FDA should finalize the proposed rule and make it effective 90 days after publication of the final rule

Docket No. FDA-2021-N-1349
for "Tobacco Product Standard for Menthol in Cigarettes"

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June 1, 2022

The Food and Drug Administration's proposed rule to prohibit menthol in cigarettes will reduce youth and young adult initiation rates of smoking cigarettes and significantly reduce premature deaths and illnesses related to tobacco use. The preamble to FDA's proposed standard correctly and unambiguously states that prohibiting menthol in cigarettes "will reduce initiation rates of smoking cigarettes, particularly for youth and young adults, and thereby decrease the likelihood that nonusers of cigarettes who experiment with these tobacco products would progress to regular cigarette smoking. Additionally, the proposed tobacco product standard is anticipated to improve the health of current smokers of menthol cigarettes by decreasing cigarette consumption and increasing the likelihood of cessation among this population."[1]

Although we will submit separate comments that question the FDA's proposed exceptions to the rule and respond to some of FDA's requests for comments on specific issues, we generally support FDA's proposed rule which is based on good science. ***Because of the tremendous health impacts that would accrue from the enactment of this proposed standard and the unconscionable length of time it has taken FDA to publish this proposed rule, we urge FDA to finalize the proposed rule and make it effective 90 days after the date of publication of the final rule.***

As FDA correctly stated, any additional delays "would only increase the numbers of youth and young adults who experiment with menthol cigarettes and become regular smokers, delay cessation by current smokers, and exacerbate tobacco-related health disparities."[2]

[1] US Food and Drug Administration, Tobacco Product Standard for Menthol in Cigarettes, May 4, 2022, Proposed Rule, 87 FR 26454 at 26458.
[2] US Food and Drug Administration, Tobacco Product Standard for Menthol in Cigarettes, May 4, 2022, Proposed Rule, 87 FR 26454 at 26489.

FDA's own analysis demonstrates that ***every month of delay in implementation will results in thousands of new cigarette smokers and premature deaths, and billions of dollars in additional expenses.***

1. Every month delay in implementing the proposed menthol standard would result in an additional 29,403 new cigarette smokers

Based on data from the 2019 National Survey on Drug Use and Health,[3] FDA determined that every day 1,500 youth and 2,600 young adults smoke their first cigarette.[4] And Wave 1 PATH data[5] show that for 43% of youth and 45% of young adults, this first cigarette is mentholated.[6] This means that 645 youth and 1,170 young adults smoke a first cigarette that is mentholated each day, and each month, 19,350 youth and 35,100 young adults (54,450 youth and young adults) smoke a first mentholated cigarette.

FDA accurately reports that 54% of flavored (i.e., menthol) youth cigarette users (62% high school, 47% middle school) would not use the product if it were not flavored.[7] In other words, if the proposed product standard prohibiting menthol as a characterizing flavor in cigarettes were implemented, about 54% of young people would not start smoking.

Thus, according to the FDA's analysis, every month delay in implementing the ban would result in an additional 29,403 new cigarette smokers.

2. FDA must not delay implementing the proposed menthol standard because each month of delay would cause at least an additional 1,362 premature deaths in future years

FDA relied on the *Levy et al.*[8] model to estimate the smoking-attributable deaths averted over the 40-year period from 2021-2060.[9] The Levy model makes several assumptions that lead it to *underestimate* the health harms attributable to smoking. But even using this model, ***a prohibition of menthol as a characterizing flavor in cigarettes would avert 654,000 premature***

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[3] Substance Abuse and Mental Health Services Administration. ''Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health (HHS Publication No. PEP20–07–01–001, NSDUH Series H–55).'' Rockville, MD: Center for Behavioral Health Statistics and Quality, 2020. Available at https:// nsduhweb.rti.org/respweb/ homepage.cfm

[4] US Food and Drug Administration, Tobacco Product Standard for Menthol in Cigarettes, May 4, 2022, Proposed Rule, 87 FR 26454 at 26463.

[5] Villanti, A.C., A.L. Johnson, B. Ambrose, et al. ''Flavored Tobacco Product Use in Youth and Adults: Findings from the First Wave of the Path Study (2013– 2014).'' American Journal of Preventive Medicine, 53(2):139–151, 2017. Available at https://doi.org/10.1016/ j.amepre.2017.01.026.

[6] US Food and Drug Administration, Tobacco Product Standard for Menthol in Cigarettes, May 4, 2022, Proposed Rule, 87 FR 26454 at 26464.

[7] Harrell MB, Loukas A, Jackson CD, Marti CN, Perry CL. Flavored tobacco product use among youth and young adults: What if flavors didn't exist?. Tobacco regulatory science. 2017 Apr 1;3(2):168-73.

