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May Nelson
Director
Office of Regulations
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

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

Dear Director Nelson,

The National Association of Convenience Stores (“NACS”) appreciates this opportunity to provide comments on the Food and Drug Administration’s (“FDA” or the “Agency”) Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Tobacco Products (“Proposed Rule”).¹ These comments are intended to ensure the Agency is fully aware of the impact this policy would have on the illicit trade of tobacco and the convenience store industry.

NACS’s members are consumer-facing entities that constantly adapt to changing consumer demands and are thus effective surrogates for consumers. It is important to remember that offering a product for sale does not guarantee that consumers will purchase it. By requiring the reduction of nicotine, these regulations will ban all of the cigarettes, non-premium cigars, cigarette tobacco, roll your own tobacco, and pipe tobacco currently on the market in the United States, which will push a huge portion of current smokers to the illicit market which will undermine the progress made on reducing youth smoking and severely injure the convenience store industry. The growth of the illicit market also will undermine FDA’s goals in putting forward the Proposed Rule. For those reasons and as further explained below, NACS opposes the Proposed Rule and strongly urges FDA to withdraw it.

I. Background on NACS

NACS is an international trade association representing the convenience store industry with more than 1,300 retail and 1,600 supplier companies as members, the majority of whom are based in the United States.²

The convenience store industry has become a fixture in America society and a critical component of the nation’s economy. In 2024, the convenience store industry employed approximately 2.74 million employees and generated \$837.4 billion in total sales, representing approximately 3.2% of U.S. Gross

¹ 90 Fed. Reg. 5032 (Jan. 16, 2025).

² All data in Section I comes from the NACS, State of the Industry Annual Report of 2024 Data (available at [NACS State of the Industry Enterprise | NACS](#)).

Domestic Product.

The industry, however, is truly an industry of small business. More than 60% of convenience stores are single-store operators. Less than 0.2% of convenience stores that sell gas are owned by a major oil company and about 4% are owned by a refining company. More than 95% of the industry, then, are independent businesses.

Members of the industry process more than 160 million transactions every single day. That means about half of the U.S. population visits one of the industry's stores on a daily basis. In fact, 93% of Americans live within 10 minutes of one of our industry's locations. These businesses are particularly important in urban and rural areas of the country that might not have as many large businesses. In these locations, the convenience store not only serves as the place to get fuel but is often the grocery store and center of a community.

Tobacco products are a vital source of revenue for the convenience store industry. Cigarettes accounted for 19.4% of convenience stores' in-store sales in 2024 and the overall tobacco product category made up 27.5% of in-store sales.

II. Comments for Consideration by the Agency

Under the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"), FDA has the authority to regulate tobacco products to reduce their use and prevent their uptake by minors.³ To that end, FDA must weigh the risks and benefits when establishing any tobacco regulation.⁴

In its most recent survey, FDA found youth cigarette smoking to be at the lowest level ever recorded.⁵ That achievement was reached through the work of the industry and regulators operating in the legal marketplace. The industry has put significant effort and resources into compliance programs, training, self-audits and more to ensure that it does what it can to prevent youth purchases of tobacco products. Those efforts are making progress. The Proposed Rule, however, risks undermining that progress by dramatically expanding the illicit market (which does nothing to prevent youth sales) at the expense of the legal market (which goes to great lengths to prevent youth sales). That is a mistake and a risk that is likely to lead to increased youth smoking, increased illegal activity, and reduced tax revenue.

Specifically, NACS believes that the FDA has failed to take into account the effect the ban will have in fueling the illicit tobacco trade and the negative costs that will entail. The ban seeks to prohibit the use of cigarettes and non-premium cigars (among other products) that are offered on the market today and it is unrealistic to assume that demand for these products will just disappear. Instead, an illicit market for these products will emerge, creating a larger problem within tobacco regulation than the FDA hopes to solve by instituting these bans. Furthermore, convenience store owners, many who operate small businesses, are facing major challenges. NACS believes that the FDA, in banning the legal sale of these products, has failed to fully appreciate the burdens these bans will place on convenience store owners.

³ However, Congress did not give FDA authority to effectively ban tobacco products, especially products that are very popular with adult smokers.

⁴ Dep't Of Health And Human Services, Food and Drug Administration; Draft Concept Paper: *Illicit Trade in Tobacco Products After Implementation of a Food and Drug Administration Product Standard*; 83 Fed. Reg. 52 (Mar. 16, 2018) ("HHS Illicit Trade in Tobacco Products")(available at <https://www.gpo.gov/fdsys/pkg/FR-2018-03-16/pdf/2018-05346.pdf>).

