

Merkley, colleagues press FDA for ban on menthol cigarettes, flavored cigars

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Oregon's U.S. Senator Jeff Merkley led 21 senators in a letter to the Food and Drug Administration (FDA) Commissioner Robert Califf, urging the FDA to promptly finalize its April 28, 2022 announced proposed rules to end the sale of menthol flavor in cigarettes and all flavors in cigars.

"We urge the FDA to act with urgency to solidify and enforce the ban on these harmful products," wrote the Senators. "The harmful effects of these products on public health have been well-understood for several years and cannot be overstated. In 2013, your agency released a report that found that menthol cigarette use is associated with increased smoking initiation among youth and young adults, greater signs of nicotine dependence, and less success in smoking cessation."

The 2013 findings, reinforced by more recent data from 2019, reports nearly 18.6 million Americans smoke menthol cigarettes. Youth who smoke are more likely to smoke menthol cigarettes, with almost half of cigarette smokers ages 12-18 choosing to smoke menthol cigarettes.

Furthermore, the Senators' letter spotlights how Big Tobacco aggressively targets minority communities through efforts at the point of sale, branding, and sponsorship to push these products. As a result, nearly 85 percent of African American smokers use menthol cigarettes, compared to 47.7 percent of Hispanic smokers, 41.1 percent of Asian smokers, and 30.3 percent of white smokers.

These scientific findings and concerning statistics, along with the FDA's slipping deadlines, strongly support the need for swift action in finalizing and enforcing these critical regulations. However, the

Senators' letter notes that past rulemaking processes have shown a concerning trend of inaction from the FDA. In 2013 and again in 2018, the FDA published a notice of proposed rulemaking to obtain information related to the potential regulation of menthol in cigarettes.

In March 2019, the FDA announced that it was considering removing flavored cigars that were on the market as of August 8, 2016. And a year ago, in April 2022, the FDA announced its intention to ban menthol as a characterizing flavor in cigarettes, and all flavored cigars. The Senators call attention to delays in the comment period for these rules—the original deadline was pushed from July 5, 2022 to August 2, 2022. Now, a year after the proposed rule was issued, the rulemaking is still not resolved. Despite these repeated overtures, the FDA has yet to issue a final rule on these topics, much less begin enforcement.

“While we appreciate the need for thorough, well-informed rulemaking, it is clear that these products pose significant and persistent threats to public health,” they continue. “The longer these products are allowed on the market, the more harm consumers and the American public will face.”

In order to better understand the FDA's timeline for finalizing and enforcing these regulations, the Senators request responses to the following questions:

When does the FDA anticipate that it will finalize these rules regarding the ban on menthol cigarettes and flavored cigars?

How does the FDA plan to coordinate with other federal agencies for the purposes of enforcing these bans and increasing consumer and retailer awareness?

How does the FDA plan to address attempts from cigarette manufacturers to circumvent the ban on menthol cigarettes by offering “fresh” or “crisp” alternatives to menthol?[1]

Are there additional resources that Congress can provide to facilitate the enforcement of these rules once finalized?

Joining Merkley, the letter is signed by Senators Dick Durbin (D-IL), Alex Padilla (D-CA), Jack Reed (D-RI), Richard Blumenthal (D-CT), Ron Wyden (D-OR), Tammy Baldwin (D-WI), Mazie Hirono (D-HI), Sheldon Whitehouse (D-RI), Tom Carper (D-DE), Martin Heinrich (D-NM), Chris Coons (D-DE), Edward J. Markey (D-MA), Brian Schatz (D-HI), Elizabeth Warren (D-MA), Patty Murray (D-WA), Chris Van Hollen (D-MD), Sherrod Brown (D-OH), Tina Smith (D-MN), Tammy Duckworth (D-IL), and Maggie Hassan (D-NH).

This letter is supported by the Campaign for Tobacco-Free Kids, the American Lung Association, American Cancer Society Cancer Action Network, and the American Heart Association.

