



# **SUPPLEMENT TO CITIZEN PETITION**

**Prohibit Menthol as a Characterizing Flavoring  
of Cigarettes and Cigarette Smoke**





January 15, 2021

Commissioner Stephen M. Hahn M.D.  
c/o Division of Dockets Management  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20825

Supplement to Citizen Petition: "Prohibit Menthol as a Characterizing Flavoring of Cigarettes and Cigarette Smoke"

## **Docket No. FDA-2013-P-0435**

Dear Commissioner Hahn:

The undersigned organizations submit this citizen petition supplement, pursuant to 21 C.F.R. § 10.30(g), to update the administrative record for this citizen petition with the most recent information on the impact of menthol in cigarettes.

On April 12, 2013, the Public Health Law Center<sup>1</sup> and eighteen co-signers<sup>2</sup> filed a citizen petition calling on the U.S. Food and Drug Administration (FDA) to add menthol to the list of prohibited characterizing flavors for cigarettes and cigarette smoke. The citizen petition included extensive information on the impacts of menthol in cigarettes, including the scientific evidence gathered by the FDA's Tobacco Products Scientific Advisory Committee (TPSAC).

The original petitioners and the undersigned organizations maintain that the FDA has had more than enough information to prohibit menthol as a characterizing flavor in cigarettes since the Family Smoking Prevention and Tobacco Control Act (TCA or the Act) was signed into law. Because the FDA has yet to substantively respond to the citizen petition nearly eight years later, we are filing this supplement to add the research on the harms of menthol cigarettes that has continued to develop since 2013, dramatically underscoring the need for immediate action.

## **I. Regulatory Background**

The FDA's regulatory dawdling on menthol has lasted a decade, during which the overwhelming evidence that removing menthol cigarettes from the marketplace is necessary for the protection of public health has grown. Since the passage of the Act in 2009, the agency has had ample evidence and opportunity to act but has responded by collecting additional information rather than acting.

- With the Act, Congress required the FDA to commission a report on menthol from TPSAC and, in 2011, the committee concluded that the “[r]emoval of menthol cigarettes from the marketplace would benefit public health in the United States.”<sup>3</sup>
- In April 2013, when the FDA did not promptly initiate a rulemaking following the clear direction of the TPSAC report, we filed this petition, requesting the removal of menthol cigarettes. The citizen petition opened a public docket that has received more than 1,000 comments.<sup>4</sup>
- A few months later, in July 2013, the FDA issued an Advanced Notice of Proposed Rulemaking (ANPRM) and published an internal scientific review of menthol, which concluded that menthol plays a key role in youth and young adult initiation, that menthol cigarette use is associated with a deeper level of addiction, and that these factors point to a greater overall health risk when compared to non-menthol cigarettes.<sup>5</sup> The FDA’s 2013 menthol ANPRM received over 170,000 public comments.<sup>6</sup>
- In July 2018, the FDA issued yet another ANPRM that focused on flavors more broadly but specifically asking for information on menthol in cigarettes. This docket received over 500,000 comments.<sup>7</sup>
- Since 2018, the FDA has continued funding research on the impact of menthol that consistently finds new ways in which menthol is harmful.<sup>8</sup>

Despite the now towering accumulation of scientific publications confirming that the removal of menthol cigarettes from the U.S. tobacco product marketplace would protect public health and decrease health disparities, the agency has never acted on this petition. Not one of these ANPRMs, collections of information, or compilations of scientific evidence has spurred the agency into action. The FDA’s inaction is an abject failure of its central purpose: to protect the American public from the harmful effects of tobacco.

In response to the lack of action on or even attention to this issue, on June 17, 2020, the African American Tobacco Control Leadership Council and Action on Smoking and Health<sup>9</sup> filed a lawsuit seeking to compel the FDA to act on this seven-year-old citizen petition. During the litigation, the government informed the plaintiffs that it would act on this petition by January 29, 2021.<sup>10</sup> In anticipation of FDA action on this petition, the undersigned organizations submit this supplement to ensure that the most up-to-date information on the impact of menthol is included in the docket upon which the FDA must rely in making its determination on the petition. Despite the fact that this supplement is being submitted only a few weeks before the FDA’s stated deadline, there is no reason for the agency to further delay a response to the merits of this citizen petition

The FDA need not delay action because this supplement is not intended to, and likely does not, provide new information to the FDA. In fact, it is highly likely that every reference cited in this supplement is

already familiar to the agency. This supplement identifies seventy-eight relevant sources of information that were not already referenced in the 2013 citizen petition.<sup>11</sup> They are discussed below and attached to this supplement. Of that seventy-eight, seventeen peer-reviewed studies were funded by the FDA and certainly known to the agency. Another thirty-five studies were funded or supported by the National Institutes of Health, the Centers for Disease Control and Prevention, or other federal agencies that work closely with the FDA as part of a coordinated effort by the federal government to study and regulate commercial tobacco products. An additional four articles were cited in comments to either the 2013 ANPRM on menthol or the 2018 ANPRM on flavors. Because the FDA is required to consider all submissions to these dockets, the agency must be familiar with this material as well. Another seven articles have been referenced by the FDA in materials readily available on the agency's website and thus, the FDA is familiar with these as well.

There is no concrete evidence that the remaining fifteen referenced materials are already known to the FDA. However, eight peer-reviewed studies were published in *Tobacco Control* and one peer-reviewed study was published in *Nicotine and Tobacco Research*. These two journals collectively publish the vast majority of tobacco control research and are certainly known to and read by FDA scientists. *Tobacco Control* is a leading journal in the field and despite its narrow focus, the publication has a higher impact factor than some more well-known journals focused on broader public health issues, such as the *American Journal of Public Health*. *Nicotine and Tobacco Research* is the official journal of the Society for Research on Nicotine and Tobacco, an organization respected for its leadership in tobacco control research. Many FDA staff are members of the organization, attend the organization's annual meetings, and publish in the journal.

This leaves only six publications that may be new to the FDA. Four peer-reviewed studies were published in other academic journals. These articles are focused on issues relevant to the FDA's work and it is likely that the agency is familiar with these studies. The final two references are focused on illicit trade. One is an article published by the Center for Public Integrity, outlining the tobacco industry's role in the illicit trade of tobacco products and the other was published by the World Health Organization. Even if the FDA is unfamiliar with these two sources, the information contained in them is directly relevant to the agency's implementation of a track and trace program, a regulatory program that Congress has mandated that the agency establish. One would hope that the agency is monitoring relevant information related to this topic.

Given the FDA's role as the federal regulator of commercial tobacco products that employs hundreds of top scientists tasked with supporting action with a robust scientific evidence base, no information in this supplement should be unfamiliar to the FDA. Any information cited in this supplement that is unknown to the agency at this point merely indicates that the FDA has not adequately prioritized understanding the harms of menthol in cigarettes in order to make a determination on the citizen petition.

A menthol prohibition is long overdue and none of the information in this supplement represents the tipping point that should spur action. Quite the contrary, this supplement is being submitted solely to ensure that the administrative record is as complete as possible should the FDA decide to deny this petition and further delay necessary action. If it did so, the agency would be acting counter to every shred of scientific evidence, the conclusions of all leading experts, the recommendations of its advisory committee, and its own conclusions based on available evidence. It is hard to imagine an action that more appropriately meets the definition of arbitrary and capricious than the denial of this citizen petition and the decision not to prohibit menthol in cigarettes.

Below is the research published since 2013 on all of the topics relevant to the FDA's analysis of the requested product standard. This supplement gathers evidence related to menthol's impact on youth initiation, adult and youth cessation, and the impact on non-users of menthol cigarettes caused by secondhand smoke exposure, thirdhand smoke exposure, and tobacco product waste pollution. This supplement also includes information on the disproportionate impact that menthol has had on several subpopulations, most of whom have been specifically targeted by the tobacco industry. We have also gathered evaluation data from several jurisdictions that have implemented prohibitions on menthol, including local jurisdictions in the United States and Canada. Additionally, while outside the required public health standard analysis, this supplement collects information on a handful of issues that the FDA is required to consider when it establishes a product standard. None of these create significant barriers to FDA action on menthol and any potential countervailing effects can be mitigated by other FDA actions that are readily available to the agency.

## **II. The Public Health Standard supports the prohibition of menthol as a characterizing flavor in cigarettes.**

The additional information and evidence presented in this supplement ensures that the administrative record is complete. The most recent evidence remains consistent with what was already known - that menthol is particularly harmful and eliminating menthol cigarettes will improve public health and promote health equity.

a. The health impacts of menthol and the tobacco industry's tactics in marketing menthol to communities that have been marginalized has had deadly consequences.

