

July 29, 2022

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
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RE: Docket No. FDA-2021-N-1349 for “Tobacco Product Standard for Menthol in Cigarettes”

As scientific experts in the fields of tobacco use¹ and addiction, we are writing to urge the Food and Drug Administration (FDA) to move swiftly to finalize and implement the proposed product standard prohibiting menthol as a characterizing flavor in cigarettes (Proposed Rule for a Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26,454 (May 4, 2022) (NPRM)). The FDA’s proposed rule to prohibit menthol as a characterizing flavor in cigarettes contains a powerful and accurate summary of the robust evidence base on the role menthol plays in promoting smoking, enhancing addiction and reducing cessation, particularly among African Americans. This rule will have a significant public health impact by reducing tobacco use initiation and tobacco-related disease and death. It will also reduce health disparities and advance health equity. As the proposed rule demonstrates, there is ample scientific evidence to support this action. In 2011, the FDA’s Tobacco Products Scientific Advisory Committee (TPSAC) concluded that, “Removal of menthol cigarettes from the marketplace would benefit the public health in the United States.” In 2013, FDA’s *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes* (FDA Report) reached the conclusion, consistent with TPSAC’s, that it is “likely that menthol cigarettes pose a public health risk above that seen with nonmenthol cigarettes.”² The TPSAC Report projected the adverse impact of menthol in cigarettes from 2011 to the present day, finding that “by 2020, about 17,000 premature deaths will occur and about 2.3 million people will have started smoking, beyond what would have occurred absent availability of menthol cigarettes.”³ In the years since these reports, the science supporting menthol’s role in increasing youth initiation and addiction, reducing cessation, and perpetuating health disparities, has only grown.

A 2021 study quantified the population harms caused by menthol cigarettes between 1980 and 2018 and found that menthol cigarettes were responsible for 10.1 million additional new smokers, 378,000 premature deaths and nearly 3 million life-years lost over the 38-year period.⁴ The harm caused by menthol cigarettes has not been borne equally. A related analysis estimated that menthol cigarettes were responsible for 1.5 million extra smokers, 157,000 smoking-related premature deaths and 1.5 million excess life-years among African Americans.⁵

¹ References to tobacco in this letter refer to commercial tobacco and not ceremonial tobacco which is used by some American Indian communities.

² FDA, *Preliminary Scientific Evaluation of the Possible Public Health effects of Menthol versus Nonmenthol Cigarettes*, 2013, <https://www.fda.gov/media/86497/download> (FDA Report).

³ TPSAC, FDA, *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations*, 2011, <https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf> (TPSAC Menthol Report).

⁴ Thuy TT Le and David Mendez, “An estimation of the harm of menthol cigarettes in the United States from 1980 to 2018,” *Tobacco Control*, published online February 25, 2021.

⁵ David Mendez and Thuy TT le, “Consequences of a match made in hell: the harm caused by menthol smoking to the African American population over 1980-2018,” *Tobacco Control*, published online September 16, 2021.

By increasing smoking cessation and preventing tobacco use initiation, published modeling studies have estimated that removal of menthol cigarettes from the marketplace would reduce overall smoking by 15% and save 650,000 lives by 2060.⁶ More recent research by the same researchers, currently in press, estimates that if menthol cigarettes were no longer available in the United States, Black adult smoking would be reduced by 35.7% in the first five years, smoking-attributable deaths among Blacks would decline by 18.5% and 255,895 premature deaths would be avoided.⁷

We could not agree more with the overarching conclusion included in the proposed rule:

“By prohibiting the addition of menthol as a characterizing flavor to cigarettes sold in the United States, FDA anticipates that reductions in population harm would be realized through long-term health benefits resulting from prevention of cigarette uptake and progression to regular cigarette smoking among youth and young adults, as well as shorter-term health benefits resulting from increased cessation of cigarette smoking among current menthol smokers. Each of these impacts alone would result in significant health benefits to the U.S. population. In totality, they provide overwhelming evidence that the proposed standard would result in substantial health benefits over both the short- and long-term.”

Given the tremendous burden of tobacco use, and particularly the use of menthol cigarettes, on the nation’s health, it is imperative that FDA issue this rule in final form without delay.

