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

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

The undersigned public health, medical, education, civil rights, and community organizations submit these comments in response to the Proposed Rule for a Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26,454 (May 4, 2022). These comments explain why the proposed rule is strongly supported by the scientific evidence and is “appropriate for the protection of the public health” under Section 907(a)(3)(A) of the Food, Drug and Cosmetic Act (FD&C Act) as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or TCA). Indeed, few actions the Food and Drug Administration (FDA) could take in exercising its authority under the TCA would have as great an impact in preventing tobacco-caused mortality, avoiding suffering from tobacco addiction and disease, and reducing persistent and tragic health disparities in the U.S., as the proposed rule prohibiting menthol as a characterizing flavor in cigarettes. The science supporting this product standard has been clear for over a decade and has grown stronger with each passing year. There is no justification, or excuse, for further delay.

I. SUMMARY OF REASONS SUPPORTING A PRODUCT STANDARD PROHIBITING MENTHOL AS A CHARACTERIZING FLAVOR IN CIGARETTES

- **Menthol cigarettes increase youth initiation of smoking and addiction to cigarettes.**
 - Menthol in cigarettes makes it easier for new users—primarily youth—to initiate smoking.
 - The tobacco industry has intentionally targeted young people with marketing for menthol cigarettes.
 - Young people initiate with and use menthol cigarettes at high rates.
 - Menthol in cigarettes enhances the addictive properties of nicotine and facilitates progression to regular smoking.

- **Menthol cigarettes make it harder to stop smoking.**
 - People who smoke menthol cigarettes are less likely to quit smoking than people who smoke non-menthol cigarettes.
 - Menthol cigarettes have slowed national progress in reducing smoking.

- **Menthol cigarettes disproportionately harm the health of Black Americans and other underserved populations.**
 - Menthol cigarette smoking is disproportionately high among Black Americans.
 - The tobacco industry has targeted Black Americans with marketing for menthol cigarettes for decades.
 - Black Americans suffer a disproportionate toll of the disease and death caused by menthol cigarettes.
 - Menthol cigarettes are disproportionately used by other underserved population groups.

- **Prohibiting menthol cigarettes will produce substantial public health benefits.**
 - Prohibiting menthol cigarettes will reduce youth smoking initiation and progression to regular use.
 - Prohibiting menthol cigarettes will increase smoking cessation.
 - Many people who smoke menthol cigarettes report that they will quit smoking if menthol cigarettes may no longer be sold.
 - Real-world evidence demonstrates that prohibiting menthol cigarettes increases smoking cessation.
 - Preventing youth initiation and increasing smoking cessation will produce tremendous public health benefits.

- Finalizing the rule prohibiting characterizing flavors in cigars will enhance the public health impacts of the menthol rule.
- **There is no public health justification for exemptions from the rule.**
 - No exemption should be considered for IQOS menthol or similar heated tobacco products.
 - No exemption should be considered for Very Low Nicotine (VLN) cigarettes or similar products.
- **Any risks of unintended and adverse consequences from prohibiting menthol cigarettes can be ameliorated and will not outweigh the public health benefits.**
 - Prohibiting menthol cigarettes will not cause the emergence of an illicit market that will nullify the public health gains from such a policy.
 - Prohibiting menthol cigarettes will not increase the likelihood of police abuse in Black and other communities of color.
 - The need to provide sufficient resources to help people stop smoking does not justify continuing to permit the manufacture and sale of menthol cigarettes.

II. STATUTORY BACKGROUND AND HISTORY OF FDA CONSIDERATION OF A PRODUCT STANDARD FOR MENTHOL IN CIGARETTES

A. The Tobacco Control Act and Menthol Cigarettes

In enacting the Tobacco Control Act, 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 of considerable proportions,”¹ and finding that “[v]irtually all new users of tobacco products are under the minimum legal age to purchase those products.”² 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.”³

As a key part of the TCA’s set of reforms directed at curbing youth smoking, Congress, in Section 907, prohibited the use of constituents or additives that impart any characterizing flavor in cigarettes, other than tobacco or menthol.⁴ Section 907 did recognize 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 Products Scientific Advisory Committee (TPSAC), as its first

¹ Tobacco Control Act § 2(1), 123 Stat. at 1777.

² *Id.* § 2(4).

³ *Id.* § 2(6).

⁴ 21 U.S.C. § 387g(a)(1)(A).

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.”⁵ Thus, Congress, in enacting the TCA, recognized the particularly adverse effect of menthol cigarettes on youth and other disproportionately affected populations long targeted by the tobacco industry. It directed TPSAC to submit its report and recommendations on menthol within the first year of TPSAC’s establishment.⁶

In Section 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.”⁷ Similar language appears as a “Rule of Construction” in the subpart of Section 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.”⁸ 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.

In addition to mandating a product standard prohibiting certain characterizing flavors in cigarettes, Section 907 also gives FDA broad authority to adopt additional tobacco product standards, including for menthol cigarettes, upon a finding that such action “is appropriate for the protection of the public health.”⁹ 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
- (3) the increased or decreased likelihood that those who do not use tobacco products will start using such products.”¹⁰

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

⁵ *Id.* § 387g(e)(1).

⁶ *Id.* § 387g(e)(2).

⁷ *Id.* § 387g(a)(1)(A).

⁸ *Id.* § 387g(e)(3).

⁹ *Id.* § 387g((a)(3)(A).

¹⁰ *Id.* § 387g(a)(3)(B)(i).

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).

In making this population-wide assessment of a proposed product standard, FDA is not required by the TCA to make conclusions with scientific certainty. Section 907 therefore speaks in terms of *likelihoods*, not certainties. Section 907 requires FDA to 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 if the product standard under consideration is adopted.¹¹ A “likelihood” would exist, for example, if it is more likely than not that adoption of a menthol 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.¹² Tobacco companies have insisted that FDA adopt a causal analysis for product standards similar to that used by the U.S. Surgeon General to determine the causal link between smoking and disease.¹³ But because Section 907 necessarily requires FDA to make a predictive judgment about the impact of a proposal on human behavior, such a causal analysis is inapplicable and there is no indication in the TCA that Congress intended such an analysis to govern FDA’s approach to product standards.

As is apparent from the Preamble to the proposed rule, and as noted below, the available science strongly establishes that the menthol product standard is appropriate for the protection of the public health.

¹¹ *Id.* (emphasis added).

¹² That Congress intended FDA to have maximum discretion to impose product standards without a requirement of scientific certainty is further confirmed by the judicial review section of the TCA. Section 912 of the TCA expressly subjects regulations establishing product standards to the lenient 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.” 21 U.S.C. §3871(a)(1)(A) and (b), *incorporating by reference* 5 U.S.C. §706(2)(A). In other analogous regulatory contexts, courts have interpreted this judicial review standard to allow broad agency discretion to act even in the face of scientific uncertainty and imperfect data. *See, e.g., FCC v. Prometheus Radio Project*, 141 S.Ct. 1150, 1160 (2021) (agency acted lawfully when it “made a reasonable predictive judgment based on the evidence it had” despite that evidence being “[f]ar from” perfect.); *Indus. Union Dept., AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 656 (1980) (agency was “not required to support its findings . . . with anything approaching scientific certainty.”); *Coalition for Responsible Regulation, Inc. v. Environmental Protection Agency*, 684 F.3d 102,120 (D.C. Cir. 2012) (per curiam) (courts “give an extreme degree of deference to the agency when it is evaluating scientific data within its technical expertise.” Given that the Clean Air Act is “designed to protect the public health,” “the existence of some uncertainty does not, without more, warrant invalidation of an endangerment finding.”).

¹³ *See, e.g.,* Altria Client Services, Comments in Docket No. FDA-2017-N-6565 (83 Fed. Reg. 12,294, March 21, 2018) “Advance Notice of Proposed Rulemaking on the Regulation of Flavors in Tobacco Products,” at 12-13, (Sep. 7, 2018), <https://www.regulations.gov/comment/FDA-2017-N-6565-23206>.

B. The History of FDA’s Consideration of Menthol Cigarettes.

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, 2011.¹⁴

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.”¹⁵

TPSAC concluded “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.”¹⁶ TPSAC found evidence that the availability of menthol in cigarettes 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.”¹⁷ TPSAC also concluded that cessation of smoking “is less likely to be successful among smokers of menthol cigarettes.”¹⁸ 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.¹⁹ 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.”²⁰ 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.”²¹

¹⁴ Tobacco Products Scientific Advisory Committee–U.S. Food and Drug Administration, *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations*, 2011, <https://wayback.archiveit.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf> (“TPSAC Report”).

¹⁵ *Id.* at 220.

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.* at 221.

²⁰ *Id.*

²¹ *Id.* at 225.

Following issuance of the TPSAC Report, FDA then conducted its own independent, peer-reviewed evaluation of the available science concerning menthol cigarettes.²² In this process, FDA evaluated the peer-reviewed literature, industry submissions and other materials provided to TPSAC, and performed, as well as 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."²³

FDA's factual conclusions in support of this assessment reinforced 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 nonmenthol cigarettes, "adequate data suggest that menthol use is likely associated with increased smoking initiation by youth and young adults."²⁴ 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."²⁵ According to FDA, "These findings, combined with the evidence indicating that menthol's cooling and anesthetic properties can reduce the harshness of cigarette smoke and the evidence indicating that menthol cigarettes are marketed as a smoother alternative to nonmenthol cigarettes, *make it likely that menthol cigarettes pose a public health risk above that seen with nonmenthol cigarettes.*"²⁶

Coincident with its Preliminary Scientific Evaluation, in July 2013 FDA issued an Advance Notice of Proposed Rulemaking (ANPRM) to obtain information related to the potential regulation of menthol in cigarettes,²⁷ and received extensive comments from public health and medical organizations supporting a rule prohibiting menthol as a characterizing flavor.²⁸ In March, 2018, FDA issued another ANPRM on flavors (including menthol) in tobacco products,²⁹ and again received comments from public health and medical organizations supporting a prohibition of menthol as a characterizing flavor.³⁰

FDA has consistently found that menthol cigarettes have an adverse impact on public health greater than that of other cigarettes. Indeed, in November of 2018, then-Commissioner

²² FDA, *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes*, 2013, <https://www.fda.gov/media/86497/download>.

²³ *Id.* at 6.

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.* (emphasis added).

²⁷ 78 Fed. Reg. 44,484 (July 24, 2013).

²⁸ See, e.g., [https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/regulatory/2013-11-22%20Menthol%20Comments%20\(Partners\).pdf](https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/regulatory/2013-11-22%20Menthol%20Comments%20(Partners).pdf).

²⁹ 83 Fed. Reg. 12,294 (Mar. 21, 2018).

³⁰ See, e.g., https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/2018_07_19_-_Flavored_Tobacco_Products_ANPRM.pdf.

Scott Gottlieb announced the agency’s intention to “advance a Notice of Proposed Rulemaking that would seek to ban menthol in combustible tobacco products, including cigarettes and cigars . . .” after expressing that he was “deeply concerned about the availability of menthol-flavored cigarettes,” which “represent one of the most common and pernicious routes by which kids initiate on combustible cigarettes” and “exacerbate troubling disparities in health related to race and socioeconomic status”³¹ Despite FDA’s consistent and long-held scientific conclusions about the damage to public health, and particularly to youth and the Black community, from menthol cigarettes, action by the agency did not follow until after a lawsuit was brought by the African American Tobacco Control Leadership Council and Action on Smoking and Health, and later joined by the American Medical Association and the National Medical Association. The lawsuit alleged that the agency had “unreasonable delay[ed]” addressing the issue of mentholated cigarettes, including the failure to respond to a Citizen Petition³² filed in 2013 by public health organizations urging FDA to remove cigarettes with menthol as a characterizing flavor.³³ On April 29, 2021, FDA announced that it had granted the Citizen Petition and would publish a notice of proposed rulemaking within a year.³⁴ The proposed rule was issued on April 28, 2022.