In 2011, TPSAC concluded that without the FDA's action on menthol, by the end of 2020, the African American population will have suffered over 4,700 excess deaths caused by menthol in cigarettes and over 460,000 more African Americans will have 6 started smoking caused by the presence of menthol in cigarettes.<sup>12</sup> Undoubtedly, a global pandemic was not part of TPSAC's calculations. Based on the statistics showing the disproportionate death of African Americans from COVID-19 and the connection

between smoking and COVID-19 outcomes, there have been significantly more deaths than TPSAC could have anticipated or calculated.<sup>13</sup>

No single policy would do more to address the health disparities in morbidity and mortality caused by commercial tobacco product use than the elimination of menthol as a characterizing flavor in cigarettes. Research has proven that many communities that have been marginalized experience disproportionate harm from smoking and that those same communities disproportionately use menthol cigarettes.

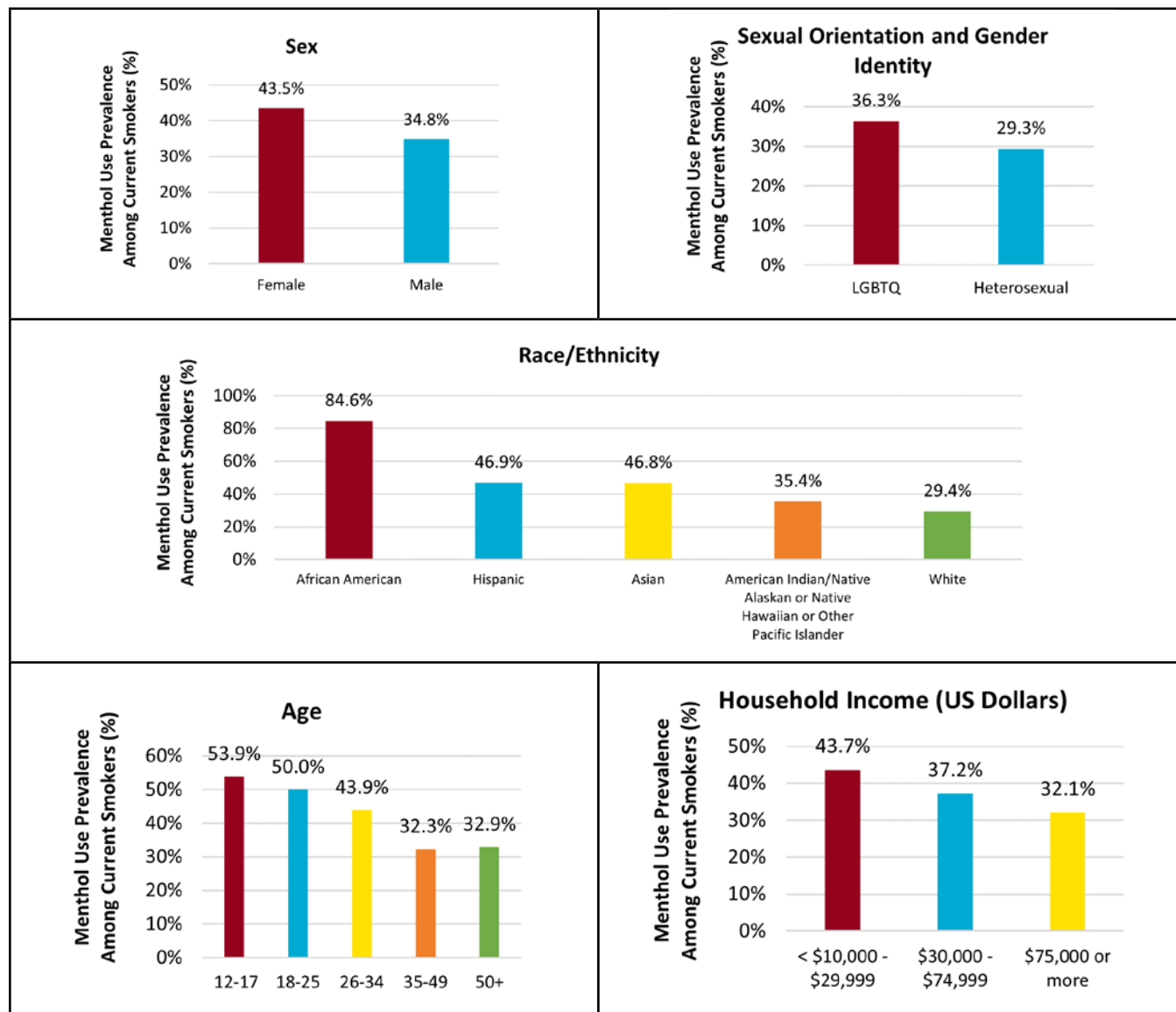
The targeting of groups that have been marginalized has been documented in many studies. In fact, the FDA's own internal report found that "tobacco companies with menthol brands use a marketing mix and concepts that target African Americans."<sup>14</sup> Historically, the industry's own documents reveal that they have used sponsorships and advertisements in magazines with a predominately African American readership, event sponsorships, free sampling, and special inner-city sales programs targeted at African American communities to promote menthol products.<sup>15</sup> Most recently, additional evidence reveals that in addition to these other practices, as the industry has shifted much of its direct marketing to the retail environment, the industry has specifically targeted African American communities with increased menthol exterior advertising, price promotions, and lowered pack prices for menthol products in the retail environment compared to non-menthol products and when compared to non-African American communities.<sup>16</sup> Additionally, research has shown that policies that restrict all flavors except menthol are particularly harmful to African Americans because of higher retailer density in their communities.<sup>17</sup>

Evidence shows that this targeted marketing and advertising works: findings from a recent study demonstrate that nearly half of African American menthol smokers in the study reported that they believed menthol cigarettes were less harmful than non-menthol cigarettes and nearly 60% reported that they were unaware that menthol cigarettes are as harmful as non-menthol cigarettes, despite indicating an awareness of the addictiveness of cigarettes and industry targeting.<sup>18</sup> Alarming, the lack of awareness of the harms of smoking menthol cigarettes were also reported in nearly half of the African American non-smokers surveyed.<sup>19</sup>

Unsurprisingly, while overall smoking rates continue to decline, menthol's hold on the market is undeniable. Although cigarette consumption has declined 26 percent since 2009, menthol's market share has only increased. In fact, 91 percent of the decline in overall consumption is attributable to non-menthol cigarettes.<sup>20</sup> The industry's own reports confirm that they have continued to expand their distribution of menthol cigarettes over time.<sup>21</sup> Additionally, although use of menthol cigarettes declined overall among youth from 2011 to 2018, there was no decline for use among African American and Hispanic youth.<sup>22</sup>

In addition to the egregiously disproportionate impact of menthol on the African American community, there are also troubling disparities in menthol use among other groups that have been marginalized.

The following chart illustrates some of the differences in menthol smoking prevalence based on several different characteristics:<sup>23</sup>



Research shows that youth and young adults have higher rates of menthol use and that racial disparities exist within the age group.<sup>24</sup> A 2013 study reports that among 12-17-year-old smokers, 71.9 percent of African Americans, 51.5 percent of Asian Americans, 47.0 percent of Hispanics, 41.0 percent of non-Hispanic whites and 34.7 percent of Native American youth reported using menthol cigarettes.<sup>25</sup> This was confirmed by a 2015 study concluding, "young Black smokers were more likely than those in other racial/ethnic groups to smoke menthol cigarettes."<sup>26</sup> More than 39,000 African Americans die from



tobacco-related cancers per year and nearly 90 percent of adult African American smokers use menthol cigarettes.<sup>27</sup>

Recent research also reveals that there are very high rates of menthol cigarette use in pregnant smokers, especially among those who identify as a member of a racial or ethnic group and those with low socioeconomic status. A study conducted in the northeast United States found that 86 percent of pregnant women who smoke used menthol cigarettes.<sup>28</sup> The study's preliminary findings also suggest an association between menthol cigarette use and reduced cessation.<sup>29</sup> Menthol smoking during pregnancy also resulted in fewer weeks without tobacco use during gestation.<sup>30</sup> Additionally, women who smoke menthol cigarettes prior to pregnancy are more likely to start smoking again postpartum than those who smoke non-menthol cigarettes, and this phenomenon is substantially greater for African American women.<sup>31</sup>

Alarming new evidence has also emerged regarding use of menthol tobacco products among those experiencing mental illness. A 2016 study found that current menthol users reported higher rates of anxiety and depression compared to non-menthol users.<sup>32</sup> Consistent with those findings, a 2017 study found that psychotic disorder and severity of psychotic symptoms were associated with menthol cigarette use in adult smokers with severe mental illness and a 2019 study found that young adult smokers with severe mental illness who use menthol cigarettes experience more psychiatric hospitalizations over their lifetimes compared to those who use non-menthol cigarettes.<sup>33</sup> Additionally, menthol smokers with mental illness have some of the lowest quit rates of any demographic.<sup>34</sup> While there are a host of factors that contribute to these statistics, the elimination of menthol products from the market could break through some of the barriers that have existed for this population.

