

November 22, 2013

Division of Dockets Management  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Comment to FDA-2013-N-0521-0001 Advanced Notice of Proposed Rulemaking seeking comments on FDA's preliminary evaluation, and data, research, or other information that may inform regulatory actions FDA might take with respect to menthol in cigarettes.

Dear Sir or Madam,

Cigarette smoking continues to be a public health problem of staggering dimensions, killing more than 440,000 Americans each year and leaving millions more to suffer from chronic disease.<sup>1</sup> Strikingly, this death and disease, along with the associated economic costs, is preventable – leading the Centers for Disease Control and Prevention to characterize the reduction of tobacco use as a public health priority, or “Winnable Battle,”<sup>2</sup> meriting continued investment and innovative strategy by national, state, and local governments. Preventing youth from starting to smoke is a particularly important element of any approach to reduce tobacco use and tobacco-related disease and death, given that the vast majority of smokers start as youth and that the lifetime risk of many tobacco-related diseases is linked to the duration of smoking.<sup>3</sup>

With the passage of the Family Smoking Prevention and Tobacco Control Act in 2009, Congress took an important step toward the goal of preventing youth smoking by prohibiting candy-like additives as characterizing flavorings of cigarettes and cigarette smoke, recognizing that such flavorings are a tool for tobacco companies to attract and hook younger generations of smokers.<sup>4</sup> Congress also recognized the urgent importance of addressing the impact of menthol cigarettes on youth and other specific populations by requiring FDA's Tobacco Product Scientific Advisory Committee (TPSAC), as its first order of business following its creation, to study “the

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<sup>1</sup>U.S. DEP'T OF HEALTH & HUMAN SERVS., THE HEALTH CONSEQUENCES OF SMOKING: A REPORT OF THE SURGEON GENERAL, ch. 7 p. 858 (2004), available at <http://www.surgeongeneral.gov/library/reports/smokingconsequences/index.html> [hereinafter SGR 2004].

<sup>2</sup>Ctrs. for Disease Control & Prevention, *Winnable Battles, Tobacco Use*, <http://www.cdc.gov/WinnableBattles/Tobacco/index.html> (last visited Feb. 22, 2013).

<sup>3</sup>U.S. DEP'T OF HEALTH & HUMAN SERVS., PREVENTING YOUTH TOBACCO USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL ch. 3 p. 134 (2012), available at <http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/index.html> [hereinafter SGR 2012]; *id.* at ch.7 pp. 850-51, tbl. 7.1 (presenting data from the 2010 National Survey on Drug Use and Health, which indicated that 88.2% of 30- to 39-year-olds who had ever smoked daily first tried a cigarette before age 18 and 65% began smoking daily before age 18; 98.8% had first tried a cigarette and 98.6% began smoking daily before the age of 25).

<sup>4</sup>Tobacco Control Act, §907(a)(1)(A), 123 Stat. at 1799-1800 (codified at 21 U.S.C. § 387g(a)(1)(A)).

issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities.”<sup>5</sup> The statute further directed TPSAC to submit its report and recommendations on menthol within the first year of TPSAC’s operation.<sup>6</sup>

TPSAC members spent months reviewing scientific data and hearing testimony from researchers and advocates in an effort to amass a comprehensive body of evidence documenting the impact of menthol cigarettes on the public health. TPSAC’s review considered the arguments and evidence of the tobacco industry, whose representatives held three non-voting seats on TPSAC and submitted their own extensive comments to the committee.

The TPSAC Report was submitted to FDA in final form on July 21, 2011, more than two years ago. Based on a comprehensive review of the scientific evidence available as of that time, TPSAC reached two primary conclusions: (1) that menthol cigarettes have an *adverse impact on public health* in the United States; and (2) that menthol cigarettes offer *no public health benefits*, compared to non-menthol cigarettes.<sup>7</sup> Specifically, TPSAC concluded that the availability of menthol cigarettes *increases the likelihood of addiction and the degree of addiction in youth smokers*.<sup>8</sup> TPSAC quantified the impact on public health, estimating 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 the availability of menthol cigarettes.<sup>9</sup> It made the following “overall recommendation” to FDA in clear and certain terms: “*Removal of menthol cigarettes from the marketplace would benefit public health in the United States.*”<sup>10</sup>

The Act explicitly grants the FDA the authority to regulate menthol in cigarettes by adopting a product standard that is “appropriate for the protection of public health.”<sup>11</sup> Yet during the two years following the completion of the TPSAC Report, the FDA responded only by initiating a “thorough review” of the TPSAC Report.<sup>12</sup> Because it received an unequivocal recommendation from the committee of experts charged by Congress to examine menthol, the FDA must promulgate a rule to set a product standard that will remove menthol cigarettes from the marketplace. FDA action on the public health harm caused by menthol is now long overdue; the agency must take action to regulate menthol in tobacco products.

