



November 9, 2020

The Honorable Stephen M. Hahn  
 Commissioner  
 U.S. Food and Drug Administration  
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RE: Public Health Imperative of Granting Citizen Petition Urging Prohibition of Menthol as Characterizing Flavor in Cigarettes (FDA-2013-P-0435-0001)

Dear Commissioner Hahn:

The undersigned public health and medical organizations write to urge the Food and Drug Administration (FDA) to grant the pending Citizen Petition referenced above and commence the requested rulemaking to prohibit menthol as a characterizing flavor in cigarettes.

I. INTRODUCTION AND RELEVANT BACKGROUND

The menthol Citizen Petition was filed over seven years ago and has yet to receive a substantive response from FDA. A lawsuit is currently pending in federal court in the Northern District of California<sup>1</sup> alleging that FDA’s failure to take action on menthol cigarettes, including its failure to respond to the Citizen Petition, constitutes “unreasonable delay” in violation of the Administrative Procedure Act. In a pleading recently filed by the government in that lawsuit, it was represented that FDA’s Center for Tobacco Products “has agreed to provide a final response to Plaintiffs’ citizen petition by January 29, 2021.”<sup>2</sup>

<sup>1</sup> *African American Tobacco Control Leadership Council, et al. v. U.S. Dept. of Health and Human Services, et al.* (AATCLC v. HHS), Case No: 4:20-cv-4012-KAW (N.D. Cal. June 17, 2020).

<sup>2</sup> Federal Defendants’ Memorandum in Support of Motion to Dismiss, *AATCLC v. HHS* (Sept. 18, 2020), at 1, n.1.

Given this announced timeline, FDA will be reaching a decision on what action to take with regard to the long pending Petition on menthol cigarettes within the next several months. If true, this decision will come at a time when FDA's credibility as an agency guided by science has never been in greater jeopardy and under such public scrutiny.<sup>3</sup> Given the strength of the scientific evidence regarding the impact of menthol cigarettes on youth initiation and adult cessation, as articulated by FDA itself, FDA's decision in this instance will have an impact on whether FDA is perceived as an agency of integrity committed to science that resonates far beyond its decision on the pending petition. You have repeatedly assured the American people that FDA's decision-making, on issues related to COVID-19 vaccines and therapeutics, as well as on other issues, will continue to be driven by science alone. For example, you recently promised that "every one of the decisions we have reached, has been made by FDA scientists based on science and data, not by politics."<sup>4</sup> In remarks to the Global Coalition for Regulatory Science Research, you commented that "we are committed to the principle that each of our decisions must be based on good data and sound science."<sup>5</sup> You have said, "I will fight for science. I will fight for the integrity of the agency, and I will put the interests of the American people before anything else."<sup>6</sup>

On the issue of menthol cigarettes, the science, as assessed by FDA itself, supports only one conclusion: *the presence of menthol as a characterizing flavor in cigarettes is harmful to public health.*

As its first order of business, and as directed by Congress in the Family Smoking Prevention and Tobacco Control Act (TCA), the Tobacco Products Scientific Advisory Committee (TPSAC) issued a report in 2011 (TPSAC Report), with two primary conclusions: (1) "Menthol cigarettes have an adverse impact on public health in the United States," and (2) "There are no public health benefits of menthol compared to non-menthol cigarettes."<sup>7</sup> Indeed, the TPSAC Report projected the adverse impact of menthol in cigarettes from 2011 to the present day, finding that "by 2020, about 17,000 premature deaths will occur and about 2.3 million people will have started smoking, beyond what would have occurred absent availability of menthol cigarettes." Based on these findings, TPSAC made the following "overall recommendation" to FDA: "Removal of menthol cigarettes from the marketplace would benefit the public health in the United States."

Two years after issuance of the TPSAC Report, FDA completed its own independent, peer-review evaluation of the available science concerning menthol cigarettes. FDA evaluated the peer-reviewed literature, industry submissions and other materials provided to TPSAC and commissioned additional

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<sup>3</sup> Anna Edney et al., *FDA Sets Up Vaccine Safeguards to Counter Pressure From Trump*, Bloomberg, Sept. 8, 2020, <https://www.bloomberg.com/news/articles/2020-09-08/will-a-vaccine-be-politicized-fda-sets-up-safeguards>.

<sup>4</sup> FDA Speech, *Dr. Hahn's Remarks to the National Consumers League on Vaccine Review Process*, Sept. 9, 2020, <https://www.fda.gov/news-events/speeches-fda-officials/dr-hahns-remarks-national-consumers-league-vaccine-review-process-09292020>.

<sup>5</sup> FDA Speech, *Remarks by Dr. Hahn to the Global Coalition for Regulatory Science Research*, Sept. 30, 2020, <https://www.fda.gov/news-events/speeches-fda-officials/remarks-dr-hahn-global-coalition-regulatory-science-research-09302020>.