Over the past decade, understanding of the nature and magnitude of the public health inequities experienced by African Americans, Hispanics, and other racial and ethnic groups has evolved. The oppressive forces that have created the social construct of race can be seen in the systemic and environmental conditions constructed to advantage white people and disadvantage others. Differences in the social determinants of health (i.e., conditions in the places where people live, learn, work, and play that affect a wide range of health risks and outcomes) accumulate and compound the widely recognized health-related disparities observed between individuals grouped into racial and ethnic categories. The importance of the social determinants of health is recognized by many health groups and has recently been included in the U.S. Department of Health and Human Services' Healthy People 2030 framework.<sup>35</sup> Operationally, the social determinants of health for African Americans were manipulated in harmful ways by the tobacco industry to create the demand for menthol cigarettes. Dr. Phillip Gardiner describes the manipulated social and economic variables as follows: "The African Americanization of menthol cigarettes by the tobacco industry included targeted marketing, use of segregated markets, capitalization

on the growing 'Black ethos' of the Civil Rights movement, and the promotion of the 'healthful' qualities of menthol."<sup>36</sup>

Moreover, in African American communities, the legacy of racist policies is correlated with substandard employment, housing, education, income, and access to health services; associated risks include occupational hazards, exposures to toxic substances and allergens in the home, low-quality schooling, lack of availability of healthy foods, easy access to illicit drugs and alcohol, violent neighborhoods, and environmental exposures – all of which can compound the risk and severity of health hazards posed by smoking, secondhand smoke, and tobacco product waste exposure.<sup>37</sup>

By delaying action on menthol, the FDA perpetuates and ratifies the status quo: that the tobacco industry preys upon and harms the health and economic prosperity of many groups that are already devastated by structural racism. Nowhere is this truer than in the African American community. With continued inaction, the agency's complicity in these harms grows. A prohibition on menthol cigarettes is the essential and urgent first step to protect health in the communities most disparately harmed by tobacco and structural racism in its myriad other forms.

b. Menthol impacts the addictiveness of cigarettes beyond merely adding a characterizing flavor to tobacco smoke.

Research since 2013 repeatedly confirms the evidence that has been available for several years: menthol is a unique additive that facilitates and increases initiation, leads to a deeper level of addiction and dependency, and makes it much more difficult to quit smoking. While previous research documented a menthol smokers' multi-factor experience of menthol – such as the smell, taste, and analgesic effect, the most recent animal research has begun to pinpoint how menthol uniquely interacts with nicotine in the brain to make physiological changes and how the respiratory system is impacted at a molecular level. Ultimately, the evidence is clear that menthol smoking is distinctly harmful.

1. The presence of menthol in cigarettes facilitates initiation.

Since the original petition was filed, further examination of industry documents revealed the industry's long-standing manipulation of menthol cigarettes as "starter" products for youth. Historical industry documents state, "menthol brands have been said to be good starter products because new smokers appear to know that menthol covers up some of the tobacco taste and they already know what menthol tastes like, vis-à-vis candy."<sup>38</sup> Industry documents also reveal the industry's recognition that youth are the key to success for menthol brands, "the success of Newport has been fantastic during the past few years. Our profile taken locally shows this brand being purchased by [B]lack people (all ages), young adults (usually college age), but the base of our business is the high school student."<sup>39</sup> Marketplace data confirms this reality – although youth smoking continues to decline, menthol cigarettes continue to

dominate the youth market share, and this concerning trend has been documented in other countries as well.<sup>40</sup>

What the industry has known for years – and recent research continues to confirm – is that while overall improvements have been made to reduce cigarette use in youth and young adults, when compared to older cigarette users, youth and young adults smoke menthol cigarettes at a much higher level. A 2015 study found that “among cigarette smokers, menthol cigarette use was more common among 12-17 year-olds (56.7%) and 18-25 year-olds (45.0%) than among older persons which ranged between 30.5% to 34.7%.”<sup>41</sup> Research indicates that preference for menthol products is also significantly higher for youth who had been smoking for less than a year compared with those that had been smoking longer than a year (49.2% v. 43.8%) and the same held true for young adults (40.2% vs. 36.4%).<sup>42</sup> When these statistics are broken down into other demographics, it is clear that menthol use is more prevalent among females and non-white youth.<sup>43</sup>

Recent studies continue to support the conclusion that menthol facilitates initiation by masking the harsh flavors in tobacco smoke, including nicotine, that youth continue to be targeted by media campaigns for menthol products (especially on the internet and social media), and that youth menthol smokers perceive menthol cigarettes to be less harmful than non-menthol cigarettes.<sup>44</sup> Recent research also continues to confirm that youth may anticipate and experience more pleasure from menthol cigarettes over non-menthol cigarettes.<sup>45</sup> Additionally, a 2018 study found that youth who initiate with menthol compared to non-menthol cigarettes were less likely to report feeling nauseated when first using.<sup>46</sup>

While the observational studies of menthol’s role in initiation have continued to confirm established research, there have been novel advancements in the understanding of menthol’s impact on biology and physiology primarily through animal studies. Menthol has the unique ability to trigger certain processes in the brain that are also triggered by nicotine – this has been demonstrated to have profound effects when the two chemicals are consumed together.<sup>47</sup> Recent studies have shown that menthol works to biologically impact the sensors in the lining of the mouth, nose, throat, and lungs (TRPM8 and k-opioid receptors), which reduces the sensation of irritation in lungs and reduces pain caused by inhaling smoke.<sup>48</sup> A 2020 meta-analysis concludes, “It is more likely that the effects of menthol on smoking topography are found in inexperienced smokers, where menthol smokers may take in more nicotine during the beginning phase of smoking compared to nonmenthol smokers...”<sup>49</sup> Essentially, this means that youth who initiate with menthol cigarettes are potentially taking in higher doses of nicotine than those that initiate with non-menthol cigarettes.<sup>50</sup>

Finally, recent research indicates that initiating smoking with a menthol cigarette over a non-menthol cigarette is uniquely harmful and has downstream impacts on dependency, cessation, and use of other harmful products (such as marijuana and alcohol). A 2020 study using PATH data from 2013 to 2017

demonstrated that young adults who initiated with menthol had higher use in the past 12 months than those who initiated with non-menthol cigarettes.<sup>51</sup> A 2013 study concluded that initiation with menthol “was related to both progression to established smoking and [greater] nicotine dependence.”<sup>52</sup> In that study, youth who initiated with menthol cigarettes were more likely to transition to established smoking over the three year study.<sup>53</sup> This is consistent with the conclusions from a 2019 study finding that in all age groups, first use of a menthol or mint-flavored cigarette was positively associated with subsequent cigarette use and a 2014 Canadian study that showed that youth smokers who started with menthol cigarettes had significantly higher odds of intending to continue smoking over those that started with non-menthol cigarettes.<sup>54</sup> In addition to the impact of initiating with menthol cigarettes on future smoking behavior, three recent studies have found that menthol cigarette use is associated with a greater use of alcohol and marijuana.<sup>55</sup>

## 2. The presence of menthol in cigarettes deepens addiction and increases dependency.

Recent studies show that menthol specifically facilitates deeper addiction and dependency in both youth and adult smokers. Several studies show that youth menthol smokers have a significantly shorter time between waking and smoking their first cigarette compared to those that smoke non-menthol cigarettes.<sup>56</sup> The time between waking and smoking one’s first cigarette is a recognized and established measure of nicotine dependency.<sup>57</sup> Additionally, two recent studies indicate that youth menthol smokers are more likely to report withdrawal symptoms, higher feelings of craving, and more irritability and restlessness after not smoking for a few hours.<sup>58</sup> Several studies, including NYTS data, reveal that youth menthol smokers have higher scores on nicotine dependence scales than those that smoke non-menthol cigarettes.<sup>59</sup> For adults, the most recent research shows that for adult daily smokers, those that smoke menthol cigarettes are significantly more likely to report reluctance to give up their first morning cigarette and to report more difficulty refraining from smoking in places where smoking is prohibited.<sup>60</sup> Importantly, some studies show that dependence may be greater for female adults and African American adults who use menthol over other demographics.<sup>61</sup>

At the biological and physiological level, animal studies show that menthol increases dependence by interacting with nicotine to produce additional nicotine-specific receptors in the brain, increasing the sensitivity and preventing desensitization of nicotine specific receptors, and by increasing dopamine release due to greater dopamine neuron excitability.<sup>62</sup> Additionally, because menthol has a distinct and recognizable odor, research in mice shows that menthol can increase relapse and drive nicotine-seeking behaviors.<sup>63</sup> Research into tobacco industry documents establishes that the industry has long been studying these physiological impacts and has used this knowledge to manipulate menthol in cigarettes to promote addiction.<sup>64</sup>

