Docket No. FDA-2024-N-5471

COMMENTS

of

WASHINGTON LEGAL FOUNDATION

to the

FOOD AND DRUG ADMINISTRATION

Concerning

REQUEST FOR WITHDRAWAL OF "TOBACCO PRODUCT STANDARD FOR NICOTINE YIELD OF CIGARETTES AND CERTAIN OTHER COMBUSTED TOBACCO PRODUCTS"

IN RESPONSE TO THE PROPOSED RULES PUBLISHED AT 90 FED. REG. 5,032 ON JANUARY 16, 2025

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Food and Drug Administration
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Re: Docket No. FDA-2024-N-5471 (90 Fed. Reg. 5,032, January 16, 2025) – Request for Withdrawal of "Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products"

Washington Legal Foundation (WLF) appreciates the opportunity to submit these comments on the U.S. Food and Drug Administration's (FDA) proposed "Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products" (Proposed Rule).[1]

Founded in 1977, WLF is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF often appears before federal courts and administrative agencies to promote free enterprise, individual liberty, a limited government, and the rule of law. To that end, WLF regularly participates in FDA administrative proceedings to encourage the agency to adhere to statutory requirements and to avoid imposing unnecessary burdens on the regulated community and consumers.[2]

President Donald J. Trump's January 20, 2025 memorandum empowered agencies to evaluate whether any non-final rule or proposed rule published by the prior Administration in the Federal Register raises a question of "law, fact, or policy" sufficient to warrant withdrawal.[3] Pursuant to the memorandum, WLF requests that FDA withdraw the Proposed Rule on the Standard for Nicotine Yield.

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[1] Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products, 90 Fed. Reg. 5,032 (Jan. 16, 2025).

[2] *See*, *e.g.*, Docket No. FDA-2021-N-1309 and 2021-N-1349 (filed July 6, 2022) (ban on flavored cigars and menthol cigarettes); Docket No. FDA-2019-N-3065 (filed Oct. 15, 2019) (graphic warnings on cigarette packaging); Docket No. FDA-2009-N-0294 (filed Sept. 29, 2009) (modified-risk tobacco products).

[3] Regulatory Freeze Pending Review, 90 Fed. Reg. 8,249 (Jan. 28, 2025).

The Proposed Rule raises questions of law and policy sufficient to warrant withdrawal. The proposal is contrary to the Family Smoking Prevention and Tobacco Control Act (TCA). Its enforcement will effectively ban categories of tobacco products. In addition, the proposal utilizes a product standard that is not in the interests of public health. The Proposed Rule is also profoundly ill-advised as a matter of public policy. Instead of utilizing regulation of *legal* products as a means to improve public health as the TCA directs, FDA proposes to *prohibit* the sale of two groups of products, conventional cigarettes and machine-made cigars, with a retail value of over $80 billion that consumers purchase in large part because of the nicotine. A massive black market will develop to meet consumer demand accompanied by the illegal activity that invariably follows product prohibition.

I. The Proposed Standard for Nicotine Yield Raises Significant Questions of Law

Through the TCA, Congress granted FDA the power to regulate tobacco products. Congress could not have been clearer about the future it envisioned. The point of FDA regulation was *not* to ban products, but rather to use science-based regulation of a *legal marketplace* to achieve better public-health outcomes, including reducing underage use, protecting adult consumers, and expanding adult consumer access to proven reduced-harm alternatives, all with the singular goal of ending tobacco-related harm.

Central to the debate over the Act was the scientific consensus that it is smoke, not nicotine, that causes all or almost all tobacco-related death and disease.[4] The Act devoted an entire section to new regulatory pathways for reduced-harm products and provided FDA all the resources necessary to put these pathways into effect for the benefit of adult consumers.[5] The idea was for cigarette smoking to be displaced by market-driven demand for less harmful options.

Congress also told FDA what *not* to do. The Act repeatedly directs the Agency *away* from prohibition-based interventions. It prohibits FDA from banning any category of tobacco products, including cigarettes.[6] It expressly prohibits FDA from reducing nicotine levels to zero.[7] And it clearly instructs FDA not to use product standards as a back-door method of implementing Prohibition. That is not what the Proposed Rule does, however. It sets nicotine limits at levels so low that no

[4] Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction. Institute of Medicine Committee to Assess the Science Base for Tobacco Harm Reduction. National Academies Press. 2001.

