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

RE: Docket No. FDA-2013-N-0521, Menthol ANPRM

The undersigned organizations submit these comments in response to the advance notice of proposed rulemaking (ANPRM) issued by the Food and Drug Administration (FDA) related to the potential regulation of menthol in cigarettes, 79 Fed. Reg. 44484 (July 24, 2013).

The undersigned organizations urge FDA to commence a rulemaking proceeding to propose, and ultimately to adopt, a product standard that will prohibit menthol as a characterizing flavor in cigarettes.¹ These comments explain why that action is strongly supported by the current scientific evidence and is “appropriate for the protection of public health” under

¹ Many of the undersigned organizations joined a Citizen Petition, filed by the Tobacco Control Legal Consortium, asking FDA to prohibit menthol as a characterizing flavor in cigarettes. See Tobacco Control Legal Consortium et al., *Citizen Petition to Food & Drug Admin. Prohibiting Menthol as a Characterizing Flavor in Cigarettes* (April 12, 2013).

§907(a)(3)(A) of the Food, Drug and Cosmetic Act (F,D&C Act), as amended by the Family Smoking Protection and Tobacco Control Act (Tobacco Control Act or TCA).

In publishing this ANPRM, FDA seeks comments on a number of specific questions related to the regulation of menthol in cigarettes. For the agency's convenience, we summarize our answers to the questions posed, adopting the numbering system in the ANPRM. We address some of the FDA's questions in greater detail in the body of our Comments.

SUMMARY ANSWERS TO FDA QUESTIONS

A. *Tobacco Product Standards*

1. *Should 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?*

For the reasons stated in the Report of the Tobacco Products Scientific Advisory Committee (TPSAC) and FDA's Preliminary Scientific Evaluation on the use of menthol as a characterizing flavor in cigarettes, and for the reasons stated in these comments, FDA should establish a product standard prohibiting the use of menthol as a characterizing flavor in cigarettes.

The use of menthol at a level below that of a characterizing flavor also raises important questions of public health. FDA should initiate a proceeding to evaluate the appropriateness of a product standard applicable to the use of menthol and other additives at a level below that of a characterizing flavor, but consideration of the use of menthol at such a level should not prevent FDA from acting promptly to issue a product standard prohibiting the use of menthol as a characterizing flavor in cigarettes. In order to ensure that no cigarette on the market has a characterizing flavor of menthol, FDA should consider setting the allowable level of menthol in a cigarette at the level no greater than the highest level of menthol in non-menthol cigarettes currently on the market.

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?*

Section 907(a)(1)(A) of the Food, Drug and Cosmetic Act, as amended by the Tobacco Control Act, already prohibits the use of any flavoring other than menthol itself (or tobacco) as a characterizing flavor in cigarettes. Any rule proposed by FDA should make it clear that the use of any constituent, additive or other substance that produces a characterizing flavor of menthol is also prohibited. All the same reasons that apply to the use of menthol apply equally to any constituent, additive or other substance that produces the characterizing flavor of 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?

Because characterizing flavors increase the likelihood of underage use, such flavors, including menthol, should be prohibited in all tobacco products. Although FDA should initiate a proceeding to consider such a prohibition, such a proceeding should not prevent FDA from acting promptly to issue a product standard prohibiting the use of menthol as a characterizing flavor in cigarettes, a standard which both TPSAC and the FDA's own peer-reviewed scientific evaluation have found would likely be appropriate for the public health.

The experience with the prohibition of characterizing flavors other than menthol in cigarettes provides a compelling reason as to why it will be so important for FDA to move forward with eliminating characterizing flavors in all tobacco products immediately after the agency prohibits the use of menthol as a characterizing flavor in cigarettes.

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?

The governing issue should not be what length of time manufacturers should be allowed to achieve compliance with the standard, but rather what time period is necessary to implement additional public education and cessation programs to assist menthol smokers to quit smoking. We do not believe a stepped approach is appropriate. The dangers to the public health posed by menthol cigarettes are not proportional to the amount of menthol in such cigarettes; indeed, the evidence demonstrates that mentholated cigarettes with lower levels of menthol are those that are most likely to increase smoking initiation.

Section 907(d)(2) of the Tobacco Control Act provides that no final product standard regulation may take effect less than one year after its publication. We believe that one year is sufficient time for FDA to implement the prohibition of menthol as a characterizing flavor in cigarettes and to simultaneously implement the public education and cessation programs needed to provide an adequate level of cessation services to menthol smokers.

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?

A product standard that is properly structured to include not only menthol as a characterizing flavor but also all other substances that produce the characterizing flavor of menthol should preclude alternatives that might dilute or nullify the effect of the product standard. FDA should also include a provision to prohibit the sale of menthol kits sold separately from cigarettes that are designed to permit the post-purchase "mentholization" of non-menthol cigarettes by consumers.

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?*

As noted above, FDA should prohibit the use of menthol as a characterizing flavor in cigarettes. Such an action would make unnecessary restrictions on the manner by which menthol cigarettes are sold. Restrictions on the sale and/or distribution of menthol cigarettes are not a sufficient substitute for a prohibition on menthol as a characterizing flavor.

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?*

It has been abundantly documented that menthol cigarettes have been advertised and marketed in a manner designed to increase the likelihood of youth initiation and progression to regular smoking. To reduce the prevalence of smoking, particularly among the young, FDA should prohibit the use of menthol as a characterizing flavor. Restrictions on the advertising and promotion of menthol cigarettes alone would not be a sufficient substitute for such a prohibition.

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?*

No tobacco product standard or other FDA action would be nearly as effective or appropriate for the protection of the public health against the adverse effect of menthol cigarettes as a product standard prohibiting the manufacture and sale of cigarettes with menthol as a characterizing flavor. As noted above, FDA should initiate a proceeding to evaluate the appropriateness of a product standard limiting the use of menthol at a level below that of a characterizing flavor, but evaluation of the use of menthol at such a level should not prevent FDA from acting promptly to issue a product standard prohibiting menthol as a characterizing flavor.

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: Is compliance with the tobacco product standard or other regulatory action you identified technically achievable? How FDA would structure a corresponding rule to maximize compliance, facilitate enforcement, and otherwise maximize public health benefits?*

Since cigarettes with menthol as a characterizing flavor are manufactured by adding menthol or other constituents to the product, compliance with the standard is easily achieved by no longer adding constituents to tobacco that are responsible for the characterizing flavor of menthol.

As discussed in more detail in the body of these Comments, two simultaneous actions should be taken in connection with a menthol product standard to maximize compliance, facilitate enforcement and otherwise maximize public health benefits:

- (1) The development of a coordinated strategy to provide support for former menthol smokers through public education and expanded availability of cessation services;
- (2) The commencement of a rulemaking proceeding to implement the statutory mandate of a comprehensive “track and trace” system to enhance the effectiveness of a menthol product standard and minimize any illicit trade in menthol cigarettes.

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 potential for illicit trade in menthol cigarettes in the event of a product standard prohibiting their manufacture and sale has been grossly exaggerated. Unlike counterfeit cigarettes and cigarettes smuggled from low-tax to high-tax jurisdictions, menthol cigarettes are readily identifiable. No widespread marketing of menthol cigarettes could occur unless such cigarettes were readily identifiable by their packaging and promotion as mentholated. Furthermore, even if such cigarettes could be sold, the use of menthol as a characterizing flavor would be readily apparent to anyone sampling them. Thus, identification of cigarettes sold in violation of such a prohibition would be far easier than identification of counterfeit or smuggled cigarettes which, by their nature, are designed to conceal rather than to disclose their true characteristics. Therefore, effective enforcement of a prohibition on mentholated cigarettes should be substantially easier than enforcement against counterfeit or smuggled cigarettes.

Concerns that illegal menthol cigarettes may not be readily identifiable by their packaging and product characteristics should be addressed by FDA’s implementation of its statutory mandate to adopt a “track and trace” system that would apply a unique, counterfeit-proof identifier to every pack of legal cigarettes and thus make illicit menthol cigarettes immediately identifiable as contraband. Several of the groups joining these Comments have filed a Citizen Petition with FDA calling for such a “track and trace” system.

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?*

See Resnick EA, et al., “Cigarette Pricing Differs by U.S. Neighborhoods – A BTG Research Brief (Dec. 2012) (finding that Newport cigarettes are significantly less expensive in neighborhoods with higher proportions of African Americans).

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?*

On August 21, 2013, Chicago Mayor Emanuel issued a press release noting that the City of Chicago Department of Business Affairs and Consumer Protection had issued a notice of violation to R.J. Reynolds for the alleged distribution of discount coupons for menthol tobacco products in the City of Chicago without the appropriate license.

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

The current advertising and marketing of such menthol products as Marlboro Smooth could be regarded as making a reduced risk claim. Sec. 911(b)(2)(A)(ii) of the Tobacco Control Act defines a “modified risk” product to include those marketed with the descriptors “light,” “mild,” or “low” “or similar descriptors.” The terms “smooth” or “cool” could be regarded as a descriptor similar to “mild”.

I. STATUTORY AND REGULATORY OVERVIEW

A. Statutory Treatment of Menthol

In enacting the Tobacco Control Act, Congress found that “tobacco products are inherently dangerous and cause cancer, heart disease, and other serious health effects,” and that nicotine, which is contained in all tobacco products, “is an addictive drug.”² Furthermore, Congress found that “tobacco use is the foremost preventable cause of premature death in America,” responsible for over 400,000 deaths each year and inflicting chronic and serious disease on an estimated 8,600,000 Americans annually.³

Congress recognized that successful efforts to reduce the toll of tobacco-related death and disease require comprehensive measures directed at curbing smoking by young people, calling the tobacco plague a “pediatric disease,”⁴ and finding that “virtually all new users of tobacco products are under the minimum legal age to purchase those products.”⁵ Congress understood that the fundamental problem posed by tobacco was that millions of young people were becoming addicted to a deadly product before they were of legal age. Past efforts, Congress found, “have failed adequately to curb tobacco use by adolescents” thus making necessary “comprehensive restrictions on the sale, promotion and distribution of such products.”⁶ The Tobacco Control Act was designed as a remedial measure to address a serious national problem by placing regulatory authority over tobacco products in the hands of the FDA. In describing its reasons for granting authority to regulate the content of tobacco products to the FDA, Congress found that “the Food and Drug Administration is a regulatory agency with the scientific expertise

² Food, Drug, and Cosmetic Act, 21 USC 387, as amended by the Family Smoking Prevention and Tobacco Control Act of 2009, 21 USC 387 note Findings(2)-(4).

³ 21 U.S.C. §387 note (Finding 13).

