



August 2nd, 2022

Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852

**Re: Docket No. FDA-2021-N-1349 for “Tobacco Product Standard for Menthol in Cigarettes.”**

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the proposed rule to establish a product standard for menthol in cigarettes. ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change, as well as legislative and regulatory solutions that will reduce the cancer burden. As the American Cancer Society’s (ACS) nonprofit, nonpartisan advocacy affiliate, ACS CAN is critical to the fight for a world without cancer.

Tobacco use is the leading cause of preventable death in the U.S., with more than 480,000 deaths each year caused by cigarette smoking and costs more than \$300 billion in medical costs and lost productivity.<sup>1</sup> This includes 30% of all cancer deaths and 80% of lung cancer deaths.<sup>2</sup> The American Cancer Society has documented the lethal consequences of smoking and its detrimental effects on almost every organ of the body; and ACS CAN has advocated for comprehensive public policies to effectively reduce tobacco use and exposure to secondhand smoke in the U.S. In fact, the national reductions in overall cancer mortality over the past few years can be partially attributed to our work in tobacco control to prevent youth from starting to use tobacco products and helping current people who use tobacco quit.

Furthermore, tobacco-related disparities exist and continue to grow. Tobacco use rates are highest for adults with: lower education attainment; incomes below the federal poverty line; who reside in the Midwest or South; are uninsured or Medicaid recipients; are disabled; who experience serious psychological distress; are American Indians & Alaska Natives; multiracial; or identify as lesbian, gay, or

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<sup>1</sup> US Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Washington, DC: US Department of Health and Human Services, CDC; 2014. Available at <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf>.

<sup>2</sup> Islami F, Goding Sauer A, Miller KD, Siegel RL, Fedewa SA, Jacobs EJ, McCullough ML, Patel AV, Ma J, Soerjomataram I, Flanders WD, Brawley OW, Gapstur SM, Jemal A (2018) Proportion and number of cancer cases and deaths attributable to potentially modifiable risk factors in the United States. *CA Cancer J Clin* 68: 31-54

bisexual.<sup>3</sup> Lung cancer death rates are higher for men than women, for non-Hispanic Black and American Indian/Alaskan Native individuals than for white individuals.<sup>4</sup> Lung cancer death rates are highest in the South and parts of Appalachia in the U.S. These disparities are not by accident, but rather a direct result, in part, of the tobacco industry's marketing directly to these communities, including the marketing of menthol cigarettes.<sup>5</sup>

The elimination of menthol as a characterizing flavor in cigarettes is perhaps one of the most important actions the Food and Drug Administration (FDA) can take to reduce initiation of smoking, promote cessation, and reduce tobacco-related health disparities. ACS CAN supports the swift finalization and implementation of the rule to prohibit menthol as a characterizing flavor in cigarettes with no exemptions. Critically important, ACS CAN recommends the FDA provide education and outreach for cessation services to people who smoke menthol cigarettes now, in anticipation of when the rule becomes effective. Additionally, ACS CAN supports the equitable enforcement of tobacco control laws and that no law enforcement agency has the authority to enforce this rule against individual consumers.

We have added our name to a comprehensive comment letter on the proposed rule submitted by the Campaign for Tobacco-Free Kids and signed by dozens of tobacco control and health partners. We also most recently signed on to an updated Citizen's Petition submitted by the Public Health Law Center in 2021 that provides updated scientific information in support of the elimination of menthol as a characterizing flavor in cigarettes. We submit these additional comments to contribute to the record in support of the tobacco product standard for menthol in cigarettes.

### **Addressing Health-Related Disparities**

Innovations in cancer prevention, detection, treatment, and survivorship have come a long way, but not everyone has benefited equally.<sup>6</sup> While overall cancer mortality rates in the U.S. are dropping, populations that have been marginalized are bearing a disproportionate burden of cancer.

For example, people who are Black have the highest death rates and shortest survival rates of any racial or ethnic group in the U.S. for most cancers.<sup>7</sup> Lung cancer is the most common cause of cancer death among Black men despite Black men having overall lower lifetime smoking rates.<sup>8</sup> More than 25,000 people who are Black will be diagnosed with lung cancer and more than 14,000 will die from it in 2022. Additionally, Black individuals also experience more illness, worse outcomes, and premature death compared to white individuals.

People who identify as lesbian, gay, bisexual, transgender or queer (LGBTQ) may have a higher risk of getting cancer than those who people identify as heterosexual or cisgender. The American Cancer

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<sup>3</sup> Cornelius ME, Loretan CG, Wang TW, Jamal A, Homa DM. Tobacco Product Use Among Adults — United States, 2020. *MMWR Morb Mortal Wkly Rep* 2022;71:397–405. DOI: <http://dx.doi.org/10.15585/mmwr.mm7111a1>

<sup>4</sup> American Cancer Society. *Cancer Facts & Figures 2019*. Atlanta: American Cancer Society, 2019.

<sup>5</sup> U.S. National Cancer Institute. *A Socioecological Approach to Addressing Tobacco-Related Health Disparities*. National Cancer Institute Tobacco Control Monograph 22. NIH Publication No. 17-CA-8035A. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute; 2017.

<sup>6</sup> <https://www.cancer.org/about-us/what-we-do/health-equity.html>

<sup>7</sup> American Cancer Society. *Cancer Facts & Figures for African American/Black People 2022-2024*. Atlanta: American Cancer Society, 2022.

<sup>8</sup> American Cancer Society. *Cancer Facts & Figures for African American/Black People 2022-2024*. Atlanta: American Cancer Society, 2022.

Society estimates there will be 1.9 million newly diagnosed cancer cases and nearly 609,000 cancer deaths in 2022 with national estimates that 5-10% of the general population identify as LGBTQ, this means there could be approximately 143,900 new cancer cases and more than 45,702 cancer deaths in the LGBTQ+ population this year.<sup>9</sup>

These cancer disparities are largely driven by social mechanisms like structural racism, but also the direct actions of the tobacco industry in designing products and targeting its marketing to specific communities, like Black and LGBTQ communities. To reduce deaths from tobacco-related cancers, everyone must not only have the ability to benefit from the advances in prevention and treatment of cancer, but also be protected from the predatory actions of the tobacco industry. Taking actions that protect those individuals that are bearing the disproportionate burden of cancer by the design of the tobacco industry meets the FDA's standard for the protection of public health.

### **Current Use and Trends in Menthol Cigarette Prevalence**

*Menthol flavoring in cigarettes has potentially slowed overall smoking declines*

Although fewer people are smoking cigarettes than in the past, consumption of menthol cigarettes (26.1%) declined more slowly than non-menthol cigarettes (52.9%) between 2000 and 2018.<sup>10</sup> In fact, it has been declining more slowly than the decline in non-menthol cigarette consumption.

Generally, menthol cigarette use is disproportionately higher for Black Americans, individuals who identify as bisexual and gay/lesbian, among individuals with limited household incomes, and younger age groups.<sup>11</sup> Additionally, progress in reducing menthol smoking has been uneven across racial and ethnic groups. Between 2000 and 2015, menthol smoking prevalence remained unchanged among American Indian/Alaska Native and Hispanic persons, while declining in other racial and ethnic groups.<sup>12</sup> Another study suggests that there is a shifting burden of menthol cigarette smoking to American Indian/Alaska Native young adult and middle-aged adults between 2004-2019.<sup>13</sup>

#### *By Race and Ethnicity:*

Non-Hispanic Black Americans who smoke are more than 2.5 times more likely to smoke menthol than non-Hispanic white Americans. Eighty-three percent of Black Americans who smoke cigarettes smoke menthol.<sup>14</sup> Menthol cigarettes are also popular among other non-white racial and ethnic populations. In 2019-2020, between 33%-57% of Hispanic, Native Hawaiian or Pacific Islander, and American Indian or Alaska Native people who smoke used menthol cigarettes.

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<sup>9</sup> <https://www.cancer.org/content/dam/cancer-org/cancer-control/en/booklets-flyers/lgbtq-people-with-cancer-fact-sheet.pdf>

<sup>10</sup> Delnevo, C.D., D.P. Giovenco, and A.C. Villanti. "Assessment of Menthol and Nonmenthol Cigarette Consumption in the US, 2000 to 2018." *JAMA Network Open*, 3(8):e2013601, 2020. Available at <https://doi.org/10.1001/jamanetworkopen.2020.13601>.