III. MENTHOL CIGARETTES INCREASE YOUTH INITIATION OF SMOKING AND ADDICTION TO CIGARETTES.

A. Menthol in Cigarettes Makes It Easier for New Users—Primarily Youth—to Initiate Smoking.

It has long been established that by masking the harshness caused by tobacco smoke, flavors make it easier for beginners—primarily young people—to experiment with and ultimately become addicted to cigarettes. Menthol has uniquely appealing qualities for people beginning to smoke, leading TPSAC to conclude over a decade ago that, “Menthol cannot be considered merely a flavoring additive to tobacco. Its pharmacological actions reduce the harshness of smoke and the irritation from nicotine, and may increase the likelihood of nicotine addiction in adolescents and young adults who experiment with smoking.”³⁵ It is well-established that menthol as a flavoring agent stimulates cold receptors, providing a sensation of

³¹ FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D. on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes*, (Nov. 15, 2018), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access>.

³² Tobacco Control Legal Consortium, et al., *Citizen Petition to Food & Drug Admin. Prohibiting Menthol as a Characterizing Flavor in Cigarettes* (April 12, 2013), <https://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fdacitizenpetition-menthol-2013.pdf>.

³³ See Complaint, *African American Tobacco Control Leadership Council et al. v. U.S. Dept. of Health and Human Services, et al. FDA*, Case No. 20-cv-04012-KAW (N.D. Cal. June 17, 2020).

³⁴ FDA, *FDA Commits to Evidence-Based Actions Aimed at Saving Lives and Preventing Future Generations of Smokers*, April 29, 2021, <https://www.fda.gov/news-events/press-announcements/fda-commits-evidence-based-actions-aimed-saving-lives-and-preventing-future-generations-smokers>.

³⁵ TPSAC Report at 225.

coolness.³⁶ As described in the proposed rule (at 26,462 and 26,469), menthol is a chemical compound that cools and numbs the throat, reducing the harshness of cigarette smoke, thereby making menthol cigarettes more appealing to youth who are initiating tobacco use. Confirming the physiological attributes of menthol cigarettes, research demonstrates that young people who smoke report greater subjective appeal of menthol cigarettes compared to non-menthol cigarettes. For example, data from the Population Assessment of Tobacco and Health (PATH) study show that youth who smoke menthol cigarettes are more likely to perceive menthol cigarettes as easier to smoke than regular cigarettes.³⁷ Young adults who smoke menthol cigarettes report that menthol cigarettes are smoother, less harsh and easier to inhale than non-menthol cigarettes.³⁸ As the proposed rule succinctly states, “Menthol in cigarettes is a significant contributor to youth and young adult initiation of cigarette smoking.” 87 Fed. Reg. at 26,469.

B. The Tobacco Industry Has Intentionally Targeted Young People with Marketing for Menthol Cigarettes.

The addition of menthol to cigarettes is no accident, but an intentional decision by the tobacco companies to increase the appeal of cigarettes to young people—the industry’s replacement smokers. Industry documents clearly show that the tobacco industry has known for decades that menthol cigarettes make it easier for new smokers—primarily young people—to initiate smoking. A review of tobacco industry documents concluded that “menthol is added to cigarettes in part because it is known to be an attractive feature to inexperienced smokers who perceive menthol cigarettes as less harsh and easier to smoke” and that the industry “carefully researched the menthol segment of the market in order to recruit younger smokers to their brands.”³⁹ For example, as noted in the proposed rule (at 26,464), a 1987 Brown & Williamson document stated that, “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.”⁴⁰ A 1986 R.J. Reynolds memo about a possible new low-level menthol cigarette stated that, “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 . . .

³⁶ Hersey, JC, et al., “Are menthol cigarettes a starter product for youth?,” *Nicotine & Tobacco Research* 8(3):403-413, 2006.

³⁷ Cohn, AM, et al., “Menthol Smoking Patterns and Smoking Perceptions Among Youth: Findings from the Population Assessment of Tobacco and Health Study,” *American Journal of Preventive Medicine* 56(4):e107-e116, 2019.

³⁸ Wackowski, OA, et al., “In their own words: young adults’ menthol cigarette initiation, perceptions, experiences and regulation perspectives,” *Nicotine & Tobacco Research* 20(9):1076-1084, 2018.

³⁹ Klausner, K., “Menthol cigarettes and smoking initiation: a tobacco industry perspective,” *Tobacco Control* 20 (Supp. 2), ii12-ii19, 2011.

⁴⁰ Cantrell, Dan V. “U.S. Exhibit 30,792, Report, ‘Kool Isn’t Getting the Starters/ 236’ DAN V. CANTRELL, BROWN & WILLIAMSON TOBACCO CORP., February 17, 1987.” Depositions and Trial Testimony (DATTA); RICO Privilege Downgrades Collection. 1987, <https://www.industrydocuments.ucsf.edu/docs/xskv0035>.

.”⁴¹ The industry also found that young people who smoke perceive menthol as having medicinal qualities that they believe 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.”⁴²

In 2014, the U.S. Surgeon General reported that “tobacco industry advertising and promotion cause youth and young adults to start smoking, and nicotine addiction keeps people smoking past those ages.”⁴³ Industry advertising and promotional activity reflect this understanding and demonstrate that the industry has long sought to target and exploit the youth market in advertising menthol cigarettes. For example, Lorillard’s marketing of Newport (now owned by R.J. Reynolds), which has long been the leading menthol brand with the largest market share, reflects the use of themes and images designed to appeal to the young. Lorillard’s “Alive with Pleasure” ad campaign for Newport, begun in 1972, showed attractive young people vigorously engaged in youth-oriented activities like playing touch football.⁴⁴ As one study of menthol cigarette marketing put it, “The 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.”⁴⁵

By 1976, the success of the Newport campaign was noticed by Lorillard’s competitor R.J. 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”⁴⁶ Reynolds also noted that the Newport brand’s advertising “talks directly to young people—situations [and] attitude.”⁴⁷ In 1982, Reynolds, which sold 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.⁴⁸ According to one review of tobacco industry documents, “Through the 1990s, Lorillard continued its image-based marketing, attributing its success to its ‘peer acceptance’ and noting that ‘Newport smokers

⁴¹ Klausner, K., *supra* note 39, at ii13.

⁴² *Id.* at ii14.

⁴³ U.S. Department of Health and Human Services, *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*, 2014, www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf_NBK179276.pdf.

⁴⁴ Klausner, K., *supra* note 39, at ii16.

⁴⁵ Sutton, CD & Robinson, RG, “The marketing of menthol cigarettes in the United States: Populations, messages and channels,” *Nicotine & Tobacco Research* 6: S83-S91 2004.

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*

perceive other Newport smokers as they do themselves—younger, outgoing, active, happy, warm, friendly, modern, extroverted.”⁴⁹

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.⁵⁰ 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.”⁵¹

Due to the advertising restrictions in the Master Settlement Agreement, the nature of industry advertising and promotion has changed, but the targeting of youth has not, as demonstrated by research on industry point-of-sale marketing. For example, 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%.⁵² 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.⁵³ Other studies show menthol marketing is especially prominent in neighborhoods with a higher proportion of Black youth. A 2013 study found that census tracts in St. Louis with a higher proportion of Black children had a higher proportion of menthol marketing near candy displays.⁵⁴ Another 2011 California study found that as the proportion of Black high school students in a neighborhood rose, the proportion of menthol advertising increased, the odds of a Newport promotion were higher, and the cost of Newport cigarettes was lower.⁵⁵ The industry’s targeting of the Black community is described in further detail in Section V.B. below.

The adverse public health consequences of point-of-sale marketing of menthol cigarettes are reinforced by a study of cigarette brand recognition and smoking initiation in an urban California school district.⁵⁶ 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

⁴⁹ Klausner, *supra* note 39, at ii17.

⁵⁰ 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* note 45, at S86.

⁵¹ Klausner, *supra* note 39, at ii17.

⁵² Widome R, et al., “The relationship of neighborhood demographic characteristics to point-of-sale tobacco advertising and marketing,” *Ethnic Health* 18(2):136-151, at 8, 2013.

⁵³ Henriksen L. et al., “Targeted advertising, promotion, and price for menthol cigarettes in California high school neighborhoods,” *Nicotine & Tobacco Research*, 14(1): 116-121, at 118, 2012.

⁵⁴ Moreland-Russell, S, et al., “Disparities and Menthol Marketing: Additional Evidence in Support of Point of Sale Policies,” *International Journal of Environmental Research and Public Health*, 10: 4571-4583, 2013.

⁵⁵ Henriksen, L., *supra* note 53.

⁵⁶ Dauphinee, AL, “Racial differences in cigarette brand recognition and impact on youth smoking,” *BMC Public Health*, 13:170, 2013.

smoke.⁵⁷ The study found that the “odds of smoking initiation increased by 49% for students who recognized the Newport brand at baseline.”⁵⁸ 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.”⁵⁹

Based on its review of “youthful imagery in menthol marketing and the studies of industry documents,” TPSAC concluded that “the industry developed menthol marketing to appeal to youth,” a strategy “particularly true of the Newport brand, but the strategy was also adopted by other tobacco companies.”⁶⁰ TPSAC further found that, “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.”⁶¹ Therefore, there is little doubt that the marketing of menthol cigarettes has targeted young people and reinforced the special appeal of menthol to younger people who smoke.

C. Young People Initiate with and Use Menthol Cigarettes at High Rates.

Menthol’s role in smoking initiation is clearly demonstrated by the high proportion of young people who report that their first cigarette was menthol. For example, data from the 2013-2014 PATH study found that half of youth (ages 12-17) who had ever tried smoking initiated with menthol cigarettes.⁶² National surveys also show a marked age gradient in preference for menthol cigarettes, demonstrating menthol’s appeal to younger populations. As reported in the proposed rule (at 26,462), data from the 2019 National Survey on Drug Use and Health (NSDUH) found that 48.6% of youth who smoke (ages 12-17) and 51% of young adults who smoke (ages 18-25) reported menthol use in the past month, compared to 39% of adults ages 26 and older who smoke. Data from the PATH study show a similar age gradient. For example, data from wave 5 of the PATH study, collected from December 2018 to November 2019, found that 54.1% of youth who smoke (ages 12-17) and 54% of young adults who smoke (ages 18-24) reported past-month menthol use, compared to 40.8% of adults ages 26 and older who smoke.⁶³

⁵⁷ *Id.* at 5.

⁵⁸ *Id.* at 5.

⁵⁹ *Id.* at 6.

⁶⁰ TPSAC Report at 71.

⁶¹ *Id.*

⁶² Ambrose, BK, et al., “Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014,” *Journal of the American Medical Association*, *JAMA* 2015;314(17):1871-1873, 2015.

⁶³ National Institute of Health & Food and Drug Administration, Population Assessment of Tobacco and Health, “Past 30-Day Use of Any Flavored Cigars Among Youth (aged 12-17), by Sociodemographics,” 2021, <https://www.icpsr.umich.edu/files/NAHDAP/pathstudy/Youth-30Day-Flavored-AnyCigar.pdf>; See National Institute of Health & Food and Drug Administration – Population Assessment of Tobacco and Health, *Past 30-Day Use of Flavored Cigarettes Among Young Adults (Aged 18-24)*, by Sociodemographics, 2021, <https://www.icpsr.umich.edu/files/NAHDAP/pathstudy/YoungAdult-30Day-Flavored-Cigarette.pdf>; National Institute of Health & FDA – Population Assessment of Tobacco and Health, *Past 30-Day Use of Any Flavored*

Contrary to older industry-funded research challenging the magnitude and consistency of the age gradient,⁶⁴ these surveys show a clear and consistent differential preference for menthol cigarettes among youth and young adults and strongly support the proposed rule’s conclusion that, “The disproportionate use of menthol cigarettes by youth and young adult smokers compared to older adults has been consistent over time and across multiple studies with nationally representative populations.” 87 Fed. Reg. at 26,462.