## 3. The presence of menthol in cigarettes suppresses cessation.

Menthol unequivocally makes it harder for smokers to quit smoking.<sup>65</sup> This remains true despite increased quit attempts or intention to quit by menthol smokers.<sup>66</sup> One recent study shows that even though menthol smokers had more quit attempts for the past year compared to non-menthol smokers, they experience significantly lower short term and longer-term quit rates.<sup>67</sup> Recent PATH data confirms that menthol smokers are less likely to quit compared to non-menthol smokers.<sup>68</sup> Additionally, a 2014 study from England confirms that menthol smokers report higher nicotine dependence and reduced confidence in quitting compared to nonmenthol smokers.<sup>69</sup>

Several studies also show that menthol's impact on cessation is even more pronounced for African Americans, Native Hawaiians and Pacific Islanders, Hispanics, and other non-white populations.<sup>70</sup> A 2020 study revealed that African American menthol smokers have approximately 12% lower odds of smoking cessation compared to non-menthol smokers.<sup>71</sup> And a 2016 study showed that while African American menthol smokers have the same overall cessation rates as their non-menthol counterparts, the menthol smokers attempted to quit significantly more often.<sup>72</sup> At least one study revealed that African American menthol smokers cited cravings as the primary impediment to successful cessation.<sup>73</sup>

Animal studies focusing on the biological and physiological impact of menthol in successful cessation further revealed that menthol may impact the metabolism of nicotine and disrupt the mechanisms that pharmaceutical medications like varenicline and bupropion engage to help smokers quit.<sup>74</sup> This is consistent with past studies that show that African American menthol smokers have less success quitting using bupropion compared to their counterparts who do not use menthol.<sup>75</sup>

c. Jurisdictions that have eliminated menthol cigarettes have already seen resulting health benefits.

In the absence of menthol prohibitions to evaluate, the 2011 TPSAC report relied heavily on modeling to estimate the lives lost and economic costs due to menthol cigarettes. Since that report, evaluation data of menthol bans has become available as many local jurisdictions, two states, and Canada have eliminated menthol cigarette sales.<sup>76</sup> Due to its scale, the most pertinent example of the benefits of a comprehensive menthol ban is in Canada.

Evaluation data of Canada's menthol ban shows that it has had positive health impacts by reducing cigarette smoking and preventing morbidity and mortality associated with menthol cigarette smoking.<sup>77</sup> Canada observed these benefits even with a relatively low percentage of menthol smokers. In contrast, the United States has a much higher percentage of menthol smokers, especially in certain regions, and researchers postulate that the United States would see significantly more benefits with a comprehensive menthol ban than Canada has.<sup>78</sup> The industry has made claims that banning menthol cigarettes will increase the illegal tobacco market; however, a study in Nova Scotia found that there was no surge of illegal cigarette sales after the implementation of their menthol ban in 2015.<sup>79</sup>

Importantly, research on the impacts of the menthol ban in Canada reveal that even when the industry tried to undermine the policy by introducing new non-menthol products designed to encourage menthol smokers to switch to non-menthol cigarettes, a significant proportion of menthol smokers increased quit attempts rather than switching.<sup>80</sup> Studies show that when implementing a menthol ban it is important for the public to have clear messaging and education about the new change. Participants in one study also noted the importance of being linked to cessation services as being key to helping menthol users to quit during this change.<sup>81</sup> In local jurisdictions that have banned the sale of menthol cigarettes, evaluation data has revealed a decrease in menthol sales and overall compliance with the laws.<sup>82</sup> At least one recent study using virtual marketplaces is consistent with the findings in Canada - even in the presence of a menthol ban, menthol smokers are unlikely to purchase non-menthol cigarettes.<sup>83</sup>

d. The presence of menthol in cigarettes harms nonsmokers.

The Tobacco Control Act specifies that the benefits of a proposed product standard must be assessed for the population as a whole, including both users and nonusers of tobacco products. The presence of menthol cigarettes in the marketplace has significantly increased the prevalence of tobacco use in the overall population. Because that excess use attributable to menthol also significantly increases the known harms of secondhand smoke, a prohibition on menthol cigarettes will substantially improve the health of nonusers.

In the absence of a federal menthol ban, the harm of menthol remaining on the market has led to continued use by some menthol smokers who would have quit smoking and has also led to initiation by millions of people who would have never started smoking if menthol cigarettes were not available. TPSAC estimated that between 2010 and 2020, an estimated 2.28 million more people would begin smoking than would have been expected to start if menthol cigarettes were not available.<sup>84</sup> This represents 2.28 million additional sources of exposure to secondhand and thirdhand smoke for nonusers and the concomitant health consequences of those exposures. While no research exists demonstrating the specific impact on nonsmokers from the secondhand effects of menthol cigarettes alone, the excess smoking caused by the presence of menthol cigarettes has profound effects on nonsmokers in the workplace and the home, those living in multiunit housing, and those in areas of the country without comprehensive smokefree laws. While this supplement does not attempt to calculate this toll specifically, the data is available to the FDA and the FDA must estimate the menthol-specific impact as it weighs the benefits of a prohibition on menthol as a characterizing flavor in cigarettes.

Further compounding the negative impacts of the excess secondhand smoke due to menthol cigarettes, secondhand smoke disproportionately harms populations that have been marginalized, including children, people with lower incomes, African Americans, and Hispanic people. For example, an analysis of data from the National Health and Nutrition Examination Survey (NHANES) assessed patterns of

secondhand smoke exposure among U.S. nonsmokers over time. Despite a substantial overall decrease in the prevalence of secondhand smoke exposure among U.S. nonsmokers during 1988-2014, from 87.5% to 25.2%, an estimated one in four non-smokers, or approximately 58 million persons, were still exposed to secondhand smoke during 2013-2014 and marked disparities persisted across demographic groups. Compared to the overall population, elevated rates of secondhand smoke exposure were observed among non-smokers who were children aged 3-11 years (37.9%); African Americans (50.3%); those living in poverty (47.9%); those living in rental housing (38.6%); those living with someone who smoked inside the home (73.0%); or those who had less than a high school education (30.7%).<sup>85</sup> Demonstrating an even starker disparity, an analysis of NHANES data through 2012 found that 70% of African American children were regularly exposed to secondhand smoke.<sup>86</sup> Because so much of the burden of menthol smoking-related morbidity and mortality is already on the African American community, banning menthol cigarettes would likely substantially improve this disparity by benefitting not just people who use menthol cigarettes but those who work with and live with them as well.

The devastating consequences of secondhand smoke exposure have been extensively documented for years. In 2006, the U.S. Surgeon General concluded:

- Secondhand smoke causes premature death and disease in children and in adults who do not smoke;
- There is no risk-free level of exposure to secondhand smoke;
- Children exposed to secondhand smoke are at an increased risk for sudden infant death syndrome (SIDS), acute respiratory infections, ear problems, and more severe asthma.
- Smoking by parents causes respiratory symptoms and slows lung growth in their children;
- Smoking by pregnant mothers causes low birth weight; and
- Exposure of adults to secondhand smoke has immediate adverse effects on the cardiovascular system and causes coronary heart disease and lung cancer (in 2014, the Surgeon General added stroke as causally related to secondhand smoke exposure<sup>87</sup>).

And recent research demonstrates secondhand smoke exposure is linked with:

- Lower academic performance in children and youth;<sup>88</sup> and
- Depressive symptoms among adolescents and adults.<sup>89</sup>

Following the U.S. Surgeon General's determination in 1986 that secondhand smoke is a cause of lung cancer in healthy non-smokers, in 1991, the National Institute for Occupational Safety and Health concluded that secondhand smoke is an occupational carcinogen.<sup>90</sup> And, despite growing adoption of smoke-free workplace policies, in 2015, the U.S. Centers for Disease Control and Prevention (CDC) estimated that nearly one-fifth of nonsmokers were exposed to secondhand smoke at work.<sup>91</sup> Blue

collar and service employees are less likely than white collar indoor workers to be covered by smoke-free policies.<sup>92</sup> The likelihood of frequent workplace secondhand smoke exposure was lowest among non-smoking workers who resided in states with comprehensive smoke-free laws that cover private worksites, bars, and restaurants.<sup>93</sup> A reduction in overall smoking rates, especially in areas with higher populations of menthol smokers and the least comprehensive smoke-free laws, such as many Southeastern States, will lead to decreased secondhand smoke exposure and improved health for non-smokers. Additionally, the normalization of non-smoking is often imperative to the passage of smoke-free laws – reductions in overall smoking could be a driving force in passing laws to protect non-smokers in these communities.