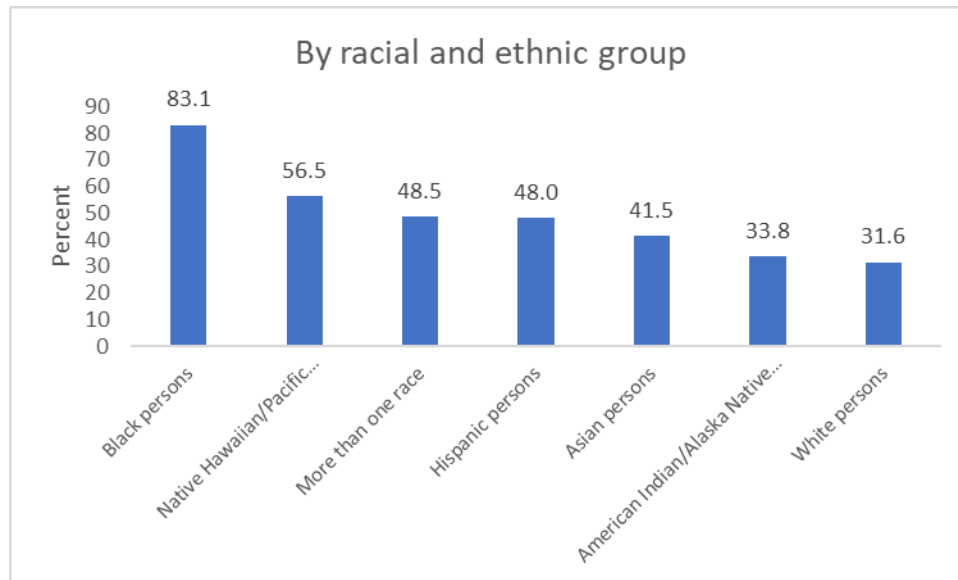
<sup>11</sup> ACS analysis of 2020 National Household Survey data.

<sup>12</sup> Mattingly et al. Trends in prevalence and sociodemographic and geographic patterns of current menthol cigarette use among U.S. adults, 2005–2015. *Prev Med Rep.* 2020 Nov 10;20:101227.

<sup>13</sup> Bandi P et al., Racial/Ethnic Disparities in Menthol Cigarette Smoking, United States, 2004-2019. SRNT Annual Conference 2022. Baltimore, MD.

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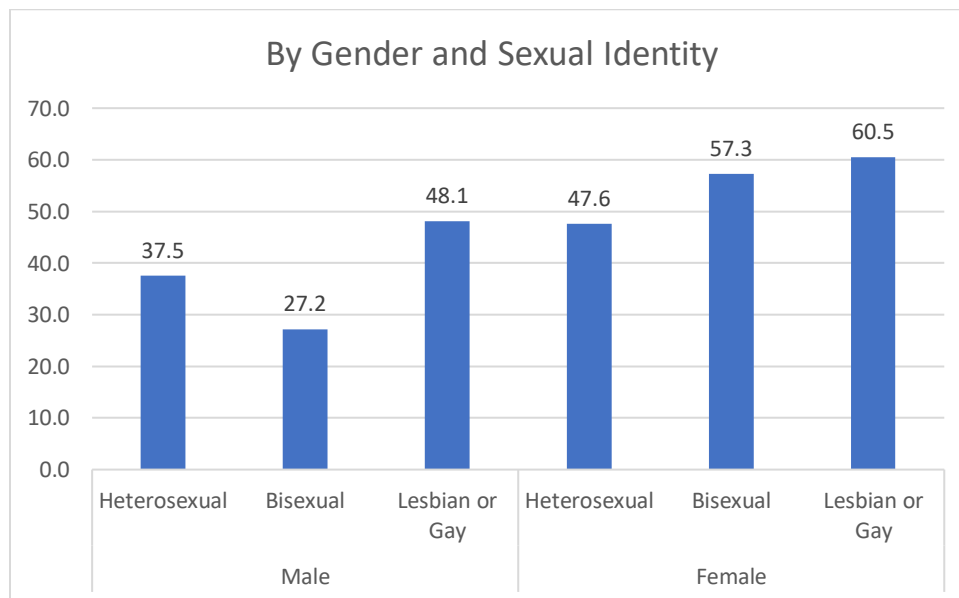
<sup>14</sup> ACS analysis of 2019-2020 National Household Survey data.



*By gender and sexual identity:*

Women who smoke are more likely to smoke menthol cigarettes (49.6%) than men who smoke (38.2%).<sup>15</sup>

Among those who smoke, women who identify as Lesbian or Gay, or Bisexual have the highest rates of menthol cigarette use compared to heterosexual women and men of any sexual orientation.<sup>16</sup>



<sup>15</sup> ACS analysis of 2019-2020 National Household Survey data.

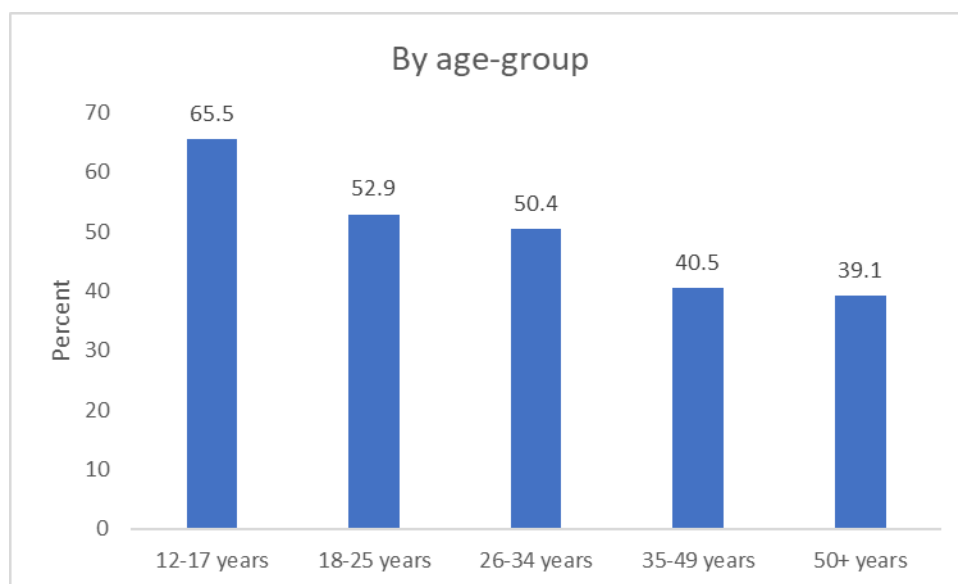
<sup>16</sup> ACS analysis of 2019-2020 National Household Survey data.

*By socioeconomic status:*

Among people who smoke, 51.8% who live at or below the poverty threshold smoke menthol cigarettes compared to 42.7% who live at twice the poverty threshold smoke menthol cigarettes, and 39.5% who live more than twice the poverty threshold smoke menthol cigarettes.<sup>17</sup> A family of 4 with a household income of \$26,200 is considered at the poverty threshold.

*Youth*

Youth aged 12-17 years old who smoke were almost twice more likely smoke menthol cigarettes than adults over the age of 50 who smoke. Sixty-five % (65.5%) of youth aged 12-17 who smoke use menthol cigarettes and 52.9% of young adults aged 18-25 who smoke use menthol, compared to their older counterparts.<sup>18</sup>



The National Youth Tobacco Survey results for 2021 show that more than 2.1 million youth ever used a cigarette and 410,000 were regularly smoking cigarettes.<sup>19</sup> Among those youth regularly smoking cigarettes, 17.1% reported buying them from a convenience store or gas station and another 7% reported buying them from a vape shop. Almost 40% of those youth who were regularly smoking cigarettes were smoking menthol cigarettes. Among all youth, over 75% reported exposure to tobacco product advertising at retail stores, on the internet, on TV, streaming services, movies, and in newspapers and advertising. The most common place youth reported seeing this advertising was at retail stores.

