

# United States Senate

WASHINGTON, DC 20510

December 20, 2018

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

Dear Commissioner Gottlieb,

We write to support the announcement by the Food and Drug Administration (FDA) that the agency will issue new rules to prohibit menthol in cigarettes, cigars, and other combustible tobacco products. Many of us called on the FDA last year to take this long overdue action to remove menthol cigarettes from the market. We urge the FDA to finalize regulations implementing this ban as quickly as possible.

Despite our support for this recent announcement, we remain concerned that allowing menthol and mint flavored e-cigarettes to remain on the market may hinder achievement of the full public health benefits possible under the FDA's proposal, particularly in light of data indicating that more than half of youth e-cigarette users use mint and menthol flavoring.<sup>1</sup> We therefore urge FDA to remove all flavored tobacco products, including mint and menthol e-cigarettes, from the market until or unless they have undergone a thorough FDA review that shows they are of benefit to the public health.

We agree with the FDA's assessment that menthol cigarettes "represent one of the most common and pernicious routes by which kids initiate on combustible cigarettes" and "exacerbate troubling disparities in health related to race and socioeconomic status."<sup>2</sup> Menthol mitigates the harshness of tobacco smoke, thereby increasing the number of youth who experiment with cigarettes and become regular smokers.<sup>3</sup> Further, the tobacco industry's deliberate and disproportionate targeting of menthol cigarettes to communities of color, particularly to African-American communities, has increased the prevalence of smoking among African Americans<sup>4</sup> and

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<sup>1</sup> Karen A. Cullen et al., *Notes from the Field: Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students — United States, 2011–2018*, Morbidity and Mortality Weekly Report (Nov. 15, 2018). <http://dx.doi.org/10.15585/mmwr.mm6745a5>.

<sup>2</sup> Press Announcement, Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes (Nov. 15, 2018). <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm>.

<sup>3</sup> Food and Drug Administration, *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes* (2013). <https://www.fda.gov/downloads/ucm361598.pdf>.

<sup>4</sup> Report by the by the Tobacco Products Scientific Advisory Committee (TPSAC) of the Center for Tobacco Products of the Food and Drug Administration (2011). <https://wayback.archive-it.org/7993/20170405201750/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM247689.pdf>.

exacerbated health disparities. In response to your announcement, the National Association for the Advancement of Colored People (NAACP) stated that, “The proposed measure by the FDA is long overdue to protect the health of African Americans and to reduce the deleterious impact of menthol smoking and tobacco use overall on America’s health,”<sup>5</sup>

The substantial harm caused by menthol has been extensively studied, including by the FDA, and is well understood. FDA’s Tobacco Products Scientific Advisory Committee (TPSAC) issued a report on menthol in 2011 and concluded that “removal of menthol cigarettes from the marketplace would benefit public health in the United States.”<sup>4</sup> As part of its 2011 report, TPSAC estimated that the continued availability of menthol cigarettes would result in 17,000 additional premature deaths and about 2.3 million more people initiating smoking by 2020.<sup>4</sup>

Additionally, the FDA conducted its own scientific analysis of menthol in 2013 and concluded that menthol cigarettes likely increase smoking initiation and progression to regular smoking among youth and young adults, increase nicotine dependence, and make it harder to quit.<sup>3</sup> Collection of this data was an important step in understanding the public health threats caused by menthol cigarettes, and should give the agency reason to move expeditiously.

As TPSAC’s projections and a wealth of public health data make clear, there are serious consequences to leaving menthol cigarettes on the market. FDA’s previous scientific analysis of menthol, along with the Advance Notices of Proposed Rulemaking it issued in 2013 and in 2018, should enable the FDA to rapidly release a proposed rule and promulgate a final rule. To better understand how the FDA intends to move forward with this important policy change, please answer the below questions by January 17, 2019:

1. What is the FDA’s anticipated timeline to issuing and implementing the proposed ban on mentholated combustibles and removing these products from the market?
2. How will the FDA evaluate whether to expand its recently announced actions and prohibit menthol and mint flavorings in e-cigarettes?
3. What additional steps will the FDA take to ensure that menthol, mint, and other flavored e-cigarettes do not hook another generation on tobacco?

Prohibiting menthol in cigarettes, cigars, and other combustible tobacco products will produce enormous gains to public health, particularly for youth and African Americans who disproportionately experience the harm caused by menthol products. We applaud the FDA for using the authority Congress gave the agency to address the serious negative consequences of menthol, and encourage FDA to likewise remove flavored e-cigarettes from the market until or unless they have undergone a thorough FDA review that shows they are of benefit to the public health.

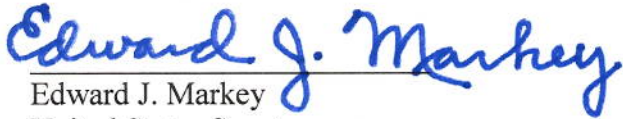
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<sup>5</sup> Press Announcement, NAACP Statement on FDA Plan to Ban Sale of Menthol and E-cigarettes (Nov. 14, 2018), <https://www.naacp.org/latest/naacp-statement-fba-plan-ban-sale-menthol-e-cigarettes/>.



We look forward to working with you to achieve our mutual goal of ending tobacco use and preventing tobacco-caused diseases and premature death. Thank you for your attention to this public health issue.

Sincerely,



Edward J. Markey  
United States Senator



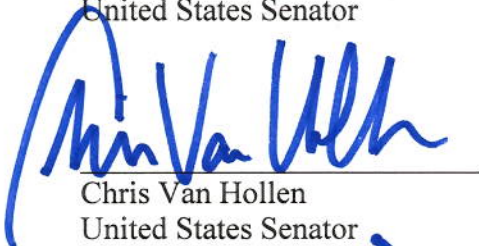
Patty Murray  
United States Senator



Sheldon Whitehouse  
United States Senator



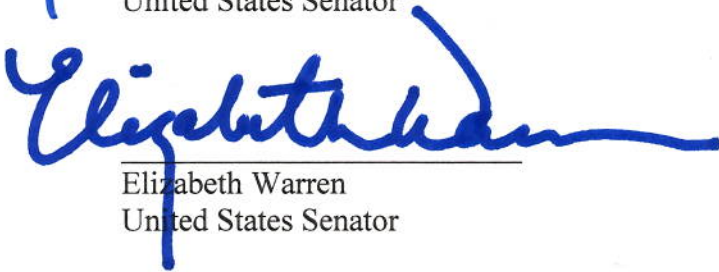
Richard J. Durbin  
United States Senator



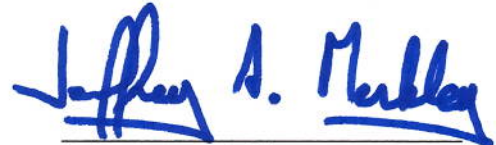
Chris Van Hollen  
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