⁵ [Results from the Annual National Youth Tobacco Survey \(NYTS\) | FDA](#)
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In fact, nothing in the Proposed Rule would ensure that there are any cigarettes or non-premium cigars that are legal to sell in the United States. All such current products would be banned. Manufacturers who wished to continue selling cigarettes or non-premium cigars would be required to reformulate their products and submit premarket approval applications to FDA before they could sell those products. FDA has demonstrated the challenges of engaging in a widespread premarket authorization process. In 2016, the FDA deemed many products such as electronic nicotine delivery systems (ENDS) to be regulated as tobacco products and required premarket tobacco product applications. The process of reviewing and deciding those applications is still unfinished today – nearly a decade later. That process still has hundreds of applications outstanding and FDA has only approved 39 vapor products for use. That is a woeful track record and demonstrates that the Proposed Rule is not a new product standard. It is a multi-year ban of indeterminate length on cigarettes, non-premium cigars and other products.

FDA does not have the legal authority to institute a ban on these products and the American people as well as the market will not be able to adjust to such a ban. Instead, adoption of the Proposed Rule would result in something closely akin to the prohibition of alcohol in the United States. Crime and lawlessness would prevail as adult consumers sought out illicit tobacco products to meet their desires for these products. And, unscrupulous individuals including organized crime would enthusiastically take steps to meet that illicit market opportunity. Meanwhile, law-abiding businesspeople such as convenience store owners would lose business and have no recourse to address the government-created lawlessness in their communities.

A. It is unlikely that the FDA’s regulations will result in an overall reduction in tobacco consumption

We recognize FDA’s desire to incentivize individuals to quit smoking and decrease the prevalence of new smokers, but prohibiting these products will not accomplish that goal. But it is unlikely that smokers who are addicted to the product will quit nor switch to new products (even if FDA can approve their availability in a timely way) that do not include enough of the substance to which smokers are addicted. Because of this, the Proposed Rule will simply cause addicted smokers to turn to the illicit tobacco market to acquire these products.

The failures of menthol bans underestimate the extent to which the illicit market would develop but are nonetheless instructive. In 2021, one of the first studies using quasi-experimental methods to evaluate the effects of menthol bans using real-world data was published.⁶ The study looked at several Canadian provinces that banned menthol flavoring in cigarettes and found the bans had no overall effect on the prevalence of smoking in both adults and youth.⁷ Provincial menthol bans were associated with significant increases in adult smokers purchasing cigarettes from First Nations reserves (where the bans were not enforceable - similar to the problems with enforcement on tribal lands in the United States).⁸ Additionally, the bans were associated with a significant increase in youth substituting other tobacco products for menthol cigarettes.⁹ Taken together, the two results indicated that the decrease in menthol cigarettes experienced in the provinces was nullified by adults evading the ban and youth switching to other tobacco

⁶ Christopher S. Carpenter, Hai V. Nguyen, *Intended and Unintended Effects of Banning Menthol Cigarettes*, *The Journal of Law and Economics*, 2021 64:3, 629-650 (2021) (finding that there is no research in economics or other disciplines that evaluates the effects of menthol bans using quasi-experimental methods).

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

products.¹⁰ Additionally, purchases of tobacco products shifted away from gas stations and grocery stores to unregulated areas (namely, First Nations reserves).¹¹

The effects of the Proposed Rule would be far worse. It would cause all currently legal cigarettes and other covered tobacco products to disappear from the market entirely. It is likely that there would be no such legal products to replace them as FDA has shown that its premarket approval processes take many, many years. Without a single legal cigarette available on the market, a significant portion of current users will have no choice but to turn to the illicit market.

Other flavor bans have shown similar unintended consequences and continued use of banned products. For example, in June of 2020, Massachusetts banned the sale of all flavored tobacco (including menthol), offering a real-world example of the problems associated with prohibition.¹² According to data obtained from the states surrounding Massachusetts, in the 12 months following the ban, menthol cigarette sales rose over 126% in border counties in Rhode Island and New Hampshire.¹³ Statewide, Rhode Island saw nearly a 43% increase in menthol cigarette sales and New Hampshire experienced a 79% increase.¹⁴ Provided that cigarette sales either decrease or stay consistent each year,¹⁵ it is safe to assume that a significant portion of the increased sales in border states went to fuel illegal tobacco markets at the expense of legitimate businesses within Massachusetts.

The foreseeable expansion of the illicit market in response to the ban in the Proposed Rule is not only dangerous for the individuals who participate, but also hurts legitimate businesses. Currently, according to a report prepared for the National Association of Tobacco Outlets, sales of cigarettes and other tobacco products amounts to more than \$90 billion per year.¹⁶ The NATO Report shows that not only will more than \$70 billion in those tobacco sales be lost due to the proposed bans, but stores would lose the sales of many other products that customers purchase at the same time that they buy tobacco products. Those losses of the sales of other products would amount to \$16.5 billion.¹⁷ That is a huge hit to the convenience store industry.