**Tobacco Industry’s Predatory Marketing of Menthol Cigarettes**

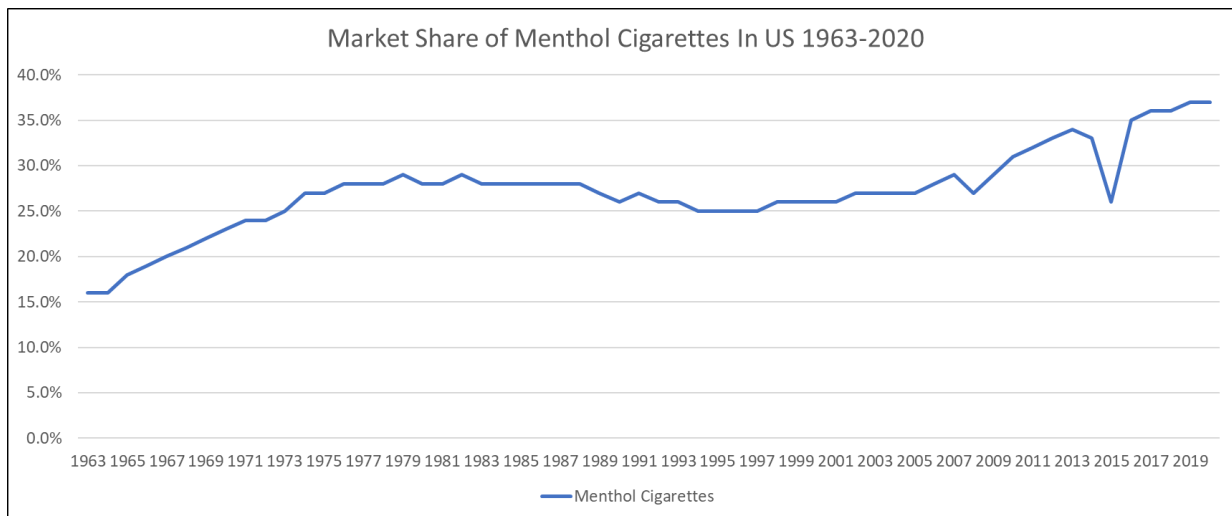
Menthol cigarettes are widely available in almost every tobacco retail store. Retail marketing, including in-store advertising, product displays, and discounts, accounts for a large portion of the tobacco industry’s marketing budget. In 2020, the most recent year data are available, cigarette companies

<sup>17</sup> ACS analysis of 2019-2020 National Household Survey data.

<sup>18</sup> ACS analysis of 2019-2020 National Household Survey data.

<sup>19</sup> Gentzke AS, Wang TW, Cornelius M, et al. Tobacco Product Use and Associated Factors Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021. MMWR Surveill Summ 2022;71(No. SS-5):1–29. DOI: <http://dx.doi.org/10.15585/mmwr.ss7105a1>

spent 97% of their total advertising and promotion budgets on strategies that facilitated retail sales, such as price discounts, point-of-sale advertising, coupons, and payments to ensure prime retail space.<sup>20</sup> In addition, while print advertising has generally gone down, by 2005 only menthol cigarettes or brands with a prominent menthol brand were advertised in magazines.<sup>21</sup> In fact, Newport and American Spirit spent an estimated \$9.4 million on print advertising for their menthol cigarettes from June 2012 to January 2013.



Menthol cigarette’s market share has increased over the last several decades, with a noticeable increase in the last ten years since other characterizing flavors in cigarettes were prohibited by federal law. In 2020, the most recent year data are available, menthol cigarettes comprised 37% of the market share, up from 26% ten years prior.

For decades, the tobacco industry has used menthol products to target specific communities: youth, communities of color, LGBTQ+ communities, women and low-income communities.<sup>22</sup> Long before cigarette companies started adding fruit, candy, alcohol and other flavorings to cigarettes, they were manipulating levels of menthol to addict new, young people to smoke. Knowing that youth who experience less negative physiological effects of smoking are more likely to continue smoking regularly, the tobacco industry has spent decades manipulating its menthol brand-specific product line to appeal to youth.

Tobacco companies disproportionately market menthol products in Black neighborhoods, magazines popular with Black Americans, and events that are aimed for Black Americans.<sup>23</sup> Within communities of color, menthol products are given more shelf space in retail stores. Many of these communities also see

<sup>20</sup> U.S. Federal Trade Commission (FTC), Cigarette Report for 2020, 2021 <https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-cigarette-report-2020-smokeless-tobacco-report2020/p114508fy20cigarettereport.pdf> [data for top 5 manufacturers only]

<sup>21</sup> U.S. National Cancer Institute. A Socioecological Approach to Addressing Tobacco-Related Health Disparities. National Cancer Institute Tobacco Control Monograph 22. NIH Publication No. 17-CA-8035A. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute; 2017.

<sup>22</sup> [https://tobaccocontrol.bmj.com/content/20/Suppl\\_2/ii20](https://tobaccocontrol.bmj.com/content/20/Suppl_2/ii20)

<sup>23</sup> U.S. National Cancer Institute. A Socioecological Approach to Addressing Tobacco-Related Health Disparities. National Cancer Institute Tobacco Control Monograph 22. NIH Publication No. 17-CA-8035A. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute; 2017.

lower prices and more advertisements for these products.<sup>24</sup> Additionally, studies have found greater tobacco retailer density nationwide in census tracts with a higher proportion of Black residents.<sup>25</sup> The more tobacco retailers, the more exposure to tobacco marketing individuals face which can lead to increased use.

Cigarette manufacturers have specifically targeted LGBTQ+ communities with menthol cigarette advertising and promotions.<sup>26</sup> Starting in the 1990s, the tobacco industry has targeted LGBTQ+ communities by developing marketing materials targeted at the LGBTQ+ community before most other industries and designing advertisements for LGBTQ+ publications that depict tobacco use as a “normal” part of LGBTQ+ life.<sup>27,28</sup> In 1995, one tobacco company created a marketing strategy known as “Project SCUM” or subculture urban marketing targeted at gay men and individuals experiencing homelessness in San Francisco.<sup>29</sup>

It is this predatory marketing practices of the tobacco industry that have led to the higher menthol cigarette use rates among youth, Black individuals, LGBTQ individuals, women and individuals with limited incomes and the resulting tobacco-related health disparities.

### **Menthol Cigarette Prohibitions Reduce Product Availability, Sales, Retailer Advertising, and Use** *Evidence from the US (state and local)*

Evidence of the effectiveness of a comprehensive menthol flavor prohibition on cigarette sales, smoking prevalence, and cessation in the US is limited because few jurisdictions have such policies in place. Massachusetts remains the only state in the US to have implemented a law restricting the sale of menthol cigarettes. As the FDA finalizes this rule, understanding the effectiveness of the Massachusetts policy is important, especially as menthol cigarettes were still available in neighboring states and online, generating both intended and unintended consequences.

To date, only one study, authored by ACS researchers, provides some evidence of the effectiveness of the Massachusetts law. The study compared cigarette sales in Massachusetts to sales in 27 other states that did not implement similar restrictions on the sale of menthol cigarettes. The study found the law reduced menthol and all (menthol and nonflavored) cigarette sales in Massachusetts but with a slight increase in nonflavored cigarette sales.<sup>30</sup>

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<sup>24</sup> Resnick, EA, et al., Cigarette Pricing Differs by U.S. Neighborhoods—A BTG Research Brief. Chicago, IL: Bridging the Gap Program, Health Policy Center, Institute for Health Research and Policy, University of Illinois at Chicago, 2012, [www.bridgingthegapresearch.org](http://www.bridgingthegapresearch.org).

