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Dockets Management Staff (HFA-305)  
U.S. Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852  
VIA Federal eRulemaking Portal

**RE: Docket No. FDA-2013-P-0435 – Comments on Tobacco Control  
Legal Consortium, et. al., Citizen Petition to the Federal Food and  
Drug Administration Related to Prohibiting Menthol as a  
Characterizing Flavor in Cigarettes**

To Whom It May Concern:

For consideration of Docket No. FDA-2013-P-0435, please accept this letter as formal comments submitted by the Attorney General of Colorado urging the U.S. Food and Drug Administration (“FDA”) to prohibit menthol as a characterizing flavor in cigarettes. In making this request, I join my state attorney general colleagues, who on January 22, 2021, submitted a letter marshalling overwhelming scientific evidence to demonstrate that a ban on menthol cigarettes will enhance public health and health equity.<sup>1</sup> The FDA should move quickly to complete rulemaking to prohibit menthol cigarettes.

The need for prompt FDA action is clear. In recent decades, state attorneys general and others acted to protect the public, particularly youth, from the harms of deadly and addictive tobacco products. Most notably, in 1998, the attorneys general of 52 states and territories—including Colorado—completed the Tobacco Master Settlement Agreement (“MSA”) with the four major tobacco manufacturers.<sup>2</sup> The MSA restricted tobacco manufacturers from engaging in certain types of advertising, marketing, and promotion of cigarettes, and all signatories committed to “reducing

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<sup>1</sup> Att’y Gen. of Conn. et al., State Attorneys General Comment on Citizen Petition (Jan. 22, 2021), <https://portal.ct.gov/-/media/AG/2021-01-22-State-Comments-on-Citizen-Petition-on-Menthol-in-Cigarettes.pdf>.

<sup>2</sup> Master Settlement Agreement (Nov. 1998), [https://coag.gov/app/uploads/2019/07/msa\\_with\\_sig\\_pages\\_and\\_exhibits.pdf](https://coag.gov/app/uploads/2019/07/msa_with_sig_pages_and_exhibits.pdf).

underage tobacco use by discouraging such use and by preventing Youth access to Tobacco Products.”<sup>3</sup> Since 1998, overall rates of cigarette smoking in the United States declined significantly,<sup>4</sup> as have rates of tobacco smoking by youths.<sup>5</sup>

But decreased consumption of non-menthol cigarettes accounts for the overwhelming majority of this progress. Indeed, 85% of the total decline in cigarette consumption was attributed to nonmenthol cigarettes.<sup>6</sup> Consider, as my colleagues noted, that “[a]s of 2018, menthol cigarettes account for 36% of all cigarette sales—the highest proportion since major tobacco companies were required to report domestic market share of menthol and non-menthol cigarettes.”<sup>7</sup> The availability of menthol cigarettes remains an impediment to efforts to limit smoking initiation and support cessation by youths. Menthol flavor masks cigarettes’ underlying harshness,<sup>8</sup> and, therefore, the availability of menthol cigarettes leads to increased initiation of smoking by youth.<sup>9</sup> Menthol cigarettes are also disproportionately marketed to African Americans and youth<sup>10</sup>—two groups at high risk for poor cessation outcomes.”<sup>11</sup> In short, as the FDA’s Tobacco Products Scientific Advisory Committee (TPSAC) report concluded, “[r]emoval of menthol cigarettes from the marketplace would benefit public health in the United States.”<sup>12</sup>

Furthermore, as Colorado’s chief law enforcement officer, I also concur with my state attorney general colleagues that “[p]rohibiting menthol cigarettes will not

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<sup>3</sup> *Id.* at 2.

<sup>4</sup> Christine D. Delnevo et al., Assessment of Menthol and Nonmenthol Cigarette Consumption in the U.S., 2000 to 2018, 2020 JAMA Network Open 3(8):e2013601 1 (Aug. 7, 2020), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2769132>.

<sup>5</sup> Andrea S. Gentzke et al., Vital Signs: Tobacco Product Use Among Middle and High School Students — United States, 2011–2018, 68 Morbidity and Mortality Weekly Report 157 (2019), <https://www.cdc.gov/mmwr/volumes/68/wr/mm6806e1.htm#suggestedcitation> (finding significant declines in combustible tobacco use among high school and middle school students).

<sup>6</sup> Delnevo et al., *supra* note 4.

<sup>7</sup> State Attorneys General Comment on Citizen Petition, *supra* note 1 at 2 (citing U.S. Federal Trade Commission (FTC), Cigarette Report for 2018. Washington: Federal Trade Commission, 2019, available at <https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-cigarette-report-2018-smokeless-tobacco-report2018/p114508cigarettereport2018.pdf>).

<sup>8</sup> FDA, TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE, MENTHOL CIGARETTES AND PUBLIC HEALTH: REVIEW OF THE SCIENTIFIC EVIDENCE AND RECOMMENDATIONS 225 (2011), <https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf> (“Menthol cannot be considered merely a flavoring additive to tobacco. Its pharmacological actions reduce the harshness of smoke and the irritation from nicotine . . .”).

<sup>9</sup> *Id.* at 217 (“the availability of menthol cigarettes increases the likelihood of experimentation and regular smoking beyond the anticipated prevalence if such cigarettes were not available.”).

<sup>10</sup> *Id.* at 92.

<sup>11</sup> *Id.* at 150.

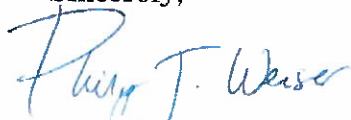
<sup>12</sup> *Id.* at 225.

create a significant black market and enforcement authorities are well-equipped to safeguard against illicit trade in menthol cigarettes.”<sup>13</sup>

To prevent our youth from suffering further negative health consequences caused by these products, I strongly urge the FDA to prohibit menthol as a characterizing flavor in cigarettes. Such a prohibition would serve the public’s best interest and is amply supported by scientific evidence.

Should you or your staff have questions as you review this matter, please contact Kurtis Morrison with the Department of Law at [kurtis.morrison@coag.gov](mailto:kurtis.morrison@coag.gov). Thank you for your consideration.

Sincerely,

A handwritten signature in blue ink that reads "Phil J. Weiser". The signature is written in a cursive style with a large initial "P".

Phil Weiser  
Attorney General  
State of Colorado

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<sup>13</sup> State Attorneys General Comment on Citizen Petition, *supra* note 1 at 13-14.