In assessing the benefits of a prohibition on menthol, the FDA must also consider the impact on the presence of menthol in cigarettes on secondhand smoke exposure in multiunit housing. Shared air/HVAC systems in multiunit housing significantly impact the exposure to secondhand smoke in this environment. It is estimated that 1 in 4 Americans live in multiunit housing and many of these residents represent disproportionate numbers of racial and ethnic minority groups, younger people, and those with lower socioeconomic status.<sup>94</sup> There is also a higher proportion of smokers living in multiunit housing than in the general population. For example, 33.6% of HUD-assisted adults smoke cigarettes, which is over twice the national smoking rate.<sup>95</sup> Additionally, residents in multiunit housing are exposed to both secondhand smoke and thirdhand smoke.

Thirdhand smoke is yet another more recently recognized harm generated by cigarette smoking that affects non-smokers. Thirdhand smoke exposure refers to contact via absorption through the skin, inhalation, and ingestion of smoke metabolites and toxins that accumulate on surfaces, such as cloth, carpets, and upholstery.<sup>96</sup> Thirdhand smoke exposure primarily occurs in the home, but automobiles and workplaces can also be sources.

The direct public health harms of the excess smoking resulting from the presence of menthol cigarettes in the marketplace were rightly recognized as significant by TPSAC in 2011 and the 2013 petition. As the FDA assesses the public health benefits of a prohibition on menthol, the immediate downstream harms to non-users in the form of secondhand and thirdhand smoke must be assessed.

Seven years of additional data has also expanded the knowledge base of the public health impacts of tobacco product pollution. Research shows that cigarette butts are toxic and made of a type of non-biodegradable plastic that breaks apart into microplastics that persist in the environment indefinitely.<sup>97</sup> Cigarette butts are also the single most littered item on earth (on a per item basis).<sup>98</sup> Hazardous substances found in cigarette butts, including arsenic, lead, nicotine, and ethyl phenol, leach from discarded butts into aquatic environments and soil.<sup>99</sup> Cigarette butts not only kill plant life<sup>100</sup> and aquatic species,<sup>101</sup> they continue to off-gas poisonous air pollution for days after they are littered.<sup>102</sup> In fact, one



cigarette butt can give off the equivalent of up to 14% of the nicotine that an actively burning cigarette emits.<sup>103</sup>

The FDA's own analysis of the environmental impact of tobacco products (conservatively) estimated that in 2017 alone, 34% of the 247 billion cigarettes consumed in the U.S. were littered.<sup>104</sup> A tobacco industry-sponsored study estimates that closer to 65% of cigarette butts are littered on an annual basis.<sup>105</sup> In 2017, menthol cigarettes were 36% of the market share among major manufacturers, meaning that between 30,232,800,000 and 57,798,000,000 menthol cigarette butts were littered in that year alone.<sup>106</sup> Removing menthol cigarettes from the market would drastically reduce consumption, thereby reducing exposure of both users and nonusers to cigarette butts and their toxic leachate.

Further, the disproportionate impact of menthol cigarettes on African American, LGBTQ+, Hispanic and other communities that have been marginalized includes environmental harms. For example, the accumulation of tobacco product waste clusters around areas where products are sold and used.<sup>107</sup> Research has shown that tobacco products are disproportionately marketed and sold in lower-income neighborhoods<sup>108</sup> and in neighborhoods with higher concentrations of African American residents,<sup>109</sup> meaning that the waste accumulates disproportionately in these communities, exposing their residents to toxic chemicals. In fact, a recent study in California traced different types of tobacco waste to high school students of different socioeconomic backgrounds, finding double the number of menthol butts at low-income schools than were found at high-income schools.<sup>110</sup>

The presence of litter also contributes to neighborhood stress and mental illness.<sup>111</sup> Exposure to greater quantities of tobacco product waste further compounds with other public health injustices such as lethal exposure to air pollution,<sup>112</sup> which exacerbates many of the illnesses caused by tobacco products.<sup>113</sup>

Ultimately, eliminating menthol tobacco products would have the added benefit of preventing billions of cigarette butts from being littered every year, thereby reducing human exposure to their toxicity and protecting the health of both users and nonusers of tobacco products alike.

#### e. Scientific Conclusion

The evidence that the presence of menthol in cigarettes creates unique harms is clear. Menthol masks the harsh flavor of tobacco smoke and increases the level of addictiveness of the world's most deadly consumer product. The presence of menthol cigarettes increases youth initiation and decreases adult and youth cessation. The combination of those two outcomes over time has led to a measurable increase in the number of smokers in the U.S. That increase has resulted in greater exposure to secondhand smoke, thirdhand smoke, and tobacco product waste pollution, which all have a significant detrimental effect to people who never smoke menthol cigarettes. The removal of menthol from cigarettes would dramatically benefit public health, both in the short term and over the long haul.

When taking any action that implicates the public health standard, but especially in establishing a product standard related to menthol in cigarettes, the FDA must examine the impact on subpopulations. While the public health standard is clearly established to ensure that the FDA makes decisions based on population-level, rather than individual-level evidence, the Act does not prohibit the FDA from analyzing an action's impact on subpopulations. In fact, the disproportionate impact of menthol is explicitly discussed in the Act, indicating that Congress clearly intended for the FDA to analyze this body of evidence. In its charge to TPSAC, for example, Congress directed a report on menthol to include information on the impact on "children, African-Americans, Hispanics, and other racial and ethnic minorities."<sup>114</sup> Congress clearly intended the FDA to have that information at its disposal as it considers action on menthol. There would be no reason to instruct TPSAC to report on the impact of menthol on those communities if Congress did not intend for that information to be part of the FDA's decision-making process.

The FDA must examine the disproportionate rates of disease and death among subpopulations to fully understand how best to design and implement a prohibition on menthol in cigarettes. This should be a part of the FDA's process in all regulatory actions. Policymaking that does not attempt to correct health disparities will inevitably perpetuate them.

### **III. When the FDA proposes a rule to prohibit menthol in cigarettes, there are other actions that it should consider taking to maximize the health benefits of the rule.**

A product standard prohibiting menthol as a characterizing flavor in cigarettes would secure tremendous health benefits. As the FDA begins the rulemaking process to establish a standard, the agency should also consider taking several other regulatory actions that will further increase the health benefits of a product standard. As is discussed above, a prohibition on menthol will create a cessation opportunity for many Americans, one that can be harnessed to significantly increase the success of quit attempts. There are several actions that the FDA can take that will have a positive impact on rates of cessation.

Upon granting this petition, the FDA must begin a rulemaking process to establish a product standard. During that proceeding, the agency is required to analyze the possible countervailing effects of a standard as that information is presented to it. The public health standard analysis is the paramount measure of whether to implement a standard, but Congress has instructed the agency to consider several other factors as well. As is discussed below, this is likely so that the agency can ensure that a potential product standard is structured such that it mitigates the potential danger of those countervailing effects as much as is possible. In the context of a product standard prohibiting menthol, the countervailing effects are minimal, and the FDA has tools at its disposal that can address any such impacts.

- a. A prohibition on menthol as a characterizing flavor in cigarettes creates an opportunity to significantly increase the success of the quit attempts of menthol smokers.

As is discussed above, the presence of menthol suppresses quit success and the removal of menthol cigarettes from the market will be an opportunity for millions of menthol smokers to make a quit attempt. If the FDA does nothing other than establish a standard, many of these quit attempts will fail. We also know that there are disparities in quit failure rates among subpopulations and thus a menthol product standard that is not supported by other actions will not advance health equity. Instead, it will likely perpetuate health disparities.

One method to increase the success of quit attempts is for the FDA to undertake a targeted education campaign to make menthol smokers aware of various resources available to them to assist them in quitting. As stated above, African American and youth menthol smokers have many misperceptions about the safety of menthol cigarettes – education is the primary way to combat those misconceptions.<sup>115</sup> In fact, education, messaging, and access to cessation services were key factors in helping menthol smokers quit after Canada banned menthol cigarettes.<sup>116</sup> The FDA's education campaigns have been very successful and are one of the most life-saving measures that the Center for Tobacco Products has implemented. Though the FDA may be unable to require the 1-800-QUIT-NOW phone number to appear directly on cigarette packages and advertisements, there is no legal issue with the FDA using the number in its own communications. The agency also needs to ensure that all its communications activities are culturally relevant to the groups that have been the most affected by menthol. Research suggests that culturally relevant smoking cessation interventions are successful in reaching communities that find it especially hard to quit.<sup>117</sup>

The FDA should also ensure that the Center for Tobacco Products is collaborating with the Center for Drug Evaluation and Research as the regulator of smoking cessation drugs. In addition, the FDA must work with its sister agencies (e.g., the Centers for Disease Control and Prevention) to ensure a coordinated response from the federal government that can maximize the public health benefits of a prohibition on menthol by taking a multi-faceted approach to increasing access to cessation resources and education.