<sup>25</sup> Campaign for Tobacco-Free Kids. Tobacco Company Marketing to African Americans. <https://www.tobaccofreekids.org/assets/factsheets/0208.pdf>

<sup>26</sup> Centers for Disease Control and Prevention (CDC). Lesbian, Gay, Bisexual, and Transgender Persons and Tobacco Use. Updated February 28, 2017. <https://www.cdc.gov/tobacco/disparities/lgbt/index.htm>

<sup>27</sup> American Lung Association. Smoking Out a Deadly Threat: Tobacco Use in the LGBT Community. 2010. <http://www.lung.org/assets/documents/research/lgbt-report.pdf>

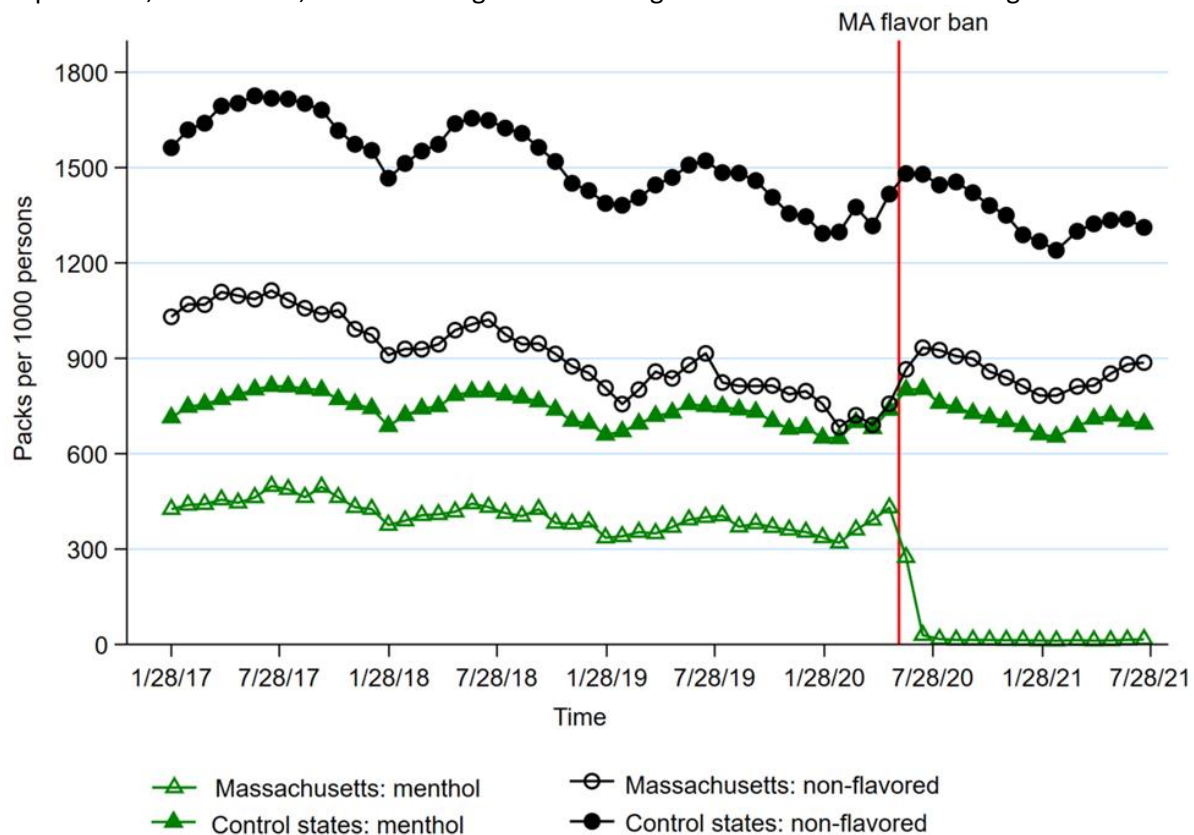
<sup>28</sup> Centers for Disease Control and Prevention (CDC). Lesbian, Gay, Bisexual, and Transgender Persons and Tobacco Use. Updated February 28, 2017. <https://www.cdc.gov/tobacco/disparities/lgbt/index.htm>

<sup>29</sup> The Truth Initiative. Tobacco Use in LGBT Communities. February 2018. <https://truthinitiative.org/news/tobacco-social-justice-issue-smoking-and-lgbt-communities>. See Also American Lung Association. Smoking Out a Deadly Threat: Tobacco Use in the LGBT Community. 2010. <http://www.lung.org/assets/documents/research/lgbt-report.pdf>

<sup>30</sup> Asare S, Majmundar A, Westmaas JL, et al. Association of Cigarette Sales With Comprehensive Menthol Flavor Ban in Massachusetts. *JAMA Internal Medicine*. Published online January 4, 2022. doi:10.1001/jamainternmed.2021.7333

The graph below summarizes the study results, which suggest decreases in cigarette smoking in Massachusetts based on a 372.27 packs per 1000 persons decline in menthol cigarette sales. Following the policy, all (menthol and nonflavored) cigarette sales declined by 282.65 packs per 1000 persons. The difference between the decline in menthol and all cigarette sales resulted from an increase in nonflavored cigarette sales by 120.25 packs per 1000 person. The decline in all cigarette sales suggests that people who smoke menthol cigarettes did not completely substitute nonflavored cigarettes for menthol cigarettes. This finding is consistent with other study findings from a local law in San Francisco that ended the sale of all flavored tobacco products including menthol cigarettes.<sup>31</sup>

The evaluation of the Massachusetts law may only provide part of story on the overall effectiveness of the law as some aspects were not assessed including switching to other tobacco products, such as cigars and electronic cigarettes, cross-border purchases, online sales, and illicit trade. For example, cross-border purchases are expected to decrease with increased distance due to travel costs. As some people who smoke menthol cigarettes in Massachusetts were expected to travel to the neighboring states to purchase menthol cigarettes after the law, we anticipated that only those in the bordering counties would engage in such trade. As discussed in an editorial on the study, FDA’s finalized rule could potentially address illicit trade, cross-border purchases, and online sales as the manufacturing, importation, distribution, and marketing of menthol cigarettes nationwide will be regulated.<sup>32</sup>



<sup>31</sup> Gammon DG, Rogers T, Gaber J, et al. Implementation of a comprehensive flavoured tobacco product sales restriction and retail tobacco sales. *Tob Control*. Published online June 4, 2021:tobaccocontrol-2021-056494. doi:10.1136/tobaccocontrol-2021-056494

<sup>32</sup> Pérez-Stable, Eliseo J., and Erik J. Rodriguez. "Association of Policy Interventions With Tobacco Use Behaviors." *JAMA Internal Medicine* 182, no. 2 (2022): 234-235.



While nonflavored cigarette sales declined in all states during the period before the implementation of the Massachusetts laws in June of 2020, menthol cigarette sales did not change in the comparison states and declined disproportionately in Massachusetts. Even during the period after the Massachusetts law went into effect, nonflavored cigarette sales in the comparison states continued to decline while menthol cigarette sales remained unchanged. These data suggest a slowing down of the overall decline in cigarette smoking in the US. Therefore, removing menthol as a characterizing flavor in cigarettes can speed up the rate of decrease in cigarette sales and smoking prevalence.

Several jurisdictions in five other states (California, Colorado, Illinois, Minnesota, and New York) have implemented local-level flavored tobacco product sales restrictions. Some studies have evaluated these local-level policies and shown that local-level menthol flavor sales prohibitions were generally associated with declines in cigarette sales and use.<sup>33</sup> One study that focused on youth tobacco use after a menthol tobacco product sale restriction in Minneapolis and St. Paul, Minnesota (also known as the Twin Cities) in 2018, provides suggestive evidence that the prevalence of tobacco product use among youth in grades 8, 10, and 11 declined after the law was implemented.<sup>34</sup> The study showed reductions in the rate of increase in the prevalence of any tobacco product use among youth by 34.6% (i.e., from 12.2% to 16.5%) in the Twin Cities compared to 44.6% (i.e., from 13.9% to 20.1%) in the rest of the state of Minnesota and increases in the prevalence of e-cigarette use by 49.5% (i.e., from 10.5% to 15.7%) compared to the rest of Minnesota that increased by 88.9% (i.e., from 10.0% to 18.8%). The finding suggests the law slowed down the rate of increase in any tobacco product use and e-cigarette use among youth.

