FDA Action Needed Immediately on Menthol Cigarette and Flavored Cigars

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) – signed into law in 2009 - granted the U.S. Food and Drug Administration (FDA) authority to regulate the manufacture, marketing, and distribution of tobacco products for the first time. Prior to the law, tobacco products were largely unregulated by the federal government outside of required warning labels. This lack of oversight likely contributed to the tobacco industry's ability to mislead the public about the harms of its products and target youth and other populations with its use of flavors, marketing, and promotions.

Missed Opportunity: Tobacco Control Act Exempted Menthol from Prohibition of Flavors in Cigarettes

Recognizing the danger that flavors in cigarettes has in attracting and addicting new smokers, especially youth, the Tobacco Control Act prohibited the use of characterizing flavors, except for menthol and tobacco, in cigarettes. Prior to the law, cigarette manufacturers aggressively marketed these flavored products, including "Twista Lime" and "Winter MochaMint," with creative campaigns like "scratch and sniff" marketing tactics, DJ nights, ads in magazines with a high proportion of youth and young adult readers, and specially themed packs to attract new young users.

To understand the consequences of limiting the flavor prohibition to only cigarettes and exempting menthol flavoring, an analysis evaluated youth tobacco use before and after the prohibition.[i] The analysis found a decrease in the likelihood of being a person who smokes (17.1 percent) and fewer cigarettes smoked (59 percent) associated with the flavor prohibition, but also a 45 percent increase in the probability that the youth who smoked used menthol cigarettes. Furthermore, the flavor prohibition was associated with increases in both cigar use (34.4 percent) and pipe use (54.6 percent). This suggests that youth who smoke, in the absence of flavored cigarettes, are substituting with menthol cigarettes or cigars and pipe tobacco, for which the flavor prohibition does not apply.

Scientific Reports on Menthol

The Tobacco Control Act required the Tobacco Products Scientific Advisory Committee (TPSAC) to submit a report and recommendations on the "issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities." The TPSAC completed the report in 2011, concluding that:

- Menthol cigarettes have an adverse impact on public health in the United States.
- There are no public health benefits of menthol compared to non-menthol cigarettes.

Based on these scientific conclusions, the TPSAC recommended that removing menthol cigarettes from the market would benefit public health.

Public Health Group's Action on Menthol Cigarettes

In 2013, 19 public health groups, including ACS CAN, filed a Citizen's Petition urging FDA to exercise its regulatory power to prohibit menthol in cigarettes.

By 2020, when FDA failed to respond to the Citizen's Petition in a timely manner, public health groups, led by the African American Tobacco Control Leadership Council (AATCLC) and Action on Smoking and Health (ASH) filed a federal lawsuit to compel the FDA to take action on menthol. FDA's 2021 announcement to issue proposed rules is a direct response to their lawsuit.

The FDA completed its own independent study on menthol cigarettes in 2013 concluding that menthol is associated with increased initiation, greater dependence, and decreased cessation. The report concluded that it is "likely that menthol cigarettes pose a public health risk above that seen with nonmenthol cigarettes."

Warning Letters on Flavored "Little Cigars"

So-called "little cigars" have the look and feel of a cigarette, and are smoked like a cigarette, yet are often sold individually and are available in a variety of flavors and have likely benefited the most from the cigarette flavor prohibition. It is possible manufacturers simply added tobacco to the wrapping paper of cigars in order to attempt to meet the definition of a cigar while still being smoked like a cigarette. In fact, in 2016, the FDA sent warning letters to four tobacco manufacturers stating that they were illegally selling flavored cigarettes labeled as "little cigars."[ii] However, it appears the FDA has stopped enforcing this violation of the Tobacco Control Act.[iii]

The FDA has also sent warning letters on various e-cigarette products.