- b. The potential countervailing effects of a product standard are minimal and can be mostly mitigated by additional FDA action.

In relevant part, the Tobacco Control Act ("Act") provides the FDA with the authority to set product standards if it finds that the standard is "appropriate for the protection of the public health."<sup>118</sup> The considerations involved in determining whether something is "appropriate for the protection of the public health" are limited to: "(I) the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard; (II) the increased or decreased likelihood that

existing users of tobacco products will stop using such products; and (III) the increased or decreased likelihood that those who do not use tobacco products will start using such products.”<sup>119</sup> Additional considerations include “scientific evidence that demonstrates that the proposed standard will not reduce or eliminate the risk of illness or injury,” submitted by “any party objecting to the proposed standard,”<sup>120</sup> as well as information relating to the “technical achievability of compliance”<sup>121</sup> with a proposed standard, and “other information submitted in connection with a proposed standard, including information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of [the Act] and the significance of such demand.”<sup>122</sup>

In other words, whether the FDA issues a product standard must be determined based on what is appropriate for the protection of the public health. Once the FDA has proposed a standard, the tobacco industry, or others objecting to the proposed standard, may submit additional information relating to scientific evidence, technical achievability, or the countervailing effects of contraband and nonconforming products. Critically, however, the Act requires the FDA to determine whether to promulgate a product standard based solely on the considerations of the public health standard. The statute lists these three other topics that the FDA must consider but the Act does not instruct the agency to abandon a product standard based on the impact of these considerations.

A commonsense reading of the FDA’s authority to promulgate product standards requires the agency to examine all of the scientific evidence related to the three prongs of the public health standard, to propose such a standard, and then allow for public comment on the evidence related to the public health standard and the three additional areas of consideration: technical achievability, contraband products, and nonconforming products.<sup>123</sup> Should any evidence presented on those topics outside of the public health standard indicate that the health benefits of a product standard may be threatened, the FDA should consider ways to mitigate that damage in its final rule implementing the product standard or consider taking other actions in addition to the standard. Even if the agency has no way to mitigate such potential damage, the FDA should move forward with the proposed standard despite the other considerations because the proposed product standard will still benefit public health. The presence of countervailing effects does not overcome the weight of the scientific analysis of the public health standard.

While the additional considerations required by the Act have no bearing on the FDA’s decision to grant or deny this citizen petition, we present information on those topics below to inform the agency’s proposal when the FDA proposes a rule prohibiting menthol. We suspect that opponents of a prohibition on menthol, largely led by cigarette manufacturers, will attempt to portray these additional considerations as so detrimental to the standard as to eliminate any benefits. This is not the case and the FDA has additional tools to address these concerns.

## 1. Technical Achievability

The Tobacco Control act requires the FDA to ascertain if the removal of menthol is technically achievable, such that tobacco industry compliance with the public health standard is practicable.<sup>124</sup> Menthol is a flavor additive in cigarettes and other tobacco products, such as cigars, hookah (waterpipe) tobacco, smokeless tobacco (dip, chew, snuff, and snus), and e-cigarettes and other electronic nicotine delivery systems (ENDS). It is added for its ability to reduce the irritation and harshness of smoking. Although, menthol is a naturally occurring chemical compound in many tobacco products, almost all cigarette marketed as “menthol” in the U.S. contain more menthol than in cigarettes that are not marketed as menthols.<sup>125</sup> It is no secret that additional menthol is added to menthol-flavored cigarettes. The various processes by which menthol is added is documented in numerous places, including TPSAC’s report on menthol.

Because additional menthol is added to cigarettes, the FDA could order tobacco companies to comply with a new product standard and to stop adding natural or synthetic menthol to cigarettes just like it has with other flavors in the past.<sup>126</sup> A product standard that prohibits the addition of something to a tobacco product is technically achievable as a manufacturer merely needs to cease the addition. Furthermore, the FDA can set up a testing and verification system to make sure that the covered tobacco products comply with the new standard.<sup>127</sup> The FDA already enforces a prohibition on other flavors in cigarettes and has adopted a much more nuanced policy for e-cigarettes, so it is clear the agency is capable of enforcing a prohibition on menthol.

## 2. Contraband

A second countervailing factor that the FDA must consider when it establishes a new tobacco product standard is whether the new standard creates, “a significant demand for contraband.”<sup>128</sup> A subset of this inquiry is the consideration of potential health effects arising from any demand for illicit products.<sup>129</sup>

In including this consideration in the Act, Congress attempted merely to make room for reasonable industry concerns and, if possible, to have the FDA, “make necessary adjustments so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade.”<sup>130</sup> However, the Act does not elevate the consideration of “countervailing effects” to that of a greater value or even equal to Congress’ concerns about the devastating health effects of tobacco use.<sup>131</sup> Yet, the tobacco industry has attempted to use this language as a pocket veto and have trotted out this straw man every time the FDA has sought to regulate tobacco in any manner.

Some of these industry arguments can be found in its response to other early-stage product standard proposals. For example, the industry has asserted that implementation of a very low nicotine content standard for cigarettes would considerably expand the illegal cigarette market, serve as a boon to

organized crime, and be a burden on law enforcement.<sup>132</sup> Similarly, the industry proffered these same unfounded red herrings when the FDA sought comments on the regulation of menthol cigarettes.<sup>133</sup> As is its custom, the industry has neglected to consider a number of mitigating factors and made its perennial predictions that any regulation of menthol would result in chaos. The industry's lack of integrity and demonstrated history of lying to avoid regulation<sup>134</sup> should influence how the FDA considers its input. The tobacco industry's priority is preserving its profits by maintaining and growing its addicted customer base; a goal that is wholly inconsistent with the public health standard that governs the FDA's regulation of tobacco products. In fact, the agency has already conducted a thorough analysis of the potential impact of illicit trade that it can rely on in implementing a product standard for menthol.

- i. FDA's 2018 draft paper represents some of the best analysis of the potential effects of illicit markets in the U.S. in response to an FDA product standard.

The FDA undertook an analysis of, "the potential for the development of a market for products that do not conform to a product standard."<sup>135</sup> According to the FDA, the illicit trade in tobacco products has six distinct components: 1) sourcing the raw tobacco; 2) manufacturing illicit tobacco products; 3) modifications of other products to evade the new tobacco product standards; 4) distribution of illicit tobacco products; 5) making the consumer aware of illicit trade; 6) and selling of illicit tobacco products.<sup>136</sup> After a thorough analysis, FDA's own expert found that the primary form of illicit trade that exists in the United States is that of tax avoidance—by buying cigarettes in a jurisdiction with little or no tax and selling them somewhere where they are taxed at a higher rate.<sup>137</sup> Second, the paper concluded that illicit trade would be of limited significance because the, "manufacturing costs for illicit tobacco products [would be] higher because of economies of scale, and large-scale production [would be] difficult to achieve."<sup>138</sup> In addition, it found that it had robust enforcement capabilities to combat illicit trade if it ever become consequential.<sup>139</sup>

The FDA's conclusions are consistent with what peer reviewed academic research shows.<sup>140</sup> In a 2019 review of the scientific literature on the topic of illicit trade in tobacco product, researchers collected 35 assessments of the black market in tobacco.<sup>141</sup> Eighteen of the assessments were peer reviewed, while all but one of the industry-funded data sources they examined were not.<sup>142</sup> In 31 of the assessments, the industry-funded estimates of the black market were higher than the reviewer's estimates - ranging from 17 percent higher to well over 100 percent higher.<sup>143</sup> In 29 assessments, there were criticisms of the methods used to gather the industry funded data.<sup>144</sup> For example, surveys of used cigarette packs/tobacco pouches were only collected in towns and cities, where illicit products are likely more common.<sup>145</sup> There was also a finding by the researchers that industry-funded reports failed to clearly convey research methods, making it harder to verify findings. The paper concluded that "the quality of industry data on illicit tobacco as a whole is below the expected standard to be considered reliable...

and that this “may indicate that the tobacco industry is deliberately producing misleading data” on this topic.<sup>146</sup>

These findings dovetail with the documented knowledge that the tobacco industry has a long history of using research and obfuscation to deceive policymakers and the public<sup>147</sup> – not to mention an intimate involvement with the tobacco smuggling it now claims it helps to prevent.<sup>148 149</sup> In short, the tobacco industry’s viewpoint is the outlier and, thus, should be given limited credence in the adoption of a product standard.

ii. Industry comments on the petition should be disregarded, or at the very least, read with a great deal of skepticism.

