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FDA Proposes to Ban Menthol Cigarettes and Characterizing Flavors in Cigars

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On April 29, the U.S. Food & Drug Administration (FDA) announced that it will issue proposed tobacco product standards within the next year that will effectively ban menthol cigarettes and characterizing flavors in cigars. Once FDA issues proposed tobacco product standards, it will need to go through the notice and comment rulemaking process (and possibly litigation), so it could take several years before FDA implements any new standards.

FDA is claiming authority under Section 907 of the 2009 Family Smoking Prevention and Tobacco Control Act (TCA) to restrict the sale and distribution of flavored tobacco products. Section 907 allows the Human and Health Services (HHS) secretary, through FDA (an HHS subagency), to "adopt tobacco product standards ... if the Secretary finds that a tobacco product standard is appropriate for the protection of the public health." See 21 U.S.C. § 387g(a)(3)(A). In making such a finding, FDA must consider scientific evidence concerning the risks and benefits to the population as a whole, including users and nonusers of tobacco products; the increased or decreased likelihood that existing users of tobacco products will stop using such products; and the increased or decreased likelihood that those who do not use tobacco products will start using such products. See 21 U.S.C. § 387(g)(a)(3)(A),(B). FDA also must consider the potential for contraband trade in developing product standards. Any party objecting to the proposed standard on the ground that it will not reduce or eliminate the risk of illness or injury may provide scientific evidence to FDA that demonstrates that the proposed standard will not reduce or eliminate the risk of illness or injury. See 21 U.S.C. § 387(g)(a)(3)(B).

The TCA banned characterizing flavors in cigarettes, except menthol cigarettes, but did not address flavored cigars. In its press release, FDA claims that after the TCA banned flavored cigarettes, the "use of flavored cigars increased dramatically, suggesting that the public health goals of the flavored cigarette ban may have been undermined by continued availability of these flavored cigars." As such, FDA states that "[t]his decision is based on clear science and evidence establishing the addictiveness and harm of these products and builds on important, previous actions that banned other flavored cigarettes in 2009."

Notably in January 2021, a coalition of 23 attorneys general submitted a petition for rulemaking asking FDA to prohibit menthol cigarettes. Attorneys general would not have enforcement authority under any finalized standards.

HHS Secretary Xavier Becerra issued his support for the measure in a separate statement, indicating the proposal reflects administration priorities and that a new flavor ban will likely be finalized in some form after completing the notice and comment rulemaking process.

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