

U.S. Food and Drug Administration Must Ban  
Menthol Cigarettes Without Delay: Lessons From  
Other CountriesJanet Chung-Hall, PhD,<sup>1</sup> Lorraine V. Craig, MHS,<sup>1</sup> Christina N. Kyriakos, MPH,<sup>2</sup>  
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On April 28, 2022, the U.S. Food and Drug Administration (FDA) announced its long-awaited proposed rule to prohibit menthol as a characterizing flavor in cigarettes.<sup>1</sup> Finalization of the proposed rule will dramatically improve and protect the health of Americans by preventing tobacco-related disease and death. The public health benefits will be greatest among population groups who suffer health disparities arising from disproportionate use of menthol cigarettes because of targeted marketing, including young people, women, and racial and ethnic minorities, particularly Black Americans.<sup>2</sup> An evaluation of the impact of Canada's menthol cigarette ban by Fong et al.<sup>3</sup> estimated that a similar ban in the U.S. would lead to quitting among >1.3 million people who smoke, of whom 381,000 would be Black Americans.

Tobacco companies are likely to intensify efforts to mobilize opposition to the FDA's proposed menthol ban while it is still under review, given their long history of using different strategies to block, delay, and undermine regulations for menthol cigarettes in other countries.<sup>4</sup> It is critical for the FDA to implement a tobacco product standard on flavors without further delay to maximize the protection of public health and minimize the opportunities for tobacco industry interference. Evaluations of menthol bans in other countries provide real-world data to guide evidence-based menthol ban regulations in the U.S. and other jurisdictions and may assist policymakers in anticipating how the tobacco industry might respond.

**NO INCREASE IN ILLICIT CIGARETTE  
PURCHASING AFTER MENTHOL CIGARETTE  
BANS IN CANADA, ENGLAND, AND THE  
NETHERLANDS**

One of the common arguments used by the industry to oppose any new tobacco control policy, including the

FDA's proposed menthol ban, is that banning menthol cigarettes will fuel the illicit cigarette market in the U.S. However, studies in three countries—Canada,<sup>5–7</sup> England,<sup>8</sup> and the Netherlands<sup>9</sup>—have found no increase in illicit cigarette purchasing after the implementation of menthol cigarette bans. For example, an evaluation of the 2020 menthol cigarette ban in the European Union (EU)<sup>9</sup> found no increase in self-reported illicit purchasing of cigarettes among adults who smoked cigarettes in the Netherlands one year after the ban (before ban: 2.4%, 95% CI=1.8, 3.2 vs after ban: 1.7%, 95% CI=1.2, 2.5). In addition, there was no difference in the proportion of adults who smoked menthol cigarettes between those who purchased illicit cigarettes before the ban and those who purchased one year after the ban (before ban: 4.6%, 95% CI=2.2%, 9.5% vs after ban: 4.2%, 95% CI=1.4%, 12.3%). Converging evidence from three countries that a menthol cigarette ban did not lead to an increase in illicit cigarette purchasing lends support to the conclusion that this is a generalized phenomenon rather than a country-specific one. An important additional argument that a menthol ban in the U.S. would not significantly increase illicit cigarette trade is that the illicit cigarette market in the U.S. is almost entirely due to bootlegging rather than illegal production. U.S. cigarette companies would thus be very unlikely to produce illicit menthol cigarettes because of the harsh legal consequences;<sup>10</sup> indeed, they may be incentivized to expose any emerging producers of menthol cigarettes.

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## FDA SHOULD BAN MENTHOL AS AN ADDITIVE IN CIGARETTES RATHER THAN AS A CHARACTERIZING FLAVOR

The FDA is proposing a tobacco product standard that would prohibit the use of menthol as a characterizing flavor in cigarettes. The proposed rule states that a characterizing flavor may be determined by the presence and amount of flavor ingredients used, multisensory experience (i.e., taste, aroma, cooling or burning sensations in mouth and throat) of flavor during product use, and other factors.<sup>1</sup> However, the proposed rule does not define the term characterizing flavor, nor does it specify the methods for determining the level of menthol that constitutes a characterizing flavor. The FDA has requested comments on alternatives to banning menthol as a characterizing flavor in cigarettes. Existing research has identified weaknesses of a menthol-characterizing flavor ban that can be exploited by tobacco companies.

First, tobacco companies could use menthol analogs as an additive under a characterizing flavor ban. This is important because menthol has effects that go beyond its flavor. In addition to improving the smell or taste of tobacco products, menthol has a cooling effect that reduces the harshness of tobacco smoke, which facilitates initiation and continued use of menthol cigarettes.<sup>11</sup> Menthol produces this cooling effect by activating TRPM8, the cold and menthol receptor.<sup>12</sup> If menthol is banned as a characterizing flavor, tobacco companies could use menthol analogs in cigarettes that activate the TRPM8 receptor to elicit a similar sensory experience without the characterizing menthol flavor. For example, tobacco manufacturers could add analogs that are TRPM8 agonists, such as geraniol, linalool, eucalyptol, isopulegol, menthone, and carvone, to cigarettes as a replacement for menthol.<sup>13</sup> Synthetic coolants, such as WS-3 and WS-23,<sup>14</sup> could also be added to nonmenthol cigarettes that are marketed as menthol substitutes. The industry is already using this tactic in the state of California, where R.J. Reynolds has introduced new cigarette products that contain a flavorless synthetic agent that has the same cooling effect as menthol in an effort to evade a statewide ban on the sale of all flavored tobacco products.<sup>15</sup>