<sup>6</sup> Kashmiri Gander, *Trump Must Stop Criticizing Scientists Amid COVID-19 Vaccine Talks: Experts to FDA*, Sept. 26, 2020, <https://www.newsweek.com/trump-criticizing-scientists-coronavirus-vaccine-1534439>

<sup>7</sup> TPSAC, FDA, *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations*, 2011, <https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterial/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf> (TPSAC Menthol Report).

analyses. FDA's *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes* (FDA Report) reached the overall conclusion, consistent with TPSAC's, that it is "likely that menthol cigarettes pose a public health risk above that seen with nonmenthol cigarettes."<sup>8</sup>

FDA has never wavered in its conclusion that menthol cigarettes are adverse to public health. Indeed, less than two years ago, then-Commissioner Gottlieb announced the agency's intention to "advance a Notice of Proposed Rulemaking that would seek to ban menthol in combustible tobacco products, including cigarettes and cigars . . . ," after expressing his "deep concern" about "the availability of menthol-flavored cigarettes," which "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>9</sup>

Thus, as discussed in more detail below, the available science overwhelmingly supports a rule prohibiting cigarettes in which menthol is a characterizing flavor. Consistent with the long held view that all consequential decisions by FDA should be driven by science and the public health of the American people, not politics and the political fortunes of the few, there is only one possible outcome in response to the pending Citizen Petition: grant the Petition and immediately commence a tobacco product standard rulemaking process leading to a prohibition of menthol cigarettes.

## II. MENTHOL CIGARETTES INCREASE YOUTH INITIATION OF SMOKING

Although the tobacco companies know that almost all new tobacco users begin their addiction as kids, they also know that, to novice smokers, tobacco smoke can be harsh and unappealing. By masking the harshness and soothing the irritation caused by tobacco smoke, menthol cigarettes make it easier for beginners to experiment with cigarettes and ultimately become addicted. Thus, young smokers are more likely to use menthol cigarettes than any other age group. As the FDA has observed, "[m]ultiple studies show a greater use of menthol cigarettes by younger smokers and less usage among older smokers."<sup>10</sup> The TPSAC Report concluded that menthol cigarettes increase the number of children who experiment with cigarettes and the number who become regular smokers, increasing overall youth smoking, and that young people who initiate using menthol cigarettes are more likely to become addicted and become long-term daily smokers.<sup>11</sup> Since 90% of adult smokers begin smoking in their teens,<sup>12</sup> as a starter product for the young, menthol cigarettes are critical to the tobacco industry's need

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<sup>8</sup> FDA, *Preliminary Scientific Evaluation of the Possible Public Health effects of Menthol versus Nonmenthol Cigarettes*, 2013, <https://www.fda.gov/media/86497/download> (FDA Report).

<sup>9</sup> FDA Statement, *FDA Commissioner Scott Gottlieb, M.D. on proposed new steps to protect youth by prevention 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>.

<sup>10</sup> Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12,294, 12,296 (proposed Mar. 21, 2018) (to be codified at 21 C.F.R. pt. 1100, 1140, 1143) ("Advance Notice of Proposed Rulemaking").

<sup>11</sup> TPSAC Menthol Report, *supra* note 7 at 136, 199-202.

<sup>12</sup> Substance Abuse and Mental Health Services Administration, HHS, *National Survey on Drug Use and Health*, 2014, <https://doi.org/10.3886/ICPSR36361.v1>.

to recruit “replacement smokers” for the half of long-term smokers who eventually die from tobacco-related disease.<sup>13</sup>

Since the reports from TPSAC and FDA, research has continued to demonstrate the popularity of menthol cigarettes among youth and menthol’s role in smoking initiation. A 2016 study demonstrated that youth smokers are more likely to use menthol cigarettes than any other age group and over half (54%) of youth smokers ages 12-17 use menthol cigarettes, compared to less than one-third of smokers ages 35 and older.<sup>14</sup> Data from Truth Initiative’s Young Adult Cohort Study, a national study of 18-34 year olds, showed that 52% of new young adult smokers initiated with menthol cigarettes. Initiation with menthol cigarettes was higher among black smokers (93.1%) compared to white smokers (43.9%).<sup>15</sup>

The impact of menthol cigarettes in attracting kids, and keeping them addicted, has profoundly adverse effects on their health. FDA has written that “smoking cigarettes during adolescence is associated with lasting cognitive and behavioral impairments, including effects on working memory in smoking teens and alterations in the prefrontal attentional network in young adult smokers.”<sup>16</sup> “Use of tobacco products,” according to the FDA, “puts youth and young adults at greater risk for future health issues, such as coronary artery disease, cancer, and other known tobacco-related diseases. Youth and young adult . . . cigarette smokers also are at increased risk for future marijuana and illicit drug use, developmental and mental health disorders, reduced lung growth and impaired function, increased risk of asthma, and early abdominal aortic atherosclerosis.”<sup>17</sup>

Thus, the science has long demonstrated that menthol in cigarettes, by masking the harshness of cigarette smoke, increase youth initiation of smoking far in excess of non-menthol cigarettes and keep kids addicted.

### III. MENTHOL CIGARETTES INCREASE ADDICTION AND REDUCE CESSATION

The TPSAC and FDA Reports found that, in addition to increasing initiation of smoking among young people, menthol cigarettes are associated with increased nicotine dependence and reduced success in smoking cessation, particularly among African American smokers.<sup>18</sup>

More recent research bolsters these findings. A 2014 randomized clinical trial of FDA-approved cessation treatments among 1,500 US adult smokers found that menthol smoking was associated with reduced likelihood of quitting, compared to non-menthol smoking (31% vs. 38%). Female African

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<sup>13</sup> U.S. Department of Health and Human Services (HHS), *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*, 2014, [https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf\\_NBK179276.pdf](https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf_NBK179276.pdf) at pg. 691.

<sup>14</sup> Andrea C. Villanti, et al., *Changes in the Prevalence and Correlates of Menthol Cigarette Use in the USA, 2004–2014*, 25 *Tobacco Control* ii14, 2016, <https://pubmed.ncbi.nlm.nih.gov/27729565/>.