The Role of Menthol in Youth Smoking Initiation and Transition to Regular Smoking

Due to its analgesic properties, the use of menthol as a characterizing flavor in cigarettes masks the harshness of tobacco smoke, making it easier for new users – particularly tobacco naïve youth – to initiate smoking. The undersigned researchers concur with the conclusions of both the TPSAC report and FDA’s own analysis, which determined that menthol cigarettes increase smoking initiation, youth addiction, and progression to regular smoking.

Half of youth who have ever tried smoking started with menthol cigarettes.⁸ According to the 2021 National Youth Tobacco Survey (NYTS), 41.1% of high school smokers use menthol cigarettes.⁹ 2017 and 2018 NYTS data also show that among middle and high school students, smoking of menthol cigarettes is associated with greater smoking frequency and intention to continue smoking, compared to non-menthol smoking.¹⁰ Data from the government’s Population Assessment of Tobacco and Health (PATH) study shows that that youth menthol smokers have significantly higher levels of certain measures

⁶ Levy, D.T., et al. "Public health impact of a US ban on menthol in cigarettes and cigars: a simulation study." *Tobacco Control*, published online September 2, 2021.

⁷ Issabakhsh, M, et al., (in press), “The Public Health Impact of a US Menthol Cigarette Ban on the Non-Hispanic Black Population: A Simulation Study,” *Tobacco Control* Published Online First: 14 June 2022. doi: 10.1136/tobaccocontrol-2022-057298.

⁸ Bridget K. Ambrose, et al., “Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014,” *Journal of the American Medical Association*, Nov 3;314(17):1871-3, 2015.

⁹ Andrea S. Gentzke, et al., “Tobacco Product Use and Associated Factors Among Middle and High School Students—National Youth Tobacco Survey, United States, 2021,” *MMWR* 71(5): 1-29, March 10, 2022, <https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7105a1-H.pdf>.

¹⁰ Sunday Azagba, et al., *Cigarette Smoking Behavior Among Menthol and Nonmenthol Adolescent Smokers*, 66 *Journal of Adolescent Health* 545-550, 2020, <https://pubmed.ncbi.nlm.nih.gov/31964612/>. Michael D. Sawdey, et al., *Trends and Associations of Menthol Cigarette Smoking Among US Middle and High School Students—National Youth Tobacco Survey, 2011-2018*, 22 *Nicotine & Tobacco Research* 1726-1735, doi:10.1093/ntr/ntaa054.

of dependence,¹¹ and that initiation with a menthol-flavored cigarette is associated with a higher relative risk of continuing to daily smoking.¹² Indeed, the rule includes strong evidence demonstrating that menthol cigarettes facilitate progression to regular use in new smokers, particularly youth and young adults, and that menthol in cigarettes contributes to greater dependence among youth.

Menthol Cigarettes Reduce Smoking Cessation

Prohibiting menthol as a characterizing flavor in cigarettes has the potential to accelerate the decline in cigarette smoking in the United States. Cigarette sales data show that declines in menthol cigarette sales lag behind those of non-menthol cigarettes. From 2009 to 2018, sales of non-menthol cigarettes have declined by 33.1% nationally, while sales of menthol cigarettes have declined by only 8.2%. Of the decline in cigarette sales between 2009 and 2018, 91% is attributable to non-menthol cigarettes.¹³ Similarly, NSDUH data show that while overall cigarette smoking has been declining, the proportion of smokers using menthol cigarettes continues to increase. Overall, about 4 out of 10 (39.9%) smokers used menthol cigarettes in 2018, an increase from 34.7% in 2008-2010.¹⁴ By reducing smoking cessation, menthol has slowed the nation's progress in reducing overall smoking.

Consistent with previous TPSAC and FDA Reports, the FDA's analysis for the proposed rule found that, in addition to increasing initiation of smoking among young people, menthol cigarettes are associated with reduced success in smoking cessation, particularly among African American smokers.¹⁵ The 2020 Surgeon General's Report on smoking cessation, citing more recent evidence, concluded that the evidence is suggestive that restricting menthol products would lead to increased smoking cessation.¹⁶ Recent studies provide strong evidence of an association between menthol cigarette use and reduced cessation at the population level. An October 2020 study published in *Nicotine & Tobacco Research* represents one of the most robust longitudinal and nationally representative assessments of the relationship between menthol cigarette smoking and cessation. Analyzing four waves of data from the government's nationally representative PATH survey, the study found that among daily smokers, menthol cigarette smokers have a 24% lower odds of quitting as compared to non-menthol smokers. Among daily smokers, African American menthol smokers had a 53% lower odds of quitting compared to African American non-menthol smokers and white menthol smokers had a 22% lower odds of quitting compared to white non-menthol smokers. While the study found no significant difference among quit rates for non-daily menthol and non-menthol smokers,¹⁷ the findings for daily smokers have greater implications for