⁴ *Id.* (Finding 1)

⁵ *Id.* (Finding 4)

⁶ *Id.* (Finding 6)

to identify harmful substances in products to which consumers are exposed [and] to design standards to limit exposure to those substances.”⁷

As a key part of the TCA’s set of reforms directed at curbing youth smoking, Congress, in §907, prohibited the use of constituents or additives to impart any characterizing flavors in cigarettes, other than tobacco or menthol.⁸ Section 907 also recognized the urgency of addressing the impact of menthol cigarettes and plainly contemplated the possibility of action to add menthol to the list of prohibited flavorings through the issuance of a product standard. Congress required FDA’s Tobacco Product Scientific Advisory Committee (TPSAC), as its first order of business following its creation, to study “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.”⁹ It directed TPSAC to submit its report and recommendations on menthol within the first year of TPSAC’s operation.¹⁰

In §907, Congress twice included language specifically protecting FDA’s authority to issue a product standard regulating menthol in cigarettes. Following the language prohibiting certain specified flavorings in cigarettes, Congress provided that “[n]othing in this subparagraph shall be construed to limit the Secretary’s authority to take action under this section or any other sections of this Act applicable to menthol or any artificial or natural flavor, herb or spice not specified in this subparagraph.”¹¹ Similar language appears as a “Rule of Construction” in the subpart of §907 on “Menthol Cigarettes” directing TPSAC to study and issue a report on menthol: “Nothing 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.”¹² The TCA thus goes to great lengths to require FDA to immediately and expeditiously study the impact of menthol in cigarettes and to protect FDA’s prerogative to take appropriate regulatory action based on the best available science.

B. The Public Health Standard

In addition to mandating a product standard prohibiting certain characterizing flavors in cigarettes, §907 also gives FDA broad authority to adopt additional tobacco product standards upon a finding that such action “is appropriate for the protection of the public health.”¹³ In making such a finding, FDA is required to “consider scientific evidence concerning” –

- (1) The risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;
- (2) The increased or decreased likelihood that existing users of tobacco products will stop using such products; and

⁷ *Id.* (Finding 44)

⁸ 21 U.S.C. §387g(a)(1)(A).

⁹ 21 U.S.C. §387g(e)(1).

¹⁰ 21 U.S.C. §387g(e)(2).

¹¹ 21 U.S.C. §387g(a)(1)(A).

¹² 21 U.S.C. §387g(e)(3).

¹³ 21 U.S.C. §387g((a)(3)(A).

- (3) The increased or decreased likelihood that those who do not use tobacco products will start using such products.¹⁴

Thus, in considering a product standard on menthol in cigarettes, FDA is required to make a population-wide assessment of the impact of such a product standard, including not only its impact on those who currently smoke (including whether it may make it less difficult for them to stop smoking), but also its impact on those who do not smoke (including whether such a product standard may reduce initiation of smoking).

The scope of the scientific evidence FDA is directed to consider when evaluating a proposed product standard flows from the Congressional finding that “tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse effects.” Given this finding, a product standard for tobacco products is “appropriate for the public health” if FDA concludes that there is a likelihood that such a standard would reduce smoking initiation or increase smoking cessation because such outcomes would per se reduce the number of people exposed to such products.

By their nature, conclusions about such questions require predictive judgments about the effects of policy changes, including effects on consumer behavior. It is impossible to predict such effects with certainty. Such judgments differ in fundamental respects from conclusions about the causal relationships between smoking and disease. In determining the causal relationship between smoking and disease, scientists had a wealth of data derived both from animal experiments and from a century’s experience of the results of smoking by tens of millions of people.¹⁵ The existence of such data drawn from actual experience made it possible for scientists to conclude that tobacco smoking causes numerous fatal diseases and results in premature death for a large percentage of smokers.

By contrast, in evaluating a proposed product standard that is not yet in effect, FDA can never have the kind of evidence that demonstrates with scientific certainty the causal relationship between cigarette smoking and disease. This is true for at least two reasons. First, in evaluating the effects of prospective policies that have not yet been implemented there is no actual data to show the effects of such policies; evaluation of the likely consequences of adopting such policies is predictive of future events, not descriptive of past events. Second, for some proposed product standards (including a standard prohibiting menthol as a characterizing flavor in cigarettes) the evaluation predicts human behavior in response to policy considerations rather than solely describing the biological consequences of chemical exposure. It is not possible to predict human behavioral responses to the implementation of regulatory policies with the same level of certainty as it is to determine the biological effects of chemical exposure.

Because of these self-evident differences, in §907 Congress did not require a degree of scientific certainty in support of a product standard analogous to the degree of certainty establishing the causal connection between smoking and disease. Section 907 therefore speaks in terms of *likelihoods*, not certainties. It is of great significance that §907 requires FDA to

¹⁴ 21 U.S.C. §387g(a)(3)(B)(i).

¹⁵ U.S. Department of Health and Human Services (HHS). *The Health Consequences of Smoking: A Report of the Surgeon General*, 2004; U.S. Department of Health and Human Services (HHS). *A Report of the Surgeon General: How Tobacco Smoke Causes Disease- The Biology and Behavioral Basis for Smoking-Attributable Disease*, 2010.

assess “the increased or decreased *likelihood*” that existing users of tobacco products will cease their use and “the increased or decreased *likelihood*” that non-users will initiate use (emphasis added) if the product standard under consideration is adopted. A “likelihood” would exist, for example, if FDA concludes that it is more likely than not that adoption of such a standard would reduce the number of people initiating smoking or that it would increase the number of people who quit smoking. In the menthol context, therefore, the statute calls on FDA to make its best judgment, informed by the available science, as to the likely population-wide impact of a product standard prohibiting the use of menthol as a characterizing flavor in cigarettes. The TCA recognizes that scientific certainty is difficult to achieve and reflects the Congressional judgment that FDA should not be frozen into inaction by the existence of less than absolute certainty about the impact of a proposed action.

The degree to which Congress allowed FDA wide discretion to establish product standards despite the absence of scientific certainty is underscored by the language of §907(a)(3)(B)(ii):

ADDITIONAL CONSIDERATIONS.-- In the event that the Secretary makes a determination, set forth in a proposed tobacco product standard in a proposed rule, that it is appropriate for the protection of public health to require the reduction or elimination of an additive, constituent (including a smoke constituent) or other component of a tobacco product because the Secretary has found that the additive, constituent, or other component *is or may be harmful*, any party objecting to the proposed standard on the ground that the proposed standard will not reduce or eliminate the risk of illness or injury may provide for the secretary’s consideration scientific evidence that demonstrates that the proposed standard will not reduce or eliminate the risk of illness or injury.¹⁶

This language establishes that FDA may make a *prima facie* case for a proposed product standard requiring the reduction or elimination of a constituent based on the agency’s informed assessment that the constituent “may be harmful,” though parties opposing the proposed standard have the right to submit evidence that the proposal will not reduce the risk of disease. Thus, §907 allows FDA to impose a product standard eliminating a constituent (like menthol) based on the agency’s informed judgment about the population-wide *risk* of harm from the constituent. In the words of the House Committee on Energy and Commerce, “[t]he public health standard is intended 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.”¹⁷

In evaluating the scope of administrative discretion with respect to other statutory schemes authorizing administrative agencies to establish standards for hazardous substances, the Supreme Court has rejected arguments that an agency charged with evaluating scientific evidence needs to rely only on conclusions that can be proved with scientific certainty. *See e.g. Indus. Union Dept., AFL-CIO v. American Petroleum Institute*, 448 US 607 (1980) (agency was “not required to support its findings . . . with anything approaching scientific certainty.”).

¹⁶ 21 U.S.C. §387g(a)(3)(B)(ii) (emphasis added).

¹⁷ H.R. Rep. 111-58(i) at 39 (2009), *reprinted in* 2009 U.S.C.C.A.N. 468, 488.

That Congress intended FDA to have discretion to impose product standards without a requirement of scientific certainty is further confirmed by the judicial review section of the TCA. Section 912 expressly subjects regulations establishing product standards to the standard for judicial review under the Administrative Procedure Act, which empowers courts to set aside agency actions found to be “arbitrary, capricious, and abuse of discretion, or otherwise not in accordance with law.”¹⁸ In other analogous regulatory contexts, particularly involving environmental standards, the courts have interpreted this judicial review standard to allow agency action even in the face of scientific uncertainty.

The level of deference given to regulatory agencies to resolve scientific issues is illustrated, for example, in Clean Air Act cases in which courts review, under the “arbitrary and capricious” standard, Environmental Protection Agency determinations that certain pollutants may “reasonably be anticipated to endanger public health or welfare.” In such cases, courts “give an extreme degree of deference to the agency when it is evaluating scientific data within its technical expertise.”¹⁹ Given that the Clean Air Act is “precautionary in nature” and “designed to protect the public health,” “the existence of some uncertainty does not, without more, warrant invalidation of an endangerment finding.”²⁰ Even where EPA conceded the existence of “uncertainties” and there were conflicting studies about the effects of various pollutants, the agency’s judgment was upheld because it was able to offer a “reasonable explanation” for its reliance on certain studies rather than others.²¹ As the U.S. Court of Appeals for the District of Columbia Circuit has written:

We owe deference to the Administrator’s determination regarding the reliability of scientific evidence. [Citation omitted.] Although we must perform a “searching and careful” inquiry into the facts, we do not look at the decision as would a scientist, but “as a reviewing court exercising our narrowly defined duty of holding agencies to certain minimal standards of rationality.”²²

Accord, State of Mississippi v. Environmental Protection Agency, 723 F.2d 246, 258 (D.C. Cir. 2013) (“We do not reweigh the evidence or second-guess technical judgments but are limited to determining whether EPA made a rational judgment.”) *Lead Industries Ass’n v. Environmental Protection Agency*, 647 F.2d 1130, 1146-47 (D.C. Cir. 1980) (Under the “arbitrary and capricious” standard, “the reviewing court may not substitute its judgment for the agency’s and must affirm the agency’s decision if a rational basis for it is presented . . . [T]he function of judicial review is to ensure that agency decisions are ‘based on a consideration of the relevant factors . . .’” where “the Administrator often had to make decisions in the face of conflicting evidence.” [citations omitted]).

Therefore, the text of §907, and the well-understood meaning of the judicial review standard in §912, establish FDA’s authority to promulgate a product standard prohibiting

¹⁸ 21 U.S.C. §3871(a)(1)(A) and (b), *incorporating by reference* 5 U.S.C. §706(2)(A).

¹⁹ *Coalition for Responsible Regulation, Inc. v. Environmental Protection Agency*, 684 F.3d 102, 120 (D.C. Cir. 2012) (per curiam).

²⁰ *Id.* at 121.

²¹ *National Environmental Development Ass’n v. Environmental Protection Agency*, 686 F.2d 803, 812 (D.C. Cir. 2012).

²² *Id.* at 810 (quoting *Ethyl Corp. v. EPA*, 541 F.2d 1, 36-37 (D.C. Cir. 1976 (en banc))).

menthol (or any other additive) if a rational assessment of the science indicates that it is more likely than not that the product standard will reduce initiation or increase cessation. No greater level of scientific certainty is required.