The 2011 TPSAC report concluded that menthol cigarettes increase the number of children who experiment with cigarettes and the number of children who smoke regularly, increasing overall youth smoking.⁶⁵ Using the same model from the TPSAC report, researchers estimated the public health harm that menthol cigarettes caused between 1980 and 2018. Due to the role that menthol plays in increasing smoking initiation, these researchers estimated that between 1980 and 2018, menthol cigarettes were responsible for 10.1 million additional new smokers, or over 265,000 new smokers each year over the 38-year period.⁶⁶

D. Menthol in Cigarettes Enhances the Addictive Properties of Nicotine and Facilitates Progression to Regular Smoking.

It has long been established that youth and young adults are more sensitive to the reinforcing effects of nicotine, as the brain continues to develop until about age 25. Adolescents are more likely to experience nicotine dependence at lower levels of exposure than adults and can feel dependent after just minimal exposure and within a relatively short period of time.⁶⁷ Menthol enhances the addictive properties of nicotine, making initiation with menthol cigarettes particularly detrimental. Specifically, menthol binds to nicotinic receptors in the brain, increases the number of nicotinic receptors in the brain, and enhances nicotine’s effect on dopamine in the brain.⁶⁸ All of these processes act to enhance the rewarding effects of nicotine. A 2020 meta-

Cigars Among Adults (Aged 25+), by *Sociodemographics*, 2021,

<https://www.icpsr.umich.edu/files/NAHDAP/pathstudy/OlderAdult-30Day-Flavored-AnyCigar.pdf>.

⁶⁴ Curtin GM, et al., “Patterns of menthol cigarette use among current smokers, overall and within demographic strata, based on data from four U.S. government surveys,” *Regul Toxicol Pharmacol* 70:189–96, 2014

⁶⁵ TPSAC report at 199.

⁶⁶ Le, TT, “An estimation of the harm of menthol cigarettes in the United States from 1980 to 2018,” *Tobacco Control* 31:564-568, 2021.

⁶⁷ HHS, *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General*, 2010; HHS, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, 2012.

⁶⁸ Alsharari, SD, et al., “Effects of Menthol on Nicotine Pharmacokinetic, Pharmacology and Dependence in Mice.” *PLoS ONE* 10(9):e0137070, 2015; Henderson, BJ, et al., “Menthol Alone Upregulates Midbrain NACHRs, Alters NACHR Subtype Stoichiometry, Alters Dopamine Neuron Firing Frequency, and Prevents Nicotine Reward,” *The Journal of Neuroscience* 36(10):2957–2974, 2016; Henderson, BJ, et al., “Menthol Enhances Nicotine Reward-Related Behavior by Potentiating Nicotine-Induced Changes in nAChR Function, nAChR Upregulation, and DA Neuron Excitability,” *Neuropsychopharmacology* 42:2285– 2291, 2017; Zhang, M., et al., “Menthol Facilitates Dopamine- Releasing Effect of Nicotine in Rat Nucleus Accumbens,” *Pharmacology, Biochemistry and Behavior* 175:47–52, 2018; Brody, AL, et al., “Up-Regulation of Nicotinic Acetylcholine Receptors in Menthol Cigarette Smokers,” *International Journal of Neuropsychopharmacology* 16(5):957–966, 2013; Wickham, RJ, “The Biological Impact of Menthol on Tobacco Dependence,” *Nicotine & Tobacco Research* 22(10):1676–1684, 2020;

analysis concluded that, “It is more likely that the effects of menthol on smoking topography are found in inexperienced smokers, where menthol smokers may take in more nicotine during the beginning phase of smoking compared to nonmenthol smokers”⁶⁹

Over a decade ago, TPSAC concluded that young people who initiate using menthol cigarettes are more likely to become addicted and smoke long-term.⁷⁰ Reviewing a more recent evidence base, the FDA’s *Scientific Review of the Effects of Menthol in Cigarettes on Tobacco Addiction: 1980-2021* echoes these conclusions, finding that, “Based on the weight of the evidence spanning 1980-2021, menthol in cigarettes is associated with progression to regular cigarette smoking among youth and young adults. This conclusion is supported by multiple, strong, longitudinal, and nationally representative studies of tobacco use among youth and young adults.”⁷¹ The Review also found that “menthol in cigarettes is associated with greater nicotine dependence among youth. This conclusion is supported by multiple strong studies, the majority of which are nationally representative and designed to collect survey data on tobacco use in youth populations.”⁷² For example, longitudinal data from the PATH study show that youth who smoke menthol cigarettes have significantly higher levels of certain measures of dependence,⁷³ and that initiation with a menthol-flavored cigarette is associated with a higher relative risk of daily smoking.⁷⁴ Another study published since the proposed rule, analyzing data from Waves 1 through 5 of the PATH study, builds upon these findings. The study found that among youth who initiated smoking between study waves, menthol use was associated with smoking on 3.1 additional days, a 59% higher risk of smoking frequently, and 10% higher nicotine dependence scores.⁷⁵ Pooled data from the 2017-2020 National Youth Tobacco Surveys (NYTS) show that youth who smoke menthol cigarettes are more likely to smoke frequently (20 or more days per month) and heavily (11 or more cigarettes per day), compared to youth who smoke non-menthol cigarettes. This study also found that people who smoke menthol cigarettes had lower odds of intentions to quit smoking and greater odds of other dependence measures, including craving tobacco and using tobacco within 30 minutes of waking.⁷⁶ Additionally, pooled data from the

Shahoei, R. & E. Tajkhorshid, “Menthol Binding to the Human A4B2 Nicotinic Acetylcholine Receptor Facilitated by Its Strong Partitioning in The Membrane,” *Journal of Physical Chemistry* 124(10):1866-1880, 2020.

⁶⁹ Wickham, RJ, *supra* note 68.

⁷⁰ TPSAC Report.

⁷¹ FDA, *Scientific Review of the Effects of Menthol in Cigarettes on Tobacco Addiction: 1980-2021*, at 30, 2022.

⁷² *Id.* at 79.

⁷³ Cwalina, SN, et al., “Adolescent menthol cigarette use and risk of nicotine dependence: Findings from the national Population Assessment on Tobacco and Health (PATH) study,” *Drug and Alcohol Dependence* 206:107715, 2020.

⁷⁴ Villanti, AC, et al., “Association of flavored tobacco use with tobacco initiation and subsequent use among US youth and adults, 2013-2015,” *JAMA Network Open* 2(10):e1913804, 2019.

⁷⁵ Leas, E.C., et al., “Use of Menthol Cigarettes, Smoking Frequency, and Nicotine Dependence Among US Youth,” *JAMA Network Open* 5(6):e2217144, 2022.

⁷⁶ Mantey, DS, et al., “Cigarette smoking frequency, quantity, dependence, and quit intentions during adolescence: comparison of menthol and non-menthol smokers (National Youth Tobacco Survey 2017–2020),” *Addictive Behaviors* 121:106986, 2021.

2017 and 2018 NYTS indicate that menthol smoking among middle and high school students is associated with greater intention to continue smoking, compared to non-menthol smoking.⁷⁷

IV. MENTHOL CIGARETTES MAKE IT HARDER TO STOP SMOKING.

A. People who Smoke Menthol Cigarettes Are Less Likely to Quit Smoking than People who Smoke Non-Menthol Cigarettes.

As described in the previous section, menthol binds to nicotinic receptors in the brain, increases the number of nicotinic receptors in the brain, and enhances nicotine's effect on dopamine in the brain. In addition to facilitating experimentation and progression to regular smoking, these same processes make it harder for people who smoke menthol cigarettes to quit. As FDA's scientific review concluded, "The weight of evidence supports that menthol in cigarettes is likely associated with reduced cessation success in the general population and that menthol is associated with reduced cessation success among Black smokers."⁷⁸ While some cross-sectional studies report mixed findings on the impact of menthol cigarettes on cessation, cross-sectional data is not sufficient to understand trajectories of use.⁷⁹ In contrast, recent nationally-representative, longitudinal studies provide robust evidence that menthol cigarettes reduce cessation across populations. For example, a recent study analyzing data from the first four waves of the PATH study found that using menthol cigarettes prior to a quit attempt decreased the probability of 30+ day abstinence by 28% and the probability of 12-month abstinence by 53%. Smokers who switched from menthol to non-menthol cigarettes increased their probability of cessation.⁸⁰ Another study analyzing PATH data found that among daily smokers, those who smoke menthol cigarettes have 24% lower odds of quitting compared to those who smoke non-menthol cigarettes.⁸¹

Research also shows that the impact of menthol cigarettes on cessation is particularly pronounced among Black people who smoke menthol cigarettes. Among daily smokers in the first four waves of the PATH study, African Americans who smoke menthol cigarettes had 53% lower odds of quitting compared to African Americans who smoke non-menthol cigarettes, while white people who smoke menthol cigarettes had 22% lower odds of quitting compared to white people who smoke non-menthol cigarettes.⁸² In addition, a 2019 meta-analysis found that among

⁷⁷ Azagba, S, et al., "Cigarette smoking behavior among menthol and nonmenthol adolescent smokers," *Journal of Adolescent Health*, 66:545-550, 2020.

⁷⁸ FDA, *Scientific Review of the Effects of Menthol in Cigarettes on Tobacco Addiction: 1980-2021*, at 109, 2022.

⁷⁹ Sulsky SI, et al., "Evaluating the association between menthol cigarette use and the likelihood of being a former versus current smoker," *Regul Toxicol Pharmacol* 70:231-41, 2014.

⁸⁰ Leas, EC, et al., "Effects of menthol use and transitions in use on short-term and long-term cessation from cigarettes among US smokers," *Tobacco Control* 056596, 2021.

⁸¹ Mills, S, et al., "The Relationship between Menthol Cigarette Use, Smoking Cessation and Relapse: Findings from Waves 1 to 4 of the Population Assessment of Tobacco and Health Study," *Nicotine & Tobacco Research* 23(6), at 966-975, 2021.

⁸² *Id.*

African Americans who smoke, those who smoked menthol cigarettes had 12% lower odds of successfully quitting smoking compared to those who smoked non-menthol cigarettes.⁸³ This disparity is also evidenced in clinical cessation studies. For example, a 2014 randomized clinical trial of FDA-approved cessation treatments found that African American women who smoked menthol cigarettes had the lowest quit rates of all groups in the study.⁸⁴ Due to the lower likelihood of smoking cessation among Black Americans who smoke menthol cigarettes, the 2020 Surgeon General Report on Smoking Cessation concluded that, “Use of menthol cigarettes has been shown to contribute to tobacco cessation-related disparities in the United States.”⁸⁵

B. Menthol Cigarettes Have Slowed National Progress in Reducing Smoking.

Due to a combination of targeted marketing by the tobacco industry and the role that menthol plays in reducing cessation, menthol cigarette smoking in the U.S. has declined slower than non-menthol smoking. From 2009 to 2018, sales of non-menthol cigarettes declined by 33.1% nationally, while sales of menthol cigarettes declined by only 8.2%. Of the decline in total cigarette sales between 2009 and 2018, 91% is attributable to non-menthol cigarettes.⁸⁶ Similarly, NSDUH data show that while overall cigarette smoking has been declining, the proportion of smokers using menthol cigarettes continues to increase. Overall, about 4 out of 10 (39.9%) smokers used menthol cigarettes in 2018,⁸⁷ an increase from 34% in 2009.⁸⁸ By reducing smoking cessation, menthol has slowed the nation’s progress in reducing overall smoking.