<sup>5</sup> Tobacco Control Act, §907(e)(1), 123 Stat. at 1804 (codified at 21 U.S.C. § 387g(e)).

<sup>6</sup> Tobacco Control Act, §907(a)(1)(A), 123 Stat. at 1799-1800 (codified at 21 U.S.C. § 387g(a)(1)(A)).

<sup>7</sup> TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMM., U.S. FOOD & DRUG ADMIN., MENTHOL CIGARETTES AND PUBLIC HEALTH: REVIEW OF THE SCIENTIFIC EVIDENCE AND RECOMMENDATIONS 220 (2011), *available at* <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf> (final as reviewed and approved by the TPSAC on July 21, 2011) [hereinafter TPSAC REPORT].

<sup>8</sup> *Id.* at 216. TPSAC also concluded that “the availability of menthol cigarettes results in a lower likelihood of smoking cessation success in African-Americans, compared to smoking non-menthol cigarettes.” *Id.* at ch. 8 p. 217.

<sup>9</sup> *Id.* at 221.

<sup>10</sup> *Id.* at 225.

<sup>11</sup> Tobacco Control Act, § 907(a)(1)(A), (a)(3)(A)-(B), 123 Stat. at 1799-1800 (codified at 21 U.S.C. 387g(a)(1)(A), (a)(3)(A)-(B)).

<sup>12</sup> U.S. FOOD & DRUG ADMIN., FREQUENTLY ASKED QUESTIONS: TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE’S REPORT AND RECOMMENDATION ON THE IMPACT OF THE USE OF MENTHOL IN CIGARETTES 2, *available at* <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM247652.pdf>.

As the evidence analyzed in the TPSAC Report and numerous other authorities have established, the science on this issue justifies immediate action to reduce the public health harm resulting from mentholated tobacco products. Although the manufacturers of menthol cigarettes have raised the specter of countervailing effects from a prohibition of menthol cigarettes, their arguments are unpersuasive and any such effects are trivial in comparison to the highly significant public health benefits that such a prohibition would produce.

On April 12, 2013, the Tobacco Control Legal Consortium led a group of nineteen prominent public health organizations in filing a Citizen Petition calling on the FDA to prohibit menthol as a characterizing flavor in cigarettes and cigarette smoke. Three months later, the FDA issued the Advanced Notice of Proposed Rulemaking (ANPRM) and requested additional information on menthol in tobacco products. This letter is submitted in response to the FDA's ANPRM request for information.

The Tobacco Control Legal Consortium respectfully requests that the FDA prohibit menthol as an additive at any level in all tobacco products. In light of the convincing evidence that menthol impacts key smoking behaviors in the entire population, there is no public health justification for refusing to act. The requested action is supported by the Consortium-led Citizen Petition, which is attached and fully incorporated by reference, and the additional information provided in this comment.<sup>13</sup>

## **A. Tobacco Product Standards**

### **1. Should the FDA consider establishing a tobacco product standard for menthol in menthol cigarettes? If so, what allowable level of menthol (e.g., maximum or minimum) would be appropriate for the protection of the public health?**

Under the broad public health standard established by the Tobacco Control Act, the scientific evidence fully justifies the FDA instituting a product standard for menthol in cigarettes.<sup>14</sup> Much of this evidence was discussed in the hundreds of public comments submitted to the Menthol Citizen Petition docket, which are enclosed and incorporated by reference for the FDA's consideration in the larger discussion about restricting menthol in tobacco products.<sup>15</sup>

The Tobacco Control Act mandates a public health standard of review that is entirely different from the "safe and effective" standard that the FDA has traditionally used to evaluate drugs and

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<sup>13</sup> See the Tobacco Control Legal Consortium's Citizen Petition Asking the U.S. Food & Drug Administration to Prohibit Menthol as a Characterizing Flavor in Cigarettes, Docket FDA-2013-P-0435-0001 (hereinafter "Menthol Petition").

<sup>14</sup> See the Menthol Petition, Docket FDA-2013-P-0435-0001.

<sup>15</sup> CTP Director Mitch Zeller has informed Consortium staff that the full content of Docket FDA-2013-P-0435-0001 cannot be formally combined with the ANPRM docket. The Consortium submitted a FOIA request on July 23, 2013, for all comments submitted on the petition docket and those comments that the FDA provided in response to the FOIA request are submitted on the enclosed compact disc. Those comments, and any submitted to that docket since that time, which the Consortium has been unable to obtain due to the fact that they are not posted online and can only be obtained through a FOIA request that must be submitted at least 60 days before the information is needed, are incorporated by reference into this comment.

medical devices, because tobacco products are inherently not “safe” or “safe and effective.”<sup>16</sup> Congress intended this new “public health standard” to be a “flexible standard that focuses on the overall goal of reducing the number of individuals who die or are harmed by tobacco products.”<sup>17</sup>

