



December 5, 2023

Hon. Shalanda Young
Director
Office of Management and Budget
1650 Pennsylvania Ave. NW
Washington, D.C. 20502

Hon. Richard L. Revesz
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
262 Old Executive Office Building
Washington, D.C. 20503

Re: Pending EO 12866 Regulatory Review, Tobacco Product Standard for Menthol in Cigarettes, RIN 0910-A160

Dear Director Young and Administrator Revesz:

The undersigned organizations write to urge the Office of Information and Regulatory Affairs (OIRA) to complete its review of the Tobacco Product Standard for Menthol in Cigarettes (menthol cigarette rule) and to allow it to be issued in final form without delay. As the U.S. Food and Drug Administration (FDA) has established, the menthol cigarette rule will save over 600,000 lives over the next four decades, by reducing initiation of smoking among young people and by enabling people who smoke menthol cigarettes to quit. It will end the industry's use of menthol cigarettes to target the Black community, save hundreds of thousands of Black lives and sharply reduce health disparities. Finalizing these rules is also imperative in reaching the administration's Cancer Moonshot goals.

Menthol cigarettes have had a devastating and disproportionate impact on the health of Black Americans. That the prevalence of menthol cigarettes among Black individuals who smoke has increased from less than 10% in the 1950s to 85% today is not the result of evolving consumer preference, but rather is due to more than 60 years of high-dollar marketing directed at

Black communities.¹ Researchers estimate that prohibiting menthol cigarettes would prevent over 255,000 deaths in the Black community by 2060.² A menthol prohibition would also help close the gap between lung cancer death rates for Black Americans and other U.S. racial and ethnic groups sooner than it otherwise would have.³ Prohibiting menthol cigarettes will also improve the health of other groups that have been targeted by the tobacco industry – youth, other communities of color, the LGBTQ+ community, socioeconomically disadvantaged populations and people with mental health conditions.⁴

Nevertheless, the tobacco industry and its allies continue to advance entirely baseless arguments to prevent the rule from being issued, or significantly delay its implementation. This letter addresses three of those arguments: (1) that the rule will result in a substantial illicit market in menthol cigarettes; (2) that the rule will increase the incidence of police abuse in Black communities; and (3) that the rule will cost jobs and have other adverse economic effects.

The Illicit Market Argument

The tobacco industry consistently raises the threat of an uncontrolled illicit market in response to every proposal to restrict the manufacture and sale of tobacco products to protect public health. The industry always exaggerates the risk of an illegal market. Some opponents of the menthol cigarette rule have even asserted that illegal sales of menthol cigarettes will fund the Mexican cartels and terrorist groups like Hezbollah. There is no evidence to support these claims.

The industry often cites the existing illegal market in cigarettes as evidence, but that largely involves the diversion of cigarettes from the legal to the illegal market in the form of smuggling of finished packs of legal cigarettes from low-tax states to high-tax states. This is entirely different than creating and sustaining an illegal market for menthol cigarettes, for which there would be significant obstacles. For example, because the menthol cigarette rule would apply nationwide, there would be no domestic, legal source of menthol cigarettes to feed the illicit market. Instead, an illicit market would have to involve large-scale manufacturing of illegal cigarettes in facilities that would have to be entirely clandestine to avoid enforcement authorities. Moreover, consumers would need to be able to identify the illicit cigarettes as mentholated from their packaging and promotion, which would also make it easier for enforcement authorities to identify. This is in contrast to the current illicit market for cigarettes, where the illegality of smuggled cigarettes is concealed through use of counterfeit tax stamps and other means.

¹ Campaign for Tobacco-Free Kids, et al. Stopping Menthol, Saving Lives – Ending Big Tobacco’s Predatory Marketing to Black Communities, February 2021.

https://assets.tobaccofreekids.org/content/what_we_do/industry_watch/menthol-report/2021_02_tfk-menthol-report.pdf

² Issabakhsh, M, et al., “Public health impact of a US menthol cigarette ban on the non-Hispanic black population: a simulation study,” *Tobacco Control*, published online June 14, 2022.

