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Congress of the United States
U.S. House of Representatives
Committee on Small Business
2361 Rayburn House Office Building
Washington, DC 20515–0315

November 16, 2023

The Honorable Shalanda Young
Director
Office of Management & Budget
Executive Office of the President
725 17th Street, NW
Washington, DC 20503

The Honorable Richard Revesz
Administrator
Office of Information & Regulatory Affairs
Office of Management & Budget
725 17th Street, NW
Washington, DC 20503

Dear Director Young and Administrator Revesz,

The House Committee on Small Business (Committee) writes to express its concern about the Food and Drug Administration's (FDA) proposed rule that would implement product standard regulations to prohibit the manufacture and sale of menthol flavored cigarettes (Rule), which is currently under review by the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA).[1] The Committee has followed the FDA's process as it relates to this rulemaking and seeks to ensure OMB/OIRA is considering both the significant economic impacts on small entities and the fueling of illicit markets that would result from implementation of this Rule.

The Regulatory Flexibility Act (RFA) requires agencies to analyze proposed rules to determine if they will have a significant economic impact on a substantial number of small businesses.[2] The FDA found that this Rule would have such an impact on small manufacturers, wholesale, and retail firms—triggering compliance costs dwarfed by losses in revenue.[3] The National Association of Convenience Stores (NACS), which represents more than 150,000 convenience stores in the U.S., reports that tobacco products are a vital source of revenue for the convenience store industry, 60 percent of which are single-store operators.[4] If implemented, this Rule would cause a single convenience store to lose $72,285 a year in non-tobacco sundry sales (nearly 4 percent of inside sales) on top of the $160,107 lost due to the reduction in sales of tobacco products.[5] Small operators in the convenience industry would collectively lose $2.16

[1] 87 Fed. Reg. 26454 (May. 4, 2022); DEPT. OF HEALTH & HUMAN SERVICES, FOOD & DRUG ADMIN, DOCKET NO. FDA-2021-N-1349, TOBACCO PRODUCT STANDARD FOR MENTHOL IN CIGARETTES (Spring 2023).
[2] Regulatory Flexibility Act, 5 U.S.C. 601-612.
[3] DEPT. OF HEALTH & HUMAN SERVICES, FOOD & DRUG ADMIN., TOBACCO PRODUCT STANDARD FOR MENTHOL IN CIGARETTES, DOCKET NO. FDA 2021-N-1349, PRELIMINARY REGULATORY IMPACT ANALYSIS, INITIAL REGULATORY FLEXIBILITY ANALYSIS, UNFUNDED MANDATES REFORM ACT ANALYSIS (2022).
[4] Letter from the National Association of Convenience Stores to Joseph R. Biden, United States, President (Nov. 8, 2022).
[5] *Id.*

billion in sales, representing $232,392 in lost sales per store.[6] This is just the convenience stores that would be impacted. While the FDA anticipates that consumers of menthol cigarettes would simply pivot to regular cigarettes and retailers would retain revenue, this unsubstantiated claim does not rectify the impact on small manufacturers who would have their revenue stream from menthol cigarettes completely wiped out. While well intentioned, the FDA's ban of menthol cigarettes will deliver a significant blow to the small businesses in this country and will not be successful in eradicating menthol cigarettes from the United States.

Menthols make up 37 percent of all retail cigarette sales in this country.[7] Disallowing the legal sale of menthol cigarettes will only incentivize the illicit tobacco market. A coalition of approximately 700,000 law enforcement officers commented on the proposed Rule saying that the ban "will increase multiple categories of crimes in our communities. The data is clear that illicit tobacco attracts gangs and organized crime."[8] Rather than continuing to have oversight of the production and sale of menthol cigarettes while generating tax revenue, the government will instead leave the production and sale to unregulated criminal enterprises and foreign producers.