In 2024, cigarettes accounted for 20% of in-store sales and more than 7% of in-store gross profits for the average convenience store.¹⁸ Total sales for cigarettes in 2024 were \$46,302,163, 237.¹⁹ The category delivered an average gross margin of 13.76% in 2024, resulting in \$5.82 billion in gross profit to the convenience and fuel retail industry.²⁰

In addition, the number of transactions that these stores would lose creates risks of losing the

¹⁰ *Id.* (although provincial menthol bans did reduce youths' and adult's menthol cigarette smoking, the ban resulted in youths substituting other tobacco products and adults evading the ban by purchasing menthol cigarettes from unregulated vendors).

¹¹ *Id.*

¹² Ulrik Boesen, *Massachusetts Ban of Flavored Cigarettes Is Getting Expensive*, Tax Foundation (Aug. 2020) (available at <https://taxfoundation.org/massachusetts-ban-on-flavored-cigarettes-is-getting-expensive/>).

¹³ ALCS Internal Store Tracking Analytical Reporting System (STARS), week ending 5/30/21.

¹⁴ *Id.*

¹⁵ Koen van Gelder, *Cigarettes sold in the United States 2001-2020*, Statista, (available at <https://www.statista.com/statistics/1092860/cigarettes-sold-in-the-us/>) (Data providing yearly sales of cigarettes shows that cigarette sales have gradually declined from 2001 to 2020 in U.S.).

¹⁶ "Economic Impact of Proposed FDA Nicotine Limit on Cigarettes," by Chmura, prepared for the National Association of Tobacco Outlets (Dec. 12, 2024) ("NATO Report") available at [economicimpactreport.pdf](#).

¹⁷ NATO Report

¹⁸ *NACS State of the Industry Report of 2024 Data*

¹⁹ NATO Report

²⁰ *NACS State of the Industry Report of 2024 Data*

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loyalty of customers who may currently come into the stores for other items at times when they are not purchasing cigarettes or non-premium cigars. The loss of these contacts with customers may mean that they forego many other transactions with local convenience stores though it is difficult to fully estimate the number of lost sales due to this substantial reduction in customer contacts.

The NATO Report estimates that these sales losses would result in job losses of more than 154,000 – a devastating hit to the national economy.²¹

Governments would also lose from the proposed bans. Tax collections from the sales of tobacco products are estimated to fall by \$24 billion per year under the proposed bans.²² That figure includes losses of federal, state and local tax revenues. Plus, the annual payments that certain cigarette manufacturers pay to states as part of the Master Settlement Agreement resolving tobacco litigation are estimated to fall by \$5.6 billion per year.²³

It is difficult to find any past regulation that threatened the negative economic impacts that this rule promises to bring. Convenience stores that follow the law will bear the brunt of those economic losses. And, the illicit purveyors of cigarettes and non-premium cigars, operating outside of the law, will not discriminate among their customers based on age, likely increasing rather than decreasing youth smoking.

C. The illicit trade of tobacco products already exists

A substantial black market for tobacco products has developed as a way to circumvent regulations and state excise taxes. Although it is difficult to quantify the extent of any illicit activity, between 8.5% and 21% of tobacco products in the U.S. are estimated to be purchased on the black market.²⁴ Since the tobacco market is a “dual” market” (i.e., there are both legal and illegal tobacco transactions), it is difficult to distinguish between legal and illegal tobacco products, which makes it hard to detect illicit products and measure their trade.

The illicit tobacco market already thrives on the U.S.-Mexico border. According to U.S. Immigration and Customs Enforcement (“ICE”) officials, established links between the smuggling of large quantities of duty-free cigarettes and transnational criminal organizations already exist.²⁵ These organizations use tobacco smuggling as a lucrative, low risk way to launder money and generate revenue.²⁶ Tobacco smuggling has also been tied to a wide range of other criminal enterprises such as human trafficking.²⁷ Furthermore, different governmental agencies’ efforts to curtail the illegal sale of duty-free cigarettes has proved troublesome and largely unsuccessful.²⁸ As described in a report produced by the Government Accountability Office (“GAO”), the tobacco black market is “like a whack-a-mole problem” and “although illicit trade may decrease following successful law enforcement efforts, these activities

²¹ NATO Report

²² *Id.*

²³ *Id.*

²⁴ Nat’l Research Council, *Comm. on the Illicit Tobacco Market, Understanding the U.S. Illicit Tobacco Market: Characteristics, Policy Context, and Lessons from International Experience* (Peter Reuter and Malay Majumdar, Editors) (Feb. 19, 2015).