C. The TPSAC Report and the FDA’s Preliminary Scientific Evaluation

As directed by Congress, TPSAC conducted an exhaustive review of the scientific evidence on the public health impact of menthol in cigarettes. It reviewed and considered multiple sources of evidence, including peer-reviewed literature, additional data and information commissioned by FDA at the request of TPSAC, tobacco company submissions, and public comments from a wide range of stakeholders. It submitted its report to FDA in its final form on July 21, 2011.²³

Based on its extensive review of the science, TPSAC reached two primary conclusions:

- “Menthol cigarettes have an adverse impact on public health in the United States.”
- “There are no public health benefits of menthol compared to non-menthol cigarettes.”²⁴

Although TPSAC did not find evidence that the addition of menthol in cigarettes itself increases the risk of disease for individual smokers, it did conclude “that the availability of menthol cigarettes has led to an increase in the number of smokers and that this increase does have [an] adverse public health impact in the United States.”²⁵ TPSAC found evidence that the availability of menthol increases initiation of smoking, noting its “particular concern” about “the high rate of menthol cigarette smoking among youth and the trend over the last decade of increasing menthol cigarette smoking among 12-17 year olds, even as smoking of non-menthol cigarettes declines.”²⁶ TPSAC also concluded that cessation of smoking “is less likely to be successful among smokers of menthol cigarettes.”²⁷ This combined impact of increased initiation and decreased cessation has yielded an “increase in the number of smokers” with a consequent impact on public health.²⁸ Indeed, the TPSAC report projected, using the best estimates, that “by 2020 about 17,000 premature deaths will occur and about 2.3 million people will have started smoking, beyond what would have occurred absent availability of menthol cigarettes.”²⁹ Based on these findings, TPSAC made the following “overall recommendation” to FDA: “Removal of menthol cigarettes from the marketplace would benefit the public health in the United States.”³⁰

Although the TPSAC Report will be discussed in more detail below, it is worth noting at this point that the evidentiary standard employed by TPSAC in reaching its conclusions is

²³ Tobacco Products Scientific Advisory Committee (TPSAC), U.S. Food and Drug Administration. *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations* (2011).

²⁴ *Id.* at 220.

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.* at 221.

²⁹ *Id.*

³⁰ *Id.* at 225.

entirely consistent with the emphasis on “likely” impacts and outcomes embedded in the TCA. On the specific factual issues addressed in the Report, TPSAC evaluated the “weight of the evidence,” employing the concept of “ equipoise” as describing the point at which the weight of the evidence for and against a given relationship are in balance, and then determining whether the evidence is sufficiently strong to conclude that an asserted factual relationship is “more likely than not,” i.e. “above equipoise.”³¹ By this methodology, TPSAC accounted for the possibility of conflicting evidence and scientific uncertainty and made its best informed scientific judgment as to the likelihood that a given relationship is factual, based on the weight of the available evidence. This methodology for regulatory science is consistent with that envisioned by §907 and the highly deferential standard of review in §912.

Following issuance of the TPSAC Report, FDA then did its own independent, peer-reviewed evaluation of the available science concerning menthol cigarettes.³² In this process, FDA evaluated the peer-reviewed literature, industry submissions and other materials provided to TPSAC, and performed or commissioned additional analyses. FDA’s *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes* reached the overall conclusion, consistent with TPSAC’s, that it is “likely that menthol cigarettes pose a public health risk above that seen with nonmenthol cigarettes.”³³

FDA’s factual conclusions in support of this assessment reinforce TPSAC’s factual conclusions. FDA found that while there is “little evidence” that menthol cigarettes themselves contribute to more disease risk to the user than non-menthol cigarettes, “adequate data suggest that menthol use is likely associated with increased smoking initiation by youth and young adults.”³⁴ FDA further found that “menthol in cigarettes is likely associated with greater addiction” and that “[m]enthol smokers show greater signs of nicotine dependence and are less likely to successfully quit smoking.”³⁵ According to FDA, “[t]hese findings, combined with the evidence indicating that menthol’s cooling and anesthetic properties can reduce the harshness of cigarette smoke and the evidence indicating that menthol cigarettes are marketed as a smoother alternative to nonmenthol cigarettes, make it likely that menthol cigarettes pose a public health risk above that seen with nonmenthol cigarettes.”³⁶

In reaching its conclusions, FDA also used a “weight of scientific evidence” approach, though not expressly employing TPSAC’s “equipoise” nomenclature. FDA’s Preliminary Evaluation sought to determine whether the weight of evidence supports an independent association between menthol in cigarettes and various outcomes and assessed how “likely” it is that such an association exists. This methodology is consistent with TPSAC’s and with the evidentiary standard for product standards embedded in the TCA.

³¹ *Id.* at 11. Where the weight of the evidence is less strong in favor of a relationship, TPSAC also posited three other classifications: (1) the evidence is sufficient to conclude that a relationship is at least as likely as not (equipoise); (2) the evidence is insufficient to conclude that a relationship is more likely than not (below equipoise); and (3) there is insufficient evidence to determine whether a relationship exists (below equipoise).

³² U.S. Food and Drug Administration. *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes* (2013).

³³ *Id.* at 6 (emphasis added).

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.* (emphasis added).

As the discussion below demonstrates, the weight of scientific evidence, as reflected in the TPSAC Report and FDA’s Preliminary Menthol Evaluation, strongly supports the conclusion that a product standard prohibiting menthol as a characterizing flavor in cigarettes would be appropriate for the protection of public health and should be issued by FDA.

II. OVERVIEW OF MENTHOL CIGARETTE USE IN THE UNITED STATES

As noted, when Congress, in the TCA, directed TPSAC to study the public health impact of menthol in cigarettes, it required TPSAC specifically to investigate “use among Children, African-Americans, Hispanics, and other racial and ethnic minorities.” By virtually any measure, it appears that menthol cigarettes are disproportionately consumed by youth and certain racial minorities.

According to the TPSAC Report, there are approximately 19.2 million menthol cigarette smokers in the U.S., between 28 percent and 34 percent of all U.S. cigarette smokers.³⁷ TPSAC also found that 1.1 million menthol smokers are adolescents aged 12 to 17.³⁸

Moreover, the younger the smoker, the more likely he/she is to smoke menthol cigarettes. As TPSAC observed, “a pattern of greater menthol smoking has been observed among youth and younger adults compared to older adult smokers in most populations of smokers.”³⁹ TPSAC cited data from the 2004-2008 National Survey on Drug Use and Health (NSDUH), showing that 44.7 percent of adolescent smokers ages 12-17 reported menthol use, compared to 36.1 percent of young adult smokers ages 18-25 and 30.2 percent of adult smokers 26 years old and older.⁴⁰ A more recent analysis of NSDUH data (2008-2010) shows menthol use among 56.7 percent of adolescent smokers, compared to 45 percent of young adult smokers and lower rates among adult smokers.⁴¹

Another analysis of the NSDUH data for 2004-2008 showed that younger adolescent smokers were more likely than older adolescent smokers to smoke menthol cigarettes. The percentages were: 48.6 percent for 12-13 year-olds, 46.3 percent for 14-15 year-olds, 43.9 percent for 16-17 year olds, and 36.3 percent for 18-25 year-olds.⁴² TPSAC also noted corroborating data on youth and young adult smokers from the 2003 National Youth Smoking Cessation Survey, finding that menthol cigarette use was highest among smokers ages 12-15 years (53.5 percent), followed by ages 16-17 years (47.0 percent), ages 18-21 (40.5 percent), and

³⁷ TPSAC, 2011 at 41.

³⁸ *Id.*

³⁹ *Id.* at 102.

⁴⁰ *Id.* (citing Rock, V.J. et al., “Menthol Cigarette Use Among Racial and Ethnic Groups in the United States, 2004-2008,” *Nicotine and Tobacco Research*, 12:S117-S124, 2010.)

⁴¹ Giovino GA, et al. “Differential trends in cigarette smoking in the USA: Is menthol slowing progress?” *Tobacco Control*, Published online first Aug 2013, at 3.

⁴² TPSAC, 2011, at 103. (citing Hersey, “Comparative Rates of Initiation of Menthol and Non-Menthol Cigarettes.” *Submission to the U.S. Food and Drug Administration’s Tobacco Products Scientific Advisory Committee* (February 10, 2011).

22-25 (34.6 percent).⁴³ TPSAC also found that, according to the NSDUH data, the percentage of adolescent smokers using menthol had increased among 12-17 year olds, from 43.4 percent of youth smokers in 2004 to 48.3 percent in 2008 – a statistically significant 11 percent increase over four years.⁴⁴ This increase in menthol cigarette use by young smokers occurred during a period when the incidence of youth smoking generally was in decline.⁴⁵

TPSAC also found significant racial disparities in menthol cigarette use, with the prevalence of menthol use “highest among African-Americans across all socio-demographic and smoking-related categories, whether stratified by income, age, gender, marital status, region, education, age of initiation, and length of time smoking.”⁴⁶ Data from the combined 2004-2008 NSDUH show that whereas menthol cigarettes are used by 23.8 percent of white smokers, they are used by 82.6 percent of African American smokers, 53.2 percent of Native Hawaiian or Pacific Islanders, 32.3 percent of Hispanics or Latinos and 31.2 percent of Asian Americans.⁴⁷ Based on this and other studies, FDA’s *Preliminary Evaluation* found that “a majority of African American smokers reported menthol cigarette use and other minority groups were more likely to smoke menthol cigarettes than White smokers.”⁴⁸

The combined NSDUH data for 2004-2008 also shows that among youth smokers, the prevalence of use of menthol was significantly higher for certain minority groups than for white smokers. Among smokers aged 12-17 years, approximately 71.9 percent of black- smokers used menthol cigarettes, followed by 51.5 percent of Asian Americans, 47 percent of Hispanics and 41 percent of whites.⁴⁹ TPSAC also cited data from the 2006 National Youth Tobacco Survey showing that 80.6 percent of African American middle school smokers and 84.8 percent of African American high school smokers regularly smoke menthol cigarettes.⁵⁰ The comparable prevalence rates for Hispanics were 57.9 percent for middle school and 56.4 percent for high school; for Asian Americans it was 57.4 percent for middle school and 43.6 percent for high school. For non-Hispanic whites, the incidence of youth menthol use was substantially lower: 43.1 percent for middle school and 37.6 percent for high school. Thus, the racial disparity in menthol cigarette use in the general population is reflected among young smokers as well.

III. THE SCIENTIFIC EVIDENCE SUPPORTS A PRODUCT STANDARD BARRING MENTHOL AS A CHARACTERIZING FLAVOR

A. Menthol as a Characterizing Flavor Leads to Initiation of Smoking, Particularly Among the Young

⁴³ *Id.* (citing Giovino, G.A., “Patterns and recent trends in the use of mentholated cigarettes in the United States.” *Submission to the U.S. Food and Drug Administration’s Tobacco Products Scientific Advisory Committee* (November 2010).)

⁴⁴ TPSAC, 2011, at 44.

⁴⁵ Rock, et al., *supra* at S117-18.

⁴⁶ TPSAC, 2011, at 41.

⁴⁷ Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (November 19, 2009). *The NSDUH Report: Use of Menthol Cigarettes*. Rockville, MD at 4.

⁴⁸ FDA *Preliminary Evaluation*, at 58.

⁴⁹ Rock, et al., *supra* at S119.

⁵⁰ TPSAC, 2011, at 42-43.

As noted above, it is now well-established that the younger the smoker, the more likely he/she is to use menthol cigarettes. As a recent analysis of NSDUH data observed, “. . . after controlling for confounders, younger age, even as young as 12-15 years old, was a significant correlate of menthol cigarette use. The relationship between age and menthol use was consistently observed across gender, household income, smoking days per month and in non-Hispanic Caucasians and Hispanics.”⁵¹ Given that nearly 90 percent of smokers try their first cigarette before age 19,⁵² the correlation between menthol use and age suggests that the availability of menthol cigarettes leads to greater initiation of smoking. About 80 percent of smokers who begin in high school will smoke into adulthood,⁵³ with resultant disease and premature death.