It is important to consider how the use of other tobacco products changed during the time the law was implemented in the Twin Cities. The study also showed declines in the use of cigarettes (6.2% to 4.8%), cigars (3.5% to 2.7%), smokeless tobacco (4.0% to 2.6%), and hookahs (2.6% to 1.6%) from 2016 to 2019.<sup>35</sup> However, excluding changes in tobacco use prevalence in the rest of the states does not invalidate that the menthol flavor sales restrictions might be associated with the decreased use of these tobacco products. While the prevalence of tobacco product use decreased in the Twin Cities between 2016 and 2019 by 40.5% for cigarettes, 42.4% for cigars, and 43.4% for hookahs, tobacco product use prevalence decreased in the rest of Minnesota by 22.6% for cigarettes, 23.7% for cigars, and 35.9% for hookahs during the same period.<sup>36</sup> The greater decline in the prevalence of cigarette, cigar, and hookah use among the youth between 2016 and 2019 may suggest that the law was associated with a decrease in their use. For smokeless tobacco, the decline in the Twin Cities (25.9%) was lower than that of the rest of Minnesota (i.e., 35.4%). However, since the prevalence of smokeless tobacco use in the Twin Cities

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<sup>33</sup> Gammon DG, Rogers T, Gaber J, et al. Implementation of a comprehensive flavoured tobacco product sales restriction and retail tobacco sales. *Tob Control*. Published online June 4, 2021:tobaccocontrol-2021-056494. doi:10.1136/tobaccocontrol-2021-056494.

Olson LT, Coats EM, Rogers T, et al. Youth Tobacco Use Before and After Local Sales Restrictions on Flavored and Menthol Tobacco Products in Minnesota. *Journal of Adolescent Health*. 2022;70(6):978-984. doi:10.1016/j.jadohealth.2022.01.129

<sup>34</sup> Olson LT, Coats EM, Rogers T, et al. Youth Tobacco Use Before and After Local Sales Restrictions on Flavored and Menthol Tobacco Products in Minnesota. *Journal of Adolescent Health*. 2022;70(6):978-984. doi:10.1016/j.jadohealth.2022.01.129

<sup>35</sup> Olson LT, Coats EM, Rogers T, et al. Youth Tobacco Use Before and After Local Sales Restrictions on Flavored and Menthol Tobacco Products in Minnesota. *Journal of Adolescent Health*. 2022;70(6):978-984. doi:10.1016/j.jadohealth.2022.01.129

<sup>36</sup> Olson LT, Coats EM, Rogers T, et al. Youth Tobacco Use Before and After Local Sales Restrictions on Flavored and Menthol Tobacco Products in Minnesota. *Journal of Adolescent Health*. 2022;70(6):978-984. doi:10.1016/j.jadohealth.2022.01.129

before the menthol flavor sales prohibition was already low (i.e., 1.6%) compared to that of the rest of Minnesota (i.e., 4.0%), the disproportionate decline in smokeless tobacco use in the Twin Cities compared to the rest of Minnesota is less concerning.

### *Evidence From Other Countries*

Some countries have implemented menthol flavor sales prohibitions exclusively or as part of comprehensive tobacco flavor sales restrictions. Canada implemented a menthol flavor restriction nationwide in October 2017.<sup>37</sup> Prior to the national prohibition, all provinces, except British Columbia, Saskatchewan, and Manitoba, had prohibited menthol flavors, with Nova Scotia and Alberta implementing the prohibition in 2015, followed by Quebec and New Brunswick in 2016, and three other provinces in early 2017.<sup>38,39</sup> Canada's experience was cited in the FDA's proposed rule for restricting menthol as a characterizing flavor.

Studies from Canada were used to demonstrate the effects of menthol flavor prohibitions on the likelihood that people who currently smoke menthol cigarettes would reduce cigarette consumption or stop cigarette smoking. As noted by the FDA in the proposed rule, there are mixed effects based on Canada's experience. Analyses of individual quitting behavior pre-post menthol flavor prohibitions showed that quitting cigarette smoking increased among people who smoke menthol cigarettes and all people who smoke following the Ontario menthol flavor prohibition<sup>40,41,42,43</sup> and the national prohibition.<sup>44</sup> However, the study did not compare changes in quitting cigarette smoking in Ontario or nationwide to changes in any other province or counterfactual. Therefore, it is difficult to estimate the exact effect of the menthol prohibition on quitting as similar outcomes could be observed in comparison provinces or countries if included in the design. One study that compared quitting behavior in provinces that implemented menthol flavor prohibitions to those without menthol flavor prohibitions found no evidence quitting among people who smoke.<sup>45</sup> However, the policy and study designs have limitations, including the availability of menthol cigarettes through First Nations reserves and cross-border purchases from provinces without menthol flavor prohibitions.

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<sup>37</sup> Chaiton M, Schwartz R, Kundu A, Houston C, Nugent R. Analysis of Wholesale Cigarette Sales in Canada After Menthol Cigarette Bans. *JAMA Network Open*. 2021;4(11):e2133673-e2133673.

<sup>38</sup> Carpenter CS, Nguyen HV. Intended and unintended effects of banning menthol cigarettes. *The Journal of Law and Economics*. 2021;64(3):629-650.

<sup>39</sup> Stoklosa M. No surge in illicit cigarettes after implementation of menthol ban in Nova Scotia. *Tobacco Control*. 2019;28(6):702-704.

<sup>40</sup> Fong GT, Chung-Hall J, Meng G, et al. Impact of Canada's menthol cigarette ban on quitting among menthol smokers: pooled analysis of pre-post evaluation from the ITC Project and the Ontario Menthol Ban Study and projections of impact in the USA. *Tobacco Control*. Published online 2022.

<sup>41</sup> Chaiton M, Schwartz R, Cohen JE, Soule E, Zhang B, Eissenberg T. Prior Daily Menthol Smokers More Likely to Quit 2 Years After a Menthol Ban Than Non-menthol Smokers: A Population Cohort Study. *Nicotine Tob Res*. 2021;23(9):1584-1589. doi:10.1093/ntr/ntab042

<sup>42</sup> Chaiton MO, Nicolau I, Schwartz R, et al. Ban on menthol-flavoured tobacco products predicts cigarette cessation at 1 year: a population cohort study. *Tobacco control*. 2020;29(3):341-347.

<sup>43</sup> Chaiton M, Schwartz R, Cohen JE, Soule E, Eissenberg T. Association of Ontario's ban on menthol cigarettes with smoking behavior 1 month after implementation. *JAMA internal medicine*. 2018;178(5):710-711.

<sup>44</sup> Chung-Hall J, Fong GT, Meng G, et al. Evaluating the impact of menthol cigarette bans on cessation and smoking behaviours in Canada: Longitudinal findings from the Canadian arm of the 2016–2018 ITC Four Country Smoking and Vaping Surveys. *Tobacco Control*. Published online 2021.

<sup>45</sup> Carpenter CS, Nguyen HV. Intended and unintended effects of banning menthol cigarettes. *The Journal of Law and Economics*. 2021;64(3):629-650.

Evaluation of sales data after the implementation of Ontario's menthol flavor prohibition shows a statistically significant reduction in menthol and all cigarette sales in Ontario compared to sales in British Columbia.<sup>46,47</sup> Also, an evaluation of wholesale cigarette sales following the implementation of provincial and nationwide menthol flavor prohibitions shows that both menthol and all cigarette sales declined in Canada compared to expected sales in the absence of the prohibitions.<sup>48</sup> The fact that the overall cigarette sales declined is an indication that the provincial and nationwide prohibition reduced consumption.

Following provincial menthol flavor prohibitions, one study showed that illicit cigarettes seized in Nova Scotia reduced drastically.<sup>49</sup> A recent study from Canada based on data from 2018-2020 shows that the prevalence of menthol cigarette smoking among Canadian youth (16-19-year-olds) following the implementation of the nationwide menthol flavor prohibition was stable at about 2-3% , which represents a decline based on data from the pre-ban.<sup>50</sup> However, the study did not investigate the sources from which the youth obtained menthol cigarettes after the prohibitions in Canada. Nevertheless, some studies have also documented that the tobacco companies attempted to maintain customers who smoke menthol cigarettes by repackaging menthol cigarettes following menthol flavor prohibitions in Canada.<sup>51,52</sup> One study also indicated that the tobacco companies sold additives, including flavor cards and menthol drops, that can add menthol flavor to cigarettes.<sup>53</sup> As the FDA plans to finalize the proposed rule to prohibit menthol as a characterizing flavor in cigarettes, efforts should be made to prevent the industry from employing tactics that allow them to circumvent the prohibition.