“The FDA's proposed rules to prohibit menthol cigarettes and flavored cigars represent some of the strongest actions our nation has ever taken to drive down the number of kids who start smoking and the number of Americans sickened and killed by tobacco. Because of the profound benefit to our nation's health, the FDA has an obligation to finalize and implement these rules with utmost urgency, and we applaud Sen. Merkley and his Senate colleagues for urging the FDA to do so,” said Matthew L. Myers, President of the Campaign for Tobacco-Free Kids. “The faster these rules are implemented, the sooner we can stop the tobacco industry's lethal targeting of Black and other communities, advance health equity, protect our nation's children and save lives.”

“Ending the sale of both menthol cigarettes and flavored cigars will save lives, and research shows that ending the sale of menthol cigarettes would result in a significant number of people quitting smoking,” said Harold Wimmer, National President and CEO of the American Lung Association. “Every day that these products remain on the market, it impacts our youth and contributes to health inequities in our country. The American Lung Association thanks Senator Merkley for his leadership in urging FDA to expedite these lifesaving rules, and we urge the Biden administration to finalize these rules no later than August 2023.”

“FDA’s delay in finalizing the proposed rules on menthol in cigarettes and all flavors in cigars only offers Big Tobacco more time to aggressively market these deadly products to new users, specifically targeting Black, LGBTQ+, and lower-income communities,” said Lisa Lacasse, President of the American Cancer Society Cancer Action Network. “Tobacco products with menthol and other flavors increase health disparities, increase use among and addiction of young people, and make it more difficult for existing users to quit. There is absolutely no scientific rationale for permitting any flavored tobacco products to remain on the market. We thank the Senators for their attention to this important issue and join them in calling on FDA to clearly explain their timeline for finalizing and enforcing these important regulations.”

“For decades, the tobacco industry has used menthol cigarettes and flavored cigars to attract and hook new users - aggressively targeting and marketing these products to communities of color, the LGBTQ+ community and youth,” said Nancy Brown, CEO of the American Heart Association. “One year ago, the FDA took a historic step and proposed ending the sale of menthol cigarettes and all flavored cigars. The American Heart Association urges the administration to quickly finalize strong rules that remove these highly addictive, deadly products from the market.”

Full text of the letter can be found here and follows below:

Dear Commissioner Califf:

We write on the one-year anniversary of the Food and Drug Administration’s (FDA’s) April 28, 2022 announcement of proposed rules to end the sale of menthol as a characterizing flavor in cigarettes and a ban on all flavors in cigars.^[2] While we were encouraged by this announcement last year, we remain concerned about the implementation of these rules, especially following the release of the Reagan-Udall Foundation’s December 2022 report on the FDA’s tobacco program.^[3] we write today to urge the FDA to act with urgency to solidify and enforce the ban on these harmful products.

The harmful effects of these products on public health have been well-understood for several years and cannot be overstated. In 2013, your agency released a report that found that menthol cigarette use is associated with increased smoking initiation among youth and young adults, greater signs of nicotine dependence, and less success in smoking cessation. This report collectively indicated that menthol cigarettes pose a greater public health risk than non-menthol cigarettes.^[4] Flavored, cigars also present a pressing public health risk—particularly for youth—with nearly 74 percent of youth cigar users aged 12 – 17 choosing to smoke cigars because of their flavors.

These findings are also reinforced by more recent data. In 2019, nearly 18.6 million Americans smoke menthol cigarettes. Youth who smoke are more likely to smoke menthol cigarettes than older smokers, with almost half of the cigarette smokers ages 12 – 18 choosing to smoke menthol cigarettes.^[5] Big Tobacco has also aggressively targeted minority communities, particularly the African American

community, through efforts at the point of sale, branding, and sponsorship to push these products. As a result, nearly 85 percent of African American smokers use menthol cigarettes, compared to 47.7 percent of Hispanic smokers, 41.1 percent of Asian smokers, and 30.3 percent of white smokers.