As TPSAC observed, “[r]egular cigarette smoking begins with experimentation, typically during adolescence.”⁵⁴ Internal tobacco industry documents reveal the industry’s understanding that initial youthful experimentation with smoking often involves the experience of an unpleasant harshness and that menthol in cigarettes helps to mitigate that harshness. It is well-established that menthol as a flavoring agent stimulates cold receptors, providing a sensation of coolness.⁵⁵ According to a 1986 RJ Reynolds memo about a possible new low-level menthol cigarette, “First-time smoker reaction is generally negative: --foreign taste:--harsh/bitter;--adoption requires slow acclimation. Initial negatives can be alleviated with a low level of menthol:--reduces harshness/bitterness;--takes edge off flavor”⁵⁶ In 1987, Brown & Williamson observed, “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.”⁵⁷ The industry also found that young smokers perceive menthol as having medicinal qualities that make menthol cigarettes less harmful:

Other industry studies found that young smokers chose menthol because they found it “relaxing” or “less harmful” or “moving away from the problem (of smoking a harmful product).” A British American Tobacco study from 1982 found that “smoking menthols functions as a guilt-reducing mechanism . . . it manages in some small measure to subtly disguise the sin.” They also reported that some smokers “ascribe(e) medicinal properties to the mentholation” and believe that “menthols are somehow less intrusive or even less harmful than regular cigarettes.”⁵⁸

Indeed, the industry has carefully manipulated menthol as an additive to ensure that menthol cigarettes are appealing to the beginning smoker. Cigarette manufacturers learned that,

⁵¹ Giovino, *supra* at 5-7.

⁵² SAMHSA, HHS, 2011 National Household Survey on Drug Use and Health (NSDUH). Calculations based on data available through Substance Abuse and Mental Health Data Archive (SAMHDA).

⁵³ U.S. Department of Health and Human Services (HHS), *Preventing Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General*, 2012 at 183.

⁵⁴ TPSAC, 2011, at 215.

⁵⁵ Hersey, JC, et al., “Are menthol cigarettes a starter product for youth?”, *Nicotine & Tobacco Research*, 8(3): 403-413, 2006, at 403.

⁵⁶ Klausner, K, “Menthol cigarettes and smoking initiation: a tobacco industry perspective,” *Tobacco Control* 20 (Supp. 2), ii12-ii19, 2011, at ii13.

⁵⁷ *Id.* at ii14.

⁵⁸ *Id.*

whereas a small amount of menthol will ameliorate just enough harshness and bitterness to enhance the appeal of smoking to the young beginner, too much menthol will be perceived as too strong. More established smokers will tend to prefer a stronger menthol presence. One study of menthol cigarettes and related industry documents concluded that “[f]or decades, tobacco manufacturers have controlled levels of menthol in commercial cigarettes to promote smoking among adolescents and young adults.”⁵⁹ The study reported:

For new or young smokers, the primary advantage of smoking a menthol cigarette is that the menthol masks the harshness and discomfort of inhaling smoke enough to allow delivery of an effective dose of nicotine. Menthol brands with the greatest market share growth among young adults had the lowest menthol levels (Newport and Marlboro Milds) among the brands we tested. Industry documents provided insight into this phenomenon, suggesting that among adolescents and young adults, lower menthol content reduced harshness, but higher menthol content was perceived as too strong.⁶⁰

According to an RJ Reynolds document, “All three major menthol brands (Salem, Kool, Newport) built their franchise with YAS (younger adult smokers) . . . using a low menthol product strategy.”⁶¹

TPSAC found that:

Menthol’s cooling and anesthetic properties reduce the harshness of cigarette smoke for new smokers. Menthol cigarettes produce sensory cues, such as a minty taste and odor, a cooling sensation and throat irritation or impact – all of which may provide strong cigarette-associated cues that reinforce smoking behavior. Thus, it is biologically plausible that menthol cigarettes lead to increased experimentation and higher risk for continued regular smoking among youth.⁶²

TPSAC’s judgment is borne out by studies showing that younger menthol smokers tend to be newer smokers. For example, one study using data from the National Youth Tobacco Survey showed that teens in middle school who had been smoking for less than one year were significantly more likely to smoke menthol cigarettes compared with middle school students who had been smoking for more than one year (62.4 percent vs. 53.3 percent).⁶³ Moreover, in NSDUH aggregated data from 2004–2008, among smokers who had been smoking less than one year, the proportion who smoked menthol cigarettes was greater than the proportion who smoked non-menthol cigarettes for both youth (49.2 percent vs. 43.8 percent) and young adult smokers (40.2 percent vs. 36.4 percent).⁶⁴

⁵⁹ Kreslake, JM, et al., “Tobacco Industry Control of Menthol in Cigarettes and Targeting of Adolescents and Young Adults,” *American Journal of Public Health*, 98(9): 1685-1692, 2008, at 1689.

⁶⁰ *Id.* at 1689.

⁶¹ *Id.* at 1686.

⁶² TPSAC, 2011, at 215-16.

⁶³ Hersey, JC, et al., *supra* at 407. A similar pattern was observed for high school students (45.9 percent vs. 41.9 percent), but the difference was smaller and not statistically significant.

⁶⁴ Rising, J. & Wasson-Blader, K., “Menthol and initiation of cigarette smoking,” *Tobacco Induced Diseases*, 9 (Supp. 1): 54, 2011. The authors cite this data as “providing further indications of greater use of menthol cigarettes among recent initiators,” noting however that “statistical significance was not reported.” at 2.

There also are data indicating that young menthol smokers are more likely to switch to non-menthol cigarettes over time than the other way around, again suggesting menthol's role as a starter product. Data from the National Youth Smoking Cessation Survey, a two-year longitudinal study of adolescent and young adult cigarette smokers aged 16-24, showed that of approximately 1,000 young smokers, 15 percent of baseline menthol smokers switched to non-menthol varieties after two years and 6.9 percent of baseline non-menthol smokers switched to menthol cigarettes after two years.⁶⁵

Another longitudinal study analyzing data from a 3-year cohort study of 12-17 year-olds found that initiating smoking with menthol was related significantly to both progression to established smoking and nicotine dependence.⁶⁶ The study found the results "consistent with a plausible biological mechanism by which the sensory properties of menthol reduce the harshness of tobacco smoke, making smoking more appealing to youth and potentially increasing the addictive potential of cigarettes."⁶⁷ It concluded that "initiating with menthol cigarettes puts youth at risk for becoming established smokers and becoming dependent as youth smokers."⁶⁸

TPSAC correctly found the evidence "sufficient to conclude that it is more likely than not there is a causal relationship between the availability of menthol cigarettes and regular smoking among youth."⁶⁹ The FDA's *Preliminary Evaluation* agrees: "From the available studies, the weight of the evidence supports the conclusion that menthol in cigarettes is likely associated with increased initiation and progression to regular cigarette smoking."⁷⁰

The impact of mentholated cigarettes on youth initiation has important effects on the nation's efforts to curb youth smoking. NSDUH data from 2004 to 2010 show that although adolescent smoking declined during that period, the rate of decline for menthol smoking was significantly less than the rate of decline for non-menthol smoking.⁷¹ Thus, whereas 5.3% of adolescents smoked mentholated cigarettes in 2004, compared to 4.5% in 2010, the decline among non-menthol smokers was from 6% in 2004 to 3.4% in 2010.⁷² A recent study based on this data noted "the prevalence of smoking non-mentholated cigarettes declining relatively more rapidly than that of mentholated cigarettes" and concluded that this trend "may have contributed to the slowing of the decline of adolescent smoking that has occurred since 2006."⁷³

The cigarette companies attempt to minimize the impact of menthol cigarettes on youth initiation by noting that the youth smoking rate has declined over the last decade, despite an increase in the market share of menthol. Lorillard asks: "[I]f menthol was playing a role in youth initiation and transitioning at a higher rate than non-menthol, would you expect to see such

⁶⁵ Giovino, G., "Patterns of and Recent Trends in the Use of Mentholated Cigarettes in the United States," Submitted to TPSAC, Nov. 9, 2010.

⁶⁶ Nonnemaker, et al., "Initiation with menthol cigarettes and youth smoking uptake," *Addiction* 108: 171-178, 2012, at 175.

⁶⁷ *Id.* 175.

⁶⁸ *Id.*

⁶⁹ TPSAC, 2011, at 219.

⁷⁰ FDA *Preliminary Evaluation*, at 5.

⁷¹ Giovino, 2013, *supra* at 4.

⁷² *Id.*

⁷³ *Id.* at 7.

a decline in the youth smoking rate while going along with the increased market share gains in menthol?”⁷⁴ The answer is simple. Since the rate of decline has been greater for non-menthol smokers than menthol smokers, were it not for the role of menthol, it is likely that the overall rate of decline in youth smoking would have been greater. Multiple factors may be affecting youth smoking rates. The weight of the evidence indicates that the availability of menthol cigarettes is one such factor, contributing to greater initiation to smoking (and thus higher youth smoking prevalence) than would be the case if menthol cigarettes were not available.

The industry also tries to sow doubt about the impact of menthol on youth initiation by noting that African-American youth start smoking later than white youth, and have a lower smoking rate than white youth, despite the popularity of menthol in the African-American population.⁷⁵ This argument, however, does not account for the possibility that there may be other social influence factors operating to delay the average age of smoking initiation for African-Americans⁷⁶ and that, were it not for the availability of menthol cigarettes, the average age of initiation for African-Americans would be even older because fewer African-American teens would initiate smoking. In any event, researchers have found that, although African-Americans, on average, adopt cigarettes more slowly during the teen years, they exhibit low cessation during their twenties, resulting in a convergence with white smoking rates by the mid-thirties.⁷⁷ As demonstrated *infra*, menthol cigarettes make cessation of smoking more difficult, particularly among African-Americans.

Thus, the industry’s arguments cast little doubt on the substantial evidence that menthol cigarettes lead to higher rates of smoking initiation among youth.

B. Menthol Leads to More Intensive Addiction, Making Cessation More Difficult, Particularly Among African-Americans and Other Minority Groups

1. Use of Menthol Cigarettes Leads to Increased Dependence in Both Youth and Adult Populations

The large majority of studies comparing tobacco dependence in menthol and non-menthol smokers conclude that there is an association between menthol and increased dependence in both youth and adults.

A commonly accepted measure of nicotine dependence is time-to-first-cigarette (“TTFC”).⁷⁸ Three 2012 studies that assessed nicotine dependence by assessing TTFC among adult smokers found that menthol smokers had a significantly shorter TTFC.⁷⁹ One of the three

⁷⁴ Bloomberg transcript of Lorillard Investor Day Management Discussion, June 27, 2013, at 16 (Statement of William R. True, Lorillard Senior VP of Research and Development).

⁷⁵ *Id.* at 15.

⁷⁶ Mermelstein, R., “Ethnicity, gender and risk factors for smoking initiation: an overview,” *Nicotine and Tobacco Research*, 1:S39-S43, 1999, at S40-S41.

⁷⁷ Pampel, FC, “Racial Convergence in Cigarette Use from Adolescence to the Mid-Thirties,” *Journal of Health and Social Behavior*, 49: 484-498, 2008, at 494.

⁷⁸ Baker TB, et al., “Time to first cigarette in the morning as an index of ability to quit smoking: implications for nicotine dependence,” *Nicotine Tob Res.* 9(Suppl 4):S555-570, 2007.

