

# United States Senate

July 22, 2022

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

Dear Commissioner Califf:

We write to express our strong support for proposed rules that the Food and Drug Administration (FDA) recently released to prohibit menthol cigarettes and flavored cigars. The evidence is compelling that these products cause substantial harm to public health and should be removed from the market. We are pleased that FDA is following the science and has taken this important step in the regulatory process. When finalized and implemented, these rules will reduce the number of youth who will become tobacco users, prevent tobacco-caused disease and premature death, and advance health equity.

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.<sup>1</sup> Menthol cigarettes are also more addictive and harder to quit.<sup>2</sup> By increasing youth smoking and making cessation more difficult, menthol cigarettes have magnified the public health harms of smoking. Between 1980 and 2018, menthol cigarettes were responsible for 10.1 million additional smokers and 378,000 premature deaths in the United States.<sup>3</sup>

Menthol cigarettes have also disproportionately harmed communities of color, particularly African-American communities. The tobacco industry has focused its marketing of menthol cigarettes on these communities, which has increased their use of menthol cigarettes and exacerbated existing health disparities.<sup>4</sup> A recent study found that African Americans made up 41 percent of the premature deaths from menthol cigarettes between 1980 and 2018 even though African Americans represent only 12 percent of the population.<sup>5</sup>

More than ten years ago, FDA's Tobacco Products Scientific Advisory Committee (TPSAC) detailed the adverse impact that menthol cigarettes have on public health and concluded that: "[r]emoval of menthol

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<sup>1</sup> 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>.

<sup>2</sup> *Id.*

<sup>3</sup> Thuy TT Le & David Mendez, *An estimation of the harm of menthol cigarettes in the United States from 1980 to 2018*, *Tobacco Control* (Feb. 25, 2021), <http://dx.doi.org/10.1136/tobaccocontrol-2020-056256>.

<sup>4</sup> Campaign for Tobacco-Free Kids, *Stopping Menthol, Saving Lives: Ending Big Tobacco's Predatory Marketing to Black Communities* (Feb. 2021), [https://www.tobaccofreekids.org/assets/content/what\\_we\\_do/industry\\_watch/menthol-report/2021\\_02\\_tfk-menthol-report.pdf](https://www.tobaccofreekids.org/assets/content/what_we_do/industry_watch/menthol-report/2021_02_tfk-menthol-report.pdf).

<sup>5</sup> David Mendez & Thuy TT Le, *Consequences of a match made in hell: the harm caused by menthol smoking to the African American population over 1980-2018*, *Tobacco Control* (Sept. 16, 2021), <http://dx.doi.org/10.1136/tobaccocontrol-2021-056748>.

cigarettes from the marketplace would benefit public health in the United States.”<sup>6</sup> 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 then that it is “likely that menthol cigarettes posed a public health risk above that seen with nonmenthol cigarettes.”<sup>7</sup>

The proposed rule to prohibit menthol cigarettes that FDA issued last month makes clear that the evidence of menthol cigarettes’ harm remains strong. The proposed rule states that FDA expects a menthol cigarette prohibition to significantly reduce “the likelihood of youth and young adult initiation and progression to regular cigarette smoking, which is expected to prevent future cigarette-related disease and death” and “would improve the health and reduce the mortality risk of current menthol cigarette smokers by substantially decreasing cigarette consumption and increasing the likelihood of cessation.”<sup>8</sup> The proposed rule references studies that estimate that smoking in the United States would be reduced by 15 percent over 40 years if menthol cigarettes were removed from the market and that between 324,000 and 654,000 smoking-caused deaths would be avoided, including between 92,000 and 238,000 African Americans.<sup>9</sup>

Prohibiting flavored cigars is also well supported by current science. Flavored cigars have proliferated in recent years.<sup>10</sup> Cigars now come in a wide assortment of flavors such as banana smash, cherry dynamite, chocolate, and menthol.<sup>11</sup> These flavors make cigars more appealing to youth and easier for them to smoke by improving the taste and masking the harshness of tobacco smoke.<sup>12</sup> High school students now smoke cigars at about the same rate as cigarettes, and African American youth have the highest rate of cigar smoking compared to other races and ethnicities.<sup>13</sup> In its proposed rule to prohibit flavored cigars, FDA said removing these products from the market is expected to reduce experimentation, nicotine dependence, regular use, and tobacco-related disease and death by reducing these products’ appeal, particularly to youth and young adults. The agency also said a prohibition would increase the likelihood of cessation among current cigar smokers and advance health equity.<sup>14</sup>

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<sup>6</sup> Tobacco Products Scientific Advisory Committee, Food and Drug Administration, *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations* (Mar. 23, 2011), <https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf>

<sup>7</sup> 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>.