Opponents of a prohibition on menthol in cigarettes have argued that the FDA cannot implement such a prohibition unless it can prove via a showing of strict causation that smoking menthol cigarettes harms individual smokers more than smoking non-menthol cigarettes.<sup>18</sup> This argument ignores the nature of the public health standard as well as the standard of proof envisioned by Congress in the Tobacco Control Act. In order to implement a tobacco product standard, Congress directs the FDA to determine that this tobacco product standard is “appropriate for the protection of public health” and frames this requirement in terms of “risks and benefits to the population as a whole” and “increased or decreased likelihood” of tobacco product cessation or initiation.<sup>19</sup> An assessment of what is “appropriate for the public health,” as defined by the Tobacco Control Act, necessarily involves broader and different considerations, requiring: 1) consideration of the *likely* impact of a product standard on smoking initiation and cessation, analyzed in the context of the serious health effects of tobacco use, and 2) a weighing of the anticipated risks and benefits to the entire population, including nonusers of tobacco.<sup>20</sup>

Not only does the FDA have the authority to adopt tobacco product standards appropriate for the protection of public health, but also Congress explicitly made menthol a priority, directing the FDA to determine the effects of menthol on public health on an expedited basis. Specifically, the Act provides that “[i]mmediately upon the establishment” of TPSAC, “the Secretary shall refer to the Committee for report and recommendation, under section 917(c)(4), the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities.”<sup>21</sup> The Act further directs TPSAC to submit its menthol report and recommendations within the first year of TPSAC’s operations.<sup>22</sup> Finally, the Act reiterates FDA’s authority ultimately to establish a product standard on menthol by providing that “[n]othing in this subsection shall be construed to limit the Secretary’s authority to take action under this section or other sections of this Act applicable to menthol.”<sup>23</sup> Similar language making clear the FDA’s authority to issue a product standard on menthol appears in the provision of the Act under which Congress banned the use of characterizing flavors (other than menthol) in cigarettes.<sup>24</sup> Moreover, Congress plainly

<sup>16</sup> H.R. Rep. 111-58(i), at 39 (2009), *reprinted in* 2009 U.S.C.C.A.N. 468, 488.

<sup>17</sup> *Id.*

<sup>18</sup> NON-VOTING INDUSTRY REPRESENTATIVES ON TPSAC AND OTHER TOBACCO INDUSTRY STAKEHOLDERS, MENTHOL CIGARETTES: NO DISPROPORTIONATE IMPACT ON PUBLIC HEALTH: THE INDUSTRY MENTHOL REPORT 54, 68, 80, 247 (2011), *available at* <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM249320.pdf> [hereinafter INDUSTRY MENTHOL REPORT].

<sup>19</sup> Tobacco Control Act, §907(a)(3)(B)(i)(I)-(III), 123 Stat. at 1800 (codified at 21 U.S.C. § 387g(a)(3)(B)(i)(I)-(III)).

<sup>20</sup> Tobacco Control Act, § 907(a)(3), 123 Stat. at 1799 (codified at 21 U.S.C. 387g(a)(3)).

<sup>21</sup> Tobacco Control Act, § 907(e)(1), 123 Stat. at 1804 (codified at 21 U.S.C. § 387g(e)(1)).

<sup>22</sup> Tobacco Control Act, § 907(e)(2), 123 Stat. at 1804 (codified at 21 U.S.C. § 387g(e)(2)).

<sup>23</sup> Tobacco Control Act, § 907(e)(3), 123 Stat. at 1804 (codified at 21 U.S.C. § 387g(e)(3)).

<sup>24</sup> *See* Tobacco Control Act, §907(a)(1)(A), 123 Stat. at 1799 (codified at 21 U.S.C. § 387g(a)(1)(A)) (“[n]othing in this subparagraph shall be construed to limit the Secretary’s authority to take action under this section or other

recognized that the FDA’s decision to regulate menthol should be informed not only by the broad public health considerations required under the Tobacco Control Act, but also more specific concerns regarding the impact of menthol use on the health of children, African Americans, Hispanics, and other racial and ethnic minorities.<sup>25</sup>

The Tobacco Control Act’s public health standard requires the FDA to consider the likely effects of removing menthol from cigarettes on initiation and cessation, and on the health of the entire population. After reviewing the overwhelming evidence gathered by TPSAC and submitted to multiple public dockets, the FDA should determine that prohibiting menthol in cigarettes is both necessary and appropriate for the protection of public health and pass a product standard that prohibits menthol.

