDA has sufficiently anticipated this potential manipulation of cigarettes by specifying in the proposed rule that liquid nicotine would be considered a component of a finished tobacco product covered under the rule's scope (at 5104).

[151] 21 U.S.C. §387t(b). Notably, Congress's inclusion of Section 920(b) shows that it did not regard the threat of illegal markets as a justification for the failure to establish strict product standards. Rather, the statute explicitly requires FDA to protect against such a threat.

people at risk for nicotine addiction and other significant health harms.[152] In recent years, FDA has significantly increased its enforcement activity directed at unauthorized e-cigarettes.[153] These enforcement efforts can guide FDA as it considers how to most effectively minimize the risk of an illicit market following implementation of the proposed rule limiting the nicotine in cigarettes and other combustibles.

FDA and its federal enforcement partners at the Department of Justice (DOJ), U.S. Customs and Border Protection (CBP) and other agencies must make clear their intention to vigorously enforce the product standard against all levels of the distribution chain, including manufacturers, distributors, importers and retailers. With respect to e-cigarettes, FDA enforcement has been complicated by the historical fact that there were millions of these products already on the market when FDA issued a rule extending its regulatory authority over e-cigarettes and the agency initially exercised enforcement discretion to allow them to remain on the market. This backdrop has created considerable marketplace confusion over which e-cigarette products are legal. With respect to the nicotine product standard, the agency has an opportunity to establish, with clarity, that after the implementation date, all non-conforming products will be subject to enforcement at every level of the supply chain. This enforcement program must start with the rigorous testing program imposed on manufacturers as discussed previously.

Additionally, FDA and its federal enforcement partners must develop a comprehensive enforcement plan prior to the rule's implementation date that recognizes that the enforcement responsibility rests not only with FDA, but also with its enforcement partners at DOJ, CBP and multiple other federal agencies. It is apparent that the burgeoning illegal market in unauthorized e-cigarettes primarily consists of foreign-made products illegally imported into the United States, not products manufactured in clandestine US factories and vape shops. CBP is therefore an absolutely essential component of any successful enforcement effort against unauthorized e-cigarettes; yet only recently have significant seizures of illicit products been made as they were about to enter the country. Similarly, DOJ must increase its efforts to seek injunctions against sellers of unauthorized products. Despite the open presence of many thousands of varieties of unauthorized products in vape shops across the country, DOJ has pursued very few injunctions.

The recent experience with unauthorized e-cigarettes shows that enforcement activity against cigarettes that violate the nicotine product standard must be a publicly declared priority of multiple agencies even before the standard's implementation date. The creation of a multi-agency task force in June 2024 to address the illegal e-cigarette problem could provide a

---

152 *See* letter from 78 public health, medical, education, community and other organizations to FDA, DOJ and CBP (May 22, 2024). https://assets.tobaccofreekids.org/content/press_office/2024/2024_05_22_coalition-letter-e-cig-enforcement.pdf?_gl=1*3a4t35*_gcl_au*NTQyMjE0MzcxLjE3NDc5MjM4NDA.

153 *See* P. Webster, *FDA escalates enforcement against vapes,* The Lancet, April 23, 2024, at 1434. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(24)00742-6/abstract

blueprint for similar coordinated activity to respond to any emerging market in illicit high-nicotine combustibles.

VII. A Robust Cessation Infrastructure Will Be Important to Maximize Quitting and Thereby Save Lives and Health Care Costs

As discussed previously, implementation of the proposed rule to reduce nicotine levels in all combustible tobacco products to minimally or non-addictive levels will prompt millions of tobacco users to make a quit attempt, with enormous public health benefits if those attempts are successful. To maximize the number of people who are able to quit when the rule is implemented, it will be critically important to significantly enhance cessation infrastructure and resources. HHS should implement a comprehensive effort to provide strong cessation support to tobacco users, building on the 2024 HHS Framework to Support and Accelerate Smoking Cessation. This Framework serves as a good starting point for the development and implementation of a concrete plan designed to help tobacco users quit successfully.

The availability of cessation services should be expanded, and people who smoke should be educated about the existing cessation services that are available. HHS should ensure collaboration and coordination across HHS agencies to develop and implement an action plan to expand coverage of comprehensive tobacco cessation treatment and encourage and promote utilization of this treatment. In addition, we encourage FDA and others to sponsor a broad media and public education campaign to inform the public of the nature of the proposed action, the reasons for it, and the resources available to support tobacco users who want to quit. Accessible and affordable tobacco cessation treatments will help maximize the number of people who respond to the new rule by quitting, rather than switching to an alternative tobacco product.

Some may raise the concern that resources to help tobacco users quit will be insufficient to meet the demand and as a result many tobacco users who want to quit will be left without adequate cessation support. This is not a persuasive argument against the proposed rule; instead, it is an argument that recognizes that the rule will have the beneficial effect of inducing many thousands of tobacco users to make serious attempts to quit. Smoking cessation interventions reduce the likelihood that individuals will develop smoking related diseases and conditions, which ultimately cuts healthcare costs on a system-wide basis.[154] Providing sufficient resources to help tobacco users quit would be an investment that not only saves lives, but reduces overall healthcare spending by preventing chronic illness.

The proposed rule to limit nicotine levels in combusted tobacco products, combined with efforts to expand and encourage use of tobacco cessation treatments, will dramatically increase the number of people who quit smoking and save millions of lives.