In May 2020, the European Union and England prohibited flavored cigarette sales, including menthol cigarettes.<sup>54</sup> Evaluation of menthol cigarette use among youth (ages 16-19) in England vs. the US and Canada between 2018 and 2020 showed a drastic decline in consumption of menthol cigarettes in England after the prohibition, while consumption among similar individuals in US and Canada were stable.<sup>55</sup>

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<sup>46</sup> Chaiton M, Schwartz R, Shuldiner J, Tremblay G, Nugent R. Evaluating a real-world ban on menthol cigarettes: an interrupted time-series analysis of sales. *Nicotine and Tobacco Research*. 2020;22(4):576-579

<sup>47</sup> Brown EM, Gammon DG, Rogers T, et al. Changes in retail sales of tobacco products in Ontario after a menthol sales restriction. *Tobacco Control*. Published online 2021.

<sup>48</sup> Chaiton M, Schwartz R, Kundu A, Houston C, Nugent R. Analysis of Wholesale Cigarette Sales in Canada After Menthol Cigarette Bans. *JAMA Network Open*. 2021;4(11):e2133673-e2133673.

<sup>49</sup> Stoklosa M. No surge in illicit cigarettes after implementation of menthol ban in Nova Scotia. *Tobacco Control*. 2019;28(6):702-704.

<sup>50</sup> Bold KW, Jatlow P, Fucito LM, Eid T, Krishnan-Sarin S, O'Malley S. Evaluating the effect of switching to non-menthol cigarettes among current menthol smokers: an empirical study of a potential ban of characterising menthol flavour in cigarettes. *Tobacco Control*. 2020;29(6):624-630.

<sup>51</sup> Borland T, D'Souza SA, O'Connor S, Chaiton MO, Schwartz R. Is blue the new green? Repackaging menthol cigarettes in response to a flavour ban in Ontario, Canada. *Tobacco Control*. 2019;28(e1):e7-e12.

<sup>52</sup> Brown J, DeAtley T, Welding K, et al. Tobacco industry response to menthol cigarette bans in Alberta and Nova Scotia, Canada. *Tobacco control*. 2017;26(e1):e71-e74.

<sup>53</sup> Chaiton MO, Schwartz R, Cohen JE, Soule E, Zhang B, Eissenberg T. The use of flavour cards and other additives after a menthol ban in Canada. *Tobacco control*. 2021;30(5):601-602

<sup>54</sup> East KA, Reid JL, Burkhalter R, et al. Evaluating the outcomes of the menthol cigarette ban in England by comparing menthol cigarette smoking among youth in England, Canada, and the US, 2018-2020. *JAMA network open*. 2022;5(5):e2210029-e2210029.

<sup>55</sup> East KA, Reid JL, Burkhalter R, et al. Evaluating the outcomes of the menthol cigarette ban in England by comparing menthol cigarette smoking among youth in England, Canada, and the US, 2018-2020. *JAMA network open*. 2022;5(5):e2210029-e2210029.

### *Projection Models for US Menthol Prohibition*

As mentioned earlier, all Canadian provinces prohibited menthol between 2015 to 2018. One study looked at the impact of these policies on quitting among people who smoke and then applied the result to project the impact of a total US prohibition on menthol cigarettes.<sup>56</sup> After the menthol prohibition in Canada, people who smoked menthol cigarettes were more likely to quit than people who smoke non-menthol cigarettes. Among people who smoked daily, people who smoked menthol cigarettes were 8 percentage points more likely to have quit than people who smoked non-menthol cigarettes. Among all people who smoked, people who smoked menthol cigarettes were 7.3 percentage points more likely to have quit than people who smoked non-menthol cigarettes.

Applying the results in Canada to the US, a menthol cigarette prohibition is estimated to increase quitting among 236,917 to 1,352,402 people who smoke daily and among 384,901 to 2,291,075 all people who smoke. Given the higher use rate of menthol cigarettes among Black people who smoke in the US, the study estimates that the prohibition would result in between 59,920 to 342,041 Black people who smoke daily quitting and between 109,681 and 652,863 all Black people who smoke quitting.

Additional studies projecting the impacts of a menthol cigarette prohibition on smoking and smoking-attributable deaths were reviewed in the FDA proposed rule. One study used data from the 2003 Tobacco Use Supplement to the Current Population Survey to estimate the impact of a menthol prohibition on smoking prevalence and smoking-attributable deaths.<sup>57</sup> It projected the impact a 30% quit rate among people who smoke menthol cigarettes and a 30% reduction in initiation among those who would start smoking if menthol cigarettes were available. These reductions in prevalence and initiation would, by 2050, generate a relative reduction in overall smoking prevalence by about 10% and approximately 25% among Black Americans, averting 633,252 deaths overall and 237,317 among Black Americans.<sup>58</sup> A recent follow-up study showed that the menthol cigarette prohibition will reduce overall smoking by 15% between 2021 and 2060, translating into saving 650,000 lives.<sup>59</sup> The new results suggest that the estimates of the number of lives expected to be saved did not change, even after accounting for the availability of e-cigarettes. Therefore, taking menthol cigarettes off the market will generate more public health impacts by saving many lives.

### **Prohibiting Menthol in Cigarettes is for the Protection of Public Health**

Menthol is derived from mint products and can be found naturally or developed synthetically.<sup>60</sup> Menthol was first added to tobacco products in the 1920s and 30s as a way to reduce the harshness of cigarette smoke and to advertise cigarettes as a “smoother, healthier” option.<sup>61</sup> Tobacco manufacturers add

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<sup>56</sup> Fong GT, Chung-Hall J, Meng G, et al. Impact of Canada’s menthol cigarette ban on quitting among menthol smokers: pooled analysis of pre–post evaluation from the ITC Project and the Ontario Menthol Ban Study and projections of impact in the USA. *Tobacco Control*. Published Online First: 28 April 2022. doi: 10.1136/tobaccocontrol-2021-057227

<sup>57</sup> Levy DT, Pearson JL, Villanti AC, et al. Modeling the future effects of a menthol ban on smoking prevalence and smoking-attributable deaths in the United States. *American journal of public health*. 2011;101(7):1236-1240

<sup>58</sup> Levy DT, Pearson JL, Villanti AC, et al. Modeling the future effects of a menthol ban on smoking prevalence and smoking-attributable deaths in the United States. *American journal of public health*. 2011;101(7):1236-1240

<sup>59</sup> Levy DT, Meza R, Yuan Z, et al. Public health impact of a US ban on menthol in cigarettes and cigars: a simulation study. *Tobacco Control*. Published online 2021.

<sup>60</sup> Tobacco Products Scientific Advisory Committee. *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations* pdf icon[PDF–15.3 MB]external icon. Rockville, MD: US Department of Health and Human Services, Food and Drug Administration; 2011.

<sup>61</sup> Food and Drug Administration. *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes* pdf icon[PDF–1.6 MB]external icon. 2013.

menthol to cigarettes to create an effect on multiple senses – including improving the taste, flavor, aroma of the product and creating a soothing or cooling effect.<sup>62</sup> Unfortunately, these positive sensory effects can reinforce use of the tobacco product because they can be felt immediately by the user making it easier to initiate, experiment with, and progress to regular smoking.

The science is clear: menthol has been shown to increase smoking initiation, decrease successful quitting, and lead to greater addiction, all independent of the damaging effects of nicotine.<sup>63,64</sup> The vast majority of people who smoke cigarettes started as youth.<sup>65</sup> Data show that both youth and young adults are more likely to try a menthol cigarette for the first time than a non-menthol cigarette.<sup>66,67</sup> Menthol may also contribute to youth progressing to regular smoking as compared to non-menthol cigarettes.