[5] Family Smoking Prevention and Tobacco Control Act § 910.

[6] *Id*. § 907(d)(3)(A).

[7] *Id*. § 907(d)(3)(B).

conventional cigarette or machine-made cigar on the market today can meet it, and at levels expressly intended to make legal products unacceptable to adult consumers.

Section 907 of the Act specifies that FDA may establish a tobacco product standard only if it finds such action is "appropriate for the protection of the public health."[8] But in making this determination, FDA must consider "scientific evidence concerning: (1) the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard; (2) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (3) the increased or decreased likelihood that those who do not use tobacco products will start using such products."[9] At a minimum, the Agency must consider the negative public-health ramifications of pushing cigarette consumers who find near-zero-nicotine choices unpalatable to instead purchasing from an unregulated black market.

Illicit tobacco markets are much more dangerous from a public health perspective than regulated markets of lawful products. By passing the TCA, Congress institutionalized the notion that FDA oversight of tobacco manufacturers, distributors, and retailers is *essential* to protect public health. That is why Congress imposed extensive requirements on regulated entities selling legal products, with a focus on underage prevention, marketing practices, manufacturing practices, reviews of product design, ingredient disclosures, and post-marketing surveillance. None of those requirements bind actors in illicit markets. The harms Congress envisioned with illicit markets are illustrated vividly in other contexts, including the EVALI outbreak of 2019 that resulted in scores of deaths and hundreds of injuries from illegal, unregulated cannabis vapor products made without any regulatory oversight.[10]

Congress also expressly required FDA to filter out any proposed product standard that risks illicit market effects typical of prohibition-based policies. Under Section 907, FDA may not propose a product standard without first considering "all

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[8] *Id*. § 907(a)(3)(A).

[9] *Id*. § 907(a)(3)(B)(i).

[10] Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products, Centers for Disease Control and Prevention. Last updated Feb. 25, 2020, https://perma.cc/68WR-ULHQ ("National and state data from patient reports and product sample testing show tetrahydrocannabinol (THC)-containing e-cigarette, or vaping, products, particularly from informal sources like friends, family, or in-person or online dealers, are linked to most EVALI cases and play a major role in the outbreak."); Statement on consumer warning to stop using THC vaping products amid ongoing investigation into lung illnesses, FDA News Release, Oct. 4, 2019, https://www.fda.gov/news-events/press-announcements/statement-consumer-warning-stop-using-thc-vaping-products-amid-ongoing-investigation-lung-illnesses ("[W]e're strengthening our message to the public in an updated consumer alert stating that they should not use vaping products containing tetrahydrocannabinol (THC), the primary psychoactive component of the cannabis plant. Additionally, consumers who choose to use any vaping products should not modify or add any substances such as THC or other oils to products purchased in stores and should not purchase any vaping products, including those containing THC, off the street or from other illicit channels.").

other information submitted in connection with a proposed standard, including information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or non-tobacco users, *such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter and the significance of such demand*."[11] As this comment will discuss below, FDA has failed to fully evaluate the negative market impacts of the Proposed Rule.

In addition to raising serious questions about compliance with the Tobacco Control Act, the Proposed Rule is unlikely to survive a legal challenge under the Administrative Procedure Act (APA). The APA requires the Agency to, among other things, engage in "reasoned decision-making."[12] FDA's consideration of the Proposed Rule's adverse impacts on the tobacco market, public health, and the economy, were at best cursory and thus do not meet the high standard courts impose for decision-making under the APA.

II. The Proposed Standard for Nicotine Yield Raises Significant Questions of Policy

An Agency rooted in objectivity and science would evaluate a prohibition-based rule like this by forthrightly acknowledging the risks of illicit markets. Here, the Proposed Rule would effectively ban the legal sale of all conventional cigarettes and machine-made cigars. The wisdom of such a policy can be judged against numerous present and past developments in tobacco control, most prominently FDA's ongoing experience with the illicit market that emerged after the Agency rejected nearly 100% of market-access applications for e-cigarettes. FDA could also look to States' experiences with the prohibition of flavored e-cigarettes and menthol conventional cigarettes, as well as market reactions to tobacco tax increases.