V. MENTHOL CIGARETTES DISPROPORTIONATELY HARM THE HEALTH OF BLACK AMERICANS AND OTHER UNDERSERVED POPULATIONS.

A. Menthol Cigarette Smoking Is Disproportionately High Among Black Americans.

Greater use of menthol cigarettes among Black Americans was first noted by the tobacco industry when a 1953 survey for Brown & Williamson showed that 5% of Black Americans preferred Kool compared to 2% of white Americans.⁸⁹ The tobacco industry capitalized on this

⁸³ Smith, PH, et al., “Use of mentholated cigarettes and Likelihood of Smoking Cessation in the United States: A Meta-Analysis,” *Nicotine & Tobacco Research*, 22(3):307-316, 2020.

⁸⁴ Smith, SS, et al., “Smoking cessation in smokers who smoke menthol and non-menthol cigarettes,” *Addiction*, 109:2107-2117, 2014.

⁸⁵ HHS, *Smoking Cessation. A Report of the Surgeon General*, 2020.

⁸⁶ Delnevo, CD, et al., “Assessment of Menthol and Nonmenthol Cigarette Consumption in the US, 2000 to 2018,” *JAMA Network Open* e2013601, 2020.

⁸⁷ Delnevo, CD, et al., “Banning Menthol Cigarettes: A Social Justice Issue Long Overdue,” *Nicotine & Tobacco Research* 22(10):1673-1675, 2020 (“Banning Menthol”).

⁸⁸ TPSAC Report at 37.

⁸⁹ Gardiner, PS, “The African Americanization of menthol cigarette use in the United States,” *Nicotine & Tobacco Research* 6 Suppl 1:S55-65, 2004; Roper, BW, “A Study of People’s Cigarette Smoking Habits and Attitudes Volume I. Philip Morris,” Bates No. 2022239249; MSA, Inc, 1953.

small difference and, as described in the following section, has ruthlessly targeted the Black community for decades with marketing for menthol cigarettes. This exploitative marketing has been tremendously effective, as indicated by the dramatic increase in use of menthol cigarettes among Black Americans. Data from the NSDUH show that since at least 2004, over 80% of Black people who smoke ages 12 and older used menthol cigarettes.⁹⁰ The latest data from the 2019 NSDUH show that 85% of Black smokers use menthol cigarettes, compared to 30% of white people who smoke. *See* 87 Fed. Reg. at 26,485. As noted in the proposed rule (at 26,462), this disparity persists regardless of age. For example, a study released after publication of the proposed rule, using data from the 2018-2019 wave of the PATH study, found that the odds of menthol smoking among Black young adults who smoke were 4.5 times that of white young adults who smoke.⁹¹

B. The Tobacco Industry Has Targeted Black Americans with Marketing for Menthol Cigarettes for Decades.

The high prevalence of menthol cigarette use among Black Americans is no accident, but the result of decades of targeted and insidious marketing by the tobacco industry. The tobacco industry has targeted Black Americans through sponsorship of community and music events, magazine advertising, and retail promotions. The industry often appropriates Black culture and music to sell these deadly and addictive products. The deadly success of these campaigns is reflected by the growth in prevalence of menthol cigarettes among Black people who smoke. As described in the previous section, menthol preference among Black people who smoke grew from less than 10% in the 1950s⁹² to 85% today. 87 Fed. Reg. at 26,485.

The establishment of popular magazines like *Ebony* and *Jet* provided marketing venues that had not previously existed for reaching Black consumers. Since the 1960s and continuing into the 21st century, the tobacco industry has strategically placed advertising for menthol cigarettes in magazines with high Black readership. These advertisements feature Black models and use themes that have been effective industry strategies over the decades, including associating smoking with a desirable lifestyle. From 1998 to 2002, *Ebony* was 9.8 times more likely than *People* to contain ads for menthol cigarettes.⁹³ Expenditures for magazine advertising of mentholated cigarettes increased from 13% of total ad expenditures in 1998 to 76% in 2006.⁹⁴

⁹⁰ Giovino, G.A., et al. "Differential trends in cigarette smoking in the USA: is menthol slowing progress?," *Tobacco Control* 24(1): 28-37, 2015.

⁹¹ Watkins, SL, et al., "Flavored Tobacco Product Use Among Young Adults by Race and Ethnicity: Evidence From the Population Assessment of Tobacco and Health Study," *Journal of Adolescent Health* S1054-139X(22)00334-2, 2022.

⁹² Gardiner, PS, *supra* note 89; Roper, BW, *supra* note 89.

⁹³ Landrine, H, et al., "Cigarette advertising in Black, Latino and White magazines, 1998-2002: An exploratory investigation," *Ethnic Disparities* 15(1):63-7, 2005.

⁹⁴ Alpert, H, Koh, HK, & Connolly, GN, "After the Master Settlement Agreement: Targeting and exposure of youth to magazine tobacco advertising," *Health Affairs* 27(6):w503-w512, 2008.

The tobacco companies also considered free sampling to be an important strategy for attracting new customers, employing mobile van programs across the country to reach Black Americans. Lorillard introduced the Newport Pleasure Van program in 1979 in New York, before expanding to other U.S. cities, to distribute free samples and coupons. Kool and Salem subsequently mimicked this exploitative strategy, reaching Black Americans in cities across the country.⁹⁵ The tobacco companies also developed specific strategies and product displays for smaller retailers, which were more common in cities, through programs like Brown & Williamson's Kool Inner City Family Program, with the explicit goal of "reach[ing] the core of Kool's franchise (young, black, relatively low income and education)."⁹⁶

Recognizing the value of brand association, sponsorship of popular community events, particularly focused around music, became another industry targeting tactic. Industry-sponsored events included Brown & Williamson's Kool Jazz Festival, R.J. Reynolds' Salem Summer Street Scenes festivals, and Philip Morris' Club Benson & Hedges promotional bar nights, which targeted clubs frequented by Black Americans.⁹⁷ R.J. Reynolds estimated that they reached at least half of Black Americans in Memphis, Detroit, Chicago, New York, and Washington, D.C. through their Salem Summer Street Scenes festivals.⁹⁸

Prior to the Master Settlement Agreement's prohibition on cigarette billboard advertising, the tobacco industry also used this medium to target underserved populations. Research from several cities across the country found that low-income and Black neighborhoods had significantly more cigarette billboard ads compared to white neighborhoods.⁹⁹ Finally, the tobacco industry targeted Black youth through branding and packaging designs featuring culturally-appropriated images. In 2004, Brown & Williamson started the Kool Mixx campaign that featured images of young Black rappers, DJs, and dancers on cigarette packs and in advertising. The campaign also included radio giveaways with cigarette purchases and a hip hop DJ competition in major cities. Attorneys General from several states promptly filed motions

⁹⁵ 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* 18:10-38, 2007; Hafez, N. & Ling, P.M. "Finding the Kool Mixx: how Brown & Williamson used music marketing to sell cigarettes," *Tobacco Control* 15:359-366, 2006.

⁹⁶ Hudson RC, *Brown & Williamson Inner city POP Program*, BROWN & WILLIAMSON TOBACCO CORPORATION, 1979, <http://legacy.library.ucsf.edu/tid/icb91d00>; Yerger, VB, *supra* note 95.

⁹⁷ Hafez & Ling, *supra* note 95; see Yerger, VB, *supra* note 95; see also RJ Reynolds, *Black Street Scenes: review and recommendations*, R.J. REYNOLDS TOBACCO COMPANY, 1983, <http://legacy.library.ucsf.edu/tid/onb19d00>.

⁹⁸ Yerger, VB, *supra* note 95; see RJ Reynolds, *supra* note 97.

⁹⁹ Hackbarth DP, et al., "Tobacco and alcohol billboards in 50 Chicago neighbourhoods: market segmentation to sell dangerous products to the poor," *J Health Policy* 16:213-30, 1995; Luke D, et al., "Smoke signs: patterns of tobacco billboard advertising in a metropolitan region," *Tobacco Control* 9(1):16-23, 2000; Stoddard JL, et al., "Targeted tobacco markets: outdoor advertising in Los Angeles minority neighbourhoods," *Am J Public Health* 87:1232-3, 1997.

against Brown & Williamson for advertising to youth in violation of the Master Settlement Agreement.¹⁰⁰

Today, menthol cigarettes continue to be more heavily advertised, widely available, and priced cheaper in Black communities, making them especially appealing to price-sensitive youth. A wealth of research indicates that Black neighborhoods have a disproportionate number of tobacco retailers, pervasive tobacco marketing, and in particular, more marketing of menthol products.¹⁰¹ Nationally, stores in neighborhoods with the highest proportion of Black Americans have more than double the odds of advertising price promotions for tobacco products, compared to stores in neighborhoods with the lowest proportion of Black Americans.¹⁰² A 2011 study of cigarette prices in retail stores across the U.S. found that Newport cigarettes are significantly less expensive in neighborhoods with higher proportions of Black residents.¹⁰³ Consistent with findings from previous California studies,¹⁰⁴ an analysis of California retailers in 2018 found that controlling for store type, neighborhood poverty, and other covariates, tobacco retailers in neighborhoods with the highest proportions of Black residents were more likely to advertise menthol cigarettes and charged an estimated 25 cents less for Newport cigarettes, compared with stores in neighborhoods with the lowest proportion of Black residents.¹⁰⁵ The disproportionate availability, advertising, and pricing of menthol cigarettes in certain retailers is not coincidental but a result of careful strategizing by the industry. For example, a recent scoping review of tobacco industry contracts with retailers identified a 2017 Reynolds American Inc. Trade Marketing Services Company Menthol Outlet Plan that required contracted retailers to have a menthol share of market of 50% or greater, to pass the full amount of any price discount directly to the customer, and to keep products and displays in highly visible locations.¹⁰⁶

¹⁰⁰ Hafez & Ling, *supra* note 95.

¹⁰¹ Lee, JGL, et al., “A Systematic Review of Neighborhood Disparities in Point-of-Sale Tobacco Marketing,” *American Journal of Public Health* 105(9):e8-18, 2015; Moreland-Russell, S, *supra* note 54; Schleicher, N, et al., “Tobacco Marketing in California’s Retail Environment (2008-2011) Final report for the California Tobacco Advertising Survey,” *Stanford Prevention Research Center*, 2013; Henriksen, L., *supra* note 53; Seidenberg, AB, “Cigarette Advertising Differs by Community Demographic Profile,” *American Journal of Health Promotion* 24(6):e26-e31, 2010.

¹⁰² Ribisl, KM, et al., “Disparities in tobacco marketing and product availability at the point of sale: results of a national study,” *Preventive Medicine* 105:381-388, 2017.

¹⁰³ Resnick, EA, et al., *Cigarette Pricing Differs by U.S. Neighborhoods—A BTG Research Brief*, HEALTH POLICY CENTER, INSTITUTE FOR HEALTH RESEARCH AND POLICY, UNIVERSITY OF ILLINOIS AT CHICAGO, 2012, www.bridgingthegapresearch.org.

¹⁰⁴ Schleicher, N, *supra* note 101; Henriksen, L., *supra* note 53.

¹⁰⁵ Henriksen, L, et al., “Menthol cigarettes in black neighbourhoods: still cheaper after all these years,” *Tobacco Control*, published online 2021.

¹⁰⁶ Reimold, AE, et al., ‘Tobacco company agreements with tobacco retailers for price discounts and prime placement of products and advertising: a scoping review.’ *Tobacco Control*, published online 2022.

