FDA's economic model underestimates the benefits of the proposed product standard prohibiting menthol in cigarettes, so the benefits would be even greater

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

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We support the Food and Drug Administration's proposed rule to prohibit menthol in cigarettes because it 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] ***Because FDA's rationale for the proposed rule uses an economic model that only considers benefits from reductions in mortality due to lower smoking without also considering lower morbidity and indirect costs benefits, it substantially underestimates the benefits of the rule. As a result, the actual benefits of the proposed rule would be even greater than the FDA estimates.***

FDA relied on the *Levy et al.*[2] model to estimate the smoking-attributable deaths averted over the 40-year period from 2021-2060.[3] However, the anticipated benefits must be understood in terms of the assumptions used in the model to derive them. In this case, the Levy model makes several assumptions that lead it to *underestimate* the health harms attributable to smoking. 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.***

The proposed menthol standard will not only reduce smoking rates and smoking attributable deaths in the general population, but will also result in considerable reductions in health disparities. A June 2022 paper using the Levy model underscores the health gains and

[1] US Food and Drug Administration, Tobacco Product Standard for Menthol in Cigarettes, May 4, 2022, Proposed Rule, 87 FR 26454 at 26458.
[2] 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.
[3] US Food and Drug Administration, Tobacco Product Standard for Menthol in Cigarettes, May 4, 2022, Proposed Rule, 87 FR 26454 at 26481.

reductions in health disparities achieved by the proposed standard among the non-Hispanic Black population. The Levy model projected that had a menthol prohibition been implemented in 2021, non-Hispanic Black adult smoking prevalence would reduce by 35.7% in 2026 and by 25.3% in 2060, leading to a reduction in cumulative averted deaths during 2021-2060 by 18.5% for the non-Hispanic Black population. For the US general population, adult smoking prevalence would reduce by 14.7% in 2026 and by 15.1% in 2060, and the reduction in cumulative averted deaths during 2021-2060 would be 4.6%.[4]

However, because the model does not consider the full range of benefits, the benefits of the proposed standard prohibiting menthol in cigarettes will be even greater for vulnerable populations and for the US as a whole than the FDA estimates.

FDA's model only considers mortality benefits and does not consider the other significant benefits of prohibiting menthol. Some of these additional benefits include reducing the addictive properties of nicotine in cigarettes; reducing the appeal of cigarettes to nonusers, particularly adolescents and young adults and thereby decreasing the likelihood of tobacco use initiation; reducing the incidence of multiple tobacco-related diseases by decreasing cigarette consumption and increasing the likelihood of cessation; reducing smoking-attributable healthcare costs due to lower smoking prevalence; reducing indirect costs of lost productivity due to decreased tobacco-related illnesses and premature deaths. Additionally, as mentioned above, a product standard prohibiting menthol would reduce tobacco-related health disparities and advance health equity.

Another weakness of the model is it that while it estimated several behaviors under a menthol ban including continued (illicit) menthol product use, switching to non-menthol tobacco products, switching to other nicotine products (such as e-cigarettes and smokeless tobacco, and complete cessation, the model does not consider dual use (use of menthol or non-menthol cigarettes with e-cigarettes or other tobacco products).

Moreover, the model uses an expert panel ("expert elicitation") to determine transition rates among tobacco use categories, which is not the strongest basis for policy analysis.

We agree with FDA's decision to not quantify consumer surplus in its analysis of the economic impacts of the proposed product standard prohibiting menthol in cigarettes. There is tremendous uncertainty in how to quantify consumer surplus when considering addictive tobacco products, and in any case ***the benefits of the proposed rule are expected to be so large, even using a model that underestimates the benefits***.

Conclusion

The rationale for FDA's proposed rule prohibiting menthol in cigarettes uses an economic model that only considers benefits from reductions in mortality due to lower smoking prevalence without also considering morbidity and indirect costs benefits. As a result, the actual benefits of the proposed rule would be substantially greater than FDA estimates. FDA should finalize the product standard for menthol in cigarettes because it will reduce youth and young

[4] Issabakhsh M, Meza R, Li Y, Yuan Z, Sanchez-Romero LM, Levy DT. Public health impact of a US menthol cigarette ban on the non-Hispanic black population: a simulation study. Tob Control. 2022 Jun 14:tobaccocontrol-2022-057298. doi: 10.1136/tobaccocontrol-2022-057298. Epub ahead of print. PMID: 35700999.

adult initiation rates of smoking cigarettes, significantly reduce premature deaths and illnesses related to tobacco use, and reduce health disparities.