While the scientific evidence supports, at a minimum, prohibiting menthol as a characterizing flavor in cigarettes, a tobacco product standard prohibiting menthol at *any* level in tobacco products would be the most effective product standard to implement and enforce. Multiple considerations point to the greater effectiveness of a total prohibition of menthol as a cigarette additive. Despite the fact that cigarette manufacturers have been prohibited from adding non-menthol “characterizing flavors” since 2009, the FDA has yet to define the thresholds at which the addition of flavor additives reaches the level of “characterizing.”<sup>26</sup> This lack of definition is problematic for the prohibition on flavored cigarettes and would likely fail to effectively eliminate menthol cigarettes. Ninety percent of tobacco products contain menthol, including cigarettes that are not explicitly labeled or marketed as menthol-flavored.<sup>27</sup> If the FDA does not define—and enforce—a threshold level of menthol, the tobacco industry may very well simply stop labeling or marketing its menthol cigarettes as menthol-flavored without actually altering the level of menthol in these products; the industry already produces menthol-containing products that are not labeled as such, and has a long, documented history of circumventing regulation.<sup>28</sup>

For example, one year after the Tobacco Control Act passed with the provision prohibiting word descriptors such as “light,” “mild,” and “low” on cigarette packages, research showed that

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sections of this Act applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.”).

<sup>25</sup>See Tobacco Control Act, § 907(e)(1), 123 Stat. at 1804 (codified at 21 U.S.C. § 387g(e)(1)) (requiring that the Secretary refer to the Tobacco Products Scientific Advisory Committee “the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African Americans, Hispanics, and other racial and ethnic minorities.”).

<sup>26</sup>Any attempt to define “characterizing flavor” is conspicuously absent from the FDA Guidance notice, guidance document, and letters relating to enforcement of the Tobacco Control Act’s ban on cigarettes with characterizing flavors. See, e.g., Ctr. for Tobacco Products, U.S. Food & Drug Admin., Guidance for Industry and FDA Staff: General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2) (Dec. 23, 2009),

<http://www.fda.gov/downloads/TobaccoProducts/ProtectingKidsfromTobacco/FlavoredTobacco/UCM195420.pdf> ; Enforcement of General Tobacco Standard Special Rule for Cigarettes, 74 Fed. Reg. 48974 (Sept. 25, 2009); Letter to Industry on Cigarettes Containing Certain Characterizing Flavors from Dr. Lawrence Deyton, Director, Center for Tobacco Products, U.S. Food & Drug Admin. (Sept. 22, 2009), *available at*

<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm182186.htm>.

<sup>27</sup> See TPSAC REPORT, *supra* note 7, at 16.

<sup>28</sup> Tobacco Control Legal Consortium, *Racketeers at the Table* (2013),

<http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-synopsis-racketeers-table-2013.pdf>.

smokers could still easily identify their brands because of color-coding that tobacco companies added to “light” packs after the ban.<sup>29</sup> These findings indicated that the tobacco companies were able to use color coding to thwart the ban on misleading wording, and thereby continue to convey the deceptive message that lights are safer than regular cigarettes.<sup>30</sup> Color coding could just as easily be deployed to circumvent a prohibition on menthol in tobacco products.

However, what is clear from the science is that the FDA will encounter difficulty, and thus, delay, in determining a single threshold level of menthol, short of a total prohibition, below which public health is adequately protected. There is increasing evidence that the sensory properties of menthol are impacted by interactions with other cigarette additives, most notably nicotine—complicating the task of defining a standard for menthol that would address menthol’s impact on smoking initiation and cessation. Moreover, there are suggestions that even very low concentrations of menthol that are otherwise undetectable can reduce the harshness or sting associated with tobacco smoke, making cigarettes more attractive to young or novice smokers.<sup>31</sup> Given the clear and present public health threat posed by menthol in cigarettes,<sup>32</sup> swift and definitive action is required by the FDA—justifying a menthol product standard that eliminates all menthol from cigarettes. A total prohibition is a bright line that will enable prompt implementation and enforcement of a menthol product standard, as well as greater certainty for the regulated industry, while ensuring that a menthol product standard benefits public health.

**2. Rather than a tobacco product standard for menthol in menthol cigarettes, should FDA consider a tobacco product standard for any additive, constituent, artificial or natural flavor, or other ingredient that produces a characterizing flavor of menthol in the tobacco product or its smoke?**

To ensure that a tobacco product standard for menthol in cigarettes is meaningful and achieves the maximum public health benefit, we urge the FDA to prohibit all menthol analogs and menthol substitutes in addition to menthol.

**3. If a tobacco product standard for menthol in menthol cigarettes were to be established, should FDA consider issuing regulations to address menthol in other tobacco products besides cigarettes? If so, what other tobacco products with menthol should be regulated: All tobacco products, just all combusted tobacco products, or some other category or group of tobacco products? If not, what distinctions should be made between products?**

There is no reason to believe that menthol’s effects of increasing initiation of tobacco use and decreasing cessation are limited to cigarettes, particularly given 1) the evidence of menthol’s

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<sup>29</sup> Gregory N. Connolly & Hillel R. Alpert, *Has the Tobacco Industry Evaded the FDA’s Ban on ‘Light’ Cigarette Descriptor?*, TOBACCO CONTROL 1, 3-4 (Published Online First Mar. 13, 2013), doi:10.1136/tobaccocontrol-2012-050746.

