

To: United States Food and Drug Administration
Department of Health and Human Services
via <https://www.regulations.gov>

From: Massachusetts Medical Society

Re: Docket Nos. FDA-2021-N-1349 and FDA-2021-N-1309

Date: August 2, 2022

On behalf of our 25,000 physician, resident, and medical student members, the Massachusetts Medical Society (MMS) appreciates the opportunity to submit comments to the United States Food and Drug Administration (FDA) regarding the *“Tobacco Product Standard for Menthol in Cigarettes”* and *“Tobacco Product Standard for Characterizing Flavors in Cigars”* published in the Federal Register on May 4, 2022 (87 FR 26454 and 87 FR 26396).

The preventable health risks posed by tobacco and nicotine, and the flavor tactics used by Big Tobacco to enable addiction, have been present for far too long. For years, the Massachusetts Medical Society has advocated for tobacco control at the state and federal levels to prohibit all flavored nicotine products and, since 2001, has urged the Massachusetts Congressional delegation to support legislative efforts to authorize the FDA’s regulation of nicotine and nicotine-delivery products.

Relative to Docket No. FDA-2021-N-1349, *“Tobacco Product Standard for Menthol in Cigarettes”*, the MMS has encouraged the American Medical Association (AMA), the national physician membership organization, to “advocate, that the FDA extend the ban on sale or distribution of any flavored cigarettes to include menthol and mint flavors and electronic nicotine delivery systems by any retailer, retail establishment, or other person or entity to any consumer.” (MMS House of Delegates, 5/4/2019)¹

The Commonwealth of Massachusetts passed landmark legislation in November 2019, which prohibited Big Tobacco’s targeting of youth, LGBTQ+, and Indigenous people, and communities of color by restricting the sale of menthol cigarettes and vaping products.

As of January 1, 2020, Massachusetts commercial health insurance plans and the state’s Group Insurance Commission and MassHealth are required to cover smoking cessation counseling and FDA-approved smoking cessation products, such as gum, lozenges, and patches, without cost-sharing. On June 1, 2020, sale of flavored combustible cigarettes and other flavored tobacco products, including menthol cigarettes and flavored chewing tobacco, was restricted in the Commonwealth to licensed smoking bars for on-site consumption only. Also beginning on June 1, 2020 was an additional 75 percent excise tax on the wholesale price of nicotine vaping products, in addition to the state’s 6.25 percent sales tax.^{2,3} The MMS was and is a proud partner

¹ Massachusetts Medical Society. MMS Policy Compendium. Tobacco/Smoking. E-Cigarettes, Nicotine Liquids, and Personal Electronic Vaporizers (p.185). [www.massmed.org/Governance-and-Leadership/Policies,-Procedures-and-Bylaws/MMS-Policy-Compendium-\(pdf\)/](http://www.massmed.org/Governance-and-Leadership/Policies,-Procedures-and-Bylaws/MMS-Policy-Compendium-(pdf)/)

² Commonwealth of Massachusetts. 2019 Tobacco Control Law. www.mass.gov/guides/2019-tobacco-control-law#-new-tobacco-control-law-

³ Commonwealth of Massachusetts. Press release. Public Health Council approves regulations restricting access to vaping and tobacco products. Dec 11, 2019. www.mass.gov/news/public-health-council-approves-regulations-restricting-access-to-vaping-and-tobacco-products

in the passage of that law and continues to work with the AMA and Tobacco Free Mass, the state's largest anti-tobacco and nicotine coalition, to create a united front against Big Tobacco.

As the FDA rightly states, tobacco use is the leading preventable cause of death and disease in the United States.⁴ Combining tobacco with menthol additives is known to make tobacco use more easily tolerated – and more addictive – by reducing the body's response to irritants found in smoke. Menthol makes it harder to quit tobacco use, and menthol cigarettes are more addictive and may be more dangerous. Studies from the FDA and other scientific entities conclude that menthol cigarettes are associated with increased nicotine dependence and reduced success in smoking cessation.^{5,6,7,8}