³ Angelino, O, et al., “How New Tobacco Control Laws Could Help Close the Racial Gap on U.S. Cancer,” Council on Foreign Relations, February 1, 2023, <https://www.cfr.org/article/how-new-tobacco-control-laws-could-help-close-racial-gap-us-cancer>.

⁴ Delnevo, CD, et al., “Banning Menthol Cigarettes: A Social Justice Issue Long Overdue,” *Nicotine & Tobacco Research*, 22(10): 1673-1675, 2020.

For these reasons, comments filed with the FDA by 23 state and territorial Attorneys General concluded that “there is little reason to believe that prohibiting menthol cigarettes will cause the emergence of a serious illicit market”⁵ Similarly, a 2018 study of the illicit tobacco market by the National Research Council and the Institute of Medicine found that “if conventional cigarettes are modified by regulations, the demand for illicit versions of them is likely to be modest.”⁶ These conclusions are supported by the recent Canadian experience with a menthol cigarette ban, where there is no evidence that people who smoked menthol cigarettes have turned to illicit products; rather, these individuals have been quitting at higher rates than people who smoke non-menthol cigarettes following the ban.⁷

The Police Abuse Argument

The rule’s opponents also have expressed concerns that the emergence of an illicit market will give rise to incidents of police harassment of Black individuals who smoke. While racial bias in policing is a serious problem, the tobacco industry’s targeting of Black communities with deadly and addictive menthol cigarettes is also a serious problem. This rule will protect children from tobacco addiction, advance health equity and save lives, especially Black lives.

Contrary to the misrepresentations of the cigarette companies and their allies, the rule does not criminalize the possession and use of menthol cigarettes. It provides only that “no person may manufacture, distribute, sell, or offer for distribution or sale”⁸ menthol cigarettes. Enforcement will not be directed at individuals. It will be directed at shutting off the supply of menthol cigarettes from commercial entities. FDA also has made it crystal clear that state and local law enforcement “do not and cannot take enforcement action against”⁹ violations of the rule. It also is worth noting that over 180 localities and two states have prohibiting or restricted the sale of menthol cigarettes¹⁰ and there is no evidence that those laws have given rise to police abuses directed at menthol smokers in the Black community.

Surely we do not need to choose between protecting the health of Black people from deadly and addictive tobacco products and protecting their safety against police violence. We can and must do both. It would be a cruel irony to allow menthol cigarettes to continue to kill many thousands of Black individuals who smoke because we have not yet solved the problem of police abuse in the Black community. As NAACP President and CEO Derrick Johnson so

⁵ Attorney General of Idaho, et. al., “Comments on Proposed Regulations to Establish Tobacco Product Standards for Menthol in Cigarettes, Docket Nos. FDA-2021-N-1349 and FDA-2021-N-1309”, at 7; *See also* “Attorney General of Connecticut, et al. Comments on Tobacco Control Legal Consortium, et al., Citizen Petition to the Federal Food and Drug Administration Related to Prohibiting Menthol as a Characterizing Flavor in Cigarettes,” at 11-12, (January 22, 2021) <https://www.regulations.gov/comment/FDA-2013-P-0435-0101>.

⁶ National Research Council and Institute of Medicine, *Understanding the U.S. Illicit Market: Characteristics, Policy Context, and Lessons from International Experiences*, National Academies Press, 2015.

⁷ Janet Chung-Hall, et al., “Evaluating the impact of menthol cigarette bans on cessation and smoking behaviours in Canada: longitudinal findings from the Canadian arm of the 2016–2018 ITC Four Country Smoking and Vaping Surveys” *Tobacco Control* 2022;**31**:556-563.

⁸ Proposed Rule for a Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26,455 (May 4, 2022).

⁹ Proposed Rule for a Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26,456 (May 4, 2022).