¹¹ Sam N. Cwalina, et al., *Adolescent menthol cigarette use and risk of nicotine dependence: Findings from the national Population Assessment on Tobacco and Health (PATH) study*, Drug and Alcohol Dependence, 2019, <https://www.sciencedirect.com/science/article/pii/S0376871619304922>.

¹² Andrea C. Villanti, et al., *Association of Flavored Tobacco Use With Tobacco Initiation and Subsequent Use Among US Youth and Adults, 2013-2015*, 2 JAMA Network Open e1913804, 2019, <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2753396>.

¹³ Christine D. Delnevo, et al., *Assessment of Menthol and Nonmenthol Cigarette Consumption in the US, 2000 to 2018*, 3 JAMA Network Open e2013601, 2020, <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2769132>.

¹⁴ Cristine D. Delnevo, et al., "Banning Menthol Cigarettes: A Social Justice Issue Long Overdue," *Nicotine & Tobacco Research*, 22(10): 1673-1675, 2020; Andrea C. Villanti, et al., *Changes in the Prevalence and Correlates of Menthol Cigarette Use in the USA, 2004-2014*, 25 Tobacco Control ii14, 2016, <https://pubmed.ncbi.nlm.nih.gov/27729565/>

¹⁵ TPSAC Menthol Report; FDA Report.

¹⁶ HHS, Office on Smoking and Health, *Smoking Cessation, A Report of the Surgeon General*, 2020, <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.

¹⁷ Sarah D. Mills, et al., *The Relationship between Menthol Cigarette Use, Smoking Cessation and Relapse: Findings from Waves 1 to 4 of the Population Assessment of Tobacco and Health Study*, *Nicotine & Tobacco Research* May 24;23(6):966-975, 2021. <https://doi.org/10.1093/ntr/ntaa212>

population health given that three-quarters (74.6%) of adult smokers are daily smokers.¹⁸ This study provides stronger evidence for the population level impact of menthol cigarettes on cessation than previous research from clinical trials, many of which have follow-up times as short as one month, and research from cessation clinic populations, which may not be generalizable to the full adult smoking population.

Given the evidence that menthol cigarettes are more difficult to quit than non-menthol cigarettes, it is likely, as the proposed rule suggests, that prohibiting menthol as a characterizing flavor in cigarettes will likely result in increased cigarette cessation, including among members of historically underserved communities, particularly African-American smokers.

Menthol Cigarettes Have Contributed Significantly to Health Disparities

Prohibiting menthol as a characterizing flavor in cigarettes is not solely a public health issue; it is a social justice issue as well. The tobacco industry has targeted African American communities with advertising for menthol cigarettes for nearly 70 years. The tobacco industry has used multiple strategies and tactics to reach the African American population, including print media, in-store advertising, community and music events, distribution of free cigarettes from mobile vans, and specialized promotions.¹⁹ This targeted marketing continues today. A 2021 study found that in California, Newport cigarettes cost an estimated 25 cents less in neighborhoods with the highest proportions of Black residents.²⁰

The legacy of this advertising is reflected in the continued high prevalence of menthol cigarette use among African American smokers. According to 2018 NSDUH data, 85% of African American smokers smoke menthols, compared to just 29% of White smokers.²¹ Preference for menthol is also disproportionately high among lesbian, gay, and bisexual smokers, smokers with mental health problems, socioeconomically disadvantaged populations, and pregnant women.²²

The high rates of menthol smoking result in a disproportionate burden of tobacco-related death and disease among African Americans due to menthol's role in decreasing cessation. This is despite high motivation to quit among African American smokers, who are more likely to have made a quit attempt and used counseling services in the previous year than White smokers.²³ In its 2011 report to FDA, TPSAC estimated that by 2020, 4,700 excess deaths among African Americans would be attributable to menthol cigarettes.²⁴ Research continues to support menthol's role in tobacco-related health disparities. A recent meta-analysis found that among African Americans, menthol smokers have a 12% lower odds of smoking cessation compared to non-menthol smokers²⁵ and, as noted above, PATH data show that among

¹⁸ MeLisa R. Creamer, et al., *Tobacco Product Use and Cessation Indicators Among Adults—United States, 2018*, 68(45) Morbidity and Mortality Weekly Report, 1013-1019, November 15, 2019.