This is not an unsubstantiated fear; after California implemented a state-wide ban on menthol cigarettes in 2022, a study found that roughly one in five cigarettes smoked were menthols even six months later, of which 27.6 percent were imported.[9] The conclusion of that report is clear: the tax losses from these policies are substantial, and illicit smuggling operators appear capable of filling the demand prohibited by legal market transactions.[10] Similar results were found in Massachusetts after it passed a state-wide ban in 2019.[11] As we saw with the FDA's attempt at tackling e-vapor products, foreign and illegal products replaced the regulated market; FDA Commissioner Califf acknowledged this failure before the House Appropriations Subcommittee on Agriculture, Rural Development, and Food and Drug Administration on March 29, 2023.[12]

Given the enormous impact this Rule will have on small entities, please provide the following documents and information as soon as possible but no later than November 30, 2023:

1. How many small businesses do you estimate will be forced to close because of the proposed Rule?

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[6] *Id*.
[7] FED. TRADE COMMISSION, CIGARETTE REPORT FOR 2020, 10 (2021).
[8] National Organization of Black Law Enforcement Executives, Comment Letter to Food & Drug Administration on Proposed Rule on Tobacco Product Standard for Menthol in Cigarettes (Aug. 3, 2022) https://www.regulations.gov/comment/FDA-2021-N-1349-175322.
[9] Adam Hoffer, *Californians Still Smoking Menthol after Ban: Evidence from a Discarded Pack Audit*, TAX FOUND. (Oct. 26, 2023).
[10] *Id*.
[11] Ulrik Boesen, *Massachusetts Flavored Tobacco Ban Has Severe Impact on Tax Revenue*, TAX FOUND. (Jan. 19, 2021).
[12] Letter from Rep. John H. Rutherford, et. al., to Robert M. Califf, M.D., U.S. Food & Drug Admin., Commissioner (Jun. 13, 2023).

a. What is your estimate on reduced employment figures associated with these small business closures?
b. What is your estimate on reduced employment figures for businesses that remain open but with reduced revenues?

2. Given that many of the small businesses projected to be impacted by the proposed Rule are sources of food and pharmaceuticals in local communities, what data can you share about the effect that the proposed Rule will have on "food deserts" and "pharmacy deserts"?

3. The FDA's Initial Regulatory Flexibility Analysis briefly details only three alternatives — a delayed effective date, prohibiting menthol as an intentional additive, and exemptions — to minimize the proposed Rule's burden on small businesses. What other alternatives has the FDA, OMB, and OIRA considered or analyzed?[13]

4. Given the FDA's expressed interest in the proposed Rule's impact on minority communities, what data did the FDA share with OMB/OIRA regarding the effect on minority-owned small businesses? Please include data related to the impact on revenue, employment, and viability for these businesses.

5. Has OMB or OIRA consulted with other agencies who oversee criminal activity in the United States over the repeatedly expressed concerns of Congress that this proposed Rule will grow the illicit tobacco market?

6. Evidence sufficient to show OMB and OIRA are taking the concerns of small businesses seriously, including but not limited to meetings that the Offices took with small businesses, and responses to their letters.

7. A nationwide ban of menthol cigarettes is estimated to result in $1.9 billion in lost tax revenue within the first year alone.[14] How does OMB plan to make up for this loss when the government is trillions of dollars in debt?

To schedule the delivery of your response or ask any related follow-up questions, please contact Committee on Small Business Majority Staff at (202) 225-5821. The Committee on Small Business has broad authority to investigate "problems of all types of small business" under House Rule X. Thank you in advance for your cooperation with this inquiry."

[13] DEPT. OF HEALTH & HUMAN SERVICES, FOOD & DRUG ADMIN., TOBACCO PRODUCT STANDARD FOR MENTHOL IN CIGARETTES, DOCKET NO. FDA 2021-N-1349, PRELIMINARY REGULATORY IMPACT ANALYSIS, INITIAL REGULATORY FLEXIBILITY ANALYSIS, UNFUNDED MANDATES REFORM ACT ANALYSIS, 214-220 (2022).
[14] Ulrik Boesen, *Federal Menthol Cigarette Ban May Cost Governments $6.6 Billion*, TAX FOUND. (Mar. 2, 2022).

In God We Trust,

Roger Williams
Chairman
Committee on Small Business

Dan Meuser
Member
Committee on Small Business

cc: The Honorable Nydia M. Velasquez, Ranking Member
Committee on Small Business