<sup>15</sup> Joanne D’Silva, et al., *Differences in Subjective Experiences to First Use of Menthol and Nonmenthol Cigarettes in a National Sample of Young Adult Cigarette Smokers*, 20 *Nicotine & Tobacco Research* 9, 1062-1068, 2018, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6093322/>.

<sup>16</sup> Advance Notice of Proposed Rulemaking, *supra* note 2, at 12,295.

<sup>17</sup> *Id.* at 12,295-96.

<sup>18</sup> TPSAC Menthol Report, *supra* note 7 at 49; FDA Report, *supra* note at 6.

American menthol smokers had the lowest quit rates (17 %) of all groups in the study.<sup>19</sup> A meta-analysis of findings from nearly 150,000 smokers found that among African Americans, menthol smokers have a 12% lower odds of smoking cessation compared to non-menthol smokers.<sup>20</sup> The 2020 Surgeon General's Report on smoking cessation also cited numerous studies finding an association between menthol use and lower cessation rates. The report concluded that the evidence is suggestive that restricting menthol products would lead to increased smoking cessation.<sup>21</sup> More recent research, analyzing four waves of data from the government's Population Assessment of Tobacco and Health (PATH) study shows that among daily smokers, menthol cigarette smokers have a 24% lower odds of quitting as compared to non-menthol smokers. This relationship held for both African American (OR=0.47) and white (OR=.78) daily menthol smokers, although there was no significant difference among quit rates for non-daily menthol and non-menthol smokers.<sup>22</sup> This study is one of the most robust longitudinal and nationally representative assessments of the relationship between menthol and cessation.

Data from the 2017 and 2018 National Youth Tobacco Surveys shows that among middle and high school students, menthol smoking was associated with greater smoking frequency (smoking on at least 10 of the last 30 days) and intention to continue smoking, compared to non-menthol smoking.<sup>23</sup> Data from the government's PATH study shows that that youth menthol smokers have significantly higher levels of certain measures of dependence,<sup>24</sup> and that initiation with a menthol-flavored cigarette is associated with a higher relative risk of daily smoking.<sup>25</sup>

The difficulty that menthol smokers have in quitting is reflected in national smoking prevalence trends. From 2008 to 2014, smoking rates generally declined, but the proportion of smokers using menthol cigarettes increased significantly. Menthol smoking rates have increased among young adults and remained constant among youth and older adults, while non-menthol smoking has decreased in all three age groups. Overall, about 4 out of 10 (38.8%) smokers used menthol cigarettes in 2012-2014, an increase from 34.7% in 2008-2010.<sup>26</sup> Sales trends echo the patterns seen in menthol smoking prevalence. Between 2009 and 2018, sales of non-menthol cigarettes have declined by 33.1% nationally

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<sup>19</sup> Stevens S. Smith et al., *Smoking cessation in smokers who smoke menthol and non-menthol cigarettes*, 109 *Addiction* 2107-2117, 2014, <https://pubmed.ncbi.nlm.nih.gov/24938369/>.

<sup>20</sup> Philip H. Smith, et al., *Use of Mentholated Cigarettes and Likelihood of Smoking Cessation in the United States: A Meta-Analysis*, 22 *Nicotine & Tobacco Research* 307-316, 2019, <https://pubmed.ncbi.nlm.nih.gov/31204787/>.

<sup>21</sup> HHS, Office on Smoking and Health, *Smoking Cessation, A Report of the Surgeon General*, 2020, <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.

<sup>22</sup> Sarah D. Mills, et al., *The Relationship between Menthol Cigarette Use, Smoking Cessation and Relapse: Findings from Waves 1 to 4 of the Population Assessment of Tobacco and Health Study*, *Nicotine & Tobacco Research*, published online October 16, 2020, <https://doi.org/10.1093/ntr/ntaa212>.

<sup>23</sup> Sunday Azagba, et al., *Cigarette Smoking Behavior Among Menthol and Nonmenthol Adolescent Smokers*, 66 *Journal of Adolescent Health* 545-550, 2020, <https://pubmed.ncbi.nlm.nih.gov/31964612/>.

<sup>24</sup> Sam N. Cwalina, et al., *Adolescent menthol cigarette use and risk of nicotine dependence: Findings from the national Population Assessment on Tobacco and Health (PATH) study*, *Drug and Alcohol Dependence*, 2019, <https://www.sciencedirect.com/science/article/pii/S0376871619304922>.

<sup>25</sup> Andrea C. Villanti, et al., *Association of Flavored Tobacco Use With Tobacco Initiation and Subsequent Use Among US Youth and Adults, 2013-2015*, 2 *JAMA Network Open* e1913804, 2019, <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2753396>.

<sup>26</sup> Gary A. Giovino, et al., *Differential trends in cigarette smoking in the USA: is menthol slowing progress?*, 24 *Tobacco Control* 28-37, 2013, <https://tobaccocontrol.bmj.com/content/tobaccocontrol/24/1/28.full.pdf>.

while sales of menthol cigarettes have declined by only 8.2% during the same period. Of the decline in cigarette sales between 2009 and 2018, 91% is attributable to nonmenthol cigarettes.<sup>27</sup>

There is little question, therefore, that menthol cigarettes not only introduce young people to smoking; they also increase addiction for youth and adults.