It is well documented that tobacco companies have targeted Black, Indigenous, Latinx, and LGBTQ+ communities with their flavored products, including menthol.^{9,10} Youth are also targeted, particularly with flavors including menthol, through vaping products and little cigars.^{11,12} The MMS and other public health-related organizations, both state-wide and nationally, have pushed back against the tobacco industry's newest tactic to promote themselves as defenders of public health through deceitful advertising and disinformation campaigns.^{13,14} A local example of this tactic is recent image polishing by Phillip Morris International (PMI) in *The Boston Globe*. The *Globe* accepted sponsored content from PMI, which included articles on "innovation" and touted PMI products as solutions to those addicted to tobacco and nicotine products.¹⁵ Similar sponsored content has also run in *The New York Times* and other newspapers across the country.¹⁶

The 2020 Surgeon General's Report on smoking cessation found that Black Americans are less likely to quit smoking due to a higher use of menthol cigarettes. More than half of all high school

⁴ U.S. Food and Drug Administration. FDA announces plans for proposed rule to reduce addictiveness of cigarettes and other combusted tobacco products. June 21, 2022. <https://www.fda.gov/news-events/press-announcements/fda-announces-plans-proposed-rule-reduce-addictiveness-cigarettes-and-other-combusted-tobacco>

⁵ Yerger VB. Menthol's potential effects on nicotine dependence: a tobacco industry perspective. *Tob Control*. 2011;20 Suppl 2(Suppl_2):ii29-ii36. doi:10.1136/tc.2010.041970

⁶ Leas EC, Benmarhnia T, Strong DR, Pierce JP. Use of Menthol Cigarettes, Smoking Frequency, and Nicotine Dependence Among US Youth. *JAMA Netw Open*. 2022;5(6):e2217144. doi:10.1001/jamanetworkopen.2022.17144

⁷ U.S. Food and Drug Administration. Scientific Review of the Effects of Menthol in Cigarettes on Tobacco Addiction: 1980-2021. <https://www.fda.gov/media/157642/download>

⁸ Levy DT, Meza R, Yuan Z, *et al* Public health impact of a US ban on menthol in cigarettes and cigars: a simulation study *Tobacco Control* Published Online First: 02 September 2021. doi:10.1136/tobaccocontrol-2021-056604

⁹ Levy DT, Meza R, Yuan Z, *et al* Public health impact of a US ban on menthol in cigarettes and cigars: a simulation study *Tobacco Control* Published Online First: 02 September 2021. doi:10.1136/tobaccocontrol-2021-056604

¹⁰ Public Health Law Center. The tobacco industry and the Black community. The targeting of African Americans. June 2021. www.publichealthlawcenter.org/sites/default/files/resources/Tobacco-Industry-Targeting.pdf

¹¹ U.S. Food and Drug Administration. Results from the Annual National Youth Tobacco Survey. 2021 Findings on Youth Tobacco Use. Mar 3, 2022.

¹² Centers for Disease Control and Prevention. Smoking and Tobacco. Tobacco industry marketing. Page reviewed May 2021.

www.cdc.gov/tobacco/data_statistics/fact_sheets/tobacco_industry/marketing/index.htm#:~:text=Scientific%20evidence%20shows%20that%20tobacco,people%20to%20start%20using%20tobacco.&text=Adolescents%20who%20are%20exposed%20to,increase%20adolescents%20desire%20to%20smoke.

¹³ Tan ASL, Bigman CA. Misinformation About Commercial Tobacco Products on Social Media-Implications and Research Opportunities for Reducing Tobacco-Related Health Disparities. *Am J Public Health*. 2020 Oct;110(S3):S281-S283. doi: 10.2105/AJPH.2020.305910. PMID: 33001728; PMCID: PMC7532322.

¹⁴ Bazell R, Koh H, Bloom BR. The tobacco wars' lessons for the vaccination wars. 2022.04.13. *New Eng Jour Med*. www.nejm.org/doi/full/10.1056/NEJMp2202618

¹⁵ Tobacco Free Mass. Boston Globe runs Phillip Morris ads. www.tobaccofreema.org/Philip-Morris-Image-Polishing

¹⁶ Truth Initiative. How the tobacco industry uses sponsored content in major media outlets to shift public perception. May 2022. <https://truthinitiative.org/research-resources/tobacco-industry-marketing/how-tobacco-industry-uses-sponsored-content-major>

students who smoke use menthol cigarettes, and over 90% of African American youth who smoke use menthol cigarettes.¹⁷ According to Truth Initiative, because African Americans use menthol cigarettes at higher rates, menthol also contributes to health inequities.¹⁸

In 2018, the National Medical Association, the largest and oldest national organization representing African American physicians and their patients, passed policy in support of banning menthol cigarettes.¹⁹ The NAACP also strongly supports a ban on menthol flavoring.^{20,21}

Carol McGruder, Co-Chair of the African American Tobacco Control Leadership Council, states that “Big Tobacco is now using race as an excuse to keep products on the market saying if menthol products are taken away, more police violence against Black Americans will ensue.”^{22,23,24} The MMS notes, however, that the FDA proposal will only address manufacturers, distributors, wholesalers, importers, and retailers, not individual consumers.