But rather than neutrally evaluate this risk, FDA chose to act as if this ban would be implemented in some idealized world not subject to the normal rules of marketplace behavior and uninformed by history. In a Proposed Rule spanning hundreds of pages, the Agency devotes just over *two pages* to the issue, claiming without any sound factual foundation that it is "unlikely" that a significant illicit market will develop.[13]

Flavored vapes: An illicit market of FDA's own making. The Proposed Rule does not mention that FDA is currently beset by a *mass-scale black-market crisis in e-cigarettes* following years of supply-side restrictions on legal access to these products.

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[11] *Id*. § 907(b)(2).

[12] *Judulang v. Holder*, 565 U.S. 42, 53 (2011) (under the APA, "courts retain a role, and an important one, in ensuring that agencies have engaged in reasoned decisionmaking").

[13] Proposed Rule, 90 Fed. Reg at 5101-03.

As Congress had hoped to facilitate with its passage of the Tobacco Control Act, millions of adult consumers have been migrating away from cigarettes to proven reduced-harm alternatives like e-cigarettes, a trend that has accelerated reductions in cigarette smoking in recent years. But rather than assist this positive trend by authorizing legal products these consumers seek, for the past four years FDA did the opposite: rejecting nearly 100% of the product applications it reviewed and clearing only a tiny fraction of mostly non-flavored vapor products for 18 million adult consumers.[14]

As a result of FDA's de-facto prohibition of flavored e-cigarettes, "a wave of illicit and unregulated vapes from China flooded in to satisfy consumer demand."[15] These products, made available both in the underground market and publicly at specialty shops, have been subject to no factory inspections, no manufacturer registrations, no ingredients disclosures, no review of product designs, and no post-marketing surveillance.[16] Chinese companies have consistently found ways around federal, state, and local officials' efforts to disrupt the supply chain. For example, in 2024, U.S. customs officials began seizing Elf Bar and EBDesign e-cigarettes at the border. The manufacturer "simply continued importing its products to the U.S.—just under a new brand called EBCreate."[17]

One can understand, though certainly not excuse, FDA's conscious indifference to the rapid development of an illicit e-cigarette market when contemplating the potential reaction to the Proposed Rule. It's only logical that if an illicit market emerged so swiftly after FDA's de-facto ban on flavored vapes, an even *bigger* illicit market response will occur with a virtual ban on the even *larger* category of conventional cigarettes. But the agency cannot escape the facts.

Developments in the flavored-vape illicit market directly contradict several statement in the Proposed Rule's analysis of whether an illegal market for conventional cigarettes and machine-made cigars could emerge:

- FDA asserts, "Moreover, importation across international borders is substantially more difficult than across State borders, particularly for the volume necessary to sustain nicotine

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[14] *See* Tobacco Product Applications: Metrics & Reporting. FDA, https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-applications-metrics-reporting.

[15] Gus Bentley, *Biden's cigarette ban will enrich the Chinese Communist Party*, Reason.com, Jan. 17, 2025, https://perma.cc/W475-3X4X.

[16] Peronne, Matthew. *Thousands of unauthorized vapes are pouring into the US despite the FDA crackdown on fruity flavors.* Associated Press, June 26, 2023, https://apnews.com/article/fda-vapes-vaping-elf-bar-juul-80b2680a874d89b8d651c5e909e39e8f.

[17] Louise Matsakis, *The US Is Being Flooded by Chinese Vapes*, Wired, June 25, 2024, https://perma.cc/EG7A-Z6VA.

addiction in people who smoke."[18] In fact, foreign exports of unapproved flavored vapes have entered the U.S. through ports of entry, and, as noted above, when faced with resistance, foreign exporters have made strategic adjustments.

- FDA also states, "…convenient and consistent access to an illicit market would be needed, which is highly unlikely."[19] In fact, today, illicit e-vapor products are abundantly available to adult consumers, so much so that they comprise more than 60% of what 18 million vapor consumers buy, including in stores within a short walk of FDA's Maryland headquarters.[20]