Additional examples of tobacco industry marketing to Black communities can be found in the report, “Stopping Menthol, Saving Lives: Ending Big Tobacco’s Predatory Marketing to Black Communities.”¹⁰⁷

C. Black Americans Suffer a Disproportionate Toll of the Disease and Death Caused by Menthol Cigarettes.

The tobacco industry’s targeted marketing of menthol cigarettes in the Black community has had a devastating health impact. Tobacco use is the number one cause of preventable death among Black Americans, claiming 45,000 Black lives every year.¹⁰⁸ Black Americans die from smoking-caused diseases at far higher rates than other Americans despite starting to smoke at a later age, smoking fewer cigarettes per day, and being more likely to make a quit attempt.¹⁰⁹ As detailed in Section IV above, menthol cigarettes reduce smoking cessation, and these effects are most pronounced among Black people who smoke. As a result, Black people who smoke suffer disproportionately from the health effects of smoking. In fact, a recent study found that among the African American community, menthol cigarettes were responsible for 1.5 million extra smokers, 157,000 smoking-related premature deaths, and 1.5 million excess life-years lost between 1980 and 2018.¹¹⁰ During this time, African Americans represented 15% of extra new smokers, 41% of excess premature deaths and 50% of excess life-years lost, despite only accounting for 12% of the population.¹¹¹

In 1998, the Surgeon General concluded that African Americans bear the greatest health burden due to cigarette smoking, compared to any other racial or ethnic group.¹¹² To this day, African Americans have the highest death rates and shortest survival for most tobacco-related cancers of any racial or ethnic group.¹¹³ Each year, more than 72,000 African Americans are diagnosed with a tobacco-related cancer and more than 39,000 die from a tobacco-related

¹⁰⁷ Campaign for Tobacco-Free Kids, *Stopping Menthol, Saving Lives: Ending Big Tobacco’s Predatory Marketing to Black Communities*, 2021, https://www.tobaccofreekids.org/assets/content/what_we_do/industry_watch/menthol-report/2021_02_tfk-menthol-report.pdf.

¹⁰⁸ HHS, *Tobacco Use Among US Racial/Ethnic Minority Groups—African Americans, American Indians and Alaskan Natives, Asian Americans and Pacific Islanders, and Hispanics: A Report of the Surgeon General*, 1998.

¹⁰⁹ Roberts, ME, et al., “Understanding tobacco use onset among African Americans,” *Nicotine & Tobacco Research* 18(S1):S49-S56, 2016; Alexander, LA, et al., “Why we must continue to investigate menthol’s role in the African American smoking paradox,” *Nicotine & Tobacco Research* 18(S1):S91-S101, 2016; CDC, “Quitting Smoking Among Adults—United States, 2000-2015,” *MMWR*, 65(52):1457-1464, 2017. www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6552a1.pdf.

¹¹⁰ Mendez, D & Le, TT, “Consequences of a match made in hell: the harm caused by menthol smoking to the African American population over 1980-2018,” *Tobacco Control* 056748, 2021.

¹¹¹ *Id.*

¹¹² HHS, *Tobacco Use Among US Racial/Ethnic Minority Groups—African Americans, American Indians and Alaskan Natives, Asian Americans and Pacific Islanders, and Hispanics: A Report of the Surgeon General*, 1998. .

¹¹³ American Cancer Society (ACS), *Cancer Facts & Figures for African American/Black People 2022-2024*, 2022. <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/cancer-facts-and-figures-for-african-americans/2022-2024-cff-aa.pdf>.

cancer.¹¹⁴ Smoking is responsible for over 80% of lung cancer deaths.¹¹⁵ Lung cancer is the second most common cancer in both African American men and women, but kills more African Americans than any other type of cancer. For Black men, lung cancer is the leading cause of cancer death, and for Black women, it's the second-leading cause.¹¹⁶ In 2022, it is estimated that 25,690 Black individuals will be diagnosed with lung cancer and 14,160 Black persons will die from it.¹¹⁷ Smoking is also a major cause of heart disease and stroke—the only conditions that kill more people in the Black community than lung cancer.¹¹⁸ Black Americans are 20% more likely to die from heart disease,¹¹⁹ 50% more likely to have a stroke, and 40% more likely to die from a stroke than white Americans.¹²⁰

Menthol cigarettes also increase harms to people who do not smoke to the extent that they increase exposure to cigarette smoking, and this is particularly true for Black Americans. Black Americans are disproportionately affected by exposure to secondhand smoke—nearly half (48.0%) are still exposed to this preventable health hazard.¹²¹ Rates are even higher among youth. Among Black youth aged 3-11 years, two-thirds (66.2%) are exposed to secondhand smoke, compared to 38.1% of white youth of the same age.¹²² Exposure to secondhand smoke is known to cause sudden infant death syndrome (SIDS), respiratory infections, ear infections, and more severe asthma attacks in children, as well as heart disease, stroke, and lung cancer in adults.¹²³

D. Menthol Cigarettes Are Disproportionately Used by Other Underserved Population Groups.

In addition to Black Americans, menthol cigarettes are also disproportionately smoked by other underserved populations:

- 50% of Hispanic people who smoke use menthol cigarettes,¹²⁴ compared to 30% for white people who smoke. Research also shows that Hispanic and Latino people who

¹¹⁴ CDC, “Vital Signs: Disparities in Tobacco-Related Cancer Incidence and Mortality—United States, 2004-2013,” *MMWR* 65(44): 1212-1218, 2016; See ACS, *supra* note 113.

¹¹⁵ ACS, *Cancer Facts & Figures 2022*, 2022, <https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2022.html>; See, HHS, *The Health Consequences of Smoking. A Report of the Surgeon General*, 2004.

¹¹⁶ ACS, *supra* note 113.

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ CDC, *National Vital Statistics Report*, Vol. 68, No. 9. Table 10, 2019, www.cdc.gov/nchs/data/nvsr/nvsr68/nvsr68_09-508.pdf.

¹²⁰ *Id.*

¹²¹ Shastri SS, et al., “Disparities in Secondhand Smoke Exposure in the United States: National Health and Nutrition Examination Survey 2011-2018,” *JAMA Intern Med.* 181(1):134–137, 2021.

¹²² Brody DJ, et al., *Secondhand smoke exposure among nonsmoking youth: United States, 2013–2016*, NCHS Data Brief, no 348,. NATIONAL CENTER FOR HEALTH STATISTICS, 2019.

¹²³ HHS, *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*, 2014.

¹²⁴ Delnevo, CD, “Banning Menthol,” *supra* note 87.

- smoke menthol cigarettes have more difficulty quitting than people who smoke non-menthol cigarettes.¹²⁵
- 51% of lesbian/gay and 46% of bisexual people who smoke use menthol cigarettes, compared to 39% of heterosexual people who smoke.¹²⁶
 - 45% of smokers with severe psychological distress use menthol cigarettes compared to 39% of smokers with no past-month serious psychological distress.¹²⁷ Menthol smokers with mental illness have some of the lowest quit rates of any demographic.¹²⁸
 - 47% of smokers who live in poverty use menthol cigarettes, compared to 36% of smokers with an income exceeding twice the federal poverty threshold.¹²⁹
 - 60% of pregnant women who smoke use menthol cigarettes.¹³⁰ Additionally, women—especially Black women—who smoke menthol cigarettes prior to pregnancy are more likely to start smoking again postpartum than those who smoke non-menthol cigarettes.¹³¹

There is evidence that the tobacco industry has also targeted some of these groups with marketing for menthol cigarettes. For example, from 1998 to 2002, the Spanish language version of *People* magazine was 2.6 times more likely to have menthol cigarette ads than the English language version.¹³² Over the same timeframe, the Spanish language versions of *Cosmopolitan* and *Glamour* were 2.6 times more likely to have menthol cigarette ads than the English versions. Sixty percent of the cigarette ads in the Spanish language *Cosmopolitan* and *Glamour* magazines were for *Kool* and *Newport* cigarettes.¹³³ There is little doubt that prohibiting menthol as a characterizing flavor in cigarettes would reduce smoking across a wide range of underserved populations and thereby enhance health equity.

¹²⁵ 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; 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; Trinidad, DR, et al., “Menthol Cigarettes and Smoking Cessation Among Racial/Ethnic Groups in the United States,” *Addiction*, 105(1): 84–94, 2010; Gandhi, K., 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.

¹²⁶ Delnevo, CD, “Banning Menthol,” *supra* note 87.

¹²⁷ *Id.*

¹²⁸ Cohn, AM, et al., “Menthol tobacco use is correlated with mental health symptoms in a national sample of young adults: implications for future health risks and policy recommendations,” *Tobacco Induced Diseases* 14(1):1-10, 2016.

¹²⁹ Delnevo, CD, “Banning Menthol,” *supra* note 87.

¹³⁰ *Id.*

¹³¹ Reitzel, L. et al., “Race/ethnicity moderates the effect of prepartum menthol cigarette use on postpartum smoking abstinence,” *Nicotine & Tobacco Research* 13(12), at 1305–1310, 2011.

¹³² Iglesias-Rios, L. & Parascandola, M., “A Historical Review of R.J. Reynolds’ Strategies for Marketing Tobacco to Hispanics in the United States,” *Am J Pub Health* 103(5): e15-27, 2013.

¹³³ *Id.*

VI. PROHIBITING MENTHOL CIGARETTES WILL PRODUCE SUBSTANTIAL PUBLIC HEALTH BENEFITS.

Experts estimate that eliminating menthol cigarettes would lead 30.1% of menthol smokers aged 18 to 24, and 20.1% of menthol smokers aged 35 to 54, to quit combustible tobacco use over two years, and prevent 39.1% of 12 to 24 year-olds from initiating tobacco use.¹³⁴ Based on these estimates, researchers projected that prohibiting menthol cigarettes in the United States in 2021 would have reduced overall smoking by 15% and saved 650,000 lives by 2060.¹³⁵ Since publication of the proposed rule, these researchers have also modeled the public health impact of eliminating menthol on Black Americans. They estimate that eliminating menthol cigarettes would reduce Black adult smoking by 35.7% in the first five years, compared to 15% nationwide. By 2060, they estimate that the proposed rule would decrease Black adult smoking-attributable deaths by about 18.5% and years of life lost by 22.1%, translating to 255,895 premature deaths averted, and 4 million life-years gained over a 40-year period. The averted deaths and life years lost among Black Americans amount to about one-third of the total savings, despite Black Americans comprising just 13% of the US population.¹³⁶ These estimates build on a previous modeling study published in 2011, which projected that prohibiting menthol cigarettes in 2011 would have saved over 630,000 lives by 2050, including over 230,000 Black lives, assuming a 30% reduction in initiation and 30% increase in cessation.¹³⁷

A. Prohibiting Menthol Cigarettes Will Reduce Youth Smoking Initiation and Progression to Regular Use.

If menthol as a characterizing flavor is prohibited in cigarettes, cigarettes would be less appealing to youth and fewer youth would repeatedly experiment with cigarettes, become addicted, and progress to regular smoking, thereby protecting youth from smoking-attributable disease and death. Reducing the appeal of cigarettes to youth is one of the most important ways to reduce population smoking levels. Indeed, 90% of adults who smoke begin while in their teens, or earlier, and two-thirds begin to smoke daily before they reach the age of 19.¹³⁸

State and local restrictions on the sale of flavored tobacco products in the United States provide preliminary evidence that these types of policies reduce youth tobacco use. For example, from 2016 to 2019—during which time Minneapolis and St. Paul enacted flavored tobacco

¹³⁴ Levy, DT, et al., “An expert elicitation on the effects of a ban on menthol cigarettes and cigars in the United States,” *Nicotine & Tobacco Research*, 23(11):1911-1920, 2021.

¹³⁵ Levy, DT, et al., “Public health impact of a US ban on menthol in cigarettes and cigars: a simulation study,” *Tobacco Control* published online 2021.

¹³⁶ Issabakhsh, M, et al., “The Public Health Impact of a US Menthol Cigarette Ban on the Non-Hispanic Black Population: A Simulation Study,” *Tobacco Control*, published online 2022.

¹³⁷ Levy, DT, 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):1236-1240, 2011.

