



January 27, 2025

U.S. Department of Health and Human Services
Food and Drug Administration

Re: Comment on FDA Proposed Tobacco Product Standard For Nicotine Yield Of Cigarettes and Certain Other Combusted Tobacco Products

Document Number: 2025-00397

Docket Number: FDA-2024-N-5471

RIN 0910-AI76

To Whom it May Concern:

My name is Jeffrey A. Singer. I am a Senior Fellow in Health Policy Studies at the Cato Institute. I am also a medical doctor specializing in general surgery and have been practicing that specialty in Phoenix, Arizona for over 35 years. The Cato Institute is a 501(c)(3) non-partisan, non-profit, tax-exempt educational foundation dedicated to the principles of individual liberty, limited government, free markets, and peace. Cato scholars conduct independent research on a wide range of policy issues. To maintain its independence, the Cato Institute accepts no government funding. Cato receives approximately 80 percent of its funding through tax-deductible contributions from individuals. The remainder of its support comes from foundations, corporations, and the sale of books and other publications. The Cato Institute does not take positions on legislation.

I would like to thank the FDA for providing me the opportunity to comment on the proposed tobacco product standard that would regulate nicotine yield by establishing a maximum nicotine level in cigarettes and other combusted tobacco products. I appreciate this opportunity to provide my perspective as a health care practitioner and policy analyst.

Nicotine is the addictive component of cigarettes, but by itself is relatively harmless.¹ The harm comes from carbon monoxide, a poisonous gas, and tobacco tar that contains carcinogens and other chemicals that harm the lungs and circulatory system. Britain's Royal Society for Public Health claims nicotine is "no more harmful than caffeine."² One of the characteristics differentiating nicotine from caffeine is that nicotine has both calming and stimulative effects.³

Tobacco cigarettes are a type of nicotine delivery system. While some smokers may enjoy the flavor of tobacco and the act of smoking, many primarily smoke for the effects of nicotine.

The rationale behind ordering cigarette makers to reduce the nicotine content of tobacco cigarettes is that it might nudge smokers to abandon smoking. In 2018, FDA researchers reported in the *New England Journal of Medicine* that they used a simulation model to suggest that reducing the nicotine content of tobacco cigarettes by 95 percent could lower the percentage of adult smokers to 1.4 percent by the year 2100.⁴ For perspective, 11 percent of adults reported cigarette smoking in 2023.⁵ The study is largely based on estimates made by eight academics using a mathematical model to guess what will happen if the policy is enacted.

Yet, one randomized controlled study—not mathematical modeling— of the efficacy of reducing nicotine content found, “In smokers not interested in quitting, reducing the nicotine content in cigarettes over 12 months does not appear to result in extinction of nicotine dependence, assessed by persistently reduced nicotine intake or quitting smoking over the subsequent 12 months.”⁶

Furthermore, some researchers have found that reducing the nicotine content of cigarettes may lead to a compensatory increase in cigarette consumption or increased puff volume to attain the desired nicotine effect.⁷ One team of researchers reported in the peer-reviewed journal *Drug and Alcohol Dependence* on the results of a novel “within-subject human laboratory study” that found “both total puff volume and CO boost per cigarette increased when cigarette nicotine level decreased, although the effect was modest. Subjective ratings of cigarette strength and satisfaction were significantly lower for the lower-nicotine cigarettes.”⁸

It is essential to point out that the proposed reduction of nicotine content to 0.7 mg of nicotine/gram of filler has no basis in scientific evidence and has never been tried in any other country or jurisdiction. It amounts to a 97 percent reduction in the nicotine content of the average cigarette. (Conventional cigarettes have 16.2 to 26.3 mg of nicotine/gram of filler.)

This effectively bans nicotine from cigarettes and amounts to de facto tobacco cigarette and cigar prohibition. It is reminiscent of the Volstead Act of 1919 (alcohol prohibition), which banned the production, sale, transportation, and possession of all products with greater than 0.5% alcohol. If the FDA follows through with the rule change after the comment period, the nicotine ban will likely have similar effects and consequences.