Among the comments on the citizen petition are two from the tobacco industry itself, specifically Altria Client services, on behalf of Philip Morris, USA Inc. and Lorillard Tobacco Company (collectively, “Industry Comments”). Conspicuously, these are the only comments of those available on regulations.gov that do not support the citizen petition.<sup>150</sup> The Industry Comments should be disregarded, or at the very least, read with a great deal of skepticism. This is primarily because (1) the tobacco industry’s input is not an element of the FDA’s decision-making at this stage in the tobacco product standard proposal process; (2) the tobacco industry has a vested interest in ensuring its own continued growth and protecting profits derived from its most addictive products; and (3) the information relied upon by the industry is selectively chosen from untrustworthy industry-sponsored studies and industry-friendly information.

A. The tobacco industry’s perspective on the public health impact of menthol should be disregarded at this point in the product standard-setting process.

In its comments, the industry has misrepresented the standard by which the Act requires the FDA to consider countervailing effects. For example, in Lorillard’s Comment on the Citizen Petition, the company states that the Act directs the FDA to consider the potential for creation of a significant demand for contraband “[p]rior to any regulation of menthol.<sup>151</sup> But, as previously discussed, this is not what the Act requires. Rather, the FDA’s determination at this stage is simply whether to propose a product standard prohibiting menthol, which is guided by the public health standard. The consideration of “countervailing effects,” including the potential creation of demand for contraband, is separately listed under the heading “other considerations” and requires the Secretary to “consider all other information submitted in connection with a proposed standard.”<sup>152</sup> In other words, once the FDA proposes a standard, the industry is free to provide information about “countervailing effects,” at which point the FDA is indeed directed to consider that information. The industry’s effort to frame the consideration of “countervailing effects” as having equal weight to the consideration of public health impacts of menthol products must be rejected. That is not what the Act says—the Act frames primary and secondary considerations that elevate what

is appropriate for the protection of the public health above the “other” or “additional” considerations. In short, the industry’s comments on the Petition should be disregarded at this stage in the product-standard setting process. After the FDA has proposed a standard that is protective of public health, the industry will have an opportunity to comment along with other members of the public.

B. The industry comments should be read with a great deal of skepticism because tobacco product manufacturers accept addiction, illness and death as the cost of doing business, a position that is incompatible with the public health standard.

The comments on the citizen petition from the tobacco industry should be read with skepticism if for no other reason than the tobacco industry has a vested interest in ensuring that the FDA does not prohibit the sale of menthol cigarettes. As evidenced by the widely accepted studies discussed earlier in this supplement, the scientific data shows the presence of menthol in cigarettes facilitates smoking initiation, leads to a deeper level of addiction, and makes quitting harder. For an industry selling addictive products, initiation, dependency, and cessation are crucial inflection points. It follows that the industry would be particularly sensitive to the elimination of its most addictive products and has an interest in funding its own research and using scare tactics to stymie regulation.

Indeed, menthol cigarettes are a critical piece of the combustible cigarette’s continued survival. As reported in a research letter published in JAMA in August of 2020, the menthol cigarette market share increased by nearly 10 percentage points from 2000 to 2018, with 85% of the decline in cigarette smoking over the last two decades attributable to non-menthol cigarettes.<sup>153</sup> The total number of menthol cigarette packs sold is strikingly large, with the sale of menthol cigarettes accounting for an average of 31.5% of combustible cigarette sales from 2011-2015, or 15,543,292,253 packs of menthol cigarettes.<sup>154</sup> This accounted for approximate total revenues of nearly \$75 billion dollars from menthol cigarettes sales alone.<sup>155</sup>

Understandably, then, the industry has no reason to support any regulatory effort that would restrict the sale of menthol cigarettes.<sup>156</sup> Menthol products are fundamentally a lucrative product for the tobacco industry. In fact, the comment on the citizen petition from the Citizens’ Commission to Protect the Truth—which assembled, for the first time, all of the living former U.S. Secretaries of Health and Human Services, U.S. Surgeons General, and Directors of the Centers for Disease Control and Prevention in support of the petition—points out that the profitability and ubiquity of menthol products should underscore the need to restrict their sale:

Opponents of a menthol ban will argue that the prevalence of menthol cigarettes among smokers makes it impractical to ban them. The fact that menthol is such a successful lure for initiating and sustaining cigarette smoking is precisely why it should be banned; such ignominious success should not serve as a rationale to prevent a ban.<sup>157</sup>



Moreover, the industry's opposition to a menthol sales restriction has been twofaced; while arguing that contraband menthol sales would overwhelm local law enforcement and the health impacts of such a market would be dire, R.J. Reynolds has simultaneously led the charge against local and state efforts to prohibit the sale of menthol cigarettes by arguing the FDA has sole authority to regulate menthol.

In fact, R.J. Reynolds is currently engaged in litigation in federal court (including two separate appeals) over four local and state efforts to limit flavored tobacco product sales, including menthol cigarettes, in both California and Minnesota.<sup>158</sup> In all those lawsuits, R.J. Reynolds has argued that local and state efforts to regulate menthol (and other flavored products) are preempted by the Tobacco Control Act. In other words, it has argued that a national sales restriction would have a negative impact on public health due to its breadth and scale, while also taking the position that only a national standard would be legal under the Act.

Finally, it is important to keep in mind that the nation's largest tobacco companies, including Philip Morris and Lorillard, were found to have violated federal racketeering statutes by engaging in a systematic, long-term strategy to mislead and deceive the government and the public about the dangers of their products.<sup>159</sup> It is pure fantasy to believe that their strategies and goals have somehow evolved to prioritize public health over profit.

C. Tobacco industry comments should be read with a great deal of skepticism because the comments defy logic and rely largely on the industry's own menthol reports.

The tobacco industry knows that menthol cigarettes are harmful. Indeed, Lorillard and R.J. Reynolds' own 2011 report on menthol acknowledged that eliminating the sale of menthol cigarettes would have a public health benefit, stating: "All cigarettes are hazardous to health. It does not require a scientific analysis by TPSAC or FDA to conclude that removal of menthol cigarettes from the market plausibly would have some public health benefit."<sup>160</sup>

In other words, the industry agrees that menthol has negative health impacts. It is therefore unsurprising that the industry chose to focus on the potential impacts of illicit trade, including potential exposure to toxins from contraband products, and the alleged increased burden on law enforcement, as support for its argument that eliminating the sale of menthol products would have a net negative impact on society. It is also unsurprising that much of the information it relies upon to support its argument surrounding illicit trade draws heavily from its own reports on the issue. As with its erroneous data on the health impacts of menthol, which have been thoroughly debunked in the previous pages, its focus on illicit trade is similarly outrageous.

The industry's claims about illicit trade are essentially that the products are so addictive that users would rather turn to contraband products than they would quit or simply choose another tobacco product. This

behavior is not supported by the FDA's analysis of consumer behavior in illicit markets, which suggests that users are likely to either stop using the product or switch to another one.<sup>161</sup> Also implicit in the industry's illicit trade argument is that their products are also so incredibly addictive that the government is unable to adequately respond. This clear recognition of the addictiveness of menthol products should not serve as a reason to continue to allow the sale of these deadly products; rather, it should underscore the need to restrict their sale. Further, under the industry's logic, it would make sense to simply allow the sale of all incredibly addictive products, such as heroin and cocaine, for the simple reason that there is an illicit market for those products as well. Yet, society comfortably restricts the sale of those products because they cause devastating health impacts.

Further, the industry comments do not reflect the current data on the likelihood of the creation of a significant market for products that do not conform to a product standard. The FDA's own report on illicit trade, described in more detail above, provides instructive analysis of this issue. Coincidentally, due to the FDA's delay in responding to the citizen petition, the agency now has the benefit of an additional seven years of data and research on the issue to help support its efforts to curb any demand for contraband.

Finally, the illicit trade argument is one that the industry has raised time and time again in response to a range of policy tools. The Citizens' Commission to Protect the Truth comment on the Citizen Petition addresses the "illicit trade" argument quite succinctly:

With respect to the anticipated illicit trade in tobacco products, numerous provisions of the Food, Drug and Cosmetic Act are designed to prevent just that. Neither of these considerations outweighs the public health benefits to the population as a whole of a menthol ban. Moreover, this is the same tired argument the tobacco companies use to oppose increasing taxes on cigarettes, an argument that has been repeatedly rejected by federal, state and local governments as they have raised such taxes in order to discourage smoking, especially the initiation of smoking by teens and children.<sup>162</sup>

Thus, even the former HHS Secretaries, US Surgeons General, and directors of the CDC agree on two critical things: (1) that the Act anticipates potential countervailing effects by providing the FDA with tools to support cessation and educational efforts; and (2) the illicit trade argument is nothing more than a red herring.

iii. The appropriate response to concerns about illicit trade and contraband products is to pursue implementation of a track and trace program.