#### IV. MENTHOL CIGARETTES DISPROPORTIONATLY HARM THE HEALTH OF AFRICAN AMERICANS AND WORSEN EXISTING HEALTH DISPARITIES

Menthol cigarettes take a disproportionately high toll in disease and death in the African American community, thus worsening existing, and already unacceptable, racial health disparities.<sup>28</sup>

As early as the 1960s, the tobacco industry targeted Black smokers with menthol cigarettes through print media and outdoor advertising.<sup>29</sup> Sponsorship of community and music events, distribution of free cigarettes from mobile vans, and specialized promotions for inner-city retailers were also common tactics to court the African American community.<sup>30</sup> More recently, a 2018 study from California found significantly more menthol advertisements at stores with a higher proportion of African American residents.<sup>31</sup> As FDA concluded in its 2013 Report, “[t]he available data show that ... it is likely that the standard marketing mix approach of price, promotion, product, and place has been used to drive menthol cigarette preference among the urban African American community.”<sup>32</sup>

The unrelenting efforts by the industry to force an association of menthol cigarettes with Black culture has led to the highest prevalence of menthol use among any racial or ethnic group in the U.S.<sup>33</sup> African American smokers smoke menthol at more than double the rate for Whites (85% compared to 29%).<sup>34</sup> New evidence consistent with the findings in the FDA and TPSAC reports also confirms that menthol reduces smoking cessation among African Americans.<sup>35</sup> This is despite high motivation to quit among African American smokers, as they are more likely to have made a quit attempt and used

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<sup>27</sup> Christine D. Delnevo, et al., *Assessment of Menthol and Nonmenthol Cigarette Consumption in the US, 2000 to 2018*, 3 JAMA Network Open e2013601, 2020, <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2769132>.

<sup>28</sup> See e.g., Comments of 47 public health, medical and other organizations in Docket No. FDA-2017-N-6565, Regulation of Flavors in Tobacco Products (July 19, 2018), available at <https://www.regulations.gov/document?D=FDA-2017-N-6565-23022> and Comments of 25 public health and medical groups in Docket No. FDA-2013-N-0521, Menthol in Cigarettes, Tobacco Products; Request for Comments, available at <https://www.regulations.gov/document?D=FDA-2013-N-0521-0443>, which we incorporate by reference here.

<sup>29</sup> *Supra* note 7 at 72, 74.

<sup>30</sup> *Supra* note 7 at 73.

<sup>31</sup> Nina Schleicher, et al., *California Tobacco Retail Surveillance Study, 2018*, Stanford Prevention Research Center 3, 22, 2019, <https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/CTCB/CDPH%20Document%20Library/ResearchandEvaluation/Reports/CaliforniaTobaccoRetailSurveillanceStudyReport-2018.pdf>.

<sup>32</sup> FDA Report, *supra* note 8, at 5.

<sup>33</sup> Andrea C. Villanti, et al., *Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004–2014*, 25(Suppl 2) Tobacco Control ii14–ii20, 2016, <https://pubmed.ncbi.nlm.nih.gov/27729565/>.

<sup>34</sup> *Id.*

<sup>35</sup> *Supra* note 20 (finding that among African American smokers, menthol smokers had 12% lower odds of successfully quitting smoking compared to non-menthol smokers).

counseling services in the previous year than White smokers.<sup>36</sup> Decreased cessation success also likely contributes to more Black Americans dying from lung cancer than any other type of cancer.<sup>37</sup> The lower likelihood of smoking cessation among African American menthol smokers is described in the 2020 Surgeon General’s Report on smoking cessation, which notes that, “Use of menthol cigarettes has been shown to contribute to tobacco cessation-related disparities in the United States.”<sup>38</sup> In its 2011 report to FDA, TPSAC estimated that by 2020, 4,700 excess African American deaths would be attributable to menthol cigarettes, and over 460,000 African Americans would have started smoking because of menthol cigarettes.<sup>39</sup>

The menthol cigarette burden borne by African Americans is just one of many long-standing health disparities among communities of color. These disparities have become even more glaring in light of the COVID-19 pandemic. A Harvard University analysis of COVID-19 mortality rates by race/ethnicity found that Black COVID-19 patients between 25 and 54 years old were approximately seven to nine times as likely to die from COVID-19 as White COVID-19 patients.<sup>40</sup> A CDC report on hospitalization rates of patients with confirmed COVID-19 across 14 states found that while only 18% of the population captured by their report are African Americans, they found that 33% of all hospitalized patients with race/ethnicity data were African American, suggesting an overrepresentation of African Americans among hospitalized patients.<sup>41</sup> Another study currently under review evaluated COVID-19 diagnoses and deaths across United States counties with disproportionate numbers of African American residents. The study found disproportionately higher COVID-19 deaths in primarily Black counties in both small metro areas as well as rural areas.<sup>42</sup> Further, the study also found that the disproportionately African American counties with higher rates of COVID-19 diagnoses and deaths also showed greater diabetes diagnoses, heart disease deaths, and hypertension disease deaths—all underlying conditions known to exacerbate COVID-19.<sup>43</sup>

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<sup>36</sup> See e.g., CDC, *Quitting Smoking Among Adults—United States, 2000-2015*, 65 *Morbidity and Mortality Weekly Report* 1457-1464, 2017, <https://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6552a1.pdf>; Jacqueline M. Royce, et al., *Smoking Cessation Factors among African Americans and Whites: COMMIT Research Group*, 83 *American Journal of Public Health* 220-226, 1993, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1694582/>.

<sup>37</sup> American Cancer Society, *Cancer Facts & Figures for African Americans, 2016-2018*, 2016, <http://www.cancer.org/acs/groups/content/@editorial/documents/document/acspc-047403.pdf>; Linda A. Alexander, et al., *Why We Must Continue to Investigate Menthol’s Role in the African American Smoking Paradox*, 18 (Suppl 1) *Nicotine & Tobacco Research* S91-S101, 2016, <https://pubmed.ncbi.nlm.nih.gov/26980870/>.