State bans on menthol cigarettes or other flavored tobacco products. FDA also ignores the lessons of state prohibition of certain tobacco products. Massachusetts was the first State to ban the sale of all flavored tobacco products, including e-cigarettes. Its law included a ban on menthol cigarettes, but the State's own data shows menthol smoking rates among adults in Massachusetts remained virtually unchanged, with 36.9% of adult smokers reporting menthol cigarette use in 2022 as compared to 37.5% in 2019.[21] Less than two years after the flavored tobacco ban was enacted, the Massachusetts Department of Revenue's Illegal Tobacco Task Force ("Task Force") said that it "…now identifies cross-border smuggling of untaxed flavored ENDS products, cigars, and menthol cigarettes as the primary challenge for tobacco enforcement in the Commonwealth."[22] The agency also reported that it had seized such an overwhelming amount of illicit tobacco products that it ran out of storage space.[23] The most recent statistics, provided by *Tobacco Insider*, report that in 2024, illegal e-cigarette seizures in Massachusetts "exploded by 744% to reach 308,100 units."[24]

California is another state where a vigorous black market for tobacco products developed in the aftermath of measures prohibiting the sale of flavored conventional

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[18] 90 Fed. Reg. at 5,102.

[19] *Id.* at 5,082, n.31.

[20] *See* Matthew Peronne, *Senators blast health and law enforcement officials over illegal e-cigarettes used by teens.* Associated Press, June 12, 2024, https://apnews.com/article/ecigarettes-fda-doj-elf-bar-congress-17d3cbfdc87b16f530703b5252c31156; U.S. Senate Committee on the Judiciary. *Combatting the Youth Vaping Epidemic by Enhancing Enforcement Against Illegal E-Cigarettes*, *Full Committee Hearing* [Recording]. June 12, 2024, https://perma.cc/7ZNZ-WWEH (00:32:30-00:33:25).

[21] Rick Sobey, *Big menthol bust in Boston is 'only the tip of the iceberg' in Massachusetts, group says*, Boston Herald, Jan. 10, 2025, https://perma.cc/FX4N-VEGT

[22] *Annual Report of Multi-Agency Illegal Tobacco Task Force*. March 1, 2022. Commonwealth of Massachusetts at 9, https://www.mass.gov/doc/task-force-fy22-annual-report/download.

[23] *Id*. at 15.

[24] Tobacco Insider, *USA: Illegal Vapes*, Mar. 13, 2025, https://perma.cc/SZ4N-CDCZ.

cigarettes, e-cigarettes, and cigars. Foreign-produced flavored e-cigarettes are widely available in specialty retail stores, even in localities that had banned such products before the statewide ban took effect. One news investigation discovered that not only were flavored e-cigarettes available for purchase over the counter, but underage consumers could order prohibited products online and pick them up at the store.[25] The ports of Southern California are a popular destination for foreign tobacco contraband, especially from China. Federal officials reportedly seized more than 1.4 million illegal e-cigarettes, valued at $18 million, at Los Angeles International Airport in December 2023.The shipments were fraudulently labeled as shoes, toys and other items.[26] Last April, FDA and Justice Department officials seized 45,000 units of unauthorized e-cigarette products worth nearly a million dollars from a warehouse in Alhambra, California associated with California distributors.[27]

Efforts to reduce cigarette consumption through sin taxes. In addition to outright prohibition, States have imposed regressive "sin" taxes as a means to reduce tobacco consumption. The consequences of artificially increasing the price of a product containing an addictive substance to a level beyond the means of many consumers offer lessons for what could result from implementing the Proposed Rule. The Mackinac Center for Public Policy's Michael Lafaive explains:

> Due in large part to tax-induced price increases, an illicit trade in cigarettes has developed, which significantly parallels the problems of the [alcohol] Prohibition era. Today's cigarette market features massive amounts of tax evasion through illegal distribution (smuggling); high risks of theft and violence; adulterated products, such as 'loosies' and 'roll-your-own;' and corruption, among other issues.[28]

States with high cigarette tax rates experience an astonishing amount of illegal smuggling. A Tax Foundation study found that 54.3% of cigarettes consumed in New York derived from smuggled sources in 2022. Not surprisingly, New York has the nation's highest per-pack sin tax rate, $5.35. Other high-percentage States include California (46.7%), New Mexico (41.2%) and Massachusetts (39.7%).[29]

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[25] Stepanie Sierra, *Despite ban, CA's flavored tobacco 'black market alive and well' due to loophole*, ABC News 7, Mar. 31, 2023, https://perma.cc/TS9U-NF5G.

[26] Matthew Perrone, *Illegal e-cigarettes are flooding the ports in Southern California and beyond*, Los Angeles Times, Jan. 2, 2024, https://perma.cc/4UC7-XNWJ.

