

# United States Senate

WASHINGTON, DC 20510

April 28, 2023

The Honorable Dr. Robert Califf  
Commissioner  
United States Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993

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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> 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 smoked 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.<sup>4</sup> 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

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<sup>1</sup> 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>

<sup>2</sup> 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>

<sup>3</sup> FDA, "Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes,"

<http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/UCM361598.pdf> (2013)

<sup>4</sup> 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.

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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 broad flavors in tobacco products.<sup>5,6</sup> In March 2019, the FDA announced that it was considering removing flavored cigars that were on the market as of August 8, 2016.<sup>7</sup> 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:

1. When does the FDA anticipate that it will finalize these rules regarding the ban on menthol cigarettes and flavored cigars?
2. How does the FDA plan to coordinate with other federal agencies for the purposes of enforcing these bans and increasing consumer and retailer awareness?
3. 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?<sup>8</sup>
4. 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. I/we look forward to your responses and continuing to work with your agency to advance public health in our country.

Sincerely,

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<sup>5</sup> "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>

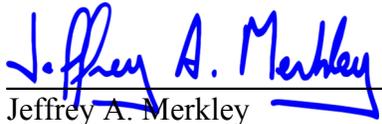
<sup>6</sup> "Regulation of Flavors in Tobacco Products," Federal Register, March 21, 2018, <https://www.federalregister.gov/documents/2018/03/21/2018-05655/regulation-of-flavors-in-tobacco-products>

<sup>7</sup> "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>

<sup>8</sup> "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>

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United States Senator



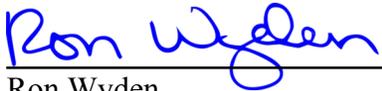
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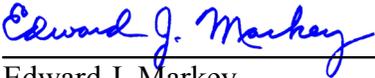
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Martin Heinrich  
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*Maggie Hassan*

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Margaret Wood Hassan

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