²⁵ Gov’t Accountability Off., GAO-18-21, *Duty-Free Cigarettes Sold in Unlimited Quantities on the U.S.-Mexico Border Pose Customs Challenges*, (Oct. 11, 2017) (available at <https://www.gao.gov/assets/gao-18-21.pdf>). Duty-free cigarettes are legally sold tax-free cigarettes that are intended to be used for personal use aboard by individuals about to leave the country.

²⁶ *Id.*

²⁷ “Research Findings: Illicit Hubs, Tobacco Trade, and Convergence with Illicit Commodities,” George Mason University (April 23, 2019) (available at [Research-Findings-Illicit-Hubs-Tobacco-Trade-and-Convergence-with-Illicit-Commodities.pdf](#)).

²⁸ GAO-18-21.

usually resume after a period.”²⁹ Furthermore, ICE and U.S. Customs and Border Protection (“CBP”) officials have warned that as smuggling becomes more lucrative – which will certainly happen if FDA implements these new regulations – the already existing link between cigarette smuggling and organized crime on the southwest border may grow stronger.³⁰

In fact, by 2023 the problem had become so bad that dozens of U.S. Senators and House Members began writing to the FDA, U.S. Department of Homeland Security, and U.S. Department of State to raise grave concerns over illicit tobacco markets, their ties to Mexican cartels, and the inadequacy of existing enforcement efforts.³¹

There is also a “gray” market for cigarettes that are manufactured legally abroad but imported into the U.S. under dubious legal circumstances. According to ICE and CBP officials, smugglers frequently import cigarettes into the U.S. by not declaring them, disguising them, and hiding them behind other items.³² Even the FDA admitted that it “is not feasible” to inspect all imported tobacco products,³³ creating a pipeline into the U.S. for illicit tobacco products.

The illicit tobacco market has also flourished on the Internet. The Internet has become a major source of illicit drug activity and is increasingly playing a role in the illicit tobacco trade with an estimated 28 million yearly internet searches for tobacco products.³⁴ More specifically, websites that operate anonymous marketplaces for illicit drugs, play a significant role in facilitating the illicit tobacco trade.³⁵ These online markets facilitate about \$550 million in illicit sales each year, and illicit tobacco products are increasingly being sold on these online markets.³⁶ Currently the majority of illicit tobacco transactions on these online markets are between the U.S. and Europe,³⁷ opening the door for more illicit tobacco trade if the FDA decides to go forward with their bans. Despite the significant increase in the frequency of

²⁹ Gov’t Accountability Off., GAO-11-313, *Illicit Tobacco: Various Schemes Are Used to Evade Taxes and Fees* (Mar. 7 2011).

³⁰ GAO-18-21.

³¹ See, e.g., “Cassidy, Rubio, Colleagues Urge Biden to Sanction International Tobacco Company with Ties to Mexican Drug Cartels,” U.S. Senator Bill Cassidy, M.D. News Release (May 10, 2023) (available at <https://www.cassidy.senate.gov/newsroom/press-releases/cassidy-rubio-colleagues-urge-biden-to-sanction-international-tobacco-company-with-ties-to-mexican-drug-cartels/>); Joint House Letter to FDA Commissioner Robert Califf, June 8, 2023 (available at https://wassermanschultz.house.gov/uploadedfiles/letter_to_fda_re_e-cigs_-_final_signed.pdf); Hammond, Hannah. “U.S. Representatives Urge FDA to Reconsider Proposed Menthol Cigarette Ban,” CSP Daily News (June 26, 2023) (available at <https://www.cspdailynews.com/tobacco/us-representatives-urge-fda-reconsider-proposed-menthol-cigarette-ban/>); “Ranking Member Cassidy, Colleagues Sound Alarm on Mexican Cartel Exploitation of Illegal Tobacco Amid New Biden Regulations,” U.S. Senator Bill Cassidy, MD. News Release (July 24, 2023) (available at <https://www.cassidy.senate.gov/newsroom/press-releases/ranking-member-cassidy-colleagues-sound-alarm-on-mexican-cartel-exploitation-of-illegal-tobacco-amid-new-biden-regulations/>); “Ranking Member Cassidy, Colleagues Sound Alarm on Mexican Cartel Exploitation of Illegal Tobacco Amid New Biden Regulations,” U.S. Senate Committee on Health, Education, Labor, and Pensions (July 24, 2023) (available at <https://www.help.senate.gov/rep/newsroom/press/ranking-member-cassidy-colleagues-sound-alarm-on-mexican-cartel-exploitation-of-illegal-tobacco-amid-new-biden-regulations/>); House Committee on Homeland Security Chairman Mark E. Green, M.D. Letter to Homeland Security Secretary Alejandro Mayorkas, August 4, 2023 (available at <https://homeland.house.gov/wp-content/uploads/2023/08/08.03.23-Green-to-Mayorkas-DHS-re-Cartels.pdf>).

