FDA should not allow any extensions of time to submit public comments about the proposed rule

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

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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 address a few concerns 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 deny any requests for extensions of time to submit public comments.***

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]

Eight tobacco industry entities including RAI Services Company (Reynolds) and Altria Client Services (on behalf of Philip Morris) submitted requests that FDA extend the comment period for the proposed rule by 60 days (120 days in total) until September 1, 2022, and Universal Leaf Tobacco Company went further to request that FDA withdraw the proposed

[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.

standard and to resubmit it to the docket with an extended comment period of a minimum of 20 days.[3] ***These delays are not warranted because the tobacco industry has known that this rule was being prepared since 2009 when the Family Smoking Prevention and Tobacco Control Act was enacted and has had more than enough time to prepare any additional comments it wishes to submit.***

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,[4] FDA determined that every day 1,500 youth and 2,600 young adults smoke their first cigarette.[5] And Wave 1 PATH data[6] show that for 43% of youth and 45% of young adults, this first cigarette is mentholated.[7] 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.[8] 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 grant any extensions of time to submit public comments and must not delay in implementing the proposed menthol standard because each month of delay would cause at least an additional 1,362 premature deaths in future years

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[3] Tobacco Product Standard for Menthol in Cigarettes, other documents submitted to docket. Available: https://www.regulations.gov/docket/FDA-2021-N-1349/document?documentTypes=Other

[4] 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

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

[6] 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.

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

[8] 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.

FDA relied on the *Levy et al.*[9] model to estimate the smoking-attributable deaths averted over the 40-year period from 2021-2060.[10] 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 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. FDA must not delay the public comment process or implementation period of the proposed standard because in addition to lives lost, every month delay would eventually cost $18-19 billion

In its Summary of Cost and Benefits,[11] FDA estimated that the annualized benefits from the proposed rule including lowering smoking-attributable mortality, decreasing illness and associated reductions in medical costs, decreased productivity loss, reductions in smoking-related fires, and reductions in cigarette butt litter and associated environmental harms would amount to $232 billion per year (discounted at 3%) or $220 billion per year (discounted at 7%). This averages to $19.3 billion per month (3%) or $18.3 billion per month (7%), so every month delay in implementing the rule would eventually cost approximately $18-$19 billion. ***Therefore, if FDA granted the requests to extend the time to submit public comments an additional two months, in addition to promoting poor health outcomes and thousands of premature deaths, FDA would incur an additional $36-$39 billion dollars in costs.***

4. The tobacco industry has had more than enough time to prepare for the proposed menthol standard

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 charact erizing flavor in cigarettes.[12] 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.

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[9] 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.
[10] US Food and Drug Administration, Tobacco Product Standard for Menthol in Cigarettes, May 4, 2022, Proposed Rule, 87 FR 26454 at 26481.
[11] US Food and Drug Administration, Tobacco Product Standard for Menthol in Cigarettes, May 4, 2022, Proposed Rule, 87 FR 26454 at 26489-26490.
[12] US Food and Drug Administration, Tobacco Product Standard for Menthol in Cigarettes, May 4, 2022, Proposed Rule, 87 FR 26454 at 26457-264861.

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.

Any arguments launched by tobacco industry entities that they need more time to assess the menthol rule are absurd, as they have had ample notice and have been researching and lobbying against a menthol standard for at least 13 years.

5. Conclusion

We urge FDA to deny these requests and to close the comment period on July 5, 2022.