



August 20, 2025

Submitted via www.regulations.gov

Dr. Marty Makary, M.D., M.P.H.

Dockets Management Staff (HFA-305)

U.S. Food and Drug Administration Center for Tobacco Products

5630 Fishers Lane, Room 1061

Rockville, Maryland 20852

Re: Docket No. FDA-2024-N-5471 (90 Fed. Reg. 5032, January 15, 2025) – Comments on “Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products” (the “Proposed Rule”)

Dear Dr. Makary:

The Energy Marketers Association (EMA), along with 48 state and regional energy marketing trade associations representing tens of thousands of small business convenience store owners, respectfully voice our strong opposition to the Proposed Rule. The Proposed Rule, which seeks to reduce nicotine levels in cigarettes and machine-made cigars to a maximum of 0.70 milligrams per gram of tobacco, would effectively ban nearly all commercially available products in these categories. If promulgated as proposed, the rule is not only impractical and unsupported by evidence, but it is also illegal under federal law and detrimental to public health, the economy, and regulated markets.

Energy marketers represent a vital link in the motor fuels distribution chain. EMA members supply 80 percent of all finished motor fuel products sold nationwide, including renewable hydrocarbon biofuels, gasoline, diesel fuels, biofuels, jet fuel, kerosene, racing fuel, and lubricating oils. EMA member companies also market tobacco products at convenience stores throughout the nation and at kiosks located adjacent to the pumps at their gasoline service stations. The sale of tobacco products is an important component of their businesses, and their interests align with those of FDA in promoting protective measures aimed at eliminating unlawful sales to minors. The vast majority of these energy marketers qualify as small businesses under U.S. Small Business Administration size categories for both wholesale and retail entities. As a result, these small businesses thrive when they have a level playing field, allowing them to compete with larger businesses, while also being freed of competing against illicit sales when tobacco products are over regulated.

The Family Smoking Prevention and Tobacco Control Act (TCA) explicitly prohibits FDA from banning cigarettes or reducing their nicotine levels to zero, including actions that would have equivalent effects. The Proposed Rule violates these statutory provisions by effectively eliminating consumer-acceptable cigarettes, as very low nicotine cigarettes have been widely rejected by adult tobacco consumers and

may not be feasible to produce at scale. According to the CDC's 2024 National Youth Tobacco Survey, smoking rates in the United States are already at historic lows, with youth smoking (middle and high school students) at 1.4% overall, and high school cigarette smoking down to 1.7%—a 95% decline since its peak in the mid-1990s.¹

In the Proposed Rule, FDA ignores ample data showing the existence of a robust and growing illicit market for tobacco products and woefully underestimates the ways in which the Proposed Rule will expand it. In reality, FDA is already struggling to contain the growing illicit market in e-vapor products. Since 2020, the U.S. has been flooded with e-vapor products made primarily by Chinese tobacco companies that have entirely ignored FDA regulatory authority – reaching over half of the ~20 million adult vapor consumers with products lacking any FDA oversight. These illicit products have grown by over 300% in just the past four years – evading import controls and enforcement to make their way across our borders and into the hands of children.²

Responsible retailers play a critical role in the legal tobacco market, verifying age, selling only FDA-regulated products, adhering to marketing restrictions, and paying required taxes. Further reductions in smoking rates can be achieved through public education and increased access to reduced-risk alternatives, such as e-cigarettes and nicotine pouches, rather than prohibitionist measures. The Proposed Rule, if promulgated as proposed, would destabilize the tobacco supply chain, causing irreparable harm to farmers, manufacturers, distributors, retailers, and state and local economies. A December 2024 Tax Foundation study estimates that the Proposed Rule would reduce legal cigarette sales by 90%, costing governments approximately \$33 billion annually in tax revenue from a current total of over \$37 billion.³

Furthermore, banning tobacco products could also have a cascading effect on fuel marketing companies who supply fuel to independently-owned and operated small business gas stations. Gas station owners may be unable to pay for their next fuel delivery due to the potential major revenue loss from a tobacco ban, which could potentially lead to motor fuel supply issues and higher prices at the pump.

Additionally, a National Association of Tobacco Outlets (NATO) report commissioned from Chmura Economics & Analytics, dated December 12, 2024, projects the loss of 154,478 total jobs (including direct, indirect, and induced impacts) and approximately \$21.7 billion in annual revenue losses for state and local governments, encompassing excise taxes, sales taxes, and Master Settlement Agreement payments.⁴

¹ [Youth Cigarette Smoking Rate Hits 25 Year Low, But 2.25 Million Youth Still Use Tobacco Products](#)

² Park-Lee E, Jamal A, Cowan H, et al. Notes from the Field: E-Cigarette and Nicotine Pouch Use Among Middle and High School Students — United States, 2024. MMWR Morb Mortal Wkly Rep 2024;73:774–778.
DOI: <http://dx.doi.org/10.15585/mmwr.mm7335a3>.

³ [FDA's Proposed Cigarette Prohibition Would Cost \\$33 Billion in Annual Tax Revenue](#)

⁴ [White Paper Report Economic Impact of Proposed FDA Nicotine Limit on Cigarettes](#)

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Moreover, the Proposed Rule, if finalized, would fuel illicit markets, encouraging illegal production, importation, and unregulated sales. As noted by Rich Marianos, former assistant director of the U.S. Bureau of Alcohol, Tobacco, Firearms and Explosives, the Proposed Rule would be "a gift with a bow and balloons to organized crime cartels with it, whether it's cartels, Chinese organized crime, or Russian mafia. It's going to keep America smoking, and it's going to make the streets more violent."⁵

We urge FDA to withdraw the Proposed Rule and instead adopt a Tobacco Harm Reduction policy that prevents underage use, supports adult choice, and maintains a legal, regulated market. This approach would build on the success of responsible retailers and protect public health without destabilizing economies or fostering criminal activity.

Thank you for considering our concerns. We request the opportunity to engage further on this matter and urge FDA to prioritize evidence-based, practical solutions over prohibitionist measures.

Sincerely,

A handwritten signature in black ink, appearing to read "Rob Underwood", is enclosed in a thin black rectangular border.

Rob Underwood
President
Energy Marketers of America

⁵ [Biden admin working to effectively ban cigarettes in 11th hour proposal a 'gift' to cartels, expert says](#)