<sup>30</sup> *Id.* at 4-5.

<sup>31</sup> See Menthol Petition, *supra* note 13, at Part III.2.A.i.a; see also Comments to Docket No. FDA-2013-P-0435; TPSAC REPORT, *supra* note 7, at 100-21, 148-50, 215-16.

<sup>32</sup> See generally Menthol Petition, *supra* note 13; see also Comments on Docket No. FDA-2013-P-0435; TPSAC REPORT, *supra* note 7, at 220, 225.

complex interactions with nicotine,<sup>33</sup> and 2) the fact that menthol has long been used for its anesthetic and cooling/soothing sensory properties in non-combusted products (e.g. cough drops). Moreover, there is evidence that use of non-cigarette tobacco products is substantially influenced by flavorings.<sup>34</sup>

Additionally, it is clear that menthol in other tobacco products needs to be addressed in order to ensure that the maximum public health benefits are gained from a product standard for cigarettes. Effectively, the FDA's failure to restrict menthol in other tobacco products, particularly cigars, would create a troublesome loophole. In light of the tobacco industry's established practice of exploiting distinctions between tobacco products to avoid regulations and taxes, concerns that the industry would exploit a failure to restrict menthol in non-cigarette tobacco products are not merely speculative. For example, in 2009, Congress passed an increase in the excise tax on small cigars, but not large cigars, in effort to address the issue of tobacco companies making cigarette-like small cigars to avoid the higher taxation of cigarettes.<sup>35</sup> There is evidence that manufacturers, in response, engineered their cigars to be slightly heavier in order to pass over the weight threshold into the large cigar category and be subject to a lower tax scheme.<sup>36</sup> Specifically, after the passage of the tax increase on small cigars, the cigar market dramatically shifted toward large cigars, with a 116% increase in the number of large cigars sold from 2008 to 2011, and a concomitant 85% decline in the number of small cigars sold.<sup>37</sup> Similarly, after the Tobacco Control Act prohibited cigarettes with characterizing flavorings, at least some flavored cigarettes reemerged as flavored cigars. For example, Djarum clove cigarettes transitioned to clove cigars, and Sweet Dreams flavored cigarettes, to Sweet Dreams flavored cigars.<sup>38</sup>

The concern that industry exploitation of minor distinctions between tobacco products will prevent realization of the maximum possible health benefit from a menthol product standard is heightened by the reality of high rates of flavored tobacco product use among young adult tobacco users, even after the 2009 ban on characterizing flavors (excepting menthol) in cigarettes. A study conducted in 2012 found that almost 20% of surveyed tobacco users age 18-34 reported current use of a flavored tobacco product, with the most commonly used flavored products including pipe tobacco (50%), little cigars/cigarillos/bidis (47%), and hooka/shisha (59%).<sup>39</sup>

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<sup>33</sup> See Menthol Petition, *supra* note 13, at Part III.2.A.ii.b; *see also* Comments on Docket No. FDA-2013-P-0435; TPSAC REPORT, *supra* note 7, at 19-27.

<sup>34</sup> See Tobacco Control Legal Consortium's Citizen Petition Asking the FDA to Assert Jurisdiction Over and Regulate All Tobacco Products, Docket No. FDA-2013-P-1127-0001, at Part II.2.A.ii.a (pp. 31-35) [hereinafter OTP Petition]; *see also* Comments to Docket No. FDA-2013-P-1127.

<sup>35</sup> UNITED STATES GOVERNMENT ACCOUNTABILITY OFFICE, TOBACCO TAXES: LARGE DISPARITIES IN RATES FOR SMOKING PRODUCTS TRIGGER SIGNIFICANT MARKET SHIFTS TO AVOID HIGHER TAXES, 19-20 (2012), *available at* <http://www.gao.gov/assets/600/590192.pdf> (hereafter GOVERNMENT ACCOUNTABILITY OFFICE).

<sup>36</sup> GOVERNMENT ACCOUNTABILITY OFFICE, *supra* note 35, at 20.

<sup>37</sup> GOVERNMENT ACCOUNTABILITY OFFICE, *supra* note 35, at 19-20.

<sup>38</sup> SGR 2012, *supra* note 3, at 205.

<sup>39</sup> Villanti, A. Richardson, D.M. Vallone, J.M. Rath, *Flavored Tobacco Product Use Among U.S. Young Adults*, 44(4) AM. J. PREV. MED. 388, 389 tbl. 1 (2013).

Given the evidence showing that flavored non-cigarette tobacco products are used by younger tobacco users, a menthol product standard should be applied to all tobacco products over which the FDA has jurisdiction, in order to ensure maximum public health benefit.