³² GAO-18-21.

³³ HHS Illicit Trade in Tobacco Products.

³⁴ R. Munksgaard, D. Decary-Hetu, A. Malm, et al., *Distributing Tobacco in the Dark: Assessing the Regional Structure and Shipping Patterns of Illicit Tobacco in Cryptomarkets*, Global Crime (Jul. 2020) available at <https://doi.org/10.1080/17440572.2020.1799787>.

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

transactions on these markets world-wide,³⁸ enforcement actions taken by U.S. and other international agencies have been largely unsuccessful at diminishing the growth of these illicit markets.³⁹ For example, following the takedown of the Silk Road (the first such large-scale international market) in 2013, sales across these markets returned to their prior level within four months.⁴⁰ Furthermore, FDA acknowledges that websites not only offer illegal tobacco products for purchase, but also information on how to procure them.⁴¹ And since these websites are anonymous, they are especially appealing to minors who do not have to provide identification to procure illicit products.⁴²

According to the Alcohol and Tobacco Tax and Trade Bureau (“TTB”), the illegal market for tobacco products is successful because “the potential for illicit gains is high and the risk to illegal operators is low.”⁴³ For example, in New York (which in 2019 had an estimated cigarette smuggling rate of 52%),⁴⁴ the penalty to bring cigarettes from Virginia is equal to the expected profit, meaning a smuggler can still break even in the unlikely event he is caught.⁴⁵ As more people participate in the illicit trade of tobacco, the risk associated for each person participating decreases.⁴⁶ And, as the individual risk decreases, even more people will be willing to participate. Although banning cigarettes and non-premium cigars on a national level is different than the intrastate smuggling already rampant in the U.S., many of the same effects are likely to be replicated on a national level. Instead of engaging in intrastate smuggling, tobacco smugglers will likely shift to the international tobacco market to get their supply of illicit tobacco.⁴⁷ The illicit trade of tobacco is already a major issue in many states in the U.S. and by banning cigarettes and non-premium cigars nationally, FDA will only offer a competitive advantage to smugglers. Furthermore, FDA is unlikely to enforce their bans against individual possession and consumption. That means current smokers will not be dissuaded from resorting to the illicit tobacco trade. Therefore, a nationwide ban has the potential to expand the existing illicit tobacco trade while also incentivizing more individuals to enter the illegal market.

D. The federal government has been unsuccessful at enforcing the current tobacco regulations – and fighting the illicit trade market

As the FDA contemplates implementing bans on cigarettes and non-premium cigars, the Agency must consider how it would administer new regulations in light of the fact that the federal government has been largely unsuccessful in enforcing current laws and regulations, which has allowed the illicit trade of tobacco to flourish. Ignoring the government’s inability to enforce tobacco regulations underestimates the

³⁸ *Id.*

³⁹ Martin Horton-Eddison, Patrick Shortis, et al., *Drug Cryptomarkets in the 2020s: Policy, Enforcement, Harm, and Resilience*, Global Drug Policy Observatory: Policy Brief (June 2021), available at https://www.swansea.ac.uk/media/Drug-Crypto-Markets_FINAL_June_2021.pdf

⁴⁰ *Id.*

⁴¹ HHS Illicit Trade in Tobacco Products.

⁴² Tom Hanson, *Teens Have Easier Access to Drugs as Illegal Trade Booms on Social Media*, CBS News (Nov. 30, 2021) available at <https://www.cbsnews.com/news/social-media-teens-drug-access/>.

⁴³ Dep’t of the Treasury Alcohol and Tobacco Tax and Trade Bureau, *Department of the Treasury Report to Congress on Federal Tobacco Receipts Lost Due To Illicit Trade and Recommendations for Increased Enforcement*, (Feb. 4, 2010) (available at <https://ttb.gov/pdf/tobacco-receipts.pdf>).

⁴⁴ Ulrik Boesen, Todd Nesbit, Michael D. LaFaive, *Estimated Cigarette Tax Avoidance and Evasion by State*, Mackinac Center for Public Policy (2020) (available at <https://www.mackinac.org/smokes#map>).

⁴⁵ Jonathan Kulick, James E. Prieger, Mark A.R. Kleiman, *Unintended Consequences of Cigarette Prohibition, Regulation, and Taxation*, Int’l Journal of Law, Crime and Justice 46 (2016).