---

[154] Smoking Cessation: A Report of the Surgeon General, Ch. 4: The Health Benefits of Smoking Cessation, U.S. DEP'T HEALTH AND HUM. SERVS. (2020), https://www.ncbi.nlm.nih.gov/books/ NBK555590/.

VIII. Conclusion

The proposed product standard, which lowers nicotine in cigarettes and certain other combustible tobacco products to non- or minimally-addictive levels, meets the statutory standard of being "appropriate for the protection of public health." The public health benefits of the proposed rule would be enhanced if expanded to include hookah and heated tobacco products. As described in our comments, there is ample scientific support to require lower nicotine levels in all combustible tobacco products and HTPs.

To summarize:

- Despite great progress in curbing smoking over the past several decades, smoking continues to be the leading cause of preventable death and disease in the United States, as well as exacting an enormous economic toll.
- Reducing the nicotine content of cigarettes and other combustibles will reduce nicotine dependence among people who currently smoke and help millions to quit smoking.
- Reducing the nicotine content of cigarettes and other combustibles will prevent youth from becoming addicted to combusted tobacco products.
- The proposed rule can reduce tobacco-related health disparities.
- The nicotine level set by the proposed rule is appropriate and will not lead to compensatory smoking.
- An immediate nicotine content reduction will yield greater public health benefits than a gradual reduction.
- It is unlikely that the rule will cause the emergence of an illicit market for high-nicotine cigarettes significant enough to nullify the public health benefits of the rule.
- Reducing nicotine in cigarettes is technologically feasible.
- Investing in a robust cessation infrastructure will save lives and be cost-effective.

To strengthen the rule, we recommend FDA:

- Expand the rule to apply to all combustible tobacco products, including cigarettes, cigars and hookah, as well as to heated tobacco products. FDA and other federal partners should sponsor and/or conduct research into the effects of nicotine levels in e-cigarettes and nicotine pouches on sustaining addiction and whether reducing nicotine levels in these products would be desirable from a public health perspective.
- Prohibit any changes in cigarettes and other products covered by the proposed rule that might dilute the reduction in dependence from reducing the nicotine content, including using FDA's regulatory authority to prevent nicotine analogs from undermining the public health benefits of the rule.

- Research how nicotine reduction in other products (e.g., e-cigarettes or nicotine pouches) would reduce the levels of nicotine exposure across the population (from in utero to death).
- Conduct a public education campaign to correct misperceptions about the harms of reduced nicotine products.
- Set the effective date at no later than one year after publication of the final rule.
- Prohibit companies from selling off existing high-nicotine products after the effective date.
- Include a rigorous method of product testing to analyze nicotine levels and ensure compliance.

For these reasons, FDA should finalize a comprehensive rule that will have the intended public health impact as soon as possible.

Respectfully submitted,

Academy of General Dentistry

Action on Smoking & Health

African American Tobacco Control Leadership Council

American Academy of Family Physicians

American Academy of Otolaryngology-Head and Neck Surgery

American Academy of Pediatrics

American Association for Cancer Research

American Association for Dental, Oral, and Craniofacial Research

American Association for Respiratory Care

American Association of Child and Adolescent Psychiatry

American Cancer Society Cancer Action Network

American College Health Association

American College of Cardiology

American College of Chest Physicians

American College of Obstetricians and Gynecologists

American College of Physicians

American Dental Association

American Dental Education Association

American Heart Association

American Indian Cancer Foundation

American Lung Association

American Medical Association

American Medical Women's Association

American Public Health Association

American Society of Addiction Medicine

Americans for Nonsmokers Rights

Asian Pacific Partners for Empowerment, Advocacy and Leadership (APPEAL)

Association for Clinical Oncology (ASCO)

Association of Black Women Physicians

Association of State and Territorial Health Officials

Big Cities Health Coalition

Breathe Southern California

CADCA

Campaign for Tobacco-Free Kids

CATCH Global Foundation

Catholic Health Association of the United States

COPD Foundation

Counter Tools

Dana-Farber Cancer Institute

Emphysema Foundation of America

First Focus on Children

HealthHIV

Kaiser Permanente

Leadership Council for Healthy Communities

NAACP

National Alliance for Hispanic Health

National Association of Pediatric Nurse Practitioners

National Association of School Nurses

National Black Justice Coalition

National Coalition for LGBTQ Health

National Council of Negro Women

National Hispanic Health Foundation

National Hispanic Medical Association (NHMA)

National LGBTQI Cancer Network

National Medical Association

National Network of Public Health Institutes

National Tongan American Society

North American Quitline Consortium

Oncology Nursing Society

Parents Against Vaping

Prevent Cancer Foundation

Preventing Tobacco Addiction Foundation/Tobacco 21

Preventive Cardiovascular Nurses Association

Public Health Law Center

Public Health Solutions

Respiratory Health Association

Right 2 Breathe

Society for Cardiovascular Angiography & Interventions

Society for Public Health Education

Society for Research on Nicotine & Tobacco

The Cancer Network

The Center for Black Health and Equity

The Society of Thoracic Surgeons

Tobacco Free Portfolios

Trust for America's Health

Truth Initiative

WomenHeart: The National Coalition for Women with Heart Disease