



August 11, 2025

Dockets Management Staff
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. FDA-2024-N-5471 (Tobacco Product Standard for Yield of Cigarettes and Certain Other Combusted Tobacco Products)

Dear Food and Drug Administration Staff:

I write today as the President and CEO of the Convenience Distribution Association. CDA is the national trade organization working on behalf of convenience products distributors in the United States. The convenience distribution sector represents more than \$100 billion in U.S. convenience product sales, serving a wide variety of small retail formats. Convenience distributors directly employ nearly 59,000 people and support over 173,000 jobs annually. The convenience distribution sector contributes billions in economic activity throughout the U.S. economy including \$30 billion in tobacco excise taxes, and \$2.3 billion in tax revenue for federal, state and local governments.

The proposed rule titled "Tobacco Product Standard for Yield of Cigarettes and Certain Other Combusted Tobacco Products" would set a maximum nicotine content level of 0.70 milligrams of nicotine per gram of tobacco in cigarettes, roll-your-own cigarette tobacco, cigars (excluding premium cigars), and pipe tobacco. As the FDA states in the proposed rule, the average "nicotine content of the top 100 cigarette brands for 2017 is 17.2 milligrams per gram of total tobacco."¹ The FDA's proposed nicotine cap of 0.70 milligrams per gram of tobacco means an average reduction of 92% to 95% in the nicotine levels of cigarettes currently on the market. Since only two FDA authorized brands of cigarettes currently on the market meet the proposed maximum nicotine content, the FDA's own analysis found that these two cigarette brands comprise "less than 0.001 percent of total cigarette dollar sales."² If adopted, this regulation would prohibit the legal sale of 99.999% of all currently constituted cigarettes sold in the U.S.

CDA strongly opposes the adoption of the proposed rule mandating maximum nicotine levels in the impacted tobacco products. This opposition is based on the fact that the rates of adult

¹ Carmines, E., and I.E. Gillman. "Comparison of the Yield of Very Low Nicotine Content Cigarettes to the Top 100 United States Brand Styles." *Contributions to Tobacco & Nicotine Research*, 28(6):253-266, 2019.

² Food and Drug Administration, *Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products*, January 6, 2025, P. 70.

and youth use of cigarettes, roll-your-own tobacco, cigars, and pipe tobacco are at all-time lows, a nationwide illicit market will result when entities seize the opportunity to produce and supply U.S. adults with tobacco products that contain conventional levels of nicotine, and the negative economic impact to federal and state governments, manufacturers, distributors, and retailers will be significant.

Historically Low Tobacco Use Rates

Current all-time low usage rates of cigarettes and tobacco products by both adults and youth do not support the adoption of the proposed rule. The most recent data summarized below demonstrates that tobacco use rates continue to decline and are at historic lows:

- 11.6% of U.S. adults currently smoke cigarettes.³
- 1.7% of high school students smoke cigarettes.⁴
- 3.7% of U.S. adults smoke any type of cigar.⁵
- 1.5% of high school students smoke a cigar.⁶
- 0.9% of U.S. adults smoke pipe tobacco.⁷
- 0.5% of high school students smoke pipe tobacco.⁸

These very low usage rates do not justify requiring a nicotine content standard that would impact the entirety of the domestic cigarette market, a substantial portion of the cigar market, and the whole pipe tobacco market. Rather, the FDA should focus its regulatory efforts on completing the review of pending Pre-Market Tobacco Applications (PMTAs) and work toward authorizing potentially lower risk products that contain nicotine to assist adults transition to non-combustible products.

Illicit Market

The size of the market for traditional tobacco products will result in illegal manufacturing and distribution entities seizing an opportunity to produce and supply U.S. adults with illicit, higher nicotine content cigarettes, cigars, and pipe tobacco. Specifically, annual retail cigarette sales total \$82.6 billion dollars,⁹ cigar sales amount to an additional \$14 billion,¹⁰ and pipe tobacco sales constitute an extra \$1.65 billion.¹¹ The maturity and extensiveness of the combined U.S. cigarette, cigar, and pipe tobacco markets, combined with a continued preference by adult consumers for tobacco products with higher nicotine content, will incentivize criminal

³ Centers for Disease Control, *Burden of Cigarette Use in the U.S.*, 2022.

⁴ National Youth Tobacco Survey (NYTS) 2024.

⁵ National Health Interview Survey (NHIS) 2022.

⁶ *Id.* NYTS.

⁷ *Id.* NHIS.

⁸ *Id.* NYTS.

⁹ Statista, <https://www.statista.com/outlook/cmo/tobacco-products/cigarettes/united-states>, 2025.

