

United States Senate

WASHINGTON, DC 20510

August 22, 2017

Scott Gottlieb, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Gottlieb,

Since enactment of the Family Smoking Prevention and Tobacco Control Act in 2009, the Food and Drug Administration (FDA) has made progress in efforts to discourage use of traditional cigarettes by youth and assist the public in understanding the health risks associated with smoking. However, the continued marketing and use of menthol cigarettes, particularly by youth, threatens to significantly undermine this progress. As Senators committed to the FDA's mission to protect public health, we believe it is time for the FDA to act on the substantial scientific data and use the authority provided by the Tobacco Control Act to remove menthol cigarettes from the marketplace.

According to numerous independent studies and FDA's own scientific assessment, menthol cigarettes frequently serve as a starter product for youth, are associated with increased nicotine dependence in young smokers, and make it more difficult to quit smoking.¹ The presence of menthol cigarettes in the marketplace is slowing progress in reducing the prevalence of smoking and making it more difficult for the FDA to execute its mission to protect public health.² Additionally, the tobacco industry has a long history of targeting menthol cigarettes to African Americans and in particular African American youth, through strategic marketing and promotional materials.³ These actions have resulted in significant health disparities in communities of color, with African Americans suffering the greatest burden of tobacco-related mortality of any ethnic or racial group in the United States.⁴

Although the Tobacco Control Act did not expressly ban menthol from cigarettes, it did require the Tobacco Products Scientific Advisory Committee (TPSAC) to review the scientific literature around menthol's impact on public health and report to the FDA. That report concluded in 2011 that "removal of menthol from cigarettes would benefit public health." FDA also conducted its

¹ <https://www.fda.gov/downloads/ucm361598.pdf>

² Giovino GA, Villanti AC, Mowery PD, *et al*
Differential trends in cigarette smoking in the USA: is menthol slowing progress?
Tobacco Control 2015;**24**:28-37.

³ Lee, JGL, et al., "A Systematic Review of Neighborhood Disparities in Point-of-Sale Tobacco Marketing,"
American Journal of Public Health, published online ahead of print July 16, 2015.

⁴ HHS, "Tobacco Use Among US Racial/Ethnic Minority Groups—African Americans, American Indians and Alaskan Natives, Asian Americans and Pacific Islanders, and Hispanics: A Report of the Surgeon General," 1998,
http://www.cdc.gov/tobacco/data_statistics/sgr/1998/complete_report/pdfs/complete_report.pdf.

own scientific review, which concluded “that menthol cigarettes pose a public health risk above that seen with non-menthol cigarettes.” Further, in 2013 FDA issued an Advanced Notice of Proposed Rule Making (ANPRM) on this issue. However, no action has been taken since this time, despite clear data showing removal of menthol cigarettes from the market would benefit public health, especially with regards to youth. Recently, as a part of FDA’s “New Plan for Tobacco and Nicotine Regulation,” the agency indicated that it will again issue an ANPRM on the role of flavors, including menthol, in attracting youth smokers. Given the significant public comment and data the FDA has already received on menthol, it is unclear what benefit yet another ANPRM provides.

Continued delay on this issue will only further worsen this public health crisis, as a new generation of smokers are initiated and become addicted to menthol cigarettes. In fact, modeling used in the TPSAC report showed that because of the availability of menthol cigarettes, 9 million individuals would initiate smoking between 2010 and 2050. Another model showed that hundreds of thousands of deaths would be averted by removing menthol. We urge FDA to use its authority to expediently remove menthol as a flavor additive. Additionally, we respectfully request that you provide us with detailed responses to the following questions by close of business on September 18, 2017:

1. What steps has the FDA taken to address the risk of menthol in cigarettes since its publication of the Advanced Notice of Proposed Rulemaking in 2013?
2. What has contributed to the delay in FDA finalizing action that would remove menthol from cigarettes?
3. Please provide us with a timeline for FDA finalizing regulations to address the risk of menthol in cigarettes.

Sincerely,



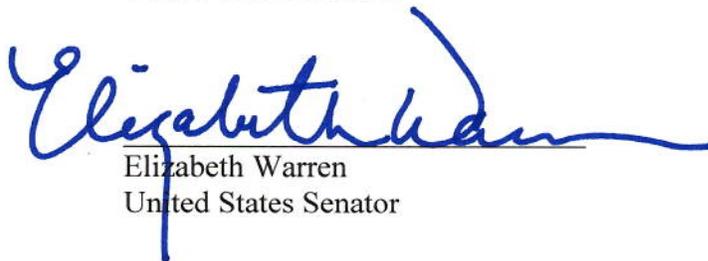
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