¹⁹ TPSAC Menthol Report.

²⁰ Henriksen L, Schleicher NC, Fortmann SP, “Menthol cigarettes in black neighbourhoods: still cheaper after all these years,” *Tobacco Control* Published Online First: 12 August 2021.

²¹ Cristine D. Delnevo, et al., “Banning Menthol Cigarettes: A Social Justice Issue Long Overdue,” *Nicotine & Tobacco Research*, 22(10): 1673-1675, 2020.

²² Cristine D. Delnevo, et al., “Banning Menthol Cigarettes: A Social Justice Issue Long Overdue,” *Nicotine & Tobacco Research*, 22(10): 1673-1675, 2020.

²³ See e.g., CDC, *Quitting Smoking Among Adults—United States, 2000-2015*, 65 Morbidity and Mortality Weekly Report 1457-1464, 2017, <https://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6552a1.pdf>; Jacqueline M. Royce, et al., *Smoking Cessation Factors among African Americans and Whites: COMMIT Research Group*, 83 American Journal of Public Health 220-226, 1993, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1694582/>.

²⁴ TPSAC Menthol Report.

²⁵ Philip H. Smith, et al., *Use of Mentholated Cigarettes and Likelihood of Smoking Cessation in the United States: A Meta-Analysis*, 22 *Nicotine & Tobacco Research* 307-316, 2019, <https://pubmed.ncbi.nlm.nih.gov/31204787/>.

daily smokers, African American menthol smokers have a 53% lower odds of quitting compared to African American non-menthol cigarette smokers.²⁶ And, as noted previously, researchers quantified the population harms caused by menthol cigarettes between 1980 and 2018 and found that African Americans bear a disproportionate toll of the public health impact of menthol cigarettes. During this timeframe, African Americans represented 15% of extra new smokers, 41% of excess premature deaths and 50% of excess life-years lost, despite only accounting for 12% of the population.²⁷

Menthol Bans Have Been Shown to Increase Smoking Cessation in Canada

The likelihood of increasing quitting following a menthol ban is supported by the recent real-world experience of Canada, which in October, 2017, became the first country to implement a total ban on menthol cigarettes. This nationwide ban came after most provinces had already banned them.

Surveillance data from the province of Ontario, which banned menthol cigarettes in January, 2017, showed an increase in quit attempts and cessation one year after the ban.²⁸ Two years later, a follow-up survey found that both daily and occasional menthol smokers were more likely than non-menthol smokers to report having quit smoking for six months (18% and 15%, vs. 7%) or having a made a quit attempt (72% and 74%, vs. 58%).²⁹

Findings on the impact of the Canadian menthol bans on additional Canadian provinces is also available. The International Tobacco Control Policy Evaluation Project (ITC) conducted a longitudinal national survey of Canadian smokers and found that after the implementation of menthol bans in seven provinces, menthol smokers were significantly more likely to try to quit than non-menthol smokers (60% vs. 48%), and were twice as likely to have quit smoking for at least six months (12% vs. 6%), and the ban had the same benefits across the provinces.³⁰

While Canada is not the US, the experience in Canada suggests that a ban on menthol would increase cessation in the US. In fact, the benefit might be greater than seen in Canada because more US smokers report intending to quit in the event of a ban than was true in Canada.³¹ A 2022 study examined

²⁶ Sarah D. Mills, et al., *The Relationship between Menthol Cigarette Use, Smoking Cessation and Relapse: Findings from Waves 1 to 4 of the Population Assessment of Tobacco and Health Study*, *Nicotine & Tobacco Research*, published online October 16, 2020, <https://doi.org/10.1093/ntr/ntaa212>.

²⁷ 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*, published online September 16, 2021.