<sup>38</sup> *Supra* note 21.

<sup>39</sup> *Supra* note 7.

<sup>40</sup> Mary T. Bassett et al, *The unequal toll of COVID-19 mortality by age in the United States: Quantifying racial/ethnic disparities*, 19 *The Harvard Center for Population and Development Studies Working Paper Series* 1-18, 2020, [https://cdn1.sph.harvard.edu/wp-content/uploads/sites/1266/2020/06/20\\_Bassett-Chen-Krieger\\_COVID-19\\_plus\\_age\\_working-paper\\_0612\\_Vol-19\\_No-3\\_with-cover-1.pdf](https://cdn1.sph.harvard.edu/wp-content/uploads/sites/1266/2020/06/20_Bassett-Chen-Krieger_COVID-19_plus_age_working-paper_0612_Vol-19_No-3_with-cover-1.pdf).

<sup>41</sup> Shikha Garg, et al., *Hospitalization rates and characteristics of patients hospitalized with laboratory-confirmed coronavirus disease 2019—COVID-NET, 14 States, March 1–30, 2020*, 69 *Morbidity and Mortality Weekly Report* 458-464, 2020, <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6915e3-H.pdf>.

<sup>42</sup> Laura Barrón-Lopez, *A new study shows just how badly black people have been hit by Covid-19*, *Politico*, May 5, 2020, <https://www.politico.com/news/2020/05/05/black-counties-disproportionately-hit-by-coronavirus-237540>.

<sup>43</sup> *Id.*

There is also a growing body of evidence that smoking increases the risk for severe illness and death from the novel coronavirus.<sup>44</sup> According to the Centers for Disease Control and Prevention, “Being a current or former cigarette smoker increases your risk of severe illness from COVID-19.”<sup>45</sup> The World Health Organization has also noted that “[t]obacco smoking is a known risk factor for many respiratory infections and increases the severity of respiratory diseases,” and that “a review of studies by public health experts convened by WHO . . . found that smokers are more likely to develop severe disease with COVID-19 compared to non-smokers.”<sup>46</sup> Given the link between smoking and severe symptoms of COVID-19, and the already disparate impact of COVID-19 on African Americans, FDA action on menthol cigarettes is now more urgent than ever.

V. PROHIBITING MENTHOL CIGARETTES WILL PROMOTE THE PUBLIC HEALTH BECAUSE IT WILL LIKELY CAUSE SIGNIFICANT NUMBERS OF CURRENT MENTHOL SMOKERS TO QUIT RATHER THAN SWITCH TO NON-MENTHOL CIGARETTES

As discussed above, the scientific evidence strongly establishes that the availability of menthol cigarettes both increases the level of smoking initiation and decreases the level of smoking cessation. There is a growing body of evidence that the elimination of menthol cigarettes would lead a substantial number of current menthol smokers to quit smoking rather than switch to non-menthol cigarettes in response to a prohibition on menthol cigarettes.

A 2010 study by Tauras, et al., examined whether a prohibition on menthol cigarettes would cause menthol smokers to simply switch to non-menthol cigarettes.<sup>47</sup> They examined the response of menthol and non-menthol smokers to price changes and smoke-free laws. The examination of price data indicated that non-menthol cigarettes are not a close substitute for menthol cigarettes; i.e., very few menthol smokers responded to price changes of non-menthol cigarettes relative to menthol cigarettes by switching to non-menthol. This pattern was particularly evident among younger smokers and African American smokers. The results of this study indicate that in the event of a prohibition on menthol cigarettes, a large number of current menthol smokers would likely quit smoking rather than switch to non-menthol cigarettes.

O’Connor, et al.<sup>48</sup> surveyed a sample of 471 adolescent and adult smokers recruited from an online survey panel. Of the menthol smokers surveyed, 36.5% reported that in the event of prohibition

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<sup>44</sup> See e.g., Mandeep R. Mehra, et al., *Cardiovascular Disease, Drug Therapy, and Mortality in Covid-19*, 382 *New England Journal of Medicine* e102, 2020,

[https://www.nejm.org/doi/full/10.1056/NEJMoa2007621?query=featured\\_home](https://www.nejm.org/doi/full/10.1056/NEJMoa2007621?query=featured_home); Wei-jie Guan, et al., *Clinical Characteristics of Coronavirus Disease 2019 in China*, 382 *New England Journal of Medicine* 1708-1720, 2020, <https://www.nejm.org/doi/full/10.1056/NEJMoa2002032>.

<sup>45</sup> CDC, *Coronavirus Disease 2019 (COVID-19) – People with Certain Medical Conditions*, Oct. 16, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>.

<sup>46</sup> World Health Organization, *WHO Statement: Tobacco use and COVID-19*, World Health Organization, May 11, 2020, <https://www.who.int/news/item/11-05-2020-who-statement-tobacco-use-and-covid-19>.

<sup>47</sup> John A. Tauras, et al., *Menthol and non-menthol smoking: the impact of prices and smoke-free laws*, 105(Suppl.1) *Addiction* 115-123, 2010, <https://pubmed.ncbi.nlm.nih.gov/21059142/>.

<sup>48</sup> Richard J. O’Connor et al., *What would menthol smokers do if menthol in cigarettes were banned? Behavioral intentions and simulated demand*, 107 *Addiction* 1330-8, 2012, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3370153/>.

on menthol cigarettes by the FDA, they would try to quit smoking. Over 17% said they would not consider using non-menthol cigarettes.

