

United States Senate

April 16, 2021

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Becerra:

We write to urge Food and Drug Administration (FDA) to grant a pending citizen petition that calls on FDA to ban menthol in cigarettes. Given the substantial harm to public health that these products cause, many of us have urged FDA over the years to take this long overdue action to remove menthol cigarettes and other menthol-flavored combustible tobacco products from the market. We have been disappointed that the agency has not acted to effectively prohibit these products, but are encouraged that FDA recently represented to a federal court that it will respond to the pending petition by April 29, 2021. We urge FDA to follow the science, grant the citizen petition, and quickly initiate and complete a rulemaking to prohibit menthol as a characterizing flavor in cigarettes and other combustible tobacco products.

The harmful effects of menthol cigarettes on public health have been extensively studied and are well understood. Menthol numbs the throat and mitigates the harshness of tobacco smoke, thereby making menthol cigarettes more appealing and easier to use for young people who are starting to smoke.¹ Menthol cigarettes are also more addictive and harder to quit.²

Furthermore, the tobacco industry continues to focus its marketing of menthol cigarettes on communities of color, particularly African-American communities.³ This targeting of communities of color, and the resulting increase in smoking by their members, serves to exacerbate existing disparities in our health care system. At a time when communities of color are already disproportionately suffering from the impacts of the COVID-19 pandemic, FDA should use its existing authority to mitigate the harm posed to those communities from other public health threats.

FDA has more than enough evidence to ban menthol cigarettes. Ten years ago this month, FDA received from its Tobacco Products Scientific Advisory Committee (TPSAC) a report detailing

¹ Food and Drug Administration, Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes (2013), <https://www.fda.gov/media/86497/download>.

² *Id.*

³ Campaign for Tobacco-Free Kids, Tobacco Company Marketing to African Americans, <https://www.tobaccofreekids.org/assets/factsheets/0208.pdf>.

the adverse impact that menthol cigarettes have on public health, including a projection that an additional 2.3 million people would start smoking and an additional 17,000 people would die prematurely by 2020 because of the availability of menthol cigarettes.⁴ The 2011 TPSAC report concluded: “Removal of menthol cigarettes from the marketplace would benefit public health in the United States.”⁵

Additionally, FDA conducted its own scientific analysis in 2013 and found 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. FDA concluded that it is “likely that menthol cigarettes pose a public health risk above that seen with nonmenthol cigarettes.”⁶ Since the TPSAC and FDA issued their reports, the evidence of the harm menthol cigarettes cause has only increased.

In 2018, in the face of strong evidence of the harm menthol cigarettes pose to public health, then-FDA Commissioner Scott Gottlieb announced that the agency would initiate rulemaking to prohibit menthol in cigarettes and other combustible tobacco products. Dr. Gottlieb noted 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.”⁷ Yet, FDA still failed to act.

FDA now has another opportunity to respond to the concrete evidence of harm that menthol cigarettes cause, particularly to the health of African Americans. Several health care professionals, civil rights groups, and other advocacy organizations, as well as prominent nicotine and tobacco researchers and state attorneys general, have continued to urge FDA to grant the citizen petition and remove menthol cigarettes from the market.⁸

The Biden administration has emphasized the need to restore trust in public health institutions and put science and facts first in federal policymaking. The evidence that menthol cigarettes significantly harm public health is clear and confirmed by FDA’s own previous assessments of the science. As FDA develops its response to the 2013 citizen petition, we urge the agency to follow the science, grant the petition, and quickly promulgate a new rule to prohibit menthol in cigarettes and other combustible tobacco products. Doing so will protect youth from nicotine addiction and tobacco use, reduce tobacco-related health disparities, and save lives.

⁴ Tobacco Products Scientific Advisory Committee, *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations* at 221 (Mar. 23, 2011), <https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf>.

⁵ *Id.* at 225.

⁶ Food and Drug Administration, *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes* at 6 (2013), <https://www.fda.gov/media/86497/download>.

⁷ 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/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access>.

⁸ See comments filed in Tobacco Control Legal Consortium, et al – Citizen Petition, Apr. 12, 2013, Docket ID: FDA-2013-P-0435, Prohibit Menthol as a Characterizing Flavoring of Cigarettes and Cigarette Smoke, <https://www.regulations.gov/document?D=FDA-2013-P-0435-0001>.

Thank you for your attention to this serious public health issue.

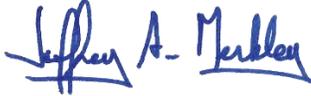
Sincerely,



Edward J. Markey
United States Senator



Sheldon Whitehouse
United States Senator



Jeff Merkley
United States Senator



Margaret Wood Hassan
United States Senator

/s/ Jack Reed

Jack Reed
United States Senator



Ron Wyden
United States Senator

/s/ Dianne Feinstein

Dianne Feinstein
United States Senator



Patty Murray
United States Senator



Kirsten Gillibrand
United States Senator

/s/ Dick Durbin

Richard J. Durbin
United States Senator



Chris Van Hollen
United States Senator



Tina Smith
United States Senator

/s/ Brian Schatz

Brian Schatz
United States Senator



Elizabeth Warren
United States Senator



Sherrod Brown
United States Senator



Cory A. Booker
United States Senator

/s/ Richard Blumenthal

Richard Blumenthal
United States Senator