¹⁰ Statista, <https://www.statista.com/outlook/cmo/tobacco-products/cigars/united-states>, 2025.

¹¹ Verified Market Research, <https://www.verifiedmarketresearch.com/product/united-states-pipe-tobacco-market/>, 2024.

elements to supply this on-going demand with illegal tobacco products that contain higher nicotine levels. The result will be a significant undermining of the agency's claimed health benefits from the nicotine content product standard.

An illicit market in unauthorized electronic cigarettes already exists in the U.S. and the federal government is struggling to control massive imports from illegal vapor products, most of which originate from China. In fact, the illicit vapor market is so difficult to bring under control that on June 10, 2024, the FDA and the U.S. Department of Justice announced "the creation of a federal multi-agency task force to combat the illegal distribution and sale of e-cigarettes."¹² With cigarettes, cigars, and pipe tobacco constituting a much more established and higher value market than e-cigarettes, a thriving illicit marketplace in these products is virtually guaranteed.

The impact of a widespread illicit market will be severalfold. First, illegal cigarettes may pose additional potential health and safety concerns because such products are unlikely to comply with the current federal regulatory standards. Second, higher levels of illegal activity would result in greater local, state, and federal government law enforcement expenditures to respond to and combat such activity. Third, illegal cigarettes would circumvent collection of federal and state cigarette and tobacco excise taxes, which, in turn, could have a devastating impact not only on the federal funding of the State Children's Health Insurance Program (SCHIP), but also state general funds. Fourth, sales made through the illicit marketplace will serve as a ready source for youth because such sellers will sell to anyone with cash.

Negative Economic Impact

An economic impact study was commissioned in 2024 by the National Association of Tobacco Outlets (NATO), a national retail trade association.¹³ This study focused on an FDA proposed maximum level of nicotine in cigarettes and utilized 2023 cigarette-related sales data. Since the study did not include an analysis of a proposed maximum level of nicotine in cigars and pipe tobacco, the economic impact would be greater than the findings of the NATO study.

The findings and conclusions of the NATO study are as follows:

- Demand for cigarettes with no more than 0.70 milligrams of nicotine per gram of tobacco may only reach approximately 6% of current legal cigarette sales volume due to adults switching to or substituting other tobacco products, a widespread illicit market, and a reduction in cigarette smoking rates as a result of quitting smoking.

¹² Food and Drug Administration, Press Release, "Justice Department and FDA Announce Federal Multi-Agency Task Force to Curb the Distribution and Sale of Illegal E-Cigarettes," June 10, 2024, <https://www.fda.gov/news-events/press-announcements/justice-department-and-fda-announce-federal-multi-agency-task-force-curb-distribution-and-sale>.

¹³ National Association of Tobacco Outlets, 2024, <https://www.natocentral.org/uploads/economic-reports/Full%20Economic%20Impact%20Report%20with%20Appendix%203.pdf>.

- \$71.4 billion reduction in cigarette sales volume and ancillary.
- \$8 billion in lower federal excise tax collections.
- \$11.8 billion in lower state and local excise tax collections.
- \$3.2 billion in decreased state sales tax collections.
- \$1.1 billion reduced local sales tax collections.
- \$5.6 billion in lower Master Settlement Agreement payments to states.
- \$30.6 billion in lower total economic output impact (direct, indirect and induced).
- 154,478 estimated total job losses.

The significant decrease in cigarette, cigar and pipe tobacco sales by retailers will cause reciprocal upstream impacts on distributors. That is, law-abiding distributors will be confronted with billions of dollars in reduced tobacco sales, lost profits, and employee layoffs.

CONCLUSION

The proposed product standard setting a maximum nicotine level in cigarettes, roll-your-own tobacco, cigars, and pipe tobacco is ill-advised. The rule's impact will be diminished due to historically low and declining adult and youth tobacco use rates. Moreover, the size of the market for these tobacco products in terms of dollar sales will virtually ensure that an illicit market will expand to meet the ongoing demand for tobacco products with higher levels of nicotine. This expansion of an illicit market will seriously undermine the FDA's claimed beneficial health impacts of the proposed rule. Finally, the regulation would result in severe negative economic consequences in the form of lost excise tax and sales tax revenue, reduced Master Settlement Agreement payments to states, declines in overall economic output, and upwards of 154,000 jobs lost.

I urge the FDA to redirect its efforts to focus on expeditiously completing pending PMTA harm reduction product application reviews, authorizing additional tobacco products to provide adults with more non-combustible tobacco product choices, increasing tobacco use cessation support, and concentrating more resources on underage tobacco use prevention rather than prohibiting legal products distributed within a highly regulated system.

Sincerely,



President and CEO
Convenience Distribution Association