The likelihood of significant quitting also is indicated by the recent experience in Canada. In October, 2017, Canada banned menthol cigarettes nationwide although most provinces had banned them prior to the nationwide law. Surveillance data from Ontario, which banned menthol cigarettes in January, 2017 showed an increase in quit attempts and cessation. A two-year follow-up survey found that both daily and occasional menthol smokers were more likely than non-menthol smokers to report having quit smoking for six months (18% and 15%, vs. 7%) or having made a quit attempt (72% and 74%, vs. 58%).<sup>49</sup> Research on the impact of Canada's national ban is also starting to emerge. Data from the International Tobacco Control Policy Evaluation Project (ITC) are consistent with the findings on the impact of the Ontario ban. Specifically, ITC researchers, using longitudinal surveys of Canadian smokers found that following the national ban, menthol smokers were more likely to try to quit than non-menthol smokers (60% vs. 48%), and were twice as likely to have quit smoking for at least six months (12% vs. 6%).<sup>50</sup>

It is important to recognize that a reduction in the number of smokers resulting from the response of current menthol smokers to a tobacco product standard prohibiting cigarettes from containing menthol as a characterizing flavor would be in addition to longer-term reductions attributable to the lower rate of initiation and the higher rate of cessation that would occur if the market were free of menthol cigarettes.

VI. ANY RISKS OF ADVERSE CONSEQUENCES FROM PROHIBITING MENTHOL CIGARETTES CAN BE AMELIORATED AND DO NOT OUTWEIGH THE CLEAR PUBLIC HEALTH BENEFITS

In its recent filing in *AATCLC v. HHS*, the government noted that “[p]olicymakers have expressed concern about menthol cigarette use among African American smokers, but have also worried about the potential negative consequences of prohibiting a product that is regularly used by a large number of addicted adult users. The feared consequences include the possibility of overwhelming the health care system if millions of smokers were to need cessation assistance at the same time, and of increasing illegal cigarette sales, which could also pose risks to public health.”<sup>51</sup> These expressed concerns parrot the longtime, and unfounded, arguments of the tobacco industry against menthol restrictions and other tobacco control policies.

A. The possible need for greater smoking cessation resources does not justify continuing to allow menthol as a characterizing flavor in cigarettes.

As noted above, one of the significant effects of a menthol prohibition would be a likely increase in the numbers of menthol cigarette smokers who want to quit. As suggested in FDA's recent court

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<sup>49</sup> Chalton, M., et al., *Impact of a menthol ban on smoking cessation: A two year follow up*, presented at the 2020 Annual Conference of the Society for Research on Nicotine and Tobacco, 2020.

<sup>50</sup> Chung-Hall, et al., *Evaluating the impact of menthol cigarette bans on cessation and smoking behaviours in Canada: Findings from the 2016-2018 ITC 4 Country Smoking and Vaping Surveys*, presented at the 2020 meetings of the Society for Research on Nicotine & Tobacco, 2020.

<sup>51</sup> *AATCLC, et al. v. HHS, et al.*, Federal Defendants' Memorandum in Support of Motion to Dismiss, at 2.

filing, opponents of action against menthol raise the prospect of millions of smokers overwhelming the nation's existing capacity to provide cessation services.

First, there is no evidence that if FDA prohibited menthol as a characterizing flavor in cigarettes, leading more smokers to want to quit, it would overwhelm the existing capacity to provide cessation services. The vast majority of Americans who quit smoking do so on their own. The capacity to assist those who need help has also advanced with the advent of online cessation assistance to complement existing quit lines.<sup>52</sup>

Even if a menthol cigarette tobacco product standard would lead more smokers to try to quit (a positive development), the answer is to expand the capacity of our current system to assist those smokers. There are multiple ways to do so. One mechanism might be a national strategy to provide support for menthol smokers through education and expanded availability of cessation services that will enable smokers motivated to quit and looking for assistance to do so successfully. If FDA were to propose a menthol cigarette tobacco product standard, the rulemaking process would provide time to develop such support. The TCA provides for an implementation period of at least one year from publication of a final rule establishing a product standard before the rule may be effective.<sup>53</sup> Advance planning for such public education and cessation efforts could begin as soon as FDA initiated the rulemaking process, which requires additional time for interagency review, a public comment period, and consideration of all comments.

Two major initiatives could accompany a rule proposing a menthol prohibition. First, FDA should sponsor a broad evidence-based media and public education campaign to inform the public of the prohibition on menthol and the resources available to support quitting by former menthol smokers. Such a campaign should prioritize reaching communities where the usage of menthol cigarettes is high. In a best case scenario, it would precede the implementation of the prohibition and inform consumers about the availability of resources to support cessation.

Second, access to cessation services should continue to be expanded. The Affordable Care Act already provides for expanded cessation coverage. It includes a requirement that all non-grandfathered group and individual insurance plans – including insurers and plans required to cover the essential health benefit, cover USPSTF recommended tobacco cessation services. States that expanded eligibility for Medicaid under the Affordable Care Act are also required to cover USPSTF recommended services. These provisions should be rigorously enforced. Further, additional resources could be devoted to expanding telephone cessation support in each state through 1-800-QUIT NOW, which can provide free counseling and other cessation services to those who do not otherwise have access to them, and in recent years a number of online resources have been developed. Finally, FDA has the authority to complement action by the Center for Tobacco Products with actions by its Center for Drug Evaluation and Research to ensure that the potential benefits of current FDA-approved nicotine

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<sup>52</sup> U.S. Department of Health and Human Services. Smoking Cessation. A Report of the Surgeon General. Atlanta, GA: 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, 2020.