**4. If a product standard prohibiting or limiting menthol were to be established, what length of time should manufacturers be provided to achieve compliance with the standard? If a product standard prohibiting or limiting menthol were to be established, would a stepped approach in which the level of menthol was gradually reduced be appropriate for the protection of the public health?**

A stepped approach should not be taken. Immediate implementation is necessary to maximize cessation, reductions in youth uptake, and the related health impact.<sup>40</sup>

Moreover, a stepped approach is not necessary. The tobacco industry has been on notice for four years that a product standard prohibiting or limiting menthol in cigarettes is a real possibility. The 2009 Tobacco Control Act not only explicitly provided the FDA with the authority to regulate menthol in tobacco products,<sup>41</sup> but also mandated that the FDA, on an expedited basis, refer “the issue of the impact of the use of menthol in cigarettes on the public health” to TPSAC for “report and recommendation.”<sup>42</sup> TPSAC issued the required report in 2011, concluding that “[r]emoval of menthol cigarettes from the marketplace would benefit public health in the United States.”<sup>43</sup> There is no basis for the industry to argue that it has not had sufficient notice to prepare for a menthol product standard and would need more than three months to achieve compliance with the standard.<sup>44</sup>

The FDA has in the past successfully implemented manufacturing restrictions by setting a date after which no manufacturing of the prohibited product is permitted, and then providing the industry with 2-3 months in which to sell down its existing stock. For example, the Act’s prohibition on candy- and fruit- flavored cigarettes was successfully implemented within three months.<sup>45</sup> Given the industry’s familiarity with this procedure, there should be no barrier to a similar implementation scheme in the context of a menthol product standard.

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<sup>40</sup> See generally, Menthol Petition, *supra* note 13, as well as the comments submitted to that docket, for evidence of the health impact of menthol cigarettes.

<sup>41</sup> Tobacco Control Act, § 907(a)(1)(A), 123 Stat. 1776, 1799 (2009) (codified at 21 U.S.C. § 387g(a)(1)(A)).

<sup>42</sup> § 907(e)(1), 123 Stat. at 1804 (codified at 21 U.S.C. § 387g(e)(1)).

<sup>43</sup> TPSAC REPORT, *supra* note 7, at 225.

<sup>44</sup> Tobacco Control Act, § 907(d)(2) provides that there is a presumption that the implementation period for a tobacco product standard will be one year unless “the Secretary determines that an earlier effective date is necessary for the protection of the public health.” However, the Act itself provided a three- month implementation period for the statutory prohibition on candy and fruit flavored cigarettes. § 907(a)(1)(A). Because a regulation prohibiting menthol in tobacco products is necessary for the protection of public health and would be similar to the statutory flavor ban, a three month implementation period is appropriate.

<sup>45</sup> Tobacco Control Act, § 907(a)(1)(A) (requiring that the ban on non-menthol characterizing flavors in cigarettes be enforced “beginning 3 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act”).



- 5. If a product standard limiting menthol were to be established, are there alternatives that could be substituted by manufacturers to maintain the effect or appeal of menthol to menthol cigarette smokers and potential initiators? If so, what are these substitutes? Should they be regulated if menthol is regulated; and if so, how should they be regulated? If not, what distinctions should be made between menthol and potential substitutes?**

As stated above in response to A.2, to ensure that a tobacco product standard for menthol in cigarettes is meaningful and achieves the maximum public health benefit, we urge the FDA to prohibit all menthol analogs and menthol substitutes in addition to menthol.

## **B. Sale and Distribution Restrictions**

- 1. Should FDA consider establishing restrictions on the sale and/or distribution of menthol cigarettes? If so, what restrictions would be appropriate and what would be the impact on youth or adult smoking behavior, initiation, and cessation?**

The FDA has the authority to prohibit menthol in tobacco products, as well as the evidence necessary to support taking such action. Any action short of instituting a product standard prohibiting menthol would be contrary to the weight of the evidence and a failure to protect the public health.<sup>46</sup>

Moreover, restricting sales and/or distribution of menthol cigarettes without restricting the manufacture, and thus supply, of menthol cigarettes could facilitate illicit trade in menthol cigarettes. In fact, some commenters' concerns regarding the effect of a menthol product standard on an illicit market are premised on the misconception that a product standard would permit the continued manufacture of menthol cigarettes while prohibiting their sale.<sup>47</sup>

- 2. Should FDA consider establishing restrictions on the advertising and promotion of menthol cigarettes? If so, what restrictions would be appropriate and what would be the impact on youth or adult smoking behavior, initiation, and cessation?**

Not only should these products be prohibited, as discussed above, but also the advertising and promotion of them should be prohibited. The tobacco companies should not be allowed to advertise or promote products that cannot be manufactured or sold.

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<sup>46</sup> See generally the Menthol Citizen Petition, Docket No. FDA-2013-P-0435-0001; see also Comments on Docket No. FDA-2013-P-0435 and TPSAC Report.

<sup>47</sup> See generally the Comments to Docket No. FDA-2013-N-0521.