¹⁰ Campaign for Tobacco-Free Kids, “Localities that have Restricted the Sale of Flavored Tobacco Products and Menthol Cigarettes,” Accessed November, 27, 2023.

eloquently put it in a recent letter to President Biden, those who “conflate the menthol ban with law enforcement are complicit in eroding public health,” noting that “[s]moking-related illnesses are the number one cause of death in the Black community, nearly 45,000 per year.” We strongly believe that the menthol cigarette rule will save thousands of Black lives and advance health equity without increasing the incidence of police harassment and abuse.

The Economic Impact Argument

The industry also argues that the menthol cigarette rule will cost jobs and have other adverse economic impacts, particularly in the retail sector. But research shows that declines in cigarette consumption do not reduce the number of convenience stores or convenience store sales revenue. A 2023 report shows that while cigarette sales have been declining in the U.S. for decades, the number of convenience stores, convenience stores sales revenue and profits have increased.¹¹ Research also shows that state and local restrictions on flavored tobacco products have not had a negative impact on tobacco retailers, either on the number of stores, the number of employees or real wages.¹² The fact is that money spent on tobacco products in retail stores does not disappear when people quit or cut back, but simply shifts to consumer spending on other products or services, including other products sold in convenience stores.

While the menthol cigarette rule can be expected to impact tobacco farming and manufacturing, the economic importance of that sector of the economy has been declining for decades. All measurements of tobacco growing, including the number of tobacco farms and the acres dedicated to tobacco farming, show significant declines since the early 1990s.¹³ Tobacco manufacturing jobs now make up less than one-tenth of one percent of all manufacturing jobs in the U.S.¹⁴

The industry’s arguments also ignore the fact that by reducing smoking, the rule will greatly reduce smoking-related health care costs. Tobacco costs the economy over \$241 billion in health care costs each year. Productivity losses due to smoking-caused illness and death total another \$365 billion annually.¹⁵ In addition, FDA’s Preliminary Regulatory Impact Analysis established that the estimated costs imposed by the rule are far outweighed by the estimated economic benefits from lower smoking-related mortality – a range of annualized benefits of \$220 to \$232 *billion* vs. annualized costs of \$291 to \$307 *million*.¹⁶

¹¹ Tauras, JA & Chaloupka, FJ, The Economic Effects of Cigarette Sales and Flavor Bans on Tobacco Retail Businesses, Tobacconomics, <https://www.tobacconomics.org/research/the-economic-effects-of-cigarette-sales-and-flavor-bans-on-tobacco-retail-businesses/>, 2023.

¹² Tauras, JA, et al., The Effects of Tobacco Flavor Restrictions on Tobacco Retail Businesses, Tobacconomics, <https://www.tobacconomics.org/files/research/882/the-effects-of-tobacco-flavor-bans-on-tobacco-retail-businesses-oct-2023-final-md.pdf>, 2023.

¹³ U.S. Department of Agriculture, 2017 Census of Agriculture, April 2019.

¹⁴ U.S. Census Bureau, Annual Survey of Manufactures, data for 2021.

¹⁵ CDC, Smoking and Tobacco Use, Costs and Expenditures, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/cost-and-expenditures.html Accessed November 27, 2023.

¹⁶ FDA, Preliminary Regulatory Impact Analysis of Tobacco Product Standard for Menthol in Cigarettes, Docket No. FDA-2021-N-1349, at 209, 2022, <https://www.fda.gov/media/158012/download>.

Conclusion

For over a decade, FDA has exhaustively studied the devastating impact of menthol cigarettes on public health, and particularly their tragic contribution to health disparities that have long plagued our nation. No action the Administration could take would more significantly advance the objective of health equity than implementation of the menthol cigarette rule. It is also one of the most impactful steps the Administration can take to achieve the goals of the White House Cancer Moonshot initiative. As the Administration has recognized, smoking causes 30% of all cancer deaths in the U.S. and is “the biggest single driver of cancer deaths in this country.”

The arguments made by industry opponents and their allies are based on misrepresentations of what the rule does and are unsupported by the relevant research. There is no reason for further delay. The rule should be issued in final form.

Respectfully submitted,

African American Tobacco Control Leadership Council

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

NAACP

Public Health Law Center

The Center for Black Health & Equity

Truth Initiative