⁷⁹ Rosenbloom J, et al., “A cross-sectional study on tobacco use and dependence among women: Does menthol matter?” *Tobacco Induced Diseases* 10(1): 19, 2012; D’Silva J, et al., “Cessation outcomes among treatment-seeking

studies found a significantly shorter TTFC among African-American menthol smokers than in white menthol smokers.⁸⁰ A 2013 study that examined nicotine dependence among youth employed a more comprehensive scale of nicotine dependence that included TTFC and other measures. The study found that youth smokers who had initiated with menthol cigarettes had higher scores for nicotine dependence.⁸¹

These results are consistent with those of most prior studies, which have found an association between menthol use and increased dependence in both youth and adult populations. A 2010 study analyzing data from the 2006 National Youth Tobacco Survey, which used a multi-factor scale to measure dependence, found that youth menthol smokers had higher dependence scores than youth non-menthol smokers.⁸² Other studies using TTFC and similar measures of dependence have also found higher nicotine dependence among adolescent menthol smokers in comparison to adolescent non-menthol smokers.⁸³ Moreover, FDA's own analysis of Altria TES data showed "significantly higher nicotine dependence for menthol smokers using a number of different criteria."⁸⁴ The only generally accepted criterion for nicotine dependence on which studies do not show higher nicotine dependence for menthol smokers is the Fagerstrom scale ("FTND").⁸⁵

FDA reached the conclusion that "based on the findings of TTFC, non FTND scales of dependence, craving measures, and waking at night to smoke, the weight of the evidence supports the conclusion that menthol in cigarettes is likely associated with increased dependence."⁸⁶ FDA's conclusion is amply supported by the evidence.

2. Menthol in Cigarettes Makes Smoking Cessation More Difficult, Particularly Among African-Americans

Prominent among the matters the Tobacco Control Act directs FDA to consider in evaluating the appropriateness of a product standard are the likely effects of such a standard on quitting by existing smokers.⁸⁷ The large majority of studies comparing the success rate of quit attempts by menthol smokers to the success rate of non-menthol smokers demonstrates that menthol smokers are less likely to succeed in quitting. This disproportionate effect is most

menthol and nonmenthol smokers," *American Journal of Preventive Medicine*. 43(5 Suppl 3):S242-248, 2012; Muscat J., et al., "Menthol smoking in relation to time to first cigarette and cotinine: Results from a community-based study," *Regulatory Toxicology and Pharmacology*, 63: 166-170, 2012 at 166.

A 2010 study using data from the Tobacco Use Supplement to the Current Population Survey reached the same result. Fagan, *supra*, at note 8.

⁸⁰ Muscat J., et al., "Menthol smoking in relation to time to first cigarette and cotinine: Results from a community-based study," *Regulatory Toxicology and Pharmacology*, 63: 166-170, 2012 at 167.

⁸¹ Nonnemaker J, et al., "Initiation with menthol cigarettes and youth smoking uptake," *Addiction* 108(1):171-178, 2013.

⁸² Hersey JC, et al., "Menthol cigarettes contribute to the appeal and addiction potential of smoking for youth," *Nicotine & Tobacco Research*, 12 (Suppl 2):136-146, 2010, at S141.

⁸³ Collins CC, Moolchan ET, "Shorter time to first cigarette of the day in menthol adolescent cigarette smokers," *Addictive Behaviors*, 31(8):1460-1464, 2006, at 1463; Wackowski O, Delnevo CD. "Menthol cigarettes and indicators of tobacco dependence among adolescents," *Addictive behaviors*. Sep 2007;32(9):1964-1969 at 1965.

⁸⁴ *FDA Preliminary Evaluation*, at 111.

⁸⁵ *Id.* at 113.

⁸⁶ *Id.*

⁸⁷ Food, Drug, and Cosmetic Act as amended by the Family Smoking Prevention and Tobacco Control Act of 2009, §907(a)(3)(B)(II), 21 USC 387(g).

pronounced in studies of non-white populations, although other studies show a similar effect among white smokers. Interestingly, most studies show that although menthol smokers are more likely to intend to quit and make quit attempts, non-menthol smokers are more likely to succeed. This evidence is consistent with the finding that menthol smokers are more nicotine-dependent than non-menthol smokers.⁸⁸ It is appropriate to conclude from this evidence that prohibiting menthol in cigarettes is likely to increase quit rates and would therefore be appropriate for the protection of the public health.

These conclusions are supported by several studies using data from the Tobacco Use Supplement to the Current Population Survey (TUS CPS).⁸⁹ These studies are persuasive because they control for a large number of confounding effects and involve large populations. For example, one such study which controlled for age, education, gender, daily/nondaily smoking, first cigarette within 30 minutes of waking, current use of other tobacco products, and motivation to quit smoking, concluded that menthol use was associated with a lower rate of cessation (defined as non-smoking for at least six months) for nearly all ethnic groups.⁹⁰ Similar results were obtained in a large study of over 65,000 subjects by Levy, et al, who concluded that the rate of successful quitting for at least three months by menthol smokers was significantly lower than that of non-menthol smokers.⁹¹ The authors found that although menthol smokers had a higher likelihood of making a quit attempt, they were 4% less likely to have quit smoking in 2003 and 12% less likely in 2007.⁹² A third recent study also concluded that there was a significant association between menthol smoking and reduced cessation among a wide variety of racial and ethnic groups, with the largest effects observed in African-American and Puerto Rican smokers.⁹³ By contrast, a fourth study that did not show a significant association between menthol use and cessation is less persuasive because it failed to control for gender or ethnicity and measured cessation as two-week abstinence—a substantially shorter time period than used in the other three studies.⁹⁴

Three studies using a different data set—the 2005 National Health Interview Survey Cancer Control Supplement—also examined the association between menthol smoking and cessation. One study found that African-American menthol smokers were significantly less likely to have quit smoking.⁹⁵ Another study that combined Hispanic and African-American smokers into one group found that non-White menthol smokers were significantly less likely

⁸⁸ See Part III.B.1., *supra*.

⁸⁹ The TUS CPS is a large, continuous federally sponsored household survey of over 56,000 households per month.

⁹⁰ Trinidad DR, et al., “Menthol cigarettes and smoking cessation among racial/ethnic groups in the United States,” *Addiction* (105 Suppl) 1:84-94, 2010, at 92.

⁹¹ Levy DT, et al., “Quit attempts and quit rates among menthol and nonmenthol smokers in the United States,” *American Journal of Public Health*, 101(7):1241-1247, 2011.

⁹² *Id.*

⁹³ Delnevo CD, et al., “Smoking-cessation prevalence among U.S. smokers of menthol versus non-menthol cigarettes,” *American Journal of Preventive Medicine*, 41(4):357-365, 2011.

⁹⁴ Fagan P, et al., “Nicotine dependence and quitting behaviors among menthol and non-menthol smokers with similar consumptive patterns,” *Addiction*, 105 Suppl(1):55-74, 2010, at 55. This study did find, however, that menthol smokers were significantly more likely than non-menthol smokers to smoke their first cigarette within five minutes after waking, a generally accepted indicator of nicotine dependence.

⁹⁵ Stahre M, et al., “Racial/ethnic differences in menthol cigarette smoking, population quit ratios and utilization of evidence-based tobacco cessation treatments,” *Addiction*, 105 Suppl(1):75-83, 2010, at 82.

than non-White non-menthol smokers to be former smokers.⁹⁶ One study found no significant difference for white smokers except for an increased duration of cessation among white female menthol smokers compared to white female non-menthol smokers.⁹⁷

The overall weight of these studies supports the conclusion that there is an association between smoking menthol cigarettes and decreased likelihood of cessation and that the association is strongest among African-American and Hispanic smokers.

An examination of cohort and randomized controlled studies also supports the conclusion that menthol usage is associated with decreased cessation success. Two studies of exclusively African-American subjects concluded that there was an association between menthol usage and decreased likelihood of cessation.⁹⁸ A study of a racially diverse group of patients at a treatment clinic found that African-American and Latino menthol smokers had significantly lower odds of cessation at four weeks and six-month follow-up compared to African-American and Latino non-menthol smokers.⁹⁹ Another recent study found that among White smokers, menthol smokers had significantly lower odds of maintaining continuous abstinence than non-menthol users.¹⁰⁰ Still another study showed a statistically significant increase in the risk of relapse among menthol smokers compared to non-menthol smokers and a trend (not statistically significant) toward lower cessation rates for menthol smokers.¹⁰¹

Although a minority of studies did not find a statistically significant association between menthol usage and reduced likelihood of cessation, FDA properly found that the results of these studies were less reliable. FDA found that one such study (Hyland 2002) “may have over-adjusted its analysis” and that a second (Cropsey 2009) was of limited use because of the non-representative sample (prisoners). A third such study (Murray 2007) included a very limited number of African-American smokers. The fourth such study (Blot 2011) relied on a sample that was non-representative because of the age group of the sample.

In sum, the substantial weight of the scientific evidence supports the conclusion that menthol usage is associated with decreased success of cessation among adult smokers. Although

⁹⁶ Gundersen DA, et al., “Exploring the relationship between race/ethnicity, menthol smoking, and cessation, in a nationally representative sample of adults,” *Preventive Medicine*. 49(6):553-557, 2009.

⁹⁷ Cubbin C, et al., “The intersection of gender and race/ethnicity in smoking behaviors among menthol and non-menthol smokers in the United States,” *Addiction (Abingdon, England)*, 105 Suppl (1):32-38, 2010.

⁹⁸ Okuyemi KS, et al., “African-American menthol and nonmenthol smokers: differences in smoking and cessation experiences,” *Journal of the National Medical Association*. Sep 2004;96(9):1208-1211 at 1208; Harris KJ, et al., “Predictors of smoking cessation among African-Americans enrolled in a randomized controlled trial of bupropion,” *Preventive Medicine* 38(4): 498-502, 2004. In the Harris study the differential effect was not present when the results were adjusted for factors related to dependence. However, dependence is properly considered an intermediate variable affecting cessation success and thus the strength of the association may have been improperly diluted.

⁹⁹ Gandhi KK, et al., “Lower quit rates among African American and Latino menthol cigarette smokers at a tobacco treatment clinic,” *International Journal of Clinical Practice*, 63(3):360-367, 2009. The study found no comparable effect among whites.

¹⁰⁰ Reitzel LR, et al., “Race moderates the effect of menthol cigarette use on short-term smoking abstinence,” *Nicotine & Tobacco Research*, 15(5):883-889, 2013.

¹⁰¹ Pletcher MJ, et al., “Menthol cigarettes, smoking cessation, atherosclerosis, and pulmonary function: the Coronary Artery Risk Development in Young Adults (CARDIA) Study,” *Archives of internal Medicine*, 166(17):1915-1922, 2006.

this conclusion is strongest with respect to African-American and Hispanic smokers, the weight of the evidence supports the conclusion that it is also associated with decreased success of cessation among all ethnic groups. Accordingly, an analysis of the population-level evidence with regard to cessation supports the adoption of a product standard prohibiting the use of menthol as a characterizing flavor in cigarettes because such a product standard would increase cessation among those who already smoke. Examination of the evidence by FDA and TPSAC produced similar conclusions and, as FDA noted, no information that has become available subsequent to the FDA evaluation provides a reason to alter these conclusions.

All of the studies understate the likely effect of a prohibition on menthol on cessation because all of them were conducted in a situation in which menthol cigarettes remained available for purchase. For many smokers, non-menthol cigarettes will not be an acceptable substitute for menthol.¹⁰² Thus, a product standard prohibiting menthol cigarettes would itself provoke a substantial increase in quit attempts and, very likely, a substantial reduction in overall smoking prevalence.

