

December 17, 2020

The Honorable Stephen M. Hahn
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993
Stephen.Hahn@fda.hhs.gov

RE: Scientific Support for Granting Citizen Petition Urging Prohibition of Menthol as Characterizing Flavor in Cigarettes (FDA-2013-P-0435-0001)

Dear Commissioner Hahn:

As scientific experts in the fields of tobacco use and addiction, we are writing to urge the Food and Drug Administration (FDA) to grant the Citizen Petition urging prohibition of menthol as a characterizing flavor in cigarettes. It has come to our attention that in response to a lawsuit pending in federal court in the Northern District of California,¹ FDA's Center for Tobacco Products "has agreed to provide a final response to Plaintiffs' citizen petition by January 29, 2021."² For an agency committed to science-based decision-making, the only defensible decision based on available evidence is to prohibit menthol as a characterizing flavor in cigarettes.

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."³ 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."⁴ 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.

We could not agree more with the statement in your recent commentary in the *New England Journal of Medicine* - "It's time we recognize smoking for what it is — our country's longest-running and deadliest epidemic — and treat it with a commensurate sense of urgency."⁵ Given the tremendous burden of tobacco use, and particularly the use of menthol cigarettes, on the nation's health, it is imperative that FDA grant the Citizen Petition.

¹ *African American Tobacco Control Leadership Council, et al. v. U.S. Dept. of Health and Human Services, et al.* (AATCLC v. HHS), Case No: 4:20-cv-4012-KAW (N.D. Cal. June 17, 2020).

² Federal Defendants' Memorandum in Support of Motion to Dismiss, *AATCLC v. HHS* (Sept. 18, 2020), at 1, n.1.

³ 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).

⁴ 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).

⁵ Robert R. Redfield, et al., *Redoubling Efforts to Help Americans Quit Smoking — Federal Initiatives to Tackle the Country's Longest-Running Epidemic*, 383 *New England Journal of Medicine*, 1606-1609, 2020, <https://www.nejm.org/doi/full/10.1056/NEJMp2003255>.

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.

Data from the National Survey on Drug Use and Health (NSDUH) shows that preference for menthol cigarettes is inversely correlated with age.⁶ According to both NSDUH and the National Youth Tobacco Survey (NYTS), about half of youth smokers use menthol cigarettes.⁷ 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.⁸ 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 of dependence,⁹ and that initiation with a menthol-flavored cigarette is associated with a higher relative risk of continuing to daily smoking.¹⁰

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.¹¹ 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 2008-2010.¹² By reducing smoking cessation, menthol has slowed the nation’s progress in reducing overall smoking.

⁶ Cristine D. Delnevo, et al., “Banning Menthol Cigarettes: A Social Justice Issue Long Overdue,” *Nicotine & Tobacco Research*, 22(10): 1673-1675, 2020.

⁷ Teresa W. Wang, et al., “Tobacco Product Use and Associated Factors Among Middle and High School Students—United States, 2019,” *MMWR* 68(12), December 6, 2019, <https://www.cdc.gov/mmwr/volumes/68/ss/pdfs/ss6812a1-H.pdf>.

⁸ 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.

⁹ 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>.

¹⁰ 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>.

¹¹ 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>.

¹² 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/>

The TPSAC and FDA Reports 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.¹³ 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.¹⁴ 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,¹⁵ the findings for daily smokers have greater implications for population health given that three-quarters (74.6%) of adult smokers are daily smokers.¹⁶ 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.

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.¹⁷ 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.¹⁸ Preference for menthol is also disproportionately high among lesbian, gay, and bisexual smokers, smokers with mental health problems, socioeconomically disadvantaged populations, and pregnant women.¹⁹

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

¹³ TPSAC Menthol Report; FDA Report.

¹⁴ 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>.

¹⁵ 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>.

¹⁶ 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.

¹⁷ TPSAC Menthol Report.

¹⁸ Cristine D. Delnevo, et al., “Banning Menthol Cigarettes: A Social Justice Issue Long Overdue,” *Nicotine & Tobacco Research*, 22(10): 1673-1675, 2020.

¹⁹ Cristine D. Delnevo, et al., “Banning Menthol Cigarettes: A Social Justice Issue Long Overdue,” *Nicotine & Tobacco Research*, 22(10): 1673-1675, 2020.

and used counseling services in the previous year than White smokers.²⁰ In its 2011 report to FDA, TPSAC estimated that by 2020, 4,700 excess deaths among African Americans would be attributable to menthol cigarettes.²¹ 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 smokers²² and, as noted above, PATH data show that among daily smokers, African American menthol smokers have a 53% lower odds of quitting compared to African American non-menthol cigarette smokers.²³

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.²⁴ 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 made a quit attempt (72% and 74%, vs. 58%).²⁵

Findings on the impact of the Canadian menthol bans on additional Canadian provinces is also starting to emerge. 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.²⁶ While Canada is not the US, the experience in Canada suggest that a ban on menthol would increase cessation in the US. In fact, the

²⁰ 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/>.

²¹ TPSAC Menthol Report.

²² 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/>.

²³ 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>.

²⁴ 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>.

²⁴ 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>

²⁵ Michael O. Chaiton, et al., "Impact of a menthol ban on smoking cessation: A two year follow up," Paper presented at the annual meeting of the Society for Research on Nicotine and Tobacco, March 2020.

²⁶ Janet Chung-Hall, et al., "Evaluating the impact of menthol cigarette bans on cessation and smoking behaviours in Canada: Findings from the 2016-2018 ITC 4 Country Smoking and Vaping Surveys. Paper presented at the annual meeting of the Society for Research on Nicotine and Tobacco, March 2020.

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.²⁷

A recent review also supports increased cessation consequent to a menthol ban. Cadham et al.²⁸ 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.”

Conclusion

The evidence available at the time of the 2013 Citizen Petition was sufficient to support a prohibition on the use of menthol as a characterizing flavor in cigarettes and the evidence base justifying such action is only more robust today. A science-based decision on the Citizen Petition must conclude that there is no public health justification for continued availability of menthol cigarettes.

Respectfully submitted,

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²⁷ 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>

²⁸ 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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