The legislative history of the Act indicates that while Congress declined to include menthol in the list of characterizing flavors in 2009, it delegated to the FDA the responsibility to "move quickly to address the unique public health issues posed by menthol cigarettes," confirming that Congress was giving

the FDA the necessary tools and resources to address both cessation and illicit trade.<sup>163</sup> One of those tools is the Act's mandate that the FDA "shall promulgate regulations regarding the establishment and maintenance of records by any person who manufactures, processes, transports, distributes, receives, packages, holds, exports, or imports tobacco products," -commonly referred to as a "track and trace" program.<sup>164</sup> The Act further requires that the track and trace regulations provide for inspection in order to monitor the movement of tobacco products "to assist in investigating potential illicit trade, smuggling, or counterfeiting of tobacco products"<sup>165</sup>

In other words, the Act mandates the FDA issue regulations specifically relating to monitoring illicit trade and contraband to address the very concerns raised by the industry in their comments. Because the FDA has yet to issue those regulations, there is no "track and trace" program that can help combat any illicit market. This means that there is a prime opportunity to address any concerns relating to illicit trade by simply fulfilling the requirements of the Act. Therefore, rather than not adopting a product standard due to concerns relating to illicit trade, the FDA should simultaneously implement a track and trace program to address those concerns.

### 3. Tobacco Products that do not meet the requirements of the product standard

The final consideration outside of the public health standard is "other tobacco products that do not meet the requirements" of a standard.<sup>166</sup> In the case of a prohibition on menthol in cigarettes, the FDA will need to consider the potential impact that the continued sale of other flavored tobacco products may have on users switching to those products from menthol cigarettes. This is a particular concern with flavored cigars and flavored e-cigarettes. The FDA should also consider the possibility of so-called "flavor cards" showing up in the U.S. market. Should they appear, the agency can readily deal with these products.

#### i. Flavored Cigars

The FDA should consider the possibility that menthol smokers switch to flavored cigars rather than stop using tobacco products entirely. Of the types of cigars that menthol smokers may switch to, the most concerning is likely menthol-flavored little cigars. Little cigars are cigars in name only. They have no meaningful distinction from cigarettes and are marketed as cigars only because a small amount of tobacco is added to the paper wrapper. These products currently make up a very small segment of the tobacco product market and many current menthol smokers will likely be unfamiliar with them. However, one could imagine that some menthol smokers may seek these products out as a replacement for menthol cigarettes.

The FDA has already recognized this issue as a problem and initiated an enforcement process against four manufacturers of little cigars in 2016, concluding that their products actually met the definition of

cigarette, and thus were being illegally marketed in a variety of flavors.<sup>167</sup> However, for unknown reasons, at some point in the last four years, the agency abandoned enforcement efforts against manufacturers of little cigars.<sup>168</sup> If, in the course of the FDA's analysis of a potential product standard for menthol in cigarettes, the agency determines that the number of menthol smokers that will switch to menthol little cigars is significant enough to warrant action, the agency should simply continue pursuing the action that it started in 2016.

While it seems even less likely that menthol smokers would switch to other types of cigars because the products are shaped, packaged, and priced differently than cigarettes, there is also a possibility that some menthol smokers would switch to flavored cigarillos and larger cigars. For cigars that were first introduced to the market after February 15, 2007, the agency can use its enforcement discretion as a part of the premarket review process to remove these products from the market immediately. The FDA should also consider denying marketing applications for any flavored combustible tobacco product, given the unique harms that flavors pose.

Separate from action on menthol, closing the regulatory gaps for flavored cigars would have important health benefits and would reduce health disparities. The FDA should also consider pursuing a separate rule prohibiting all flavors in all tobacco products. The agency issued an Advance Notice of Proposed Rulemaking on this issue in 2018 and as a result, it already has much of the relevant data at the ready.<sup>169</sup> Such a rule should not be prioritized over a prohibition on menthol cigarettes but the FDA should initiate more comprehensive action on flavored products as well.

#### ii. Flavored E-cigarettes

The FDA should also consider the potential role that e-cigarettes may play in product switching as a result of a prohibition on menthol. The ultimate goal in prohibiting menthol should be to encourage as many menthol smokers as possible to quit smoking and cease using tobacco products altogether. While e-cigarettes may pose less of a health risk to an individual, they are far from harmless. The health benefits of a prohibition on menthol will be diminished if menthol smokers who may have otherwise quit, instead switch to flavored e-cigarettes.

The FDA has struggled with how to regulate flavors in e-cigarettes over the past four years.<sup>170</sup> In exercising enforcement discretion in the premarket review process, the FDA has targeted some flavors in only cartridge-based e-cigarettes. Against the advice of public health experts, the FDA has allowed all e-cigarette manufacturers to continue to manufacture and sell menthol-flavored e-cigarettes. One of the agency's justifications for exempting menthol was that menthol was still an available flavor in combustible cigarettes. The logic seems to flow that allowing e-cigarettes to be sold in a menthol flavor would provide a pathway for menthol cigarette users to theoretically switch to a potentially less harmful product. Setting aside the fact that the existing evidence does not support this assumption, a prohibition

on menthol in cigarettes breaks the chain of logic. When the FDA initiates a rulemaking to eliminate menthol, it should also close the regulatory gap that exists for menthol flavored e-cigarettes.

As is the case with cigars, the FDA should also take action to prohibit flavors in e-cigarettes. The agency's 2018 Advance Notice of Proposed Rulemaking provides a significant amount of information for the FDA to begin this process.<sup>171</sup> Again, such a rule should not be prioritized over a prohibition on menthol in cigarettes, but it is a logical, complementary action that the FDA should continue pursuing.

### iii. Flavor Cards

No doubt, the FDA is aware of the Canadian experience with menthol, discussed in more detail above. Thus, the FDA is certainly aware of the presence of so-called "flavor cards."<sup>172</sup> Their impact on the implementation of Canada's menthol prohibition has been studied and documented.<sup>173</sup> Should these products be introduced to the U.S. with the intention of being used to add flavor to cigarettes, they would be subject to the FDA's authority over tobacco products as they would be components or parts of tobacco products due to their ability to alter the characteristics of a tobacco product by adding a characterizing flavor.<sup>174</sup> Introduction of these products without marketing authorization from the FDA would make them adulterated and misbranded tobacco products, subject to immediate removal from the market. Of all the non-compliant products that could jeopardize the benefits of a prohibition on menthol, flavor cards represent perhaps the simplest for the FDA to address. Entirely removing the products from the market requires no change to the FDA's regulatory infrastructure.

## IV. Conclusion

More than a decade of inaction on menthol is a failure that can be measured in lives lost – especially African American lives. During the last twelve years, thousands of people have become daily smokers of menthol cigarettes; thousands of people have been unsuccessful in their attempts to quit smoking because of menthol cigarettes; thousands of people have become sick and died from using menthol cigarettes; and the tobacco industry has continued to wield menthol to target groups that are already disproportionately harmed by tobacco.

Since 2009, the FDA has had the authority to get menthol cigarettes off the market. Over the last twelve years, reports, studies, information collections, and public comments have shown again and again that removing menthol cigarettes from the marketplace will protect public health, the standard which governs the agency's actions. After all of this, the only appropriate FDA response to the citizen petition is to immediately initiate a rulemaking to prohibit menthol cigarettes.

The time for action is now.

Respectfully submitted,

Public Health Law Center  
Action on Smoking & Health  
African American Tobacco Control Leadership Council  
American Academy of Pediatrics  
American Cancer Society - Cancer Action Network  
American Heart Association  
American Lung Association  
American Medical Association  
American Public Health Association  
American Thoracic Society  
Americans for Nonsmokers' Rights  
Association of State and Territorial Health Officials  
Campaign for Tobacco-Free Kids  
Center for Black Health & Equity  
ClearWay Minnesota<sup>SM</sup>  
Legal Resource Center for Public Health Policy  
Massachusetts Association of Health Boards  
National LGBT Cancer Network  
National Medical Association  
Parents Against Vaping E-Cigarettes  
Public Health Advocacy Institute  
Truth Initiative  
Valerie Yerger, N.D.

cc: Mitchell Zeller, JD, Center Director, Center for Tobacco Products

## Endnotes

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- 2 African American Tobacco Control Leadership Council, American Academy of Pediatrics, American Association for Cancer Research, American Cancer Society – Cancer Action Network, American Heart Association, Truth Initiative (formerly known as The American Legacy Foundation), American Public Health Association, Americans for Nonsmokers’ Rights, Asian Pacific Partners for Empowerment, Advocacy and Leadership (APPEAL), Association for the Treatment of Tobacco Use and Dependence, Campaign for Tobacco-Free Kids, Corporate Accountability International, Center for Black Health and Equity (formerly known as NAATPN, Inc.), National Association of County and City Health Officials, National Latino Alliance for Health Equity, Society for Research on Nicotine and Tobacco, Summit Health Institute for Research and Education, Inc, and Valerie B. Yerger, N.D
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