IV. THE TOBACCO INDUSTRY’S TARGETED MARKETING TO YOUTH AND AFRICAN-AMERICANS HAS EXACERBATED THE ADVERSE IMPACT OF MENTHOL CIGARETTES ON PUBLIC HEALTH

A. Tobacco Industry Advertising and Promotion Has Exploited the Special Appeal of Menthol Cigarettes to Youth

As noted, internal tobacco industry documents demonstrate the industry’s long-time understanding that mentholated cigarettes have a particularly powerful appeal to youth because they tend to ameliorate the harshness of the initial smoking experience, thus leading to more established smoking among young people. Industry advertising and promotional activity reflect this industry understanding and demonstrate that the industry has long sought to target and exploit the youth market in marketing menthol cigarettes.

As a general proposition, the tobacco industry’s targeting of youth in its advertising and promotional activities is now well-established. As TPSAC noted, “there is an abundance of empirical studies to show that the tobacco industry does target its marketing efforts toward youth and young adults and that youth are strategically important for the customer base. As concluded by Pollay et al. (1996), ‘the battle of the brands for market share is waged largely among the young, for it is a brand’s success among the young that leads to greater brand sales and profit in the long term.’”¹⁰³ TPSAC also noted the conclusion of the National Cancer Institute that there is a “causal relationship between tobacco advertising and promotion and increased tobacco use, as manifested by increased smoking initiation and increased per capita tobacco consumption in

¹⁰² Tauras JA, et al., Menthol and non-menthol smoking: the impact of prices and smoke-free laws, *Addiction*, 105(Suppl.1): 115-123, 2010.

¹⁰³ TPSAC, 2011, at 69 (quoting Pollay RW, et al., “The last straw? Cigarette advertising and realized market shares among youth and adults, 1979-1993,” *Journal of Marketing*, 60:1-16, 1996).

the population.”¹⁰⁴ Adolescents have high receptivity to tobacco advertisements, which in turn is associated with enhanced appeal of smoking, smoking initiation, and smoking progression (an increase in smoking behavior) among youths.¹⁰⁵

The industry’s marketing of menthol cigarettes has been particularly youth-oriented. For example, Lorillard’s marketing of Newport, which has continued for many years to be the menthol brand with the largest market share, reflects the use of themes and images calculated to appeal to the young. Lorillard’s “Alive with Pleasure” ad campaign for Newport, begun in 1972, shows attractive young people vigorously engaged in youth-oriented activities like playing touch football.¹⁰⁶ As one study of menthol cigarette marketing put it, “[t]he visuals showed people having fun, often engaged in activities that would be more appropriate for a child of elementary school age than a teenager or an adult.”¹⁰⁷

By 1976, the success of the Newport campaign was noticed by competitor RJ Reynolds, which noted that Newport was putting “increased emphasis on both young female and young male publications” and that the “trend is toward younger readers . . .”¹⁰⁸ Reynolds also noted that the Newport brand’s advertising “talks directly to young people – situations, attitude.”¹⁰⁹ In 1982, Reynolds, which sells the competing mentholated Salem brand, responded to Newport’s increasing popularity by commencing its own youth-oriented “Salem Spirit” campaign, imitating Lorillard’s images of active young people.¹¹⁰ According to one review of tobacco industry documents, “[t]hrough the 1990s, Lorillard continued its image-based marketing, attributing its success to its ‘peer acceptance’ and noting that ‘Newport smokers perceive other Newport smokers as they do themselves – younger, outgoing, active, happy, warm, friendly, modern, extroverted.”¹¹¹

The advertising of menthol cigarettes also has included implicit suggestions that menthol is a “healthier” alternative, using phrases like “cool and clean,” “fresh,” or “refreshing” designed to appeal to the new smoker reacting to the harshness of smoking.¹¹² Based on a survey of industry documents, one study found that “[t]he industry also understood that some youths smoke menthols because they perceived them to be less harmful than non-menthol cigarettes, an idea the industry encouraged through its advertising.”¹¹³

¹⁰⁴ TPSAC, 2011, at 69 (quoting National Cancer Institute, The role of the media in promoting and reducing tobacco use, Monograph No. 19, U.S. Dept. of Health and Human Services, National Institutes of Health, National Cancer Institute. NIH Publication No. 07-6242, 2008).

¹⁰⁵ Rising, J., Alexander, L., “Marketing of menthol cigarettes and consumer perceptions,” *Tobacco Induced Diseases*, 9(Supp. 1): 52, 2011.

¹⁰⁶ Klausner, *supra* at ii16.

¹⁰⁷ Sutton, CD, Robinson, RG, “The marketing of menthol cigarettes in the United States: Populations, messages and channels,” *Nicotine and Tobacco Research*, 6: S83-S91, 2004.

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ *Id.* at ii17.

¹¹² Anderson SJ, “Marketing of menthol cigarettes and consumer perceptions: a review of tobacco industry documents,” *Tobacco Control* 20(Suppl 2): ii20-ii28, 2011; Sutton & Robinson, *supra* at S86.

¹¹³ Klausner, *supra* at ii17.

Due to the advertising restrictions in the Master Settlement Agreement, the nature of industry advertising and promotion may have changed, but the targeting of youth has not, as demonstrated by research on industry point-of-sale marketing. A Minnesota study of 2007 data showed that for every 10% increase in the percentage of youth (under the age of 18) in a census block group, the number of menthol advertisements increased by 12%.¹¹⁴ California data for 2006 showed that for every 10 percentage point increase in the proportion of neighborhood residents aged 10-17 years, there was an 11.6 percentage point increase in the share of menthol cigarette advertising and the odds of a Newport promotion were 5.3 times greater.¹¹⁵

The adverse public health consequences of point-of-sale marketing of menthol cigarettes are suggested by a recent study of cigarette brand recognition and smoking initiation in an urban California school district.¹¹⁶ Of the three brands studied – Camel, Marlboro and Newport – only recognition of the Newport brand predicted a higher likelihood of smoking initiation, adjusting for other risk factors, such as the presence of a smoker at home and exposure to peers who smoke.¹¹⁷ The study found that the “odds of smoking initiation increased by 49% for students who recognized the Newport brand at baseline.”¹¹⁸ It concluded that “[r]egardless of race, recognition of Newport predicted smoking initiation, which is consistent with other suggestions that menthol advertising encourages youth smoking.”¹¹⁹

Based on its review of “youthful imagery in menthol marketing and the studies of industry documents,” TPSAC correctly concluded that “the industry developed menthol marketing to appeal to youth,” a strategy “particularly true of the Newport brand, but also adopted by other tobacco companies.”¹²⁰ TPSAC further found:

Marketing messages positioned menthol cigarettes as an attractive starter product for new smokers who are unaccustomed to intense tobacco taste and/or high levels of menthol. Empirical studies provide further evidence of targeting: youth pay attention to and are attracted to menthol cigarette advertising.¹²¹

Therefore, there is little doubt that the marketing of menthol cigarettes has targeted young people and reinforced the special appeal of menthol to younger smokers.

¹¹⁴ Widome R, et al., “The relationship of neighborhood demographic characteristics to point-of-sale tobacco advertising and marketing,” *Ethnic Health*, 18(2): 136-151, 2013, at 8.

¹¹⁵ Henriksen L, et al., “Targeted advertising, promotion, and price for menthol cigarettes in California high school neighborhoods,” *Nicotine & Tobacco Research*, 14(1): 116-121, 2012, at 118.

¹¹⁶ Dauphinee, AL, “Racial differences in cigarette brand recognition and impact on youth smoking,” *BMC Public Health*, 13:170, 2013.

¹¹⁷ *Id.* at 5.

¹¹⁸ *Id.*

¹¹⁹ *Id.* at 6.

¹²⁰ TPSAC, 2011, at 71.

¹²¹ *Id.*

B. Menthol Cigarettes are Disproportionately Marketed, Advertised and Promoted in African-American Communities

Both the TPSAC and FDA Reports adduced a large amount of evidence demonstrating that menthol cigarettes have been disproportionately marketed, advertised and promoted in African-American communities for many years. This pattern continues to the present day. Given the disproportionate marketing of menthol cigarettes to these communities, the much higher prevalence of menthol smoking among African-American smokers, both youth and adults, is hardly surprising.

Companies promoting menthol brands employ a comprehensive marketing strategy to promote such brands disproportionately in African-American neighborhoods and in media outlets likely to reach heavily African-American readers or viewers. Intense competition among the major tobacco companies for menthol sales in the African-American community led to extensive marketing efforts specifically targeting that community.¹²² Tobacco companies have employed marketing consultants with particular expertise in the African-American community to develop and implement targeted strategies for the promotion of their menthol brands in that community.¹²³ A wide variety of strategies has been adopted, including extensive free sampling, heavy advertising in targeted print media, extensive point of sale advertising and promotion, attempts to associate brands with popular images, company sponsorship of events and attempts to associate brands with community aspirations, and targeted price discounting. These conclusions have been documented in numerous studies over a long period of time.¹²⁴

¹²² Yerger VB, et al., “Racialized geography, corporate activity, and health disparities: tobacco industry targeting of inner cities,” *Journal of health care for the poor and underserved*. Nov2007;18(4 Suppl):10-38 at 26-28.

¹²³ *Id.*

¹²⁴ Cummings KM, et al., Cigarette advertising and black-white differences in brand preference. *Public health reports*, Nov-Dec 1987;102(6):698-701 at 700 (finding that magazines directed to black readers include a much greater proportion of ads for menthol cigarettes); Laws, MB, et al., “Tobacco availability and point of sale marketing in demographically contrasting districts of Massachusetts,” *Tobacco Control* 11:71-73, 2002 (“mentholated brands were marketed most heavily in the predominantly African American neighborhood”; Sutton CD & Robinson RG. The marketing of menthol cigarettes in the United States: populations, messages, and channels. *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco*. Feb 2004;6 Suppl 1:S83-91 (“the tobacco industry has performed its most blatant targeting for menthol cigarettes over the years in Black communities, with billboards located throughout urban communities, financial support of Black organizations, segmented advertising in various media, and flashy productions of so-called “black” cigarettes”); Landrine H, et al., “Cigarette advertising in Black, Latino, and White magazines, 1998-2002: an exploratory investigation,” *Ethnicity & disease*. Winter 2005;15(1):63-67; White VM, et al., “Cigarette promotional offers: who takes advantage?” *American journal of preventive medicine*. Mar 2006;30(3):225-231 (finding that African Americans who smoked menthol brands were particularly likely to use promotional offers compared to African-American smokers of other brands); Glanz K, et al., “Operation storefront Hawaii: tobacco advertising and promotion in Hawaii stores,” *J Health Commun*. Oct-Nov 2006;11(7):699-707 (“there is evidence that youth of color are being targeted by cigarette advertising and promotions, particularly from the makers of menthol brand cigarettes”); Boley-Cruz T, et al., “The Menthol Marketing Mix: Targeted Promotions For Focus Communities in the United States,” *Nicotine & Tobacco Research*, Volume 12, Supplement 2 (December 2010) S147–S153 at S151 (“menthol, as flavoring, is the lynchpin in a tightly integrated series of campaigns aimed at the urban poor, especially Blacks who suffer disproportionately high rates of tobacco-related diseases”); Allen B, Jr., et al., “Development and validation of a scale to assess attitudes and beliefs about menthol cigarettes among african american smokers,” *Evaluation & the health professions*. Dec 2010;33(4):414-436 at 417 (“Historically, tobacco companies created an association between African-American identity and menthol smoking and used this association to market menthol cigarettes to African-Americans”).