¹³⁸ HHS, *Preventing Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General*, 2012; HHS, *Youth and Tobacco: Preventing Tobacco Use among Young People: A Report of the Surgeon General*, at 49, 1994.

restrictions—cigarette use prevalence decreased to a greater extent in the Twin Cities than the rest of the state.¹³⁹ A study in Massachusetts found that counties with greater implementation of flavored tobacco product restrictions were associated with reductions in the frequency of cigarette use among users.¹⁴⁰ Research shows that in addition to reducing the availability of menthol cigarettes, local flavor restrictions may also reduce retail cigarette advertising. As described in Section III.B., the tobacco industry has intentionally targeted young people with marketing for menthol cigarettes and it is well-established that industry marketing causes youth smoking. A study of retailers in the San Francisco Bay Area found that in addition to reduced availability of menthol cigarettes, communities that had passed sales restrictions on flavored tobacco products had significant reductions in exterior advertising for both non-menthol and menthol cigarettes.¹⁴¹ As many of these policies have only been passed in recent years, evidence is still emerging. In addition, it is likely that studies on local laws underestimate the potential impact of a national policy since some local laws have retailer exemptions and because, under a national policy, flavored tobacco products will not be available in neighboring jurisdictions.

B. Prohibiting Menthol Cigarettes Will Increase Smoking Cessation.

1. Many People who Smoke Menthol Cigarettes Report that They Will Quit Smoking if Menthol Cigarettes May No Longer Be Sold.

According to national data, 68% of all people who smoke want to quit, suggesting that many people who smoke menthol cigarettes will attempt to quit in response to a menthol prohibition. While Black people who smoke report greater interest in quitting than white smokers (72.8% vs. 67.5%) and a greater proportion of Black people who smoke report a past-year quit attempt (63.4% vs. 53.3%), fewer Black smokers than white smokers successfully quit (4.9% vs. 7.1%), due in large part to their preference for menthol cigarettes, which are harder to quit.¹⁴² Since Black smokers disproportionately use menthol cigarettes, prohibiting menthol cigarettes will have a more pronounced increased cessation benefit among Black smokers, helping to reverse disparities in smoking cessation and smoking-related disease.

Studies that assess the anticipated reactions to a menthol prohibition from people who smoke suggest that many would quit smoking rather than switch to non-menthol cigarettes, with Black smokers being particularly likely to report that they would quit smoking. For example, a nationally representative survey conducted in 2010 found that 38.9% of all people who smoke menthol cigarettes, including 44.5% of African American menthol smokers, say they would try

¹³⁹ Olson, LT, et al., “Youth Tobacco Use Before and After Local Sales Restrictions on Flavored and Menthol Tobacco Products in Minnesota,” *Journal of Adolescent Health* 70(6):978-984, 2022.

¹⁴⁰ Hawkins, S, et al., “Flavoured tobacco product restrictions in Massachusetts associated with reductions in adolescent cigarette and e-cigarette use,” *Tobacco Control* 31:576-579, 2021.

¹⁴¹ Holmes, LM, et al., “Flavored Tobacco Sales Restrictions Reduce Tobacco Product Availability and Retailer Advertising.” *International Journal of Environmental Research and Public Health* 19(6):3455, 2022.

¹⁴² CDC, “Quitting Smoking Among Adults—United States, 2000-2015,” *MMWR*, 65(52):1457-1464, 2017.

to quit smoking if menthol cigarettes were prohibited.¹⁴³ A 2011–2016 analysis of data from the Truth Initiative Young Adult Cohort showed that among people who smoked menthol cigarettes in the past 30 days, African American smokers had greater odds of reporting that they would quit smoking if menthol cigarettes were unavailable compared to white smokers.¹⁴⁴

2. Real-World Evidence Demonstrates that Prohibiting Menthol Cigarettes Increases Smoking Cessation.

While the menthol cigarette market is notably smaller in Canada as compared to the United States, evidence from Canada’s menthol prohibition is informative for understanding the potential behavioral impacts of a menthol product standard in the United States. Surveillance from Ontario, which prohibited menthol cigarettes in January 2017, shows promising evidence that ending the sale of menthol cigarettes increases quit attempts and cessation:

- A 1-year follow-up survey found that people who smoked menthol cigarettes daily and those who smoked occasionally were more likely than people who smoked non-menthol cigarettes to report having quit smoking (24% and 20%, vs 14%) or having made a quit attempt (63% and 62%, vs 43%).¹⁴⁵
- A 2-year follow-up survey found that people who smoked menthol cigarettes were more likely to report having quit smoking for at least the last 6 months (12% for people who smoked menthol cigarettes daily and 10% for people who smoked menthol cigarettes occasionally), compared to people who smoked non-menthol cigarettes (3%), with no significant differences in relapse rates. People who smoked menthol cigarettes also reported more quit attempts than people who smoked non-menthol cigarettes. People who smoked menthol cigarettes daily reported an average of 3 quit attempts, compared to 2.6 for people who smoked menthol cigarettes occasionally and 1.2 for people who smoked non-menthol cigarettes.¹⁴⁶

Data from the International Tobacco Control Policy Evaluation Project (ITC), evaluating the impact of Canada’s national prohibition, are consistent with the findings on the impact of the Ontario menthol prohibition. Specifically, ITC researchers, using longitudinal surveys of Canadian smokers in seven provinces from 2016-2018 found that following provincial prohibitions and the national prohibition, people who smoked menthol cigarettes were more

¹⁴³ Pearson JL, et al., “A Ban on Menthol Cigarettes: Impact on Public Opinion and Smokers’ Intention to Quit,” *American Journal of Public Health* 102(11):e107-e114, 2012.

¹⁴⁴ Rose, SW, et al., “Longitudinal Response to Restrictions on Menthol Cigarettes Among Young Adult US Menthol Smokers, 2011– 2016,” *American Journal of Public Health* 109:1400–1403, 2019.

¹⁴⁵ Chaiton, M, et al., “Ban on menthol-flavoured tobacco products predicts cigarette cessation at 1 year: a population cohort study,” *Tobacco Control* 29(3):341-347, 2019.

¹⁴⁶ Chaiton, M, et al., “Prior daily menthol smokers more likely to quit two years after a menthol ban than non-menthol smokers: a population cohort study,” *Nicotine & Tobacco Research* 23(9):1584-1589, 2021.

likely to try to quit than people who smoked non-menthol cigarettes (59% vs. 49%), and were twice as likely to have quit smoking for at least six months (12% vs. 6%).¹⁴⁷

Even since publication of the proposed rule, evidence from Canada has continued to emerge regarding the public health benefits of prohibiting menthol cigarettes. Pooled findings from the previously described ITC data and one-year analysis of Ontario's law show that, following these prohibitions, quit rates among people who smoked menthol cigarettes were 7.3 percentage points (22.3% vs. 15%) higher than among people who smoked non-menthol cigarettes. Applying this effect size to the United States, researchers estimate that a menthol product standard in the United States would lead over 1.3 million people who smoke to quit, including 381,000 Black people.¹⁴⁸ It is important to note that due to differences in the marketplace and population of people who smoke menthol cigarettes, it is likely that these findings from Canada underestimate the benefits of a menthol product standard in the United States.

In addition to Canada, research is emerging on the impact of the European Union's May 2020 menthol prohibition. Data from the ITC Netherlands survey show that pre-prohibition menthol smokers were more likely than non-menthol smokers to make a quit attempt (62.4% vs. 47.8%) and quit (18.9% vs. 12.0%) by June/July 2021. Due to small sample sizes, these results did not remain significant after controlling for covariates. However, it is compelling that the effect size for Dutch smokers (6.9%) is similar to the experience in Canada (7.3%). Applying the effect size from the Netherlands to the rest of the European Union and United Kingdom population, researchers estimate that the menthol prohibition could lead more than half a million people who smoke menthol cigarettes to quit.¹⁴⁹

To the extent that sales data can be considered a proxy for smoking behavior, evidence from state and local menthol prohibitions in the United States also suggest that these policies reduce both menthol and overall smoking. Following implementation of San Francisco's comprehensive prohibition on all flavored tobacco product sales, predicted average weekly sales of menthol cigarettes decreased by 96% and predicted average weekly sales of all cigarettes decreased by 23%. That the flavor prohibition led to decreases in both flavored and total tobacco sales led the study's authors to conclude that, "A reduction in total tobacco sales in SF suggests

¹⁴⁷ Chung-Hall, et al., "Evaluating the impact of menthol cigarette bans on cessation and smoking behaviours in Canada: longitudinal findings from the Canadian arm of the 2016-2018 ITC Four Country Smoking and Vaping Surveys," *Tobacco Control* 31:556-563, 2021.

¹⁴⁸ Fong, GT, et al., "Impact of Canada's menthol cigarette ban on quitting among menthol smokers: pooled analysis of pre-post evaluation from the ITC Project and the Ontario Menthol Ban Study and projections of impact in the USA." *Tobacco Control*, published online 2022.

¹⁴⁹ Kyriakos, CN, et al., "The impact of the EU menthol cigarette ban on cessation and smoking behaviors: Longitudinal findings from the 2020-2021 ITC Netherlands survey," *presented at the 2022 Annual Conference of the Society for Research on Nicotine and Tobacco*, March 2022.

there was not a one-to-one substitution of tobacco/unflavored products for flavored products.”¹⁵⁰ Likewise, the Massachusetts statewide menthol prohibition was associated with a statistically significant decrease in both state-level menthol and overall cigarette sales. Adjusted 4-week sales of cigarettes in Massachusetts, compared to baseline states that had not passed flavor policies, decreased by 372.27 packs per 1000 people for menthol cigarettes but increased by 120.25 packs per 1000 people for nonflavored cigarettes. Overall, the adjusted 4-week sales of all cigarettes decreased by 282.65 packs per 1000 people in Massachusetts versus the baseline states.¹⁵¹ As noted, it is likely that research on state and local policies underestimate the potential impact of a national policy since menthol cigarettes will not be available in neighboring jurisdictions.

C. Preventing Youth Initiation and Increasing Smoking Cessation Will Produce Tremendous Public Health Benefits.

By preventing cigarette uptake and progression to regular smoking among youth and young adults, as well as increasing cessation among people who currently smoke menthol cigarettes, the proposed rule will yield substantial population health benefits. As noted in the proposed rule, given the tremendous toll of tobacco in the United States, “Even small changes in initiation and cessation would result in a significant reduction in the burden of death and disease in the United States caused by smoking, including reductions in smoking-related morbidity and mortality, diminished exposure to secondhand smoke among non-smokers, decreased potential years of life lost, decreased disability, and improved quality of life for the current and future generations to come.” 87 Fed. Reg. at 26,485. Smoking remains the leading cause of preventable death in the United States, killing nearly half a million Americans each year. In addition, for every person who dies from smoking, 30 more—a total of about 16 million Americans—are living with a smoking-attributable disease.¹⁵²

Based on the evidence that menthol increases smoking initiation and progression to regular smoking, the proposed rule concludes that “a menthol restriction will prevent a substantial number of youth, and especially Black youth, from initiating menthol cigarette smoking, thereby decreasing progression to regular cigarette smoking, resulting in reduced tobacco-related morbidity and mortality associated with menthol cigarette smoking.” 87 Fed. Reg. at 26,477. Preventing youth from ever trying cigarettes will save them from a lifetime of smoking-attributable disease. It is estimated that roughly one-third of all youth who smoke will eventually die prematurely from smoking-caused disease.¹⁵³

¹⁵⁰ Gammon, DG, et al., “Implementation of a comprehensive flavoured tobacco product sales restriction and retail tobacco sales,” *Tobacco Control*, published online June 4, 2021.

¹⁵¹ Asare, S, et al., “Association of Cigarette Sales with Comprehensive Menthol Flavor Ban in Massachusetts,” *JAMA Internal Medicine* 182(2):231–234, 2021.

¹⁵² HHS, *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*, 2014.

¹⁵³ CDC, “Projected Smoking-Related Deaths Among Youth-United States,” *MMWR* 45(44):971-974, 1996.