⁴⁶ *Id.*

⁴⁷ Tax Foundation, *Federal Menthol Cigarette Ban May Cost Governments \$6.6 Billion* (Mar. 2 2022) (available at <https://taxfoundation.org/federal-menthol-cigarette-ban/>).

burden associated with FDA promulgating new regulations.⁴⁸

The enforcement of current tobacco regulations is shared by many federal agencies – including the Bureau of Alcohol, Tobacco, Firearms and Explosives (“ATF”) in the U.S. Department of Justice (“DOJ”); ICE and CBP in the U.S.; the TTB in the U.S. Department of the Treasury (“Treasury”); and the Center for Tobacco Products (“CTP”) in the U.S. Department of Health and Human Services’ (“HHS”) Food and Drug Administration. Moreover, states and localities have additional laws to regulate tobacco. However, the enforcement of regulations is not consistent or coordinated between these entities, especially considering the scope of the black market.

ATF is primarily responsible for enforcing the Contraband Cigarette Trafficking Act⁴⁹ and the Prevent All Cigarette Trafficking Act,⁵⁰ laws implemented to combat the illicit trade of tobacco products. In 2010, ATF announced that it would primarily focus on combating violent and organized crime rather than nonviolent alcohol and tobacco investigations.⁵¹ As a result, ATF’s investigations into alcohol and tobacco crimes plummeted 85% – to a mere 25 investigations in 2013.⁵² Additionally, an audit conducted by the DOJ found “a serious lack of oversight by ATF” in its investigation of the illicit trade of tobacco, including the failure to meet its own standards when conducting investigations.⁵³ Since 2014, ATF’s Budget Submissions have not included any specific funding for tobacco enforcement.⁵⁴

If FDA’s proposed bans were to take effect, it would be illegal to import these products into the U.S. and under the Food, Drug, and Cosmetic Act (“FD&C Act”) they would be subject to import inspection.⁵⁵ However, FDA has largely been ineffective at preventing other banned products from entering U.S. ports. According to a GAO report, FDA’s oversight program to ensure that imported seafood is free of harmful drugs “did not consistently follow key procedures or meet key goals.”⁵⁶ In light of this, serious questions arise on whether the FDA has the ability to adequately prevent an influx of illicit tobacco from entering U.S. ports.

In fact, analysis of FDA’s publicly available OASIS database confirms that FDA has not done what is required to stem the tide of illicit tobacco products even under current law.⁵⁷ Those records show that illicit vapor products have poured into the United States without sufficient interdiction by the FDA. The data makes it apparent that many of the major agencies responsible for enforcing tobacco regulations have failed to effectively combat the illicit tobacco market, especially in light of a very adaptive black market. Without a domestic and legal source for the tobacco products they prefer, smokers will simply purchase

⁴⁸ Mark A.R. Kleiman, James E. Prieger, Jonathan Kulick, *Illicit Trade as a Countervailing Effect: What the FDA Would Have to Know to Evaluate Tobacco Regulations*, Journal of Drug Policy Analysis (Apr. 12, 2016).

⁴⁹ 18 U.S.C. § 2341-2346.

⁵⁰ 18 U.S.C. § 375-378, as amended.

⁵¹ Gov’t Accountability Off., GAO-14-553, *Bureau Of Alcohol, Tobacco, Firearms And Explosives: Enhancing Data Collection Could Improve Management Of Investigations*, (June 30, 2014) (available at <https://www.gao.gov/assets/670/664514.pdf>).

⁵² *Id.*

⁵³ Dep’t of Justice, Office of the Inspector General Audit Division, *Audit Of The Bureau Of Alcohol, Tobacco, Firearms And Explosives’ Use Of Income Generating, Undercover Operations*, Audit Report 13-36 (Sept. 2013) (available at <https://oig.justice.gov/reports/2013/a1336.pdf>).

⁵⁴ Bureau of Alcohol, Tobacco, Firearms and Explosives, *Congressional Budget Submissions*, (FY 2014–25), available at [Budget & Performance | ATF](#).

⁵⁵ HHS Illicit Trade in Tobacco.

⁵⁶ Gov’t Accountability Off., GAO 21-231, “Imported Seafood Safety: GAO Should Improve Its Monitoring of its Warning Letter Process and Better Assess its Effectiveness” (March 2021).

⁵⁷ See Letter of Aug. 19, 2024 from Paige Magness, Altria Senior VP of Regulatory Affairs to Brian King, Director, Center for Tobacco Products.

the products they want over the Internet or rely on illicit importers and distributors. As noted, the illicit tobacco trade already flourishes and the Proposed Rule would exacerbate the issue by banning all existing cigarettes and non-premium cigars. NACS can only imagine the effect these nationwide bans will have on the expanding illicit tobacco market.