### C. Other Actions and Considerations

1. **Are there other tobacco product standards, regulatory, or other actions that FDA could implement that would more effectively reduce the harms caused by menthol cigarette smoking and better protect the public health than the tobacco product standards or regulatory actions discussed in the preceding questions?**

As stated in response to question B.1, above, no regulation would be as effective as a product standard that eliminates the use of menthol in tobacco products. To maximize the public health benefit of a prohibition on adding menthol to tobacco products, the FDA should exercise its authority to assert jurisdiction over all tobacco products.<sup>48</sup>

2. **To the extent that you have identified a tobacco product standard or other regulatory action in response to the prior questions, please provide additional information and comments on:**

- 2.1 **Is compliance with the tobacco product standard or other regulatory action you identified technically achievable?**

A total prohibition of menthol in tobacco products not only would be the best from a public health standpoint, but also would be the easiest to administer and enforce. If the FDA chose to prohibit menthol as a characterizing flavor, it would be possible but more difficult to identify the level of menthol additive that qualified as a “characterizing flavor.” This challenge exists in part due to the fact that Congress did not define the term “characterizing flavor” as applied to the candy and fruit flavored cigarettes prohibition found in the Act and the FDA has not provided any further clarity.

- 2.2 **How FDA would structure a corresponding rule to maximize compliance, facilitate enforcement, and otherwise maximize public health benefits?**

As discussed above, ninety percent of tobacco products contain menthol,<sup>49</sup> including many products that are not explicitly labeled or marketed as menthol flavored. If the FDA does not define—and enforce—a threshold level of menthol, the tobacco industry could very well simply stop labeling or marketing its menthol cigarettes as menthol flavored without actually altering the level of menthol in these products. For example, tobacco manufacturers could use color-coding to indicate menthol products, just as it has done to circumvent the prohibition on light, mild, and low-tar descriptors on cigarettes.<sup>50</sup> The industry already produces menthol-containing products that are not labeled as such, and has a long, documented history of circumventing regulation.<sup>51</sup>

However, what is clear from the science is that the FDA will encounter difficulty, and thus, delay, in determining a single threshold level of menthol, short of a total prohibition, below

<sup>48</sup> See generally, OTP Petition, *supra* note 34.

<sup>49</sup> TPSAC REPORT, *supra* note 7, at 16.

<sup>50</sup> See generally, Connolly & Alpert, *supra* note 29.

<sup>51</sup> See generally Tobacco Control Legal Consortium, *supra* note 28, for a summary of the Tobacco Industry’s documented efforts to circumvent or hijack the regulatory process.

which public health is adequately protected. There is increasing evidence that the sensory properties of menthol are impacted by interactions with other cigarette additives, most notably nicotine—complicating the task of defining a standard for menthol that would address menthol’s impact on smoking initiation and cessation. Moreover, there are suggestions that even very low concentrations of menthol that are otherwise undetectable can reduce the harshness or sting associated with tobacco smoke, making cigarettes more attractive to young or novice smokers.<sup>52</sup> Given the clear and present public health threat posed by menthol in cigarettes,<sup>53</sup> swift and definitive action is required by the FDA—justifying a menthol product standard that eliminates all menthol from cigarettes. A total prohibition is a bright line that will enable prompt implementation and enforcement of a menthol product standard, as well as greater certainty for the regulated industry, while ensuring that a menthol product standard benefits public health.

**3. If menthol cigarettes could no longer be legally sold, is there evidence that illicit trade in menthol cigarettes would become a significant problem? If so what would be the impact of any such illicit trade on public health? How would any such illicit trade compare to the existing illicit trade in cigarettes?**

The Consortium is not aware of any data from the United States or any other country on the specific issue of the impact of a total prohibition on the sale or manufacture of tobacco products with menthol on illicit trade. While the tobacco industry asserts that illicit trade in menthol cigarettes would become a substantial problem, the industry overstates the willingness of tobacco users to purchase illegal products and ignores the potential for recent legislation (e.g., the Prevent All Cigarette Trafficking Act) and strategic implementation of a menthol prohibition to mitigate expansion of illicit trade.<sup>54</sup>

Notably, the FDA has the authority to take specific actions that would reduce the potential for expansion of the contraband cigarette market. With the passage of the Tobacco Control Act in 2009, Congress called on the FDA to address illicit trade by implementing a track and trace program. Section 920(b) of the Act directs the FDA to propose regulations mandating that each tobacco product produced or sold in the United States bear a unique counterfeit-resistant identifying code that allows its origin to be identified, and links to a computer database of required records that permits the product to be tracked and traced. Tracking and tracing means the ability to track goods from the point of manufacture through each stage in the supply chain to the ultimate point of retail sale, and the capacity to trace back those goods to identify points along the chain where the goods changed hands. A track and trace system can help to ensure the integrity of the supply chain, deter smuggling or trafficking, and strengthen enforcement efforts to prevent illegal diversion. A track and trace system also provides a mechanism enabling the

<sup>52</sup> Menthol Petition, *supra* note 13, at Part III.2.A.i.a.