Among people who currently smoke menthol cigarettes, smoking cessation will yield substantial health benefits. According to the Surgeon General, “Smoking cessation is beneficial at any age. Smoking cessation improves health status and enhances quality of life.”¹⁵⁴ As described in Part V, menthol cigarettes are disproportionately smoked by Black Americans and other underserved populations. By increasing cessation in these communities, the proposed rule will reduce smoking-related health disparities and increase health equity. The findings in the proposed rule strongly support FDA’s conclusion that, “Prohibiting menthol as a characterizing flavor in cigarettes would likely result in increased cigarette cessation among members of historically underserved communities, including Black smokers, due to increased quit attempts and lower likelihood of switching to non-menthol cigarettes.” 87 Fed. Reg. at 26,474.

D. Finalizing the Rule Prohibiting Characterizing Flavors in Cigars Will Enhance the Public Health Impacts of the Menthol Rule.

Pairing this rule with the rule prohibiting all characterizing flavors (other than tobacco) in cigars with the same effective dates will increase the likelihood that people who smoke menthol cigarettes will quit rather than switch to other combustible products. The tobacco industry has a well-documented history of manipulating products to take advantage of regulatory loopholes and is likely to encourage people who smoke menthol cigarettes to switch to menthol cigars, especially little cigars, if cigars with menthol and other non-tobacco characterizing flavors remain available. According to Nielsen data, from 2011-2015, menthol products represented 18% of little cigar sales.¹⁵⁵ The 2012 Surgeon General’s report, *Preventing Tobacco Use Among Youth and Young Adults*, highlighted the need to address flavored cigars, particularly because cigar manufacturers have manipulated flavored cigarettes so that they technically qualify as flavored cigars in an effort to circumvent the Tobacco Control Act’s prohibition on flavored cigarettes (other than menthol).¹⁵⁶

Evidence from the United Kingdom, which prohibited menthol as a characterizing flavor in cigarettes in May 2020 as part of the European Tobacco Products Directive, clearly demonstrates that the tobacco industry will try to shift people who smoke menthol cigarettes to menthol-flavored cigars if these products remain on the market. Five months before the United Kingdom’s prohibition, Japan Tobacco International introduced cigarillos with menthol capsules and the Scandinavian Tobacco Group subsequently launched a cigarillo with menthol capsules. While the overall cigar market has been declining, cigarillo sales in the United Kingdom have been growing since 2016 when the menthol prohibition was originally slated to go into effect.¹⁵⁷ Similarly, a study from Ontario, Canada found that after its prohibition on menthol cigarettes,

¹⁵⁴ HHS, *Smoking Cessation. A Report of the Surgeon General*, 2020.

¹⁵⁵ Kuiper, NM, et al., “Trends in sales of flavored and menthol tobacco products in the United States during 2011-2015,” *Nicotine & Tobacco Research* 20(6):698-706, 2017.

¹⁵⁶ HHS, *Preventing Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General*, 2012.

¹⁵⁷ Hiscock, R., et al., “Tobacco industry tactics to circumvent and undermine the menthol cigarette ban in the UK,” *Tobacco Control* 29(e1), e138-e142, 2020.

people who smoked menthol cigarettes daily or occasionally were more likely to use flavored cigars compared to people who smoked non-menthol cigarettes.¹⁵⁸

VII. THERE IS NO PUBLIC HEALTH JUSTIFICATION FOR EXEMPTIONS FROM THE RULE.

FDA requests comment on whether the rule should include a provision for “requesting an exemption from the standard for certain products within particular categories, on a case-by-case basis” and “for what types of products should firms be eligible to request an exemption.” 87 Fed. Reg. at 26,487. FDA also requests comments on various procedural issues related to the exemption process.

There is no public health justification for exemptions from a rule prohibiting menthol as a characterizing flavor in cigarettes, even for cigarettes already on the market that have received marketing orders and modified risk orders from FDA. Any cigarette with menthol as a characterizing flavor creates a risk of increasing youth initiation of cigarettes and may discourage people who smoke menthol cigarettes from using approved FDA therapies to stop smoking. It would undermine the purpose and impact of the rule prohibiting menthol cigarettes if FDA created a system to consider industry requests for exemptions.

The public health risks of exemptions from the menthol rule are demonstrated by the two categories of products cited by FDA as possible candidates for exemptions: non-combusted products and reduced nicotine products.

A. No Exemption Should Be Considered for IQOS Menthol or Similar Heated Tobacco Products.

As to non-combusted cigarette products, FDA has authorized the marketing of the Philip Morris International (PMI) IQOS heated tobacco product, including “Smooth Menthol” and “Fresh Menthol” Heatsticks (which have been renamed to “Green Menthol” and “Blue Menthol,” respectively). It also has authorized the use of reduced exposure claims allowing the company to claim that, because the IQOS system heats the tobacco, it “significantly reduces the production of harmful and potentially harmful chemicals” and that “scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body’s exposure to harmful or potentially harmful chemicals.” Exempting these IQOS products from the proposed rule would not be appropriate for the public health, as made clear by the Preamble to the proposed rule itself.

In the Preamble, FDA concluded that “menthol in cigarettes increases smoking initiation.” 87 Fed. Reg. at 26,463. By producing “a minty taste and cooling sensation when

¹⁵⁸ Chaiton M, et al., “Product Substitution After A Real-World Menthol Ban: A Cohort Study,” *Tobacco Regulatory Science* 6(3):205-212, 2020.

inhaled” menthol makes cigarettes more palatable for new users and facilitates “experimentation and regular use, particularly among younger smokers.” *Id.* These findings are likely as applicable to heated cigarette products like IQOS as they are to combustible cigarettes.

FDA also found that the interaction of menthol and nicotine in the brain enhances nicotine addiction, particularly among young people, resulting in increased nicotine dependence and making it more difficult for users to stop using such products. FDA stated, “[M]enthol, like nicotine, binds to nicotinic receptors in the brain . . . and menthol alone can increase the number of nicotinic receptors in the brain.” *Id.* at 26,457. An increase in nicotinic receptors is associated with the development of nicotine addiction. *Id.* at 26,468. FDA also noted that the combination of these chemicals is particularly damaging to young people, “The combined effects of nicotine and menthol in the developing brain make youth who smoke menthol cigarettes particularly vulnerable to the effects of menthol on nicotine dependence.” *Id.* at 26,465. The end result is that “menthol facilitates repeated experimentation and progression to regular smoking among youth and young adults.” *Id.* at 26,465.

FDA presented additional evidence demonstrating that the combined effects of menthol and nicotine also make it more difficult to stop using nicotine-containing products.

When an individual stops smoking, such as overnight or when attempting to quit, the nicotine levels in the brain decrease as the body clears nicotine, but the number of nicotinic receptors does not (Ref. 115). The combination of high levels of nicotinic receptors and low levels of nicotine in the brain produces the discomfort smokers feel when experiencing symptoms of nicotine withdrawal (Ref. 115). This is consistent with reports that smokers with greater brain nicotinic receptor levels have more difficulty quitting than smokers with lower brain nicotinic receptor levels.

Id. at 26,468.

In the Preamble, FDA documented the extensive data showing that, “In combination with menthol’s flavor and sensory effects, menthol’s interaction with nicotine in the brain plays a role in making it easier to experiment, progress to regular smoking and dependence, and harder to quit smoking.” *Id.* at 26,464. These findings rest on menthol’s flavor and sensory effects and the interaction between menthol and nicotine in the brain—features that are present in heated cigarette products like IQOS. Given that menthol increases initiation of tobacco products, leads to more regular use of tobacco products, and makes it harder to stop using such products, an exemption for IQOS menthol or similar menthol heated tobacco products would undercut the goals of the proposed rule to reduce smoking initiation and to make it easier for people who smoke menthol cigarettes to escape their addiction. There is no public health justification for FDA to consider an exemption for heated cigarette products like IQOS menthol.

In its modified risk applications to FDA, PMI did not submit any data on the impact of its menthol varieties of Heatsticks on U.S. youth or Black Americans, so it is unknown to what degree these populations are more or less susceptible to using these products if they were the only menthol options left on the market. There is a high likelihood that marketing these menthol Heatsticks, particularly with reduced exposure claims, would also have a disproportionately large impact on adolescents, including Black youth. A study showing high levels of current interest in and susceptibility to trying IQOS among U.S. youth noted that it studied only an “unflavoured” version of IQOS, but the marketing of menthol versions may raise the levels of interest and susceptibility among youth because menthol products “are associated with greater appeal among youth and young adults.”¹⁵⁹

PMI also failed to show that menthol heated tobacco products are necessary to encourage people who smoke menthol cigarettes to switch completely. Given the historical targeted marketing of menthol cigarettes in Black communities, a more likely result of leaving menthol heated tobacco products on the market would be to attract more Black users and discourage Black people who smoke from quitting tobacco entirely.

B. No Exemption Should Be Considered for Very Low Nicotine (VLN) Cigarettes or Similar Products.

FDA also has authorized the marketing of 22nd Century Group’s VLNTM Menthol combustible cigarettes. It has further authorized their marketing with various reduced exposure claims, including “95% less nicotine” and “greatly reduces nicotine consumption.” FDA also is requiring the company to include the phrase, “Helps you smoke less.” Exempting these products from the proposed menthol rule would undermine public health.

First, if VLNTM Menthol cigarettes were the only menthol cigarettes on the market, the reduced exposure claims, combined with the sensory impact of menthol, would create a risk of smoking initiation by youth, who may interpret the reduced exposure claims as suggesting that VLNTM cigarettes are safer cigarettes, when, in reality, they deliver the same level of toxicants as normal nicotine content (NNC) cigarettes. Indeed, FDA itself raised this concern in its PMTA review of VLNTM menthol, stating that, “As menthol in NNC cigarettes facilitates experimentation and progression to regular smoking, it is unknown to what degree smoking VLNTM Menthol King cigarettes may influence progression to regular smoking compared to NNC menthol cigarettes in new and inexperienced users, particularly youth and young adults.”¹⁶⁰ Further, there is no safe level of nicotine exposure for the developing brain. Given the potential risks to youth posed by VLN Menthol products and the continued presence of child-

¹⁵⁹ Czoli, CD, et al., “Awareness and interest in IQOS heated tobacco products among youth in Canada, England and the USA,” *Tobacco Control* 29(1):89-95, 2020.

¹⁶⁰ FDA, PMTA Scientific Review: Technical Project Lead (TPL) of 22nd Century Group, Inc’s Moonlight® and Moonlight® Menthol, PM0000491-0000492, at 8, 2019, <https://www.fda.gov/media/133633/download>.

appealing menthol flavoring, smoking initiation through use of VLNTM Menthol cigarettes will undoubtedly be harmful to youthful smokers. It may also lead to use of highly addictive NNC cigarettes and other nicotine products. There is also reason for concern that youth who may be addicted to menthol e-cigarettes and are seeking to reduce their exposure to nicotine would be enticed by VLN Menthol's nicotine reduction claims. If young people addicted to menthol e-cigarettes switch to or dual use VLNTM Menthol cigarettes, they will increase their toxicant exposure. These concerns are heightened given the existing evidence that youth e-cigarette use increases risk for smoking initiation.¹⁶¹

Second, the presence of VLNTM Menthol cigarettes on the market gives people who smoke menthol cigarettes a perceived alternative to using FDA-approved medications to quit, and likely will result in substantial dual use with other high-nicotine combustible cigarettes. This is particularly likely since the authorized reduced exposure claims do not make it clear that the smoker needs to completely switch to VLNTM cigarettes to substantially reduce nicotine consumption and to "smoke less." Moreover, because of the widespread public misperception that nicotine itself causes cancer,¹⁶² people who smoke menthol cigarettes are likely to believe that such dual use reduces disease risk, when in fact VLNTM cigarettes deliver the same level of toxins as high-nicotine cigarettes. Because the prevalence of menthol cigarette smoking is far greater among Black people who smoke than among white people who smoke, the risk that the continued marketing of VLNTM Menthol cigarettes will further delay cessation and the associated disease burden will fall disproportionately on Black smokers.

VIII. ANY RISKS OF UNINTENDED AND ADVERSE CONSEQUENCES FROM PROHIBITING MENTHOL CIGARETTES CAN BE AMELIORATED AND WILL NOT OUTWEIGH THE PUBLIC HEALTH BENEFITS.