<sup>53</sup> 21 U.S.C. 387g(d)(2).

replacement products are maximized and the availability of new and innovative cessation products is encouraged.

Thus, the federal government has the ability to take action to address the likely beneficial increase in demand for cessation services to produce a positive public health response. The expected increase in the number of smokers who will try to quit is not a justification for inaction; it is a reason to act now to prohibit menthol cigarettes.

- B. Prohibiting menthol cigarettes will not cause the emergence of an illicit market that will nullify the public health gains from such a policy.

The tobacco industry historically has itself both contributed to whatever illicit market in cigarettes that has existed in the United States and used the claim that virtually every tobacco control strategy will create an uncontrolled illicit market to argue against the adoption of tobacco control strategies proven to reduce smoking prevalence and save lives – like higher cigarette taxes, stronger health warnings, and stronger regulation. The risk of an illegal market has invariably been exaggerated by the industry, including the unlikely feared scenario that such an illicit market would be large enough to undermine the public health benefit of a menthol cigarette tobacco product standard. FDA has the tools to prevent the growth of any potential illicit market. There is little reason to believe, however, that a substantial illicit market would arise from a menthol cigarette prohibition. As the National Research Council and the Institute of Medicine found, “the limited evidence now available suggests that if conventional cigarettes are modified by regulations, the demand for illicit versions of them is likely to be modest.”<sup>54</sup>

First, there is no evidence that menthol restrictions have given rise to an illicit market in the jurisdictions in which restrictions have been implemented. For example, a study of illicit cigarette seizures in Nova Scotia, which in 2015 became the first jurisdiction in the world to ban menthol cigarettes, found that the number of illegal cigarettes seized did not increase after the menthol ban was implemented, despite an intensification of enforcement efforts. Thus, the study found that “illicit cigarette sales in the province are similarly unlikely to be increasing.”<sup>55</sup>

Second, contrary to the industry’s contention, the experience of states and cities in increasing cigarette taxes does not support the view that a burgeoning illicit market would largely replace the legal market in menthol.<sup>56</sup> The strong consensus of economic studies is that every 10% increase in the real price of cigarettes reduces overall cigarette consumption by approximately 3-5%, reduces the number of

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<sup>54</sup> National Research Council and Institute of Medicine, *Understanding the U.S. Illicit Market: Characteristics, Policy Context, and Lessons from International Experiences*, National Academies Press, 2015, at 9.

<sup>55</sup> Michael Stoklosa, *No surge in illicit cigarettes after implementation of menthol ban in Nova Scotia*, 28 *Tobacco Control* 702-794, 2018, <https://tobaccocontrol.bmj.com/content/28/6/702.full>.

<sup>56</sup> The industry’s suggestion that restrictions on menthol in cigarettes would lead to increased black market activity is largely based on its own self-serving misrepresentation of “the history of cigarette black markets that have developed in the United States and Canada following tax-driven increases in cigarette prices.” Compass Lexecon, *Estimating consequences of a ban on the legal sale of menthol cigarettes*, presented at TPSAC, Nov. 18 and Jan. 10, 2011, at 3 (study commissioned by Lorillard Tobacco Company); See also Non-Voting Industry Representatives of TPSAC, *The Industry Menthol Report, Menthol Cigarettes: No Disproportionate Impact on Public Health* 216, Mar. 23, 2011, <https://permanent.fdlp.gov/gpo41693/UCM249320-508ed.pdf>.

young-adult smokers by 3.5%, and reduces the number of kids who smoke by 6-7%.<sup>57</sup> Data collected subsequent to tax increases in these jurisdictions also verify significant and measurable reductions in consumption despite industry claims about illicit sales.<sup>58</sup> Thus, whatever illicit market arises from cigarette tax increases, it does not come close to nullifying the effects of tax increases in reducing cigarette consumption, particularly among the young.

Third, sustaining an underground market for menthol cigarettes would be uniquely difficult. In order for widespread marketing of menthol cigarettes to occur, the cigarettes must be readily identifiable as mentholated from their packaging and promotion. Put differently, the illegality of the cigarettes will be clear from the packaging and promotion of the cigarettes themselves, especially if FDA were to fulfill its statutory mandate to implement a comprehensive track-and-trace system (discussed more fully below). This is in stark contrast to current illicit cigarette markets (on which the industry relies for its speculation about menthol illicit markets), in which the illicit market functions to conceal the illegality of the product. Thus, counterfeit cigarettes are disguised as legitimate and cigarettes smuggled from low-tax to high-tax jurisdictions often have counterfeit tax stamps. Moreover, even if it were not clear from the packaging or promotion that cigarettes were mentholated, the use of menthol as a characterizing flavor would be readily apparent to anyone inspecting or sampling them.

In addition, whereas interstate smuggling to avoid high taxes involves diversion of finished products into the illegal market, a menthol cigarette illegal market must involve the large-scale manufacturing of illegal products. The establishment of a clandestine manufacturing facility capable of producing and shipping a substantial number of menthol cigarettes – in violation of a host of federal laws – is highly implausible. Moreover, the enactment of the Prevent All-Cigarette Trafficking (PACT) Act, requiring pre-payment of taxes on Internet, mail order and other non-face-to-face cigarette sales (known as “delivery sales”), as well as prohibiting sending cigarettes through the U.S. mail, also has diminished illegal sales of cigarettes direct to consumers<sup>59</sup> and would continue to be a potent tool against the emergence of a significant illegal market in menthol cigarettes.