<sup>53</sup> See generally, the Menthol Petition, *supra* note 13; see also Comments on Docket No. FDA-2013-P-0435; TPSAC REPORT, *supra* note 7, at 220, 225.

<sup>54</sup> See the Menthol Petition, *supra* note 13, at Part III.2.B.ii, for a detailed discussion of 1) the opportunities the FDA and other health agencies have to minimize the likelihood and magnitude of a contraband market in menthol cigarettes, 2) the gross over-exaggerations of the tobacco industry regarding the likely extent of a menthol cigarette contraband market, and 3) the availability of enforcement mechanisms to minimize illicit trade in menthol cigarettes; see also M. Stoklosa and H. Ross, *Contrasting academic and tobacco industry estimates of illicit cigarette trade: evidence from Warsaw, Poland*, TOBACCO CONTROL (Published First Online, Aug. 13, 2013), doi:10.1136/tobaccocontrol-2013-051099.

FDA to implement and enforce regulations related to product standards, adulteration, misbranding, and other packaging requirements. Because, as mentioned above, the creation of a track and trace system is specifically called for by Section 920(b) of the Tobacco Control Act, any concerns about illicit trade should be addressed, at least in part, through the implementation of such a system. Further details about the FDA's authority and responsibility to implement a track and trace program to combat illicit trade is found in a Citizen Petition filed with the FDA on March 6, 2013 (FDA-2013-P-0285-0001) which is attached and incorporated by reference.

Moreover, a menthol product standard defeats the illicit trade claims made by the industry and opponents of any restriction on menthol in cigarettes. First, the current scope of illicit cigarette trade in the US is based in part on the ability of smugglers to take advantage of tax or regulatory differentials between the states. A federal product standard would ensure consistency among the states, eliminating a major motivation for interstate smuggling of menthol cigarettes. Moreover, part of the incentive for illegal operators is the low risk, facilitated in part by the fact that cigarettes are legal and "can be transported and sold on the open market."<sup>55</sup> Prohibiting the *manufacture* of menthol cigarettes—would mean that there is no legal supply chain for menthol cigarettes, prohibiting the open transport and marketing of menthol cigarettes and increasing the risks for illegal operators. This will have the effect of reducing the incentive for illegal trade in the context of menthol cigarettes and reducing the ability of cigarette smugglers to operate in the open--making the industry's dire warnings of "massive expansion" of an illicit market highly suspect.

**4. What additional information and research beyond that described in the evaluation is there on the potential impact of sale and distribution restrictions of menthol cigarettes on specific subpopulations, such as those based on racial, ethnic, socioeconomic status, and sexuality/gender identity?**

Please see the relevant evidence collected in the Menthol Citizen Petition (FDA-2013-P-0435-0001) and in all of the public comments submitted on that docket, which are incorporated by reference here

**5. To what extent are you aware of current (within the past 5 years) advertising and/or promotion of menthol cigarettes that have targeted specific communities, subpopulations, and locations, beyond that described in the evaluation?**

Please see the evidence collected in the Menthol Citizen Petition (FDA-2013-P-0435-0001) and in all of the public comments submitted on that docket, which are incorporated by reference here.

**6. Might any current advertising or other marketing or public statements concerning menthol cigarettes, or menthol in other tobacco products, constitute reduced risk claims?**

It may be true that the marketing of menthol tobacco products include reduced risk claims in violation of the Tobacco Control Act, but pursuing enforcement measures for marketing violations would simply nibble around the edge of the public health devastation of menthol

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<sup>55</sup> GOVERNMENT ACCOUNTABILITY OFFICE, *supra* note 35, at 14.

tobacco products. Prohibiting menthol in tobacco products would eliminate the need to address false advertising claims while also achieving a far more significant public health benefit.

Smoking remains the leading cause of preventable death in the United States, costing the United States billions in health costs and lost productivity each year. In this context, preventing young people from becoming regular, addicted smokers and increasing the likelihood of successful smoking cessation are key health goals that, in fact, are the focus of the Tobacco Control Act's public health standard and should be the goal of FDA regulation. Prohibiting menthol in cigarettes and other tobacco products is not only expressly within the regulatory authority granted to the FDA by the Tobacco Control Act, but also would make meaningful progress toward serving these critical goals by preventing the marketing and sale of a product that facilitates experimentation and progression to continued smoking and that poses greater barriers to successful smoking cessation. The importance of a prohibition on menthol is further highlighted by the high, growing prevalence of menthol cigarette use among youth and other populations, affecting the health of the population as a whole. In total, the benefits of a menthol prohibition would outweigh the purported challenges, justifying the prohibition of menthol in tobacco products under the broad, public health considerations required by the Tobacco Control Act.

Sincerely,



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Staff Attorney



Maggie Mahoney  
Deputy Director