[8] Levy, D.T., R. Meza, Z. Yuan, et al. ''Public Health Impact of a US Ban on Menthol in Cigarettes and Cigars: A Simulation Study.'' Tobacco Control, 2021. Available at https://doi.org/ 10.1136/tobaccocontrol-2021-056604.

[9] US Food and Drug Administration, Tobacco Product Standard for Menthol in Cigarettes, May 4, 2022, Proposed Rule, 87 FR 26454 at 26481.

deaths over a 40-year period. This averages to 16,350 deaths per year, or 1,362 deaths per month.

Based on this model, which *underestimates* the likely effect, ***each day that FDA delays action translates to more than 45 premature deaths attributable to smoking that could have been averted, and a 60-day (two-month) extension of time as requested by several tobacco industry entities would lead to 2,724 premature deaths.***

To protect public health and avoid preventable premature deaths, FDA must not delay a single additional day.

3. To protect public health and save lives, FDA should set the effective date for the proposed standard 90 days after publication of the final rule

FDA noted that the Family Smoking Prevention and Tobacco Control Act banned all characterizing flavors (except menthol) in cigarettes with a 90-day effective date, however it proposed a longer effective date of one year in the proposed standard prohibiting menthol as a characterizing flavor in cigarettes.[10] Tobacco Control Act section 907(d)(2) provides that product standards should take effect at least one year after the date of its publication *"unless the Secretary [FDA] determines that an earlier effective date is necessary for the protection of the public health."* FDA requested comments as to whether a shorter effective date (such as 90 days) would be necessary for the protection of the public health.

An earlier effective date is necessary to protect the public health. As we explained above using FDA's own analyses, every month of delay in implementing the proposed standard translates to 29,403 new cigarette smokers and an additional 1,362 premature deaths. This means that ***shortening the effective date by nine months (from one-year to 90-days) would prevent an additional 264,627 young people from initiating cigarette smoking and would prevent an additional 12,258 premature deaths.***

Tobacco companies successfully removed multiple flavors of cigarettes from store shelves within 90 days of implementation of the 2009 Tobacco Control Act; they can certainly manage to remove one flavor (menthol) from market shelves within 90 days.

There is no justification for extending the period beyond what was necessary in 2009, and 12,258 reasons to shorten the time.

4. The tobacco industry has had more than enough time to prepare for the proposed menthol standard as they have had ample notice and have been researching and lobbying against a menthol standard for at least 13 years.

In the preamble to the proposed rule, the FDA lays out in detail the background and relevant regulatory history of the proposed standard that would prohibit menthol as a

[10] US Food and Drug Administration, Tobacco Product Standard for Menthol in Cigarettes, May 4, 2022, Proposed Rule, 87 FR 26454 at 26488-26489.

characterizing flavor in cigarettes.[11] The industry has known since long before the Tobacco Control Act was enacted in June 2009 that FDA was considering prohibiting menthol as a characterizing flavor in cigarettes and has strenuously worked to oppose this outcome.

In March 2010 FDA's Tobacco Product Scientific Advisory Committee (TPSAC) began a review of the available evidence concerning the health impacts of menthol cigarettes and solicited input from the tobacco industry as well as other researchers and public health experts. In March 2011 TPSAC submitted its report on the health impacts of menthol, and in particular its impact on vulnerable populations and children. Additionally, industry representatives on TPSAC submitted as separate document reflecting the tobacco industry's perspective. FDA prepared its own report on the health impacts of menthol in 2013. In April 2013, the Tobacco Control Legal Consortium along with several other public health organizations submitted a citizen petition requesting that FDA ban menthol as a characterizing flavor in cigarettes. In July 2013 FDA issued an Advanced Notice of Proposed Rule Making (ANPRM) related to regulation of menthol in cigarettes. FDA issued another ANPRM related to flavors (including menthol) in tobacco products in March 2018. In June 2020 the African American Tobacco Control Leadership Council and several other public health organizations filed a lawsuit alleging that FDA unreasonably delayed addressing the menthol issue. In April 2021 FDA issued its final response to the citizen petition and determined that FDA should issue a proposed rule to prohibit menthol as a characterizing flavor. After further delays and litigation, FDA finally issued this proposed rule in May 2022.

5. Conclusion

The industry's efforts to further delay this life-saving standard are motivated by a desire to protect their bottom line and increase profits; in contrast, the FDA's mandate is to protect the public health and reduce smoking-attributable deaths and disease. Therefore, we urge FDA to finalize the rule and make it effective 90 days after publication of the final rule.

[11] US Food and Drug Administration, Tobacco Product Standard for Menthol in Cigarettes, May 4, 2022, Proposed Rule, 87 FR 26454 at 26457-264861.