Moreover, this strategy is well documented in publicly available industry documents.¹²⁵ Two results of these efforts are the greatly disproportionate market share of menthol cigarettes in the African-American market and the emergence of Lorillard's Newport brand as the dominant brand in that market.

Recent research demonstrates that lower-income, minority communities continue to be bombarded with tobacco advertising. A 2010 study in the *American Journal of Health Promotion* compared characteristics of storefront tobacco advertisements in a low-income, minority community and a high-income, nonminority community. It found that the low-income, minority community had more tobacco retailers and advertisements were more likely to be larger and promote menthol products.¹²⁶ A 2012 study documented the targeting of African-American communities with extensive advertising and price promotions for menthol cigarettes.¹²⁷ The study examined neighborhoods with high schools in California and found that as the proportion of African-American high school students rose by ten percent, the proportion of advertising for menthol cigarettes increased by 5.9 percentage points, the odds of a Newport promotion were 50 percent higher and the cost of Newport cigarettes was 12 cents lower. The Minnesota study cited earlier also showed that census block groups with higher proportions of African-Americans were more likely to have more tobacco ads and more ads for menthol tobacco products.¹²⁸ A 2013 study conducted in California concludes that advertising for menthol brands is disproportionately concentrated in communities with a greater portion of African-Americans.¹²⁹

Moreover, recent surveys conducted by the American Legacy Foundation demonstrate that the retail price of menthol cigarettes is disproportionately discounted in proportion to the percentage of the African-American population in the neighborhood and that point-of sale advertising for menthol brands is disproportionately higher in these neighborhoods.¹³⁰

The dominance of menthol cigarettes—and the Newport brand—in African-American communities is no accident. It is the result of a strategic policy carefully planned and consistently implemented for many years. That policy is to target advertising, promotion and price discounting of these products to African-Americans.

¹²⁵ Sutton CD & Robinson RG. The marketing of menthol cigarettes in the United States: populations, messages, and channels. *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco*. Feb 2004;6 Suppl 1:S83-91; Johnson DM et al., "Designing a tobacco counter-marketing campaign for African American youth," *Tobacco Induced Diseases* August, 2008; Boley-Cruz T, et al., "The Menthol Marketing Mix: Targeted Promotions For Focus Communities in the United States," *Nicotine & Tobacco Research*, Volume 12, Supplement 2 (December 2010) S147–S153; Klausner, K, "Menthol cigarettes and smoking initiation: a tobacco industry perspective," *Tobacco Control* 20 (Supp. 2), ii12-ii19, 2011; Yerger VB, et al., "Racialized geography, corporate activity, and health disparities: tobacco industry targeting of inner cities. *Journal of health care for the poor and underserved*," Nov 2007;18(4 Suppl):10-38.

¹²⁶ Seidenberg, AB, "Cigarette Advertising Differs by Community Demographic Profile," *American Journal of Health Promotion*, 24(6):e26-e31, 2010.

¹²⁷ Henriksen L. et al., "Targeted advertising, promotion, and price for menthol cigarettes in California high school neighborhoods," *Nicotine & Tobacco Research*, 14(1): 116-121, 2012, at 116.

¹²⁸ Widome R, et al., "The relationship of neighborhood demographic characteristics to point-of-sale tobacco advertising and marketing," *Ethnic Health*, 18(2): 136-151, 2013 at 8.

¹²⁹ Dauphinee AL, et al., "Racial differences in cigarette brand recognition and impact on youth smoking," *BMC Public Health*, 13:170, 2013.

¹³⁰ Legacy comments filed in Docket No FDA-2013-N-0521 (Menthol ANPRM).

V. A PRODUCT STANDARD PROHIBITING MENTHOL AS A CHARACTERIZING FLAVOR WOULD SIGNIFICANTLY REDUCE THE PREVALENCE OF SMOKING AND SAVE HUNDREDS OF THOUSANDS OF LIVES

The prior two sections have demonstrated that the availability of menthol cigarettes has (1) increased the level of smoking initiation and (2) decreased the level of cessation. It follows that the elimination of menthol cigarettes would reduce the level of initiation and increase the level of cessation. In addition to these long-term effects, it is likely that a substantial number of current menthol smokers would quit smoking in response to a prohibition on menthol cigarettes rather than switch to non-menthol cigarettes.

Two recent studies have examined the likelihood that existing menthol smokers would quit smoking as a result of a prohibition on menthol cigarettes. A 2010 study by Tauras, et al., used the 2003 and 2006/7 Tobacco Use Supplements to the Current Population Survey to examine the question of whether smokers find menthol and non-menthol cigarettes to be close substitutes for each other and therefore whether, in the event of a prohibition on menthol cigarettes, menthol smokers would switch to non-menthol cigarettes.¹³¹ They examined the response of menthol and non-menthol smokers to price changes and smoke-free laws. The examination of price data indicated that non-menthol cigarettes are not a close substitute for menthol cigarettes; i.e., very few menthol smokers responded to price changes of non-menthol cigarettes relative to menthol cigarettes by switching to non-menthol. This pattern was particularly evident among younger smokers and African American smokers. The results of this study indicate that in the event of a prohibition on menthol cigarettes, a large number of current menthol smokers would likely quit smoking rather than switch to non-menthol cigarettes.

O'Connor, et al.¹³² surveyed a sample of 471 adolescent and adult smokers recruited from an online survey panel. Of the menthol smokers surveyed, 36.5% reported that in the event of prohibition on menthol cigarettes by the FDA, they would try to quit smoking. Over 17% said they would not consider using non-menthol cigarettes. Given that there are over 19 million menthol cigarette smokers, even if a substantial number of those who responded that they would try to quit were unsuccessful, if even a small fraction of current menthol smokers quit smoking as a result of such a prohibition, the benefit to public health would be significant. It is important to recognize that a reduction resulting from the response of current menthol smokers to a prohibition on the sale of menthol cigarettes would be distinct from and in addition to reductions in the number of smokers attributable to the lower rate of initiation and the higher rate of cessation that would occur if the market were free of menthol cigarettes.

The health consequences of reduced initiation resulting from the elimination of menthol cigarettes have been modeled separately by both David Mendez, in a study submitted to TPSAC¹³³, and by David Levy.¹³⁴ The results of Dr. Mendez's study are summarized in the

¹³¹ Tauras JA, et al., "Menthol and non-menthol smoking: the impact of prices and smoke-free laws," *Addiction*, 105(Suppl.1): 115-123, 2010.

¹³² O'Connor RJ, "What would menthol smokers do if menthol in cigarettes were banned? Behavioral intentions and simulated demand," *Addiction*, 107(7):1330-8, 2012.

¹³³ TPSAC, 2011, at 220-24; Appendix A.

¹³⁴ Levy, et al. "Modeling the future effects of a menthol ban on smoking prevalence and smoking-attributable deaths in the United States," *American Journal of Public Health*, 101(7): 1236-40, 2011; TPSAC, 2011, at 224.

TPSAC report. Dr. Mendez's report estimated both the number of deaths that would be avoided as a result of menthol prohibition and the number of individuals who would have initiated smoking but for such a prohibition under numerous different scenarios. In the scenario deemed most likely by TPSAC, by 2020 more than 17,000 deaths would have been avoided and nearly 2.3 million people would not have initiated smoking as a result of such a prohibition. By 2050, more than 327,000 deaths would have been avoided and over 9.1 million people would not have initiated smoking. It is important to note that Dr. Mendez's results do not include any reduction in smokers or deaths resulting from increased cessation or decisions by current menthol smokers to quit smoking as a result of a regulatory prohibition.

The Levy study used data from the 2003 Tobacco Use Supplement to the Current Population Survey and simulation modeling to estimate the effect of a prohibition on menthol. The study estimated cumulative deaths averted through 2050 based on alternative assumptions of a total change of 10%, 20%, and 30% in smoking prevalence as a result of a prohibition on menthol cigarettes. Through 2050, the cumulative number of smoking attributable deaths averted as a result of a prohibition on menthol cigarettes was 323,000 if there were a 10% reduction in prevalence, 478,000 if there were a 20% reduction in prevalence, and 633,000 if there were a 30% reduction in prevalence.

As with all modeling studies, these studies are not intended to predict with precision the actual results of a policy change. They are sufficient, however, to demonstrate that a prohibition on menthol cigarettes would have a positive impact on smoking prevalence and on the number of deaths attributable to smoking.

VI. ANY RISKS OF ADVERSE CONSEQUENCES FROM ELIMINATING MENTHOL AS A CHARACTERIZING FLAVOR IN CIGARETTES CAN BE AMELIORATED AND DO NOT OUTWEIGH THE CLEAR PUBLIC HEALTH BENEFITS

A. Risks Associated with Difficulty of Cessation Can Be Addressed

Many of those who emphasize the disruption that would be caused by a large influx in cessation attempts also argue—inconsistently—that elimination of mentholated cigarettes would not result in a significant reduction in smoking prevalence. The undersigned organizations strongly believe that the reduction in smoking prevalence resulting from such a prohibition would be quite large. However, the implementation of a coordinated strategy to provide support for former menthol smokers through education and expanded availability of cessation facilities will enable millions of smokers who are motivated to quit by the prohibition on menthol to do so successfully.

In arguing against a prohibition on menthol as a characterizing flavor in cigarettes, opponents of regulatory action have argued that a prohibition would overwhelm facilities to treat cessation and would therefore leave former menthol smokers without adequate support. Such arguments present no valid objection to prohibition. A rule prohibiting menthol as a characterizing flavor in cigarettes should not be adopted in isolation, but should be part of an overall strategy designed to provide strong support to former menthol smokers. Even if FDA were to reach a prompt decision to propose such a prohibition, there would be ample time to

develop such support. The Tobacco Control Act provides for an implementation period of at least one year from publication of a final product standard rule before the rule may be effective. Moreover, advance planning for such public education and cessation efforts could certainly begin during the rulemaking process itself.

Two major initiatives should accompany a rule proposing a menthol prohibition. First, FDA should sponsor a broad media and public education campaign to inform the public of the nature of the proposed action, the reasons for it, and the resources available to support former menthol smokers. Such a campaign should particularly target communities where the usage of menthol cigarettes is high. It should precede the implementation of the prohibition and inform consumers about the availability of resources to support cessation.

The second major initiative would be to ensure access to cessation services to support a large influx of smokers deciding to quit. It is very likely that a prohibition on mentholated cigarettes would result in decisions to quit by a large number of smokers. Thus, it would be important in connection with the implementation of such a prohibition to ensure that cessation programs are provided with adequate resources to support those wishing to quit. HHS must effectively implement the cessation provisions of the Affordable Care Act, which includes a requirement that all non-grandfathered group and individual insurance plans – including insurers and plans required to cover the essential health benefit -- cover recommended tobacco cessation services. For the first time, the vast majority of smokers with private insurance, Medicaid and Medicare are, or soon will be, receiving coverage for tobacco cessation counseling and/or FDA-approved medications, many without cost-sharing requirements. Further, HHS must continue to support telephone cessation support in each state through 1-800-QUIT NOW, which can provide free counseling and other cessation services to those who do not otherwise have access to them. In addition to expanding access to current cessation treatments, FDA should make it a priority to bring together CTP and CEDR to develop a coordinated program to ensure that the potential benefits of current FDA-approved nicotine replacement products are maximized and the availability of new and innovative cessation products is encouraged.