Adults who smoke menthol cigarettes make more quit attempts but have less success compared to adults who smoke non-menthol cigarettes.<sup>68</sup> This situation is exacerbated by race and ethnicity; where non-Hispanic Black adults who smoke report the greatest interest in quitting, but the least success.<sup>69</sup>

The FDA’s Tobacco Product Scientific Advisory Committee (TPSAC) Report *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations* and the FDA’s *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes* and *Scientific Review of the Effects of Menthol in Cigarettes on Tobacco Addiction: 1980-2021* all provide the scientific evidence to support a product standard to prohibit menthol as a characterizing flavor in cigarettes.

The TPSAC report concluded that “Removal of menthol cigarettes from the marketplace would benefit public health in the United States.”<sup>70</sup>

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<sup>62</sup> U.S. National Cancer Institute. A Socioecological Approach to Addressing Tobacco-Related Health Disparities. National Cancer Institute Tobacco Control Monograph 22. NIH Publication No. 17-CA-8035A. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute; 2017.

<sup>63</sup> Food and Drug Administration. Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes pdf icon[PDF–1.6 MB]external icon. 2013.

<sup>64</sup> Tobacco Products Scientific Advisory Committee. Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations pdf icon[PDF–15.3 MB]external icon. Rockville, MD: US Department of Health and Human Services, Food and Drug Administration; 2011

<sup>65</sup> U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014

<sup>66</sup> Villanti, A.C., A.L. Johnson, M. Halenar, et al. “Menthol and Mint Cigarettes and Cigars: Initiation and Progression in Youth, Young Adults and Adults in Waves 1-4 of the PATH Study, 2013-2017.” *Nicotine & Tobacco Research*, 23(8): 1318-1326, 2021. Available at <https://doi.org/10.1093/ntr/ntaa224>

<sup>67</sup> D’Silva, J., A.M. Cohn, A.L. Johnson, et al. “Differences in Subjective Experiences to First Use of Menthol and Nonmenthol Cigarettes in a National Sample of Young Adult Cigarette Smokers.” *Nicotine & Tobacco Research*, 20(9):1062-1068, 2018. Available at <https://doi.org/10.1093/ntr/ntx181>.

<sup>68</sup> Villanti AC, Collins LK, Niaura RS, Gagosian SY, Abrams DB. Menthol cigarettes and the public health standard: a systematic review external icon. *BMC Public Health* 2017;17:983.

<sup>69</sup> U.S. National Cancer Institute. A Socioecological Approach to Addressing Tobacco-Related Health Disparities. National Cancer Institute Tobacco Control Monograph 22. NIH Publication No. 17-CA-8035A. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute; 2017.

<sup>70</sup> Tobacco Product Scientific Advisory Committee, FDA. Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations. 2011.

The FDA's Preliminary Evaluation<sup>71</sup> concluded that: "These findings, combined with the evidence indicating that menthol's cooling and anesthetic properties can reduce the harshness of cigarette smoke and the evidence indicating that menthol cigarettes are marketed as a smoother alternative to nonmenthol cigarettes, make it likely that menthol cigarettes pose a public health risk above that seen with nonmenthol cigarettes."

The FDA's most recent scientific review<sup>72</sup> concluded menthol is associated with:

- "...positive smoking experiences that contribute to cigarette smoking...
- ...progression to regular cigarette smoking among youth and young adults...
- ...greater dependence in youth..
- ...reduced cessation success among African American smokers...and...likely associated with reduced cessation success among the general population."

The consequences of this tobacco industry targeting of menthol cigarettes have been great, and likely not fully quantified. One study that looked at how menthol increased the number of people who smoked and died found that from 1980 to 2018, menthol cigarettes were responsible for 10.1 million extra people who smoke, 3 million life years lost and 378,000 premature deaths.<sup>73</sup> Specifically among Black Americans, menthol cigarettes were responsible for 1.5 million new people who smoke, 1.5 million life-years lost, and 157,000 smoking-related premature deaths.<sup>74</sup> To understand this disparity, these figures represent, respectively, 15%, 41% and 50% of the total harm caused by menthol cigarettes while Black Americans comprise 12% of the total U.S. population.

### **The Product Standard Should Eliminate Menthol as a Characterizing Flavor in all Cigarettes**

ACS CAN supports a comprehensive product standard that eliminates menthol as a characterizing flavor by addressing the multi-sensory and biological mechanisms in which menthol affects smoking initiation, dependence and cessation. Such a product standard should give the FDA appropriate discretion to determine whether a product has a characterizing flavor.

*The product standard should include products that have already received marketing orders.*

The product standard should apply to all cigarettes without any exemptions. This should include those products that have already received marketing orders. If the manufacturer of a current menthol cigarette wants to sell a non-menthol version of their product that is not currently on the market, they should be required to undergo the appropriate marketing pathway. If the non-menthol product raises new questions of public health it must submit to the requirements of premarket review applications.

*The product standard should include any analog products and tobacco product flavor components and parts.*

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<sup>71</sup> FDA. Scientific Review of the Effects of Menthol in Cigarettes on Tobacco Addiction: 1980-2021 April 2022. <https://www.fda.gov/media/86497/download>

<sup>72</sup> FDA. Scientific Review of the Effects of Menthol in Cigarettes on Tobacco Addiction: 1980-2021 April 2022. <https://www.fda.gov/media/157642/download>

<sup>73</sup> Le TT, Mendez D. An estimation of the harm of menthol cigarettes in the United States from 1980 to 2018. *Tob Control*. 2021 Feb 25;tobaccocontrol-2020-056256. doi: 10.1136/tobaccocontrol-2020-056256. Epub ahead of print. PMID: 33632809; PMCID: PMC8384947.

<sup>74</sup> Mendez D, Le TTT. Consequences of a match made in hell: the harm caused by menthol smoking to the African American population over 1980-2018. *Tob Control*. 2021 Sep 16;tobaccocontrol-2021-056748. doi: 10.1136/tobaccocontrol-2021-056748. Epub ahead of print. PMID: 34535507; PMCID: PMC8924008.

The product standard should include any menthol analogs or components and parts that can turn a cigarette into a menthol flavored cigarette. Cigarette manufacturers use flavor capsules in cigarette filters as way to deliver one or more flavors, which can potentially help them avoid flavor prohibitions that have been imposed in other countries.<sup>75</sup> Limited data from the US suggest flavor capsule products are more popular with young adults than older adults, and part of their appeal is the taste and perceived less risk.<sup>76,77</sup> In addition to taste, those younger adults who use menthol flavored capsule cigarettes report package design and lesser expensive as top reasons for using them – all indications that manufacturers are targeting young people with the advertising of these products.

*The product standard should include explicit and implicit descriptors, colors or other flavor representations in the product packaging and advertising.*

The Tobacco Control Act prohibited the false and misleading descriptors of “light,” “low,” and “mild” because consumers incorrectly believed these products posed less harm or less risk than other cigarettes. After the prohibition, tobacco manufacturers substituted the descriptors with colors on packaging and advertising to allow consumers to continue to identify these so-called “light,” “low,” and “mild” cigarettes. Evidence shows that use of these colors perpetuated the incorrect belief among consumers that these products posed less harm or less risk than other cigarettes, thereby undermining the intent of the prohibition on the descriptors.<sup>78</sup> Several studies from provinces in Canada show that cigarette manufacturers reacted similarly in response to a menthol cigarette prohibition by replacing menthol with other descriptors, such as “smooth,” and colors on packaging.<sup>79,80</sup> The FDA must prohibit any descriptors, colors or other representations of flavor in product packaging and advertising to ensure the rule has the intended public health effect.

*The FDA should consider whether the product standard should prohibit menthol entirely as an additive, as well as other additives or constituents that contribute to the multi-sensory experience of a menthol flavor for the protection of public health.*

The TPSAC report concluded that “Menthol cannot be considered merely a flavoring additive to tobacco. Its pharmacological actions reduce the harshness of smoke and the irritation from nicotine.” FDA is proposing to address the multi-sensory experience of menthol with four proposed factors. We ask the FDA to consider prohibiting additives that create the multi-sensory experience in addition to flavor additives, for example cooling additives. As with menthol capsule cigarettes, the FDA should consider whether these other additives, like cooling additives, can be sold separately as a tobacco product component or part.