Second, a characterizing flavor ban would allow tobacco manufacturers to continue adding menthol additives to cigarettes at low concentrations. There is evidence that even low levels of menthol that are well below the threshold of a characterizing menthol flavor can still activate the TRPM8 cold receptor to produce a cooling effect.<sup>13</sup> The fact that nearly all cigarettes available in the U.S. market contain menthol as an

ingredient, including those that are marketed as nonmenthol cigarettes,<sup>16</sup> suggests that the tobacco companies are aware that menthol can achieve desirable sensory effects even at subliminal levels. On the basis of current research, the FDA should completely prohibit the use of any level of menthol and its analogs as an additive rather than as a characterizing flavor in cigarettes.

## FDA SHOULD BAN ALL ACCESSORIES THAT ALLOW USERS TO ADD MENTHOL FLAVOR TO CIGARETTES

The FDA has stated that it would extend its proposed rule to ban menthol as a characterizing flavor in cigarettes to include the provision that “a cigarette or any of its components or parts (including the tobacco, filter, wrapper, or paper, as applicable) shall not contain, as a constituent (including a smoke constituent) or additive, menthol that is a characterizing flavor of the tobacco product or tobacco smoke.” The proposed definition of component or part would include menthol flavoring that is separate from the cigarette and can be added to nonmenthol cigarettes, including drops, capsules, filter tips for roll-your-own tobacco, or cards that can be inserted into a cigarette pack or pouch of rolling tobacco.<sup>1</sup> This is a key provision to prevent tobacco companies and other manufacturers from developing and marketing products designed to add menthol flavoring to nonmenthol cigarettes.

In response to bans on the use of menthol flavor in cigarettes with the exception of tobacco accessories sold separately in Canada,<sup>17</sup> the EU,<sup>18</sup> and the United Kingdom (UK),<sup>4</sup> tobacco companies introduced new products onto the marketplace to provide consumers in these countries with alternatives for banned menthol cigarettes. This includes a diverse range of products that are sold separately from cigarette packs, such as menthol flavor cards, liquid drops, oils, filters, and crush ball capsules, which allow users to add menthol flavor to nonmenthol cigarettes.<sup>19</sup> A 2023 study by Kyriakos et al.<sup>9</sup> provides additional evidence for industry strategies to circumvent the EU’s ban on the use of menthol as a characterizing flavor in cigarettes, which excludes accessories that add flavors to unflavored cigarettes. Nearly all self-reported use of menthol cigarettes among adults in the Netherlands after the EU menthol cigarette ban was driven by the use of legal flavor accessories and/or a nonmenthol replacement brand. Specifically, 42.5% of adults who reported that their usual cigarette brand was menthol also reported using legal flavor accessories (flavor cards, frutasticks, filters, menthol drops, and/or

other products) after the ban. Although only 4.4% of adults who smoked reported using flavor accessories overall, results showed that adults who smoked menthol cigarettes were significantly more likely to use flavor accessories than adults who smoked nonmenthol cigarettes (42.5% vs 3.0%, AOR=17.33,  $p<0.001$ ). In addition, 70.0% of adults who reported using a menthol brand after the ban were using a nonmenthol replacement brand (marketed as a nonmenthol brand and/or described as a menthol brand replacement/alternative), suggesting that some people who smoke perceive that these products still contain menthol. It is clear from the experiences of Canada, the EU, the UK, and the Netherlands that the FDA should ban accessories to add menthol to cigarettes.

## CONCLUSIONS

The FDA should complete steps within its authority to finalize the proposed rule to end the sale of menthol-flavored cigarettes. There is a converging body of evidence showing the positive impacts of a menthol cigarette ban in different countries. For example, evaluation studies have found no increase in illicit cigarette purchasing after menthol cigarettes were banned in Canada<sup>5–7</sup> and the Netherlands.<sup>9</sup> Similarly, menthol cigarette bans in these 2 countries significantly increased quit attempts and quitting among adults who use menthol cigarettes.<sup>3,20</sup> The experiences in Canada,<sup>17</sup> the EU,<sup>18</sup> and the UK<sup>4</sup> also point to the importance of closing loopholes in the FDA's proposed rule to prevent tobacco industry workarounds to provide users of menthol cigarettes with substitutes for banned products. To maximize the effectiveness of its proposed ban on menthol cigarettes for increasing smoking cessation and preventing smoking uptake, the FDA should take steps to eliminate opportunities for the tobacco industry to evade the regulation. This could be achieved by completely banning the use of any level of menthol and its analogs as an additive in cigarettes as well as any accessories to add menthol to cigarettes. In addition, banning menthol additives in cigars would encourage those who smoke menthol cigarettes to quit instead of switching to menthol cigars. Future research that uses additional data other than self-report (e.g., sales data) is needed to understand how the prevalence of menthol cigarette use, size of the illicit cigarette market, regulatory environment, and other contextual factors may affect the generalizability of findings on the real-world impact of a menthol cigarette ban across different countries.

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## CREDIT AUTHOR STATEMENT

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