We are also aware of additional delays in the comment period for these rules, with the original deadline falling from July 5, 2022, to August 2, 2022. While we appreciate the need for thorough, well-informed rulemaking, it is clear that these products pose significant and persistent threats to public health, and the longer these products are allowed on the market, the more harm consumers and the American public will face.

Because of these scientific findings, concerning statistics, and slipping deadlines, the need to act swiftly in finalizing and enforcing these regulations is critical. However, past rulemaking processes have shown a concerning trend of inaction from the FDA. Almost a decade ago, in 2013, the FDA published an advance notice of proposed rulemaking (ANPRM) to obtain information related to the potential regulation of menthol in cigarettes, and again in 2018 related to the regulation of board flavors in tobacco products.[6] [7] In March 2019, the FDA announced that it was considering removing flavored cigars that were on the market as of August 8, 2016.[8] And a year ago, in April 2022, the FDA announced its intention to ban menthol as a characterizing flavor in cigarettes, and all flavored cigars. Despite these repeated overtures, the FDA has yet to issue a final rule on these topics, much less begin enforcement.

In order to better understand the FDA's timeline for finalizing and enforcing these regulations, we request responses to the following questions within 30 days of receipt of this letter:

When does the FDA anticipate that it will finalize these rules regarding the ban on menthol cigarettes and flavored cigars?

How does the FDA plan to coordinate with other federal agencies for the purposes of enforcing these bans and increasing consumer and retailer awareness?

How does the FDA plan to address attempts from cigarette manufacturers to circumvent the ban on menthol cigarettes by offering "fresh" or "crisp" alternatives to menthol?[9]

Are there additional resources that Congress can provide to facilitate the enforcement of these rules once finalized?

Thank you for your attention to this critical public health concern and these questions. We look forward to your responses and continuing to work with your agency to advance public health in our country.

[1] "R.J. Reynolds Pivots to New Cigarette Pitches as Flavor Ban Takes Effect," New York Times, January 11, 2023. <https://www.nytimes.com/2023/01/11/health/cigarettes-flavor-ban-california.html>

[2] Office of the Commissioner, "FDA Proposes Rules Prohibiting Menthol Cigarettes and Flavored Cigars to Prevent Youth Initiation, Significantly Reduce Tobacco-Related Disease and Death," FDA, 2022.

<https://www.fda.gov/news-events/press-announcements/fda-proposes-rules-prohibiting-menthol-cigarettes-and-flavored-cigars-prevent-youth-initiation>

[3] Reagan-Udall Foundation, “Operational evaluation of Certain Components of FDA’s Tobacco Program,” Reagan-Udall Foundation, (December 2022). <https://reaganudall.org/sites/default/files/2022-12/Tobacco%20report%20210pm.pdf>

[4] FDA, “Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes,” <http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/UCM2013>

[5] United States Department of Health and Human Services. Substance Abuse and Mental Health Services Administration (SAMHSA). Center for Behavioral Health Statistics and Quality. National Survey on Drug Use and Health, 2019.

[6] “Menthol in Cigarettes, Tobacco Products, Request for Comments,” Federal Register, July 24, 2013, <https://www.federalregister.gov/documents/2013/07/24/2013-17805/menthol-in-cigarettes-tobacco-products-request-for-comments>

[7] “Regulation of Flavors in Tobacco Products,” Federal Register, March 21, 2018, <https://www.federalregister.gov/documents/2018/03/21/2018-05655/regulation-of-flavors-in-tobacco-products>

[8] “Statement from FDA Commissioner Scott Gottlieb, M.D., on Advancing New Policies Aimed at Preventing Youth Access to, and Appeal of, Flavored Tobacco Products, Including E-Cigarettes and Cigars,” FDA (FDA, March 13, 2019), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-advancing-new-policies-aimed-preventing-youth-access>

[9] “R.J. Reynolds Pivots to New Cigarette Pitches as Flavor Ban Takes Effect,” New York Times, January 11, 2023. <https://www.nytimes.com/2023/01/11/health/cigarettes-flavor-ban-california.html>