A comprehensive prohibition on menthol as a characterizing flavor in all cigarettes is necessary for the protection of public health. There is no scientific rationale for permitting any menthol cigarette to

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<sup>75</sup> Kyriakos CN, Zatoński MZ, Filippidis FT. Flavour capsule cigarette use and perceptions: a systematic review. *Tobacco Control*. Published Online First: 04 October 2021. doi: 10.1136/tobaccocontrol-2021-056837

<sup>76</sup> Thrasher JF, Abad-Vivero EN, Moodie C, et al. Cigarette brands with flavour capsules in the filter: trends in use and brand perceptions among smokers in the USA, Mexico and Australia, 2012–2014. *Tobacco Control* 2016;25:275-283.

<sup>77</sup> Emond JA, Soneji S, Brunette MF, et al. Flavour capsule cigarette use among US adult cigarette smokers. *Tobacco Control* 2018;27:650-655.

<sup>78</sup> Connolly GN, Alpert HR. Has the tobacco industry evaded the FDA's ban on ‘Light’ cigarette descriptors? *Tobacco Control* 2014;23:140-145.

<sup>79</sup> Brown J, DeAtley T, Welding K, et al. Tobacco industry response to menthol cigarette bans in Alberta and Nova Scotia, Canada. *Tobacco Control* 2017;26:e71-e74.

<sup>80</sup> Borland T, D’Souza SA, O’Connor S, et al. Is blue the new green? Repackaging menthol cigarettes in response to a flavour ban in Ontario, Canada. *Tobacco Control* 2019;28:e7-e12.

remain on the market. Only a comprehensive prohibition can counter the scientifically proven effects of menthol on initiation, progression to regular smoking, dependence, and cessation, and eliminate any potential loopholes for the tobacco industry to exploit to continue to sell a menthol flavored cigarette.

### **Dispute Countervailing Effects**

ACS and ACS CAN previously provided comments regarding an ANPRM for *Draft Concept Paper: Illicit Trade in Tobacco Products After Implementation of a Food and Drug Administration Product Standard*. In our letter we argued that any risk of illicit trade is overstated by the tobacco industry and would be extremely challenging due to geographical coverage of the policy and current manufacturing in the US. Additionally, any potential for illicit trade can be mitigated by FDA implementing an effective track and trace system.

### **Effective Dates**

We support an effective date of no more than one year from final publication, and there should be no “sell-off” period for retailers after the effective date. This is more than sufficient time for retailers to remove menthol cigarettes from their inventory.

### **Prohibiting Flavors in All Tobacco Products**

To maximize the public health impact of this proposed rule, the FDA should finalize its proposed rule to prohibit all characterizing flavors in cigars. Doing so would decrease the likelihood that people who currently use menthol cigarettes would switch to another flavored tobacco product rather than quit.

### **Enforcement Should Target Manufacturers, Retailers and Distributors, not Individuals**

ACS CAN endorses the joint statement on principles for addressing systemic racism in the enforcement of commercial tobacco control and would encourage FDA to use the principles in its own enforcement and in the education and training of state and local law enforcement.<sup>81</sup> The principles recommend entrusting to public health officials or other non-law enforcement personnel the enforcement of tobacco control laws and eliminating laws, policies and enforcement practices that target individuals, especially youth or communities of color, rather than businesses and industry actors.

FDA has reiterated in the proposed rule that:

“FDA’s enforcement will only address manufacturers, distributors, wholesalers, importers, and retailers. This regulation does not include a prohibition on individual consumer possession or use, and FDA cannot and will not enforce against individual consumers for possession or use of menthol cigarettes. In addition, state and local law enforcement agencies do not independently enforce the FD&C Act. These entities do not and cannot take enforcement actions against any violation of chapter IX of the Act or this regulation on FDA’s behalf.”

This is a critical statement from FDA and FDA must follow through with appropriate education and training of federal, state, local and tribal law enforcement and public health partners in order to ensure communities that have already been targeted by the tobacco industry are not also targeted by law enforcement for compliance of the rule.

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<sup>81</sup>[https://www.fightcancer.org/sites/default/files/Tobacco%20Control%20Enforcement%20for%20Racial%20Equity\\_FINAL\\_20201011.pdf](https://www.fightcancer.org/sites/default/files/Tobacco%20Control%20Enforcement%20for%20Racial%20Equity_FINAL_20201011.pdf)



As disparities in tobacco product advertising and access persist, so do disparities in the enforcement of commercial tobacco control laws and policies. FDA must ensure its enforcement practices occur in a data-driven, evidence-based, and equitable manner. Enforcement practices should not unfairly target communities that have been marginalized. If businesses in certain communities have a greater number or rate of violations, FDA should seek to identify compliance barriers and offer technical assistance to help businesses comply with the law. Law enforcement should not approach, harass, or arrest communities that have been historically marginalized because they have a tobacco product in their possession. Tobacco control partners can work with the FDA and others to address where and how public health laws contribute to systemic racism and discrimination.

Lastly, ACS CAN recognizes the important role of ceremonial tobacco for many indigenous communities. This letter is intended to address commercial tobacco, not the provision, possession, or use of tobacco products as part of an indigenous practice or other recognized religious or spiritual ceremony or practice. All references to tobacco and tobacco products in this letter refer to commercial tobacco.

### **Outreach and Cessation Services**

As summarized above, there are millions of people in the U.S. who currently smoke menthol cigarettes, most of whom want to quit and many of whom may have less access to resources to quit. Efforts must be made to offer free, accessible, confidential, and culturally appropriate cessation and counseling services. There are evidence-based proven resources available, including medications, counseling and quitlines. What's lacking are strategies specifically designed to support and provide education to individuals who smoke menthol cigarettes, including people who are Black, LGBTQ+, have limited incomes and youth. The FDA should immediately implement new and improved outreach to these populations with evidence-based cessation resources in anticipating of a finalized rule prohibiting menthol as a characterizing flavor.

FDA has run highly successful campaigns designed to reduce youth initiation and to promote cessation. FDA should consider restarting these campaigns with messages about menthol cigarettes. FDA has previously partnered with the National Cancer Institute (NCI) on the "*Every Try Counts*" campaign and should consider other partners for collaborations on education campaigns, including the Centers for Disease Control and Prevention (CDC). The "*Tips from Former Smokers*" campaign has been highly successful at promoting quit attempts and successful quitting. The FDA should work with the NCI and CDC to develop messaging and cessation resources most appropriate for people who smoke menthol cigarettes.

The FDA should consider partnering with healthcare systems to reach people who smoke menthol cigarettes. Such systems can include behavioral health clinics, federally qualified health centers, Veteran Affairs hospitals and clinics, and Indian Health Services hospitals and clinics. Even for people with health insurance, it can be difficult to know what services are available. Additionally, as stated earlier people who smoke are more likely to be uninsured or underinsured. FDA should consider opportunities to reach those individuals with cessation services, such as through quitlines or other programs that can provide such resources free of charge.

The FDA should look at opportunities to partner with non-tobacco programs both at the federal and state level, such as offices of health equity, women and maternal health, and minority health, as well as non-government health organizations that focus on supporting populations that have been marginalized and are often the target of tobacco industry marketing.

To maximize the public health impact of this effort, FDA should also consider including messaging on lung cancer screening for those individuals who may be eligible. The U.S. Preventive Services Task Force recommends lung cancer screening for individuals who are aged 50 or older, with a 20-year pack history, and are currently still smoking or quit in the last 15 years.<sup>82</sup> These individuals would benefit from information on screening as well as cessation message.

ACS CAN believes FDA currently has the capacity to support people who want to quit and does not need to delay the rule.

**Conclusion**

Thank you for the opportunity to provide input on this important topic. If we can provide additional information, please contact Katie McMahon, MPH, Policy Principal, at ACS CAN at 202-869-3876 or [katie.mcmahon@cancer.org](mailto:katie.mcmahon@cancer.org). Thank you.

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<sup>82</sup> <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/lung-cancer-screening>