

United States Senate

WASHINGTON, DC 20510

November 6, 2023

The Honorable Shalanda D. Young
Director of Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Mrs. Young,

I write to you in support of the Food & Drug Administration (FDA) proposed rules to prohibit menthol as a characterizing flavor in cigarettes and prohibit all characterizing flavors (other than tobacco) in cigars.¹ The FDA recently sent these proposed rules to the White House Office of Management and Budget (OMB) for review as part of the regulatory process. I urge OMB to promptly complete the review and finalize the FDA's rules.

In 2009, the FDA prohibited all characterizing flavors other than tobacco and menthol in cigarettes as required under the *Family Smoking Prevention and Tobacco Control Act*. The recent proposed rule published in the Federal Register in May 2022 and now under OMB review builds on to the 2009 act by prohibiting menthol as a characterizing flavor.

In addition to banning menthol as a characterizing flavor in cigarettes, the FDA proposed a rule to ban characterizing flavors (except tobacco) from cigars.² The FDA suggests that flavors increase the appeal of cigars particularly among youth and young adults, and a ban will decrease the likelihood of experimentation, development of nicotine dependence, and progression to regular use. A ban will also improve public health by increasing the likelihood that existing cigar smokers may quit.³

Menthol is added to cigarettes to enhance flavor, painkilling properties, and addictive effects.⁴ Menthol-flavored cigarettes can be more difficult to quit than non-menthol cigarettes.⁵ The Centers for Disease Control and Prevention (CDC) states that the proportion of people who tried and succeeded in quitting non-menthol cigarettes is greater than the proportion of people who have tried and succeeded in quitting menthol cigarettes.⁶ The FDA expects a menthol cigarette product standard will reduce the appeal of cigarettes, particularly to youth and young adults, by

¹ https://www.federalregister.gov/documents/2022/05/04/2022-08994/tobacco-product-standard-for-menthol-in-cigarettes?utm_medium=email&utm_source=govdelivery
https://www.federalregister.gov/documents/2022/05/04/2022-08993/tobacco-product-standard-for-characterizing-flavors-in-cigars?utm_medium=email&utm_source=govdelivery

² https://www.federalregister.gov/documents/2022/05/04/2022-08993/tobacco-product-standard-for-characterizing-flavors-in-cigars?utm_medium=email&utm_source=govdelivery

³ https://www.federalregister.gov/documents/2022/05/04/2022-08993/tobacco-product-standard-for-characterizing-flavors-in-cigars?utm_medium=email&utm_source=govdelivery

⁴ <https://www.fda.gov/media/162350/download>

⁵ <https://www.fda.gov/media/162350/download>

⁶ https://www.cdc.gov/tobacco/basic_information/menthol/related-health-disparities.html

decreasing the likelihood that nonusers who would otherwise experiment with menthol cigarettes and progress to regular smoking.⁷

Cigarettes and cigars contain tobacco, and tobacco use is one of the leading preventable causes of cancer and cancer deaths. Decreasing cigarette consumption and substantially increasing the likelihood of cessation also improves health and reduces mortality risk.⁸ Studies cited by the FDA's proposed rules estimate that smoking in the U.S. would be reduced by 15% over 40 years if cigarettes were no longer available as a characterizing flavor. Furthermore, an estimated 324,000 to 654,000 smoking-related deaths could be avoided under the menthol product standard within the same timeframe. Future cigarette-related disease and death are preventable.⁹

The tobacco industry aggressively targets its marketing to certain populations, including young people, women, and racial and ethnic minority groups, particularly African Americans. These groups are more likely to smoke menthol cigarettes compared to other population groups. Research indicates that most people who smoke cigarettes began in adolescence or young adulthood.¹⁰ Studies also show that youth and young adults are more likely to try a menthol cigarette as their first cigarette, rather than a non-menthol cigarette.¹¹

It is estimated that approximately 40% of excess deaths due to menthol cigarette smoking in the U.S. between 1980-2018 were those of African Americans, despite African Americans making up only about 12% of the U.S. population. At least 157,000 premature African American deaths between 1980-2018 are attributed to menthol cigarettes. About 70% of African Americans 18-34 years old who reported smoking between 2018-2019 reported using menthol cigarettes compared to 39% of white adults 18-34 years old in the same timeframe.¹²

I commend the Biden Administration's commitment to end cancer with the White House Cancer Moonshot efforts. I also commend the Biden Administration's support of CDC's program to help increase awareness of smoking cessation services and coverage options and the National Cancer Institute's initiative to promote smoking cessation. Moving ahead with these bans supports the Cancer Moonshot mission and CDC program to reduce the impact of commercial tobacco products in communities that experience health disparities.¹³

The OMB should move with great urgency to approve the FDA's proposed rules prohibit menthol as a characterizing flavor in cigarettes and prohibit all characterizing flavors (except tobacco) in cigars. I appreciate your attention to this critical issue and stand ready to work

⁷ https://www.federalregister.gov/documents/2022/05/04/2022-08994/tobacco-product-standard-for-menthol-in-cigarettes?utm_medium=email&utm_source=govdelivery#:~:text=This%20proposed%20product%20standard%20would%20reduce%20the%20appeal%20of%20cigarettes%2C%20particularly%20to%20youth%20and%20young%20adults%2C%20and%20thereby%20decrease%20the%20likelihood%20that%20nonusers%20who%20would%20otherwise%20experiment%20with%20menthol%20cigarettes%20would%20progress%20to%20regular%20smoking

⁸ <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>

⁹ <https://public-inspection.federalregister.gov/2022-08994.pdf>

¹⁰ Mendez, D and Le, TT, "Consequences of a match made in hell: the harm caused by menthol smoking to the African American population over 1980-2018," *Tobacco Control*, 2022 31:569-571.

¹¹ https://www.cdc.gov/tobacco/basic_information/menthol/related-health-disparities.html#:~:text=The%20tobacco%20industry%20aggressively%20targets%20minority%20groups%2C%20particularly%20Black%20people.&text=These%20groups%20are%20more%20likely%20compared%20to%20other%20population%20groups

¹² https://www.cdc.gov/tobacco/basic_information/menthol/related-health-disparities.html

¹³ <https://www.whitehouse.gov/briefing-room/statements-releases/2023/09/13/fact-sheet-as-part-of-president-bidens-unity-agenda-white-house-cancer-moonshot-announces-new-actions-and-commitments-to-end-cancer-as-we-know-it/>

collaboratively to ban menthol to expectedly decrease smoking rates in the U.S. and address the menthol-related deep racial disparities disproportionately affecting African Americans brought on by years of industry advertising targeting this community.

Sincerely,



Kirsten Gillibrand
United States Senator