An effective cigarette ban is likely to ignite a robust black market in nicotine-containing cigarettes. In 2010, Bhutan became the first country to ban the sale of all tobacco products. This generated a robust underground tobacco market, with many tobacco products coming in clandestinely from India. By 2017, Bhutan had a 24.6 percent smoking rate, the highest in Southeast Asia, and 29.3 percent of Bhutanese adolescents smoked.⁹ In 2021, with smuggling of black-market tobacco rampant and no significant drop in the smoking rate during the 11 years since the government had imposed the ban, the government ended tobacco prohibition, opting instead to tax and regulate tobacco sales.¹⁰ Bhutanese policymakers also cited concerns that cross-border tobacco trafficking might increase the risk of spreading the COVID-19 virus amid the coronavirus pandemic.

Enacting what amounts to de facto tobacco prohibition will enrich underworld criminal organizations, including the drug cartels, which already have effective distribution networks in place. Expect this also to cause violent crime and corruption of law enforcement and other government officials that often attend prohibition. Unfortunately, it may also further exacerbate racial disparities in criminal justice outcomes.

Prohibition fuels an underground market where peaceful, voluntary transactions become crimes. It gives law enforcement another reason to interact with non-violent people who commit these victimless crimes. Like everyone else, police respond to incentives. Arrests and convictions reward them. Low-level street dealers in illegal substances are “low-hanging fruit.” They are much easier to find in dense inner cities and less dangerous to confront than violent felons. Law enforcement tends to scour racial or ethnic minority communities for victimless crimes because they are “easy pickings.” That’s how we wind up with African Americans

arrested for marijuana violations four times as often as whites, even though both ethnicities use marijuana roughly equally.

Consider New York City's flirtation with cigarette prohibition by taxing packaged cigarettes at exorbitantly high levels, aiming to discourage smokers from buying them. This ignited a robust black market for individual unpackaged cigarettes, called "loosies." In 2014, police infamously encountered 43-year-old Eric Garner selling loosies on a street corner, and a policeman's chokehold led to his death as he repeated, "I can't breathe."

New York City didn't wholly ban cigarettes. It merely made the cost of smoking prohibitive for many of its residents. The proposed nicotine reduction rule would be more comprehensive and would effectively mean nationwide tobacco prohibition.

The best approach to take toward tobacco smoking is harm reduction. Nicotine e-cigarettes, especially the flavored ones, are a proven way to reduce tobacco's harm for those who like the feeling of smoking and the "kick" of nicotine. Over 90 percent of adults trying to quit combustible tobacco prefer flavored e-cigarettes, including menthol.¹¹ Nicotine pouches are another safe and effective way for people to obtain their nicotine while avoiding the toxic and carcinogenic components of combusted tobacco.¹²

The FDA recently withdrew its proposal to ban menthol cigarettes and flavored cigars after civil liberties organizations warned it could create a black market and exacerbate racial disparities in law enforcement.¹³ For the same reasons, the FDA should reconsider its proposed nicotine cap on tobacco products, which risks triggering similar unintended consequences.

Respectfully submitted,

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- ¹ <https://www.nhsinform.scot/healthy-living/stopping-smoking/reasons-to-stop/tobacco/>
 - ² <https://www.rsph.org.uk/about-us/news/nicotine--no-more-harmful-to-health-than-caffeine-.html>
 - ³ <https://www.cato.org/blog/what-causing-nicotinophobia>
 - ⁴ <https://www.nejm.org/doi/full/10.1056/NEJMs1714617>
 - ⁵ <https://www.lung.org/research/trends-in-lung-disease/tobacco-trends-brief/overall-smoking-trends>
 - ⁶ <https://pubmed.ncbi.nlm.nih.gov/articles/PMC4565734/>
 - ⁷ https://cancercontrol.cancer.gov/sites/default/files/2020-08/m07_12.pdf
 - ⁸ <https://www.sciencedirect.com/science/article/abs/pii/S0376871606002791>
 - ⁹ <https://kuenselonline.com/bhutan-tops-tobacco-and-marijuana-users-in-south-east-asia/>
 - ¹⁰ <https://blogs.bmj.com/tc/2023/02/01/bhutan-reverses-sales-ban-on-tobacco/>
 - ¹¹ https://www.dropbox.com/s/b8uwoxay6i2fzb2/Docket%20No.%20FDA-2017-N-6565_FARSALINOS.pdf
 - ¹² <https://www.cato.org/commentary/why-attack-tobacco-harm-reduction>
 - ¹³ <https://www.cato.org/blog/breathe-fresh-air-trumps-fda-takes-step-back-menthol-ban>