[27] Diane Adam, *California Continues Investment to Combat the Illegal Sale of Tobacco Products to Youth*, CSP, Mar. 14, 2024, https://perma.cc/R2ED-Q9Y5.

[28] Michael Lafaive, *Prohibition by Price: Cigarette Taxes and Unintended Consequences*, in Adam J. Hoffer & Todd Nesbit, eds., For Your Own Good: Taxes, Paternalism, and Fiscal Discrimination in the Twenty-First Century, Arlington, VA: Mercatus Center at George Mason University, 2018, at 328.

[29] Adam Hoffer & Jacob Macumber-Rosin, *Cigarette Taxes and Cigarette Smuggling by State, 2022*, Tax Foundation, Nov. 26, 2024, https://perma.cc/2USR-KD7E.

Theft and violence are endemic to black markets and impose a substantial toll on consumers that pursue illegal product purchases and society as a whole. Mr. Lafaive's book chapter offers several pages of examples of crimes being committed by cigarette smuggling operations, including stealing from reputable businesses, theft of smuggled products from other smuggling rings, and deadly force used to resolve business disputes.[30]

Devastating Economic Impact. The Proposed Rule fails to fully appreciate or consider the devastating economic impact of a very-low-nicotine standard for conventional cigarettes and machine-made cigars. A white paper from the National Association of Tobacco Outlets estimates that drastic nicotine reduction will result in over $30 billion per year in lost output and over 154,000 lost jobs.[31] Every employee and industry along the value chain would suffer, from tobacco growers to retailers. Growers would be forced to switch to other, less profitable crops or exit farming altogether. Most tobacco retailers, especially convenience stores, will lose sales as consumers turn to an illicit market to purchase cigarettes. Many of these tobacco retailers will be unable to recover the lost profits by selling alternative tobacco products and will have no choice but to close.

The Proposed Rule would deprive local, state, and federal governments of a significant revenue source. In Fiscal Year 2021, States collected $19.2 billion in taxes on conventional cigarettes.[32] In Fiscal Year 2023, the federal government collected $10.3 billion in cigarette taxes.[33] Paradoxically, the proposal would eviscerate tax revenues with a regulatory measure that will massively *increase* the burden on federal, state, and local governments to combat the very illicit market it would foster.

Conclusion

The "Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products" raises questions of law and policy sufficiently significant that, consistent with the purpose and goals of President Trump's January 20, 2025 memorandum, FDA should withdraw the Proposed Rule.

Even though the Tobacco Control Act directs FDA to avoid prohibition and the negative consequences for consumers and the economy that accompany such a

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[30] *See* Lafaive, *supra* note 28 at 340-43.

[31] White Paper Report: Economic Impact of Proposed FDA Nicotine Limit on Cigarettes. National Association of Tobacco Outlets. Dec. 12, 2024, https://perma.cc/9XNG-7XC8.

[32] Earmarks of Tobacco State Excise Tax Revenues and the Distribution of Tobacco Settlement Agreement Payments, National Association of Tobacco Outlets, https://perma.cc/HVX2-3QM7.

[33] Statista, *Tobacco tax revenue and forecast in the United States from 2000 to 2029*, Nov. 18, 2024, https://perma.cc/D235-65PL.

radical approach, FDA ignores the law and leans in to prohibition. Conventional cigarette and cigar consumers who use such products due to the nicotine are unlikely to embrace the Agency's cold-turkey edict and smoke very-low-nicotine tobacco. They will seek out alternatives from the black market that is certain to develop. FDA's refusal to acknowledge the black market the Agency created for flavored e-cigarettes, or the consequences of state bans on flavored products or sky-high excise taxes, or the health risks posed by criminal sales renders the Proposed Rule non-compliant with the TCA.

The prior Administration's actions and inaction left FDA's tobacco policy at a crossroads. The current Administration and its new public-health leadership has an opportunity to take FDA down the correct path. Withdrawing the Proposed Rule is an essential first step. In prohibiting tobacco prohibition, Congress acknowledged that adult consumers should be allowed to maintain their agency and make their own choices. Congress also understood that FDA had a role to play in moving the tobacco market in the direction of reduced harm through the development of products that eliminated the smoke—and the tobacco-related diseases that it causes. With a tobacco policy that works, and with consumers that wish to reduce their risk of harm, the market will react and provide what government should not be forcing through regulation.

Respectfully submitted,

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