

United States Senate

WASHINGTON, DC 20510

January 12, 2024

Dear OMB Director Shalanda Young:

We write to you regarding the Biden administration's recent indication in the Unified Agenda of Regulatory and Deregulatory Actions that it would delay finalizing a long-overdue federal rule to prohibit the manufacture and retail sale of menthol as a characterizing flavor in cigarettes.¹ We are extremely concerned that the rule is now expected to be released in March 2024, which is two years after the Food and Drug Administration's (FDA's) April 2022 announcement of the proposed rule.² Likewise, we are also awaiting a final rule to ban all flavors in cigars, a proposed rule that was also announced in April 2022. We write today to urge the FDA and OMB to act with urgency to solidify and enforce the bans on these harmful products as soon as possible. Simply put, delays in finalizing these rules will only bring more addiction and death.

The harmful effects of these products on public health have been well-understood for several years and cannot be overstated. In 2013, the FDA 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.³ 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.⁴ 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, among individuals who smoke, nearly 85 percent of African Americans use menthol cigarettes, compared to 47.7 percent of Hispanics, 41.1 percent of Asians, and 30.3 percent of whites.

We are also aware of additional delay in the comment period for these rules, with the original comment deadline falling from July 5, 2022, to August 2, 2022. In addition, the unified federal

¹ Dan Diamond and David Ovalle, "Biden Ban On Menthol Cigarettes to Be Delayed Among Political Concerns, Officials Say," *The Washington Post*, December 6, 2023,

<https://www.washingtonpost.com/health/2023/12/05/menthol-ban-delayed-biden-administration/>.

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 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)

⁴ 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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agenda indicated that the rules were supposed to be finalized in August 2023, and then administration officials indicated that they would finish by December 2023. 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. More than 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.⁵ In March 2019, the FDA announced that it was considering removing flavored cigars that were on the market as of August 8, 2016.⁶ And almost two years 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—which the FDA has been clear would only fall upon manufacturers, distributors, wholesalers, importers, and retailers for violations of the Federal Food, Drug, and Cosmetic Act, and would not take place against individuals either by the FDA or by state and local law enforcement.

The data uncovered over the last decade is more than clear. Menthol cigarettes and flavored cigars have contributed to a public health crisis, and the administration must center those impacted and finalize these rules immediately.

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

Sincerely,



Jeffrey A. Merkley
United States Senator




Richard J. Durbin
United States Senator

⁵ “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>; “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>.

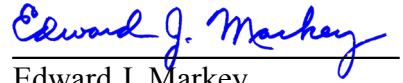
⁶ “Statement from FDA Commissioner Scott Gottlieb, M.D., on Advancing New Policies Aimed at Preventing Youth Access to, and Appeal of, Flavored Tobacco Products, Including E-Cigarettes and Cigars,” FDA (FDA, March 13, 2019), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-advancing-new-policies-aimed-preventing-youth-access>

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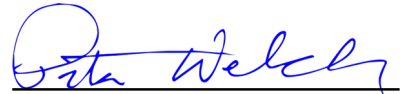
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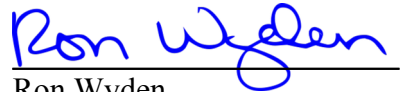
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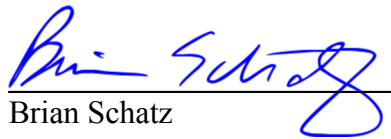
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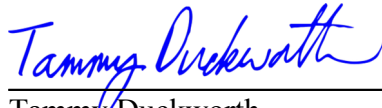
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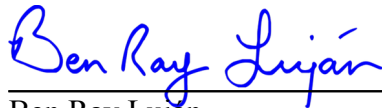
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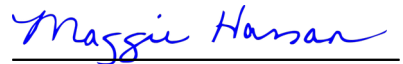
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Margaret Wood Hassan
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Benjamin L. Cardin
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CC: Dr. Robert Califf, Commissioner, U.S. Food and Drug Administration
CC: Neera Tanden, Director, Domestic Policy Council at the White House