²⁸ Michael O. Chaiton, et al., “Ban on menthol-flavoured tobacco products predicts cigarette cessation at 1 year: a population cohort study,” *Tobacco Control* 2020; 29:341-347. <http://dx.doi.org/10.1136/tobaccocontrol-2018-054841> Findings from Waves 1 to 4 of the Population Assessment of Tobacco and Health Study, *Nicotine & Tobacco Research*, published online October 16, 2020, <https://doi.org/10.1093/ntr/ntaa212>.

²⁸ Michael O. Chaiton, et al., “Ban on menthol-flavoured tobacco products predicts cigarette cessation at 1 year: a population cohort study,” *Tobacco Control* 2020; 29:341-347. <http://dx.doi.org/10.1136/tobaccocontrol-2018-054841>

²⁹ Michael O. Chaiton, et al., “Prior daily menthol smokers more likely to quit 2 years after a menthol ban than non-menthol smokers: a population cohort study. *Nicotine and Tobacco Research*. Sep;23(9):1584-9, 2021.

³⁰ Janet Chung-Hall, et al., “Evaluating the impact of menthol cigarette bans on cessation and smoking behaviors in Canada: Longitudinal findings from the Canadian arm of the 2016-18 ITC Four Country Smoking and Vaping Surveys. *Tobacco Control*. Published online April 6, 2021. <http://dx.doi.org/10.1136/tobaccocontrol-2020-056259>.

³¹ Christopher J. Cadham, et al. The actual and anticipated effects of a menthol cigarette ban: a scoping review. *BMC Public Health* 2020;20:1055. <https://doi.org/10.1186/s12889-020-09055-z>; See also, Krysten W. Bold, et al., “Evaluating the effect of switching to non-menthol cigarettes among current menthol smokers: an empirical study of a potential ban of characterising menthol flavour in cigarettes,” *Tobacco Control* 29(6):624-630, November 2020. <https://tobaccocontrol.bmj.com/content/29/6/624>

the impact of Ontario’s and Canada’s prohibition on menthol cigarettes by pooling data from two cohort studies and found that menthol smokers were significantly more likely to quit smoking as a result of the ban. Specifically, after the bans on menthol cigarettes, 22.3% of menthol smokers had quit vs. 15.0% of non-menthol smokers, so 7.3% percent *more* menthol smokers quit in response to the ban compared to non-menthol smokers. Using this increased quit rate among menthol smokers, researchers estimate that a menthol ban in the United States would lead more than 1.3 million smokers to quit, including 381,000 Black smokers.³²

A review also supports increased cessation consequent to a menthol ban. Cadham et al.³³ identified 24 studies on the potential impact of menthol bans, concluding that “extending the US cigarette flavor ban to menthol products would promote smoking cessation and reduce initiation.”

A Rule Establishing a Tobacco Product Standard for Menthol Cigarettes Should be Finalized Along with the Rule Prohibiting Characterizing Flavors in Cigars

Pairing the two proposed rules – for a tobacco product standard in menthol cigarettes and for a prohibition on characterizing flavors in cigars will enhance the public health impacts of each of the rules. Pairing the rules will increase the likelihood that menthol smokers quit rather than switch to other combustible products. The tobacco industry has a well-documented history of manipulating products to take advantage of loopholes in regulation and is likely to encourage menthol smokers to switch to menthol cigars, especially little cigars, if cigars with menthol and other characterizing flavors continue to be available. This can be avoided if the rules are finalized together.

Conclusion

The available scientific evidence strongly supports a prohibition on the use of menthol as a characterizing flavor in cigarettes and the evidence base justifying such action is robust and has only grown stronger over time. The FDA should act swiftly to finalize this life-saving rule.

Respectfully submitted,

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³² Geoffrey T. Fong, et al., “Impact of Canada’s menthol cigarette ban on quitting among menthol smokers: pooled analysis of pre–post evaluation from the ITC Project and the Ontario Menthol Ban Study and projections of impact in the USA,” *Tobacco Control*, published online first April 28, 2022, [doi:10.1136/tobaccocontrol2021-057227](https://doi.org/10.1136/tobaccocontrol2021-057227).

³³ Christopher J. Cadham., et al. The actual and anticipated effects of a menthol cigarette ban: a scoping review. *BMC Public Health* 2020;20:1055. <https://doi.org/10.1186/s12889-020-09055-z>

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