B. The Risk of an Illicit Market in Menthol Cigarette Has Been Exaggerated by the Industry and Measures Can be Taken to Protect Against It

The tobacco industry historically has both contributed to the illicit market in cigarettes and used the existence of the illicit market to argue against tobacco control strategies – like higher cigarette taxes and stronger regulation – proven to reduce smoking prevalence and save lives. Consistent with its history, the industry grossly exaggerates the extent to which an illicit market will arise from FDA action to prohibit menthol as a characterizing flavor.

First, the industry's analysis does not account for the unique difficulty of sustaining an underground market for menthol cigarettes. In order for widespread marketing of menthol cigarettes to occur, the cigarettes must be readily identifiable as mentholated from their packaging and promotion. Put differently, the illegality of the cigarettes will be clear from the packaging and promotion of the cigarettes themselves. This is in stark contrast to current illicit cigarette markets (on which the industry relies for its speculation about menthol illicit markets), in which the illicit market functions to conceal the illegality of the product. Thus, counterfeit cigarettes are disguised as legitimate and cigarettes smuggled from low-tax to high-tax jurisdictions often have counterfeit tax stamps. Moreover, even if it were not clear from the

packaging or promotion that cigarettes were mentholated, the use of menthol as a characterizing flavor would be readily apparent to anyone sampling them.

Second, contrary to the industry's contention, the experience of states and cities in increasing cigarette taxes does not support the view that a burgeoning illicit market would largely replace the legal market in menthol, resulting in little decline in menthol cigarette consumption from prohibiting menthol cigarettes.¹³⁵ However, the general consensus of economic studies is that every 10% increase in the real price of cigarettes reduces overall cigarette consumption by approximately 3-5%, reduces the number of young-adult smokers by 3.5%, and reduces the number of kids who smoke by 6-7%.¹³⁶ This is not to deny the existence of illicit markets that function to reduce the effectiveness of tax increases in reducing smoking. Rather, it is to establish that illicit markets do not come close to nullifying the effects of tax increases in reducing cigarette consumption, particularly among the young, who are especially sensitive to price. As the President's Cancer Panel found in a 2007 report, "[i]ncreases in tobacco excise taxes, which are passed along to consumers in the form of higher tobacco product prices, have proven highly effective in reducing tobacco use"¹³⁷ Ironically, the tobacco industry itself repeatedly has acknowledged that tax increases lead to reduced consumption of cigarettes. In the words of a Philip Morris executive, "A high cigarette price, more than any other cigarette attribute, has the most dramatic impact on the share of the quitting population . . . price, not tar level, is the main driving force for quitting."¹³⁸ In short, nothing in the history and economics of cigarette tax and price increases suggests that an illicit market in menthol would be so substantial as to nullify the public health gains from prohibiting menthol as a characterizing flavor.

Third, the industry's illicit market analysis understandably leaves unmentioned its own role in cigarette smuggling. Tobacco companies repeatedly have been implicated in international smuggling operations; as one study put it, "the key to understanding cigarette smuggling is understanding the role of the tobacco industry."¹³⁹ For example, although the industry offers studies invoking Canada as a prime example of a significant illicit market in a high-tax country,¹⁴⁰ its own complicity in maintaining that market is conspicuously omitted from the discussion. Affiliates of R.J. Reynolds, Philip Morris and BAT were implicated in operations in

¹³⁵ The industry's suggestion that restrictions on menthol in cigarettes would lead to increased black market activity is largely based on its analysis of "the history of cigarette black markets that have developed in the United States and Canada following tax-driven increases in cigarette prices." Compass Lexecon, "Estimating consequences of a ban on the legal sale of menthol cigarettes," presented at TPSAC, Nov. 18 and Jan. 10, 2011, at 3 (study commissioned by Lorillard). See also "The Industry Menthol Report, Menthol Cigarettes: No Disproportionate Impact on Public Health," submitted to FDA by the Non-Voting Industry Representatives on TPSAC (March 23, 2011), at 216.

¹³⁶ See generally, Chaloupka, FJ, et al., "Macro-Social Influences: The Effects of Prices and Tobacco Control Policies on the Demand for Tobacco Products," *Nicotine and Tobacco Research* 1(Supp. 1): S105-09, 1999; Campaign for Tobacco-Free Kids, *Raising Cigarette Taxes Reduces Smoking, Especially Among Kids (and the Cigarette Companies Know It)*, 2012 and sources cited therein.

¹³⁷ President's Cancer Panel, *Promoting Healthy Lifestyles, 2006-2007 Annual Report*, August 2007.

¹³⁸ Philip Morris Executive Claude Schwab, "Cigarette Attributes and Quitting," March 4, 1993, Bates No. 2045447810. See also, *Raising Cigarette Taxes Reduces Smoking*, Campaign for Tobacco-Free Kids and sources cited therein.

¹³⁹ Joossens L. & Raw, M., "Turning off the tap: the real solution to cigarette smuggling," *Int. J. Tuberc. Lung Dis.*, 7(3):214-222, 2003, at 214.

¹⁴⁰ Compass Lexecon study for Lorillard, at 18-22.

which they knew that their Canadian-made cigarettes would be exported to the U.S., only to be smuggled back into Canada.¹⁴¹ An RJR company, Northern Brands International, and its former president, each pled guilty to charges of being directly involved in the Canadian smuggling.¹⁴² In 1997, two former Brown & Williamson sales managers pled guilty to providing smugglers who were illegally bringing cigarettes into Canada with untaxed cigarettes from a bonded B&W warehouse in Alabama.¹⁴³ The Canadian experience is far more an illustration of the industry's role in supplying the illicit market than an indication that menthol restrictions would be rendered ineffective by an illicit market in menthol cigarettes.

Fourth, the industry's illicit market analysis does not account for the enactment of the Prevent All Cigarette Trafficking (PACT) Act,¹⁴⁴ which went into effect in June, 2010 and requires pre-payment of taxes on Internet, mail order and other non-face to face cigarette sales (known as "delivery sales"), as well as prohibiting sending tobacco products through the U.S. mail.¹⁴⁵ The PACT Act also instituted stricter criminal penalties and additional enforcement mechanisms to create stronger disincentives to engage in illegal tobacco transactions.

Fifth, to the extent that greater enforcement tools are needed to prevent any increase in illicit trade, FDA should supply those tools by implementing the mandate in §920(b) of the Tobacco Control Act¹⁴⁶ to adopt a "track and trace" system that would place a unique, counterfeit-proof identifier on every pack of cigarettes and further require companies to maintain records that would make firms at every level of the supply chain accountable to ensure that each pack gets to its lawful buyer. As noted above, illegal menthol products will be inherently difficult to conceal from law enforcement. However, to the extent that their packaging, promotion and product characteristics do not themselves evidence their illegality, the absence of a legally-required identifier would do so.

Therefore, to the extent that FDA is concerned that an illicit market for menthol cigarettes will reduce the public health benefits of a menthol product standard, it should expedite adoption of the "track and trace" system mandated by the statute. It is clear from the text of the Tobacco Control Act that Congress did not regard the threat of illegal markets as a justification for the failure to establish strict product standards. Rather, the statute explicitly requires FDA to protect against such a threat – whether real or posited by the tobacco industry as a pretext for opposing strong regulation. Several of the groups joining these Comments have filed a Citizen Petition with FDA calling for such a "track and trace" system.¹⁴⁷ It is revealing that Altria, which has opposed a prohibition of menthol cigarettes in part because of the risk of an illicit market, recently filed its opposition to the Citizen Petition.¹⁴⁸

¹⁴¹ Campaign for Tobacco-Free Kids, *Illegal Pathways to Illegal Profits: The Big Cigarette Companies and International Smuggling*, 2003, at 27.

¹⁴² *Id.* at 28.

¹⁴³ *Id.*

¹⁴⁴ Pub.L.No. 111-154, 124 Stat. 1087 (2010).

¹⁴⁵ Although a federal appeals court has affirmed a preliminary injunction against the "delivery sale" tax provisions of the PACT Act on due process grounds, it affirmed the denial of an injunction against the prohibition of sending tobacco products through the mail, a key anti-trafficking provision of the statute. *Gordon v. Holder*, No. 12-5031 (D.C. Cir. June 28, 2013).

¹⁴⁶ 21 U.S.C. §387t.

¹⁴⁷ Citizen Petition, Docket #FDA-2013-P-0285 (March 6, 2013).

¹⁴⁸ Altria Response to Citizen Petition, Docket #FDA-2013-P-0285 (Sept. 6, 2013).

Finally, there is no question that FDA can significantly reduce the need for menthol smokers to resort to the illicit market by providing sufficient resources, through public education and cessation services, to encourage menthol smokers to quit. One study found that a greater number of current menthol smokers would try to quit smoking in response to a prohibition on menthol cigarettes than would seek out alternative sources of menthol.¹⁴⁹ It is reasonable to assume that the greater the FDA's commitment to helping menthol smokers quit, the less likely it will be that an illicit menthol market will undercut the public health gains from a menthol product standard.

Therefore, the risk of an illicit market in menthol cigarettes has been grossly exaggerated by the industry, particularly in light of the unique difficulty of sustaining such a market and the tools available to FDA to prevent its emergence to a degree that would compromise the public health gains from a menthol product standard.

VII. CONCLUSION

The weight of scientific evidence supports the conclusion that a product standard eliminating menthol as a characterizing flavor in cigarettes will reduce initiation of smoking among young people, increase cessation among current smokers, and save hundreds of thousands of lives over the next several decades. Such compelling public health benefits outweigh any conceivable countervailing effects of such a product standard. Given that both TPSAC and the FDA's own peer-reviewed Preliminary Scientific Evaluation have concluded that menthol cigarettes likely have an adverse impact on public health, FDA should proceed, without further delay, to issue a Notice of Proposed Rulemaking prohibiting menthol as a characterizing flavor in cigarettes as the next step toward the final implementation of such a product standard. The price of undue delay will be paid in untold suffering and lost lives from tobacco-related disease.

Sincerely,

Campaign for Tobacco-Free Kids
American Academy of Family Physicians
American Academy of Pediatrics
American Association for Respiratory Care
American Cancer Society Cancer Action Network
American College of Cardiology
American College of Preventive Medicine
American Congress of Obstetricians and Gynecologists
American Heart Association
American Lung Association
American Psychological Association
American Public Health Association
American Society of Addiction Medicine

¹⁴⁹ O'Connor RJ, "What would menthol smokers do if menthol in cigarettes were banned? Behavioral intentions and simulated demand," *Addiction*, 107(7):1330-8, 2012.

American Society of Clinical Oncology
American Thoracic Society
Association of Black Cardiologists
Association of State and Territorial Health Officials
General Board of Church & Society of the United Methodist Church
Lung Cancer Alliance
National Association of County & City Health Officials
National Latino Alliance for Health Equity
North American Quitline Consortium
Oncology Nursing Society
Partnership for Prevention
Society for Cardiovascular Angiography and Interventions