Fourth, FDA has not only clear authority, but a statutory mandate to implement a comprehensive track-and-trace system “to assist in investigating potential illicit trade, smuggling, or counterfeiting of tobacco products.”<sup>60</sup> Section 920 of the TCA requires that FDA ensure the risk of illegal markets does not diminish the capacity of regulations to deliver the full range of public health protections envisioned by the statute. Congress did not conclude that the potential threat of illicit markets is a reason to refrain from regulation, but rather explicitly required the FDA to protect against such a threat – whether real or posited by the tobacco industry as a pretext for opposing effective regulation. A track-and-trace system would reduce the potential threat of evasion of a menthol cigarette

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<sup>57</sup> See generally, Frank J. Chaloupka, et al., *Macro-Social Influences: The Effects of Prices and Tobacco Control Policies on the Demand for Tobacco Products*, 1(Supp. 1) *Nicotine and Tobacco Research* S105-09, 1999, <https://pubmed.ncbi.nlm.nih.gov/11072413/>; Campaign for Tobacco-Free Kids, *Raising Cigarette Taxes Reduces Smoking, Especially Among Kids (and the Cigarette Companies Know It)*, 2012, [https://www.tobaccofreekids.org/microsites/passthebuck\\_sc/resources/sccigtaxandkids.pdf](https://www.tobaccofreekids.org/microsites/passthebuck_sc/resources/sccigtaxandkids.pdf) (and sources therein).

<sup>58</sup> Campaign for Tobacco-Free Kids, *Raising State Cigarette Taxes Always Increases State Revenues (and Always Reduces Smoking)*, 2020, <https://www.tobaccofreekids.org/assets/factsheets/0098.pdf>.

<sup>59</sup> Rebecca S. Williams, et al., *Cigarette sales to minors via the internet: how the story has changed in the wake of federal regulation*, 26 *Tobacco Control* 415-20, 2017, <https://pubmed.ncbi.nlm.nih.gov/27413060/>.

<sup>60</sup> 21 U.S.C. 387t(b).

tobacco product standard by making non-compliant products without identifying codes more easily identifiable to distributors, retailers, consumers, and inspectors.

Finally, the federal government can reduce the potential demand for illegal cigarettes by taking the actions necessary to provide adequate cessation services to menthol smokers who want to quit.

Therefore, as with higher tobacco taxes and other tobacco control policies, there is no reason to believe that an illegal market will threaten the public health gains from prohibiting menthol cigarettes.

## VII. CONCLUSION

Since the 2011 TPSAC Report recommended removal of menthol cigarettes from the marketplace, FDA has consistently found that the scientific evidence establishes that menthol as a characterizing flavor in cigarettes is harmful to public health. Indeed, the scientific evidence supporting a menthol prohibition has only grown more compelling. Thus, the menthol issue presents a true test of FDA's pledge to "fight for science" and "fight for the integrity of the agency." Only a decision to grant the pending Citizen Petition and commence a rulemaking leading to the prohibition of menthol cigarettes will honor that pledge.

Respectfully submitted,

Action on Smoking and Health (ASH)  
African American Tobacco Control Leadership Council (AATCLC)  
Allergy & Asthma Network  
American Academy of Nursing  
American Academy of Oral and Maxillofacial Pathology  
American Academy of Oral and Maxillofacial Radiology  
American Academy of Otolaryngology–Head and Neck Surgery  
American Academy of Pediatrics  
American Association for Cancer Research  
American Association for Dental Research  
American Association for Respiratory Care  
American Cancer Society Cancer Action Network  
American College Health Association  
American College of Cardiology  
American College of Physicians  
American Dental Association  
American Heart Association  
American Lung Association  
American Psychological Association  
American Public Health Association  
American Society of Addiction Medicine  
American Thoracic Society  
Americans for Nonsmokers' Rights  
Asian Pacific Partners for Empowerment, Advocacy and Leadership (APPEAL)  
Association for Clinical Oncology  
Association for the Treatment of Tobacco Use and Dependence

Association of Black Cardiologists  
Association of Schools and Programs of Public Health  
Association of State and Territorial Health Officials  
Association on Women’s Health, Obstetric and Neonatal Nurses  
Big Cities Health Coalition  
Black Women’s Health Imperative  
Campaign for Tobacco-Free Kids  
Cancer Prevention and Treatment Fund  
Catholic Health Association of the United States  
ClearWay Minnesota  
Community Anti-Drug Coalitions of America (CADCA)  
COPD Foundation  
Counter Tools  
Eta Sigma Gamma – National Health Education Honorary  
First Focus Campaign for Children  
GO2 Foundation for Lung Cancer  
March of Dimes  
NAACP  
National Alliance for Hispanic Health  
National Association of County and City Health Officials  
National Association of Pediatric Nurse Practitioners  
National Association of School Nurses  
National Association of Social Workers  
National Black Nurses Association  
National Coalition for Cancer Survivorship  
National Hispanic Medical Association  
National LGBT Cancer Network  
National Network of Public Health Institutes  
North American Quitline Consortium  
Oncology Nursing Society  
Parents Against Vaping e-cigarettes (PAVe)  
Prevent Cancer Foundation  
Public Health Law Center  
Public Health Solutions  
Society for Research on Nicotine & Tobacco  
Students Against Destructive Decisions (SADD)  
The Center for Black Health & Equity  
The Links, Incorporated  
The Society of State Leaders of Health and Physical Education  
The Society of Thoracic Surgeons  
Truth Initiative  
US PIRG

CC: Mitchell Zeller, Director, FDA Center for Tobacco Products