<sup>8</sup> Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26,454 (May 4, 2022) (to be codified at 21 C.F.R. pt. 1162).

<sup>9</sup> *Id.*

<sup>10</sup> Cristine D Delnevo et al., *Changes in the Mass-merchandise Cigar Market Since the Tobacco Control Act*, Tobacco Regulatory Science (Apr. 2017), [https://doi.org/10.18001/TRS.3.2\(Suppl1\).2](https://doi.org/10.18001/TRS.3.2(Suppl1).2).

<sup>11</sup> Laura Bach, Campaign for Tobacco-Free Kids, *Flavored Tobacco Products Attract Kids* (Apr. 4, 2022), <https://www.tobaccofreekids.org/assets/factsheets/0383.pdf>.

<sup>12</sup> Ganna Kostygina et al., *Tobacco industry use of flavours to recruit new users of little cigars and cigarillos*, Tobacco Control (Jan. 2016), <https://tobaccocontrol.bmj.com/content/25/1/66>.

<sup>13</sup> Andrea S. Gentzke et al., *Tobacco Use and Associated Factors Among Middle and High School Students – National Youth Tobacco Survey, United States, 2021*, Morbidity and Mortality Weekly Report (Mar. 11, 2022), <https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7105a1-H.pdf>.

<sup>14</sup> Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26,454 (May 4, 2022) (to be codified at 21 C.F.R. pt. 1162).

The Honorable Robert Califf

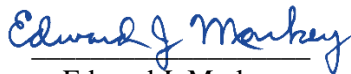
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We applaud FDA for issuing these proposed rules and are pleased to see the agency using the regulatory authority that Congress gave it to reduce the death and disease caused by tobacco products. We also applaud FDA's efforts to account for the disparate impact of menthol tobacco products on Black Americans and address any potential racial or social justice implications of the proposed rule. This careful approach is why a broad coalition, including prominent civil rights and public health groups, support FDA action to remove menthol tobacco products from the market.<sup>15</sup>

We urge you to move promptly to consider public comments, finalize the rule, and implement it so that these life-savings requirements can take effect as soon as possible.

Sincerely,



Edward J. Markey  
United States Senator



Jeffrey A. Merkley  
United States Senator



Ron Wyden  
United States Senator



Sherrod Brown  
United States Senator



Richard J. Durbin  
United States Senator



Richard Blumenthal  
United States Senator



Maggie Hassan  
United States Senator



Tammy Baldwin  
United States Senator



Chris Van Hollen  
United States Senator



Alex Padilla  
United States Senator



Sheldon Whitehouse  
United States Senator



Tina Smith  
United States Senator

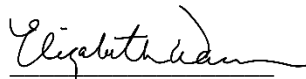
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<sup>15</sup> See comments filed in Tobacco Control Legal Consortium, et al – Citizen Petition, Apr. 12, 2013, Docket ID: FDA-2013-P-0435, Prohibit Menthol as a Characterizing Flavoring of Cigarettes and Cigarette Smoke, <https://www.regulations.gov/document?D=FDA-2013-P-0435-0001>.

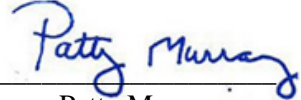
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Elizabeth Warren  
United States Senator



Patty Murray  
United States Senator



Benjamin Cardin  
United States Senator

/s/

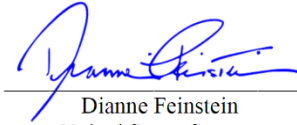
Martin Heinrich  
United States Senator



Tammy Duckworth  
United States Senator

/s/

Jack Reed  
United States Senator



Dianne Feinstein  
United States Senator