Tobacco companies have advertised at sexual- and gender-diverse community events, have contributed to HIV/AIDS organizations, and are visible at gay pride festivals, evidencing their targeting of these communities.²⁵ The American Lung Association details that, according to the CDC, approximately 36% of LGBTQ+ smokers report smoking menthol cigarettes compared to 29% of heterosexual smokers.

Relative to Docket No. FDA-2021-N-1309, “*Tobacco Product Standard for Characterizing Flavors in Cigars*”, flavors make it easier for kids to start using tobacco products, as those grape, watermelon, and other additives mask the harsh taste of tobacco. As the FDA did with flavored electronic cigarettes (with the exclusion of menthol flavoring), the MMS supports banning these flavors to decrease the number of youth and young adults who try and quickly become addicted to nicotine.

The benefits of reducing tobacco-related health disparities and advancing health equity to historically marginalized people and protecting all young people from tobacco are compelling. The MMS applauds the FDA’s proposal of a tobacco product standard that would prohibit characterizing flavors (other than tobacco) in all cigars and their component parts, as well as the proposal to prohibit menthol as a characterizing flavor in cigarettes. As these proposals are intended to reduce uptake of tobacco use, we urge the FDA to similarly prohibit menthol as a

¹⁷ U.S. Department of Health and Human Services. Smoking cessation. A report of the Surgeon General. 2020. www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf

¹⁸ Truth Initiative. Menthol: facts, stats, and regulation. Apr 22, 2022. <https://truthinitiative.org/research-resources/traditional-tobacco-products/menthol-facts-stats-and-regulations>

¹⁹ National Medical Association. NMA supports FDA to ban menthol cigarettes and flavored cigars. Nov 16, 2018. www.nmanet.org/news/428134/NMA-Supports-FDA-to-Ban-Menthol-Cigarettes-and-Flavored-Cigars.htm

²⁰ NAACP. Resolution: Support state and local restrictions on the sale of flavored tobacco products. 2016. <https://naacp.org/resources/support-state-and-local-restrictions-sale-flavored-tobacco-products>

²¹ Truth Initiative. NAACP delegates endorse push to say no to menthol. Jul 21, 2016. <https://truthinitiative.org/research-resources/targeted-communities/naacp-delegates-endorse-push-say-no-menthols>

²² African American Tobacco Control Leadership Council (AATCLC). Carol McGruder, founding member/co-founder. www.savingblacklives.org/carol-mcgruder

²³ Interact for Health. Q&A with Carol McGruder, founding member and co-chair of the African American Tobacco Control Leadership Council. Feb. 15, 2021. www.interactforhealth.org/whats-new/313/qa-with-carol-mcgruder-founding-member-and-co-chair-of-the-african-american-tobacco-control-leadership-council.

²⁴ Truth Initiative. Tobacco industry has fueled false claims that eliminating menthol cigarettes will put Black Americans at greater risk from law enforcement. <https://truthinitiative.org/research-resources/targeted-communities/tobacco-industry-has-fueled-false-claims-eliminating>

²⁵ American Lung Association. The impact of menthol cigarettes on the health of the LGBTQ+ community. June 16, 2022. www.lung.org/blog/menthol-lbgq-community

characterizing flavor in electronic nicotine delivery systems, while also considering enforcement mechanisms and messaging that will promote equity.

The Massachusetts Medical Society appreciates the opportunity to provide comments to the FDA in our shared goal of providing the highest quality health and health care to patients. The MMS' comments and recommendations are guided by our policies, our membership, and our commitment to providing high quality, equitable care to all patients. Should you have any questions, please contact Casey Rojas, Federal Relations and Health Equity Manager, at crojas@mms.org or (781) 434-7082.