E. The black market creates health concerns

In satisfying customer demand, tobacco manufacturers create products that are fully scrutinized and regulated by the FDA, but illegal manufacturers do not operate within the confines of FDA regulations. FDA cannot oversee the contents and purity of counterfeit cigarettes and are therefore subject to illicit manufacturers' whims. In fact, smokers who smoke illicit tobacco products have reported significantly worse health outcomes than individuals who use legal tobacco products and have also reported higher rates of underage smoking.⁵⁸

According to the ATF, the manufacturing of counterfeit tobacco products is a rapidly growing industry.⁵⁹ Counterfeit cigarettes are in some cases imitations of legitimate brand name cigarettes that are smuggled into the U.S. and not regulated by any governmental agency.⁶⁰ Chinese counterfeit cigarettes have been found to emit higher levels of nicotine and carbon monoxide than brand-name cigarettes – and include insect eggs and human feces in their composition.⁶¹ It is unreasonable to assume that manufacturers producing an illicit product will adhere to the FDA's regulation on nicotine levels.

When Congress gave FDA authority to regulate tobacco products under the Tobacco Control Act, it did so with the intent that FDA should play a role in monitoring the production of cigarettes and cigars. FDA's Proposed Rule will incentivize more illicit trade and increase the amount of unregulated and dangerous tobacco products produced and sold. In doing so, the bans will do more damage than good by increasing the health risks of individuals who resort to the black market.

F. Banning existing cigarettes and non-premium cigars could increase violence

Enforcement of the FDA's bans could increase violence. A study found that if enforcement of a ban is to follow the pattern set by other illicit drug markets, revenue in the illicit market will increase, which leads to greater violence.⁶² The research shows that when a highly sought after good is banned and enforcement measures are specifically targeted at suppliers,⁶³ violence within the illicit market increases.⁶⁴

Illicit markets also tend to form in close proximity to the customers they serve. That means that the heaviest burden of violence is likely to fall on the people that FDA is intending to help with its Proposed Rule.

Minimizing total harm from cigarettes and cigars means minimizing the sum of social harms from

⁵⁸ Campbell K, Aitken, Tim R. L. Fry, Lisa Farrell, et al., *Smokers of Illicit Tobacco Report Significantly Worse Health Than Other Smokers*, Nicotine & Tobacco Research, Vol 11,8 at pp. 996 –1001(Aug. 2009) (available at <https://doi.org/10.1093/ntr/ntp102>).

⁵⁹ Bureau of Alcohol, Tobacco, Firearms and Explosives, *Fact Sheet – Tobacco Enforcement* (May 2018) (available at <https://www.atf.gov/resource-center/fact-sheet/fact-sheet-tobacco-enforcement>).

⁶⁰ *Id.*

⁶¹ Te-Ping Chen, *China's Marlboro Country*, Ctr. Of Public Integrity (June 29, 2009) (available at <https://www.publicintegrity.org/2009/06/29/6341/china-s-marlboro-country>).

⁶² Jonathan Kulick, James E. Prienger, *Unintended Consequences of Enforcement in Illicit Markets*, Economic Letters, (2014).

⁶³ HHS Illicit Trade in Tobacco Products.

⁶⁴ Kulick and Prienger.

the consumption of these goods and the additional harms inadvertently caused by enforcement. Accordingly, FDA should also consider the indirect costs of enforcement when calculating the costs and benefits of their regulations.

G. Growth in the black market will reduce tax revenues for the federal, state, and local governments

Tobacco products are taxed to raise revenue for public health programs and to deter tobacco use. As such, cigarettes are often one of the highest taxed commodities.⁶⁵ However, the illegal sale of tobacco products significantly reduces tobacco tax revenue. For example, New York lost an estimated \$1.2 billion in tax revenue to the illegal tobacco trade in 2019.⁶⁶ Furthermore, estimates indicate that a nationwide ban of menthol cigarettes would result in \$1.9 billion in lost tax revenue in the ban's first year.⁶⁷ FDA's Proposed Rule goes much farther by banning all cigarettes currently on the market. Its negative impact on tax revenues is likely to be much larger than that from a menthol cigarette ban. By pushing a large portion of the legal cigarette and cigar market to the illicit market, the U.S. would be stuck with costs associated with tobacco consumption, but without the revenue from taxing tobacco products.