Premarket Review

One of the most powerful provisions of the Tobacco Control Act is that all new tobacco products must undergo premarket review and receive a marketing order from FDA before the product can be sold legally in the U.S. To receive a marketing order, a manufacture must prove its product is "appropriate protection of public health" taking into account the risks and benefits to the population as a whole, including people who would use the proposed new tobacco product as well as nonusers. Through this process, the FDA could deny a marketing order for a flavored tobacco product as not appropriate for the protection of public health.

Against the tobacco control community's urging, FDA has granted marketing orders for two menthol cigarettes, as well as several flavored smokeless tobacco products. More recently, FDA denied marketing orders for certain flavored e-cigarettes. As part of those denials, FDA has concluded that they "are not aware of access restrictions that, to date, have been successful in sufficiently decreasing the ability of youth to obtain and use" e-cigarettes. The tobacco control community has advocated that access restrictions are not an effective measure to prevent youth from obtaining any tobacco product, including flavored products.

Rulemaking for Product Standards on Flavors

The Tobacco Control Act gives the FDA the authority to require product standards, such as the removal of flavors from tobacco products. Product standards require the FDA to undergo rulemaking in which a rule to remove flavors from products is proposed, the public is permitted to comment on the proposal, and after consideration of public comments, the FDA can finalize the rule implementing the product standards. The FDA also has the authority to issue an Advanced Notice of Proposed Rulemaking (ANPRM) in which they request information from the public on a specific topic. An ANPRM does not include a specific proposal and FDA can issue an ANPRM at any time.

In 2013, FDA issued an ANPRM on the regulation of menthol cigarettes. ACS CAN, with our tobacco control partners, submitted a comment letter in support of FDA adopting a product standard that prohibits menthol in cigarettes. FDA issued an additional ANPRM on the role of flavors in tobacco products in 2018, after it asserted authority over all tobacco products. Once again, ACS CAN, with our tobacco control partners, submitted a comment letter in support of FDA adopting a product standard that prohibits menthol in cigarettes and flavors in other tobacco product.

FDA's Announcement of Intention to Issue Proposed Rules

On April 29, 2021, FDA announced its intention to issue two product standards: (1) to prohibit menthol as a characterizing flavor in cigarettes, and (2) to prohibit all characterizing flavors in cigars. This decision was based on the clear evidence of the harm and addictiveness of this products and that such actions will reduce youth initiation, support successful quitting, and reduce health disparities caused by the intentional targeting of this products by the tobacco industry to communities of color, particularly Black communities, LGBTQ, and low-income populations. In its announcement, the FDA cited a study that projected that 633,000 deaths, including 237,000 African American deaths would be averted with a product standard prohibiting menthol in cigarettes. FDA has committed to issuing the proposed rules within one year.

ACS CAN's Position on FDA Action on Flavors

ACS CAN looks forward to the opportunity to participate in the public comment period to advocate that the FDA implement a comprehensive and swift prohibition on menthol in cigarettes and all flavors in cigars. Additionally, ACS CAN will continue to advocate for the prohibition of all flavors in all tobacco products at all levels of government until they are no longer available to addict new consumers. Any flavored product left on the market will allow Big Tobacco to continue to target youth, communities of color, the LGBTQ+ community and others with its deadly products. The FDA should use its authority through premarket review and rulemaking to remove all flavored tobacco products from the market.

April 2022

---

[i] Courtemanche, C. J., Palmer, M. K., & Pesko, M. F. (2017). Influence of the Flavored Cigarette Ban on Adolescent Tobacco Use. American journal of preventive medicine, 52(5), e139–e146. https://doi.org/10.1016/j.amepre.2016.11.019

[ii] https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm532563.htm

[iii] Eric N. Lindblom et al. Has FDA abandoned its efforts to make fake-cigar cigarettes comply with federal tobacco control laws that apply to cigarettes but not cigars? 29 Tobacco Control at 606-611 (2020). Desmond Jenson, A cigarette by any other name is still a cigarette, 29 Tobacco Control at 604-605 (2020).