H. Banning cigarettes and non-premium cigars will harm small businesses and their employees

Pursuant to the Regulatory Flexibility Act ("RFA"), FDA must minimize any significant burdens imposed on small entities by their regulatory actions.⁶⁸ Specifically, the RFA requires FDA to provide an Initial Regulatory Flexibility Analysis ("IRFA") that includes: (1) a description of the reasons why the regulatory action is being taken; (2) the objectives and legal basis for the proposed regulation; (3) a description and estimate of compliance requirements, including any differential for different categories of small entities; (5) identification of duplication, overlap and conflict with other rules and regulations and (6) a description of significant alternatives to the rule.⁶⁹ FDA has not met these statutory requirements. It has not included many small businesses, specifically small retailers of tobacco products, in its analysis at all.

I. The Proposed Rule does not adequately describe and estimate the impacts on small entities

FDA's analysis of costs is remarkably deficient. The agency does not factor into its Proposed Rule the billions of dollars of lost sales that will impact retailers of these products. The agency does not look at lost tobacco sales nor lost ancillary sales of other products that consumers buy when they purchase tobacco products today.⁷⁰ The majority of impacted retail businesses are small businesses. Among convenience stores, for example, more than 60% of the stores are single-store operators. These businesses will suffer large economic losses due to FDA's proposed bans. The FDA analysis broadly assumed that the money previously used by consumers to purchase the banned products would be used to purchase other goods at retail. This is a faulty assumption and is unsupported by the facts.

One major problem with this assumption is that it ignores that previous cigarette and non-premium

⁶⁵ Ulrik Boesen, *Cigarette Taxes and Cigarette Smuggling by State, 2019*, Tax Foundation (Nov. 2021) available at <https://files.taxfoundation.org/20211201101747/Cigarette-Taxes-and-Cigarette-Smuggling-by-State-2019.pdf>.

⁶⁶ *Id.*

⁶⁷ Tax Foundation, *Federal Menthol Cigarette Ban May Cost Governments \$6.6 Billion* (Mar. 2 2022) available at <https://taxfoundation.org/federal-menthol-cigarette-ban/>.

⁶⁸ 5 U.S.C. § 601-612, as amended.

⁶⁹ *Id.* at § 603.

⁷⁰ See Proposed Rule at 5113.

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cigar purchasers will turn to the illicit market. By ignoring that fact, FDA is ignoring the real-world experience of other tobacco bans. Second, the assumption fails to do any real economic analysis of the impact the regulation has on small businesses and instead, broadly asserts that the lost revenue from tobacco products might be offset through other sales – and offers no economic data or evidence to support this claim. By failing to do so, FDA obscures the real impact these bans will have on small entities. Unlike larger chain retailers, small convenience stores have a limited retail catalog and are less able to diversify in case of a ban on one of their products. Instead, small convenience store owners will bear the full extent of lost sales due to the regulation.

Small convenience stores rely more heavily on cigarette sales than do their larger competitors – a fact that FDA completely ignores. Based on NACS Research Department data, the FDA Proposed Rule would amount to losses of 29% of in-store sales and 12% of in-store gross profits for single-store operators. And, the loss of non-tobacco sales would be devastating. Convenience stores rely on tobacco sales to drive foot traffic into their stores so that people will buy other items. Single-store operators have about 16,000 in-store transactions per month. Losing 29% of those customers (or anything close to it) would likely render those stores no longer commercially viable.

J. The Proposed Rule does not adequately consider alternatives

Although FDA included alternatives in its regulatory impact analysis (though it did not discuss them in its Proposed Rule), those alternatives are inadequate and essentially assume the desired outcome. The main alternative considered by FDA is a gradual reduction of nicotine levels rather than one large reduction. That is not a real alternative. It would entail many of the downsides of the Proposed Rule (a ban, long approval process for new products, and significant illicit sales) without the purported benefits that FDA seeks.

A real alternative would be things like enhanced education or the enhanced use of age restriction technologies.⁷¹ Smoking has fallen dramatically in recent years. There are real questions about the need for the policy that FDA is proposing. Unfortunately, FDA refused to ask those fundamental questions.

III. Conclusion

NACS appreciates this opportunity to present our views on the impact of the FDA's proposed bans on all cigarettes and non-premium cigars currently on the market. The proposed bans risk expanding the illicit trade of tobacco in the U.S. while severely injuring the convenience store industry. NACS believes the federal government should enforce the tobacco regulations that currently exist and reduce the large problem of the illicit trade in tobacco before promulgating new regulations. The Proposed Rule will move in the wrong direction by dramatically expanding the illicit market and reducing compliance with age verification and safety laws. The Proposed Rule should be withdrawn to avoid these bad outcomes.

Sincerely,



Doug Kantor
General Counsel

⁷¹ This might include the TruAge technology ([TruAge | Homepage](#)) that NACS has pioneered.
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