A. Prohibiting Menthol Cigarettes Will Not Cause the Emergence of an Illicit Market that Will Nullify the Public Health Gains from Such a Policy.

FDA has requested comment on the extent to which the proposed rule "would result in an increased illicit trade in menthol cigarettes and how any such increase could impact the marketplace or public health." 87 Fed. Reg. at 26,484. The tobacco industry historically has both contributed to the global illicit market in cigarettes¹⁶³ and then distorted the facts to create a false

¹⁶¹ National Academies of Sciences, Engineering, and Medicine, *Public health consequences of e-cigarettes*, THE NATIONAL ACADEMIES PRESS, 2018.

¹⁶² Byron, MJ, et al., "Public misperception that very low nicotine cigarettes are less carcinogenic," *Tobacco Control* 27:712-714, 2018; O'Brien, EK, et al., "U.S. adults' addiction and harm beliefs about nicotine and low nicotine cigarettes," *Preventive Medicine* 96: 94-100, 2017; Denlinger-Apte, RL, et al., "Low nicotine content descriptors reduce perceived health risks and positive cigarette ratings in participants using very low nicotine content cigarettes," *Nicotine & Tobacco Research* 19(10):1149-1154, 2017; Pacek, LR, et al., "Perceived nicotine content of reduced nicotine content cigarettes is a correlate of perceived health risks," *Tobacco Control* 27:420-426, 2017.

¹⁶³ National Research Council and Institute of Medicine, *Understanding the U.S. Illicit Market: Characteristics, Policy Context, and Lessons from International Experiences*, NATIONAL ACADEMIES PRESS, at 62-63, 2015.

narrative of an uncontrolled illicit market to oppose tobacco control strategies proven to reduce smoking prevalence and save lives—including higher cigarette taxes, stronger health warnings, and stronger regulation. The industry always exaggerates the risk of an illegal market,¹⁶⁴ including the fear of the unlikely scenario that the illicit market in the affected products would be so large as to completely undermine the public health benefits of the proposed tobacco control policy. Such is the case with the industry’s opposition to the prohibition of menthol as a characterizing flavor in cigarettes. For the reasons given below, there is little reason to believe that an illicit market would arise from the proposed rule that would come close to nullifying the public health gains from that rule. As the National Research Council and the Institute of Medicine found, “[T]he limited evidence now available suggests that if conventional cigarettes are modified by regulations, the demand for illicit versions of them is likely to be modest.”¹⁶⁵

The industry’s arguments focus largely on the current illicit market, which consists of the diversion of cigarettes from the legal market to the illegal market in the form of smuggling finished packs of legal cigarettes from low-tax states to high-tax states.¹⁶⁶ As FDA’s Preliminary Regulatory Impact Analysis (RIA) of the proposed menthol rule observed:

[Whereas e]ase of cigarette transport across State lines is one of the factors allowing tax-evading illicit trade to flourish in certain parts of the United States . . . [t]his . . . would not be the case under the proposed product standard; because the proposed standard would apply nationwide, there would no legal domestic sales of nonconforming products to consumers. This suggests that absent other factors, the rates of existing tax-evading illicit trade in cigarettes will be higher than any illicit trade that could arise as a result of implementing this product standard.¹⁶⁷

Indeed, the industry fails to account for the substantial, unique barriers to sustaining a robust underground market for menthol cigarettes that would make maintaining such a market much more difficult than maintaining the current illicit market. For the reasons given below, there is a sound basis for FDA’s view that it “does not anticipate that a significant and consistently large supply of illicit menthol cigarettes would be available following rule implementation.”¹⁶⁸

¹⁶⁴ *Id.* at 9-10.

¹⁶⁵ *Id.* at 9.

¹⁶⁶ *See e.g.*, Altria Client Services, Comments in Docket No. FDA-2018-N-0529 (83 Fed. Reg. 11,754, March 16, 2018), “Draft Concept Paper: Illicit Trade in Tobacco Products After Implementation of a Food and Drug Administration Product Standard” (July 16, 2018), <https://www.altria.com/-/media/Project/Altria/Altria/about-altria/federal-regulation-of-tobacco/regulatory-filings/documents/ALCS-Comments-to-Dkt-No-FDA-2018-N-0529-Draft-Concept-Paper-Illicit-Trad.pdf> (Cigarette black markets in United States “due primarily to price differentials driven by state and municipal taxation.”).

¹⁶⁷ FDA, *Preliminary Regulatory Impact Analysis of Tobacco Product Standard for Menthol in Cigarettes*, Docket No. FDA-2021-N-1349, at 209, 2022, <https://www.fda.gov/media/158012/download> (“RIA”).

¹⁶⁸ *Id.* at 206.

First, whereas interstate smuggling involves the diversion of finished products into the illegal market, a substantial illicit market in menthol cigarettes must involve the large-scale manufacturing of illegal products. The establishment of a clandestine manufacturing facility, involving multiple individuals and capable of producing and shipping a substantial number of menthol cigarettes—in violation of a host of federal laws—is highly implausible. Moreover, the enactment of the Prevent All-Cigarette Trafficking (PACT) Act, which requires the pre-payment of taxes on internet, mail order, and other non-face-to-face cigarette sales (known as “delivery sales”), and prohibits the sending of cigarettes through the U.S. mail, will be a potent tool against the emergence of a significant illegal market of menthol cigarettes.¹⁶⁹

Second, 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, in which the illicit market functions to conceal the illegality of the product. Thus, cigarettes smuggled from low-tax to high-tax jurisdictions often have counterfeit tax stamps and thus are not immediately apparent as illegal; even counterfeit cigarettes are disguised as legitimate. Moreover, even if it were not clear from the packaging or promotion that cigarettes were mentholated, the use of menthol as a characterizing flavor would be readily apparent to anyone inspecting or sampling them. Therefore, the manufacture and sale of illicit menthol cigarettes is inherently difficult to conceal from the authorities.

Third, given the difficulties in conducting the clandestine manufacture, promotion, and sale of significant numbers of illicit menthol cigarettes, there is every likelihood that federal enforcement will be sufficient to minimize the illegal market. This was the conclusion of 23 state and territorial Attorneys General, the leading law enforcement officials in their jurisdictions, in comments filed in support of the Citizen Petition to Prohibit Menthol as a Characterizing Flavor in Cigarettes:

Federal enforcement ranges from U.S. Customs and Border Protection actions to prevent the importation of prohibited products, to Alcohol and Tobacco Tax and Trade Bureau inspections of cigarette manufacturers and to the FDA’s own requirements that manufacturers report ingredients. Also, the FDA’s Office of Enforcement and Compliance operates a nationwide tobacco retailer inspection and enforcement program, inspecting tens of thousands of stores every year. Thus, at all levels—manufacturing, importing and selling—there are nationwide

¹⁶⁹ Although it is possible that some menthol smokers would seek out products that could be used to add menthol to non-menthol cigarettes, as FDA notes, those products (like flavor cards, drops, oils or other additives) also would be subject to the proposed rule (87 Fed. Reg. at 26,483) and thus also would require large-scale illicit manufacturing enterprises in order to significantly impact the efficacy of the rule.

programs that make it unlikely that an illicit trade in menthol cigarettes will emerge.¹⁷⁰

Moreover, the experience of states and cities in increasing cigarette taxes itself undermines the industry's assertion that a burgeoning illicit market in menthol cigarettes would undermine any public health gains from the proposed rule. Despite interstate smuggling of cigarettes, 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 adults who smoke by 3.5%, and reduces the number of youth who smoke by 6-7%.¹⁷¹ 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. As CDC found, "Significant increases in state and local tobacco taxes generate reductions in tobacco use and raise tobacco tax revenues for the jurisdiction, despite the tax avoidance and evasion that results from significant tax and price differentials in the United States."¹⁷² 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."¹⁷³ In short, nothing in the history and economics of cigarette tax and price increases suggests that an illicit market in menthol cigarettes would be so substantial as to nullify the public health gains from prohibiting menthol as a characterizing flavor.

The national experience with cigarette flavor prohibitions in the U.S. and Canada provides no support for the likelihood that the proposed rule would lead to a burgeoning illicit market in menthol cigarettes. In the U.S., there is no evidence that the Special Rule for Cigarettes in the Tobacco Control Act, prohibiting all flavors in cigarettes other than menthol, has led to an illicit market in flavored cigarettes. Indeed, in the Preamble to the proposed rule, FDA cites studies showing that the Special Rule for Cigarettes was associated with a significant reduction in cigarette smoking for youth, *see* 87 Fed. Reg. at 26,470, which would not be expected if youth were able to access illicit flavored cigarettes as substitutes for the legally prohibited products.

¹⁷⁰Attorney General of Connecticut, et. al., Comment in Docket No. FDA-2013-P-0435 "Comments on Tobacco Control Legal Consortium, et al., Citizen Petition to the Federal Food and Drug Administration Related to Prohibiting Menthol as a Characterizing Flavor in Cigarettes," at 11-12, (January 22, 2021), <https://www.regulations.gov/comment/FDA-2013-P-0435-0101>.

¹⁷¹ *See generally*, Chaloupka, FJ, et al., "Macro-Social Influences: The Effects of Prices and Tobacco Control Policies on the Demand for Tobacco Products," *Nicotine & 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)*, 2021, and sources cited therein.

¹⁷² CDC, *Preventing and Reducing Illicit Tobacco Trade in the United States*, at 6, 2015.

¹⁷³ Philip Morris Executive Claude Schwab, "Cigarette Attributes and Quitting," March 4, 1993, Bates No. 2045447810; *See*, Campaign for Tobacco-Free Kids, *supra* note 171.

The Canadian experience with a national prohibition of menthol cigarettes further indicates the low likelihood that the rise of an illicit market in the U.S. will nullify the public health benefits of the proposed menthol rule. Between May 2015 and July 2017, seven out of 10 Canadian provinces implemented menthol cigarette prohibitions, with a federal prohibition on menthol in cigarettes effective in October 2017. A study of illicit cigarette seizures in Nova Scotia (noted by FDA, *see* 87 Fed. Reg. at 26,484), which in 2015 became the first jurisdiction in the world to prohibit menthol cigarettes, found that the number of illegal cigarettes seized did not increase after the menthol prohibition was implemented, despite an intensification of enforcement efforts. Thus, the study found that “illicit cigarette sales in the province are similarly unlikely to be increasing.”¹⁷⁴ A subsequent analysis of the pre- and post-prohibition behavior of Canadians who smoke (also noted by FDA, *see* 87 Fed. Reg. at 26,484) showed that 19.5% of people who smoked menthol cigarettes reported still smoking menthol cigarettes after the law took effect.¹⁷⁵ However, after removing incorrect reporting of post-prohibition menthol cigarettes, less than 10% of people who smoked menthol cigarettes (13 of 138) were smoking illicit menthol cigarettes and there was no statistically significant difference between the percentage of pre-prohibition menthol and non-menthol smokers who purchased cigarettes from illegal sources after the prohibition. Further, of the 13 post-prohibition menthol smokers who reported a menthol cigarette brand as their last purchase, over half (54.7%) reported buying them from a First Nations reserve.¹⁷⁶ That the FDA’s proposed rule would apply to all retailers and manufacturers, including those on Tribal lands, negates a substantial avenue for illicit trade. Thus, the data suggest that the Canadian menthol cigarette prohibition has had a negligible effect on the illicit market, with a similar effect to be expected in the U.S. Moreover, the fact that menthol cigarettes are prohibited in Canada will make it less likely that the smuggling of menthol cigarettes from Canada to the U.S. will be a substantial source of illicit products in the U.S.

Of primary importance, as discussed previously, the data indicate that the Canadian menthol prohibition is having a significant positive impact on public health by causing people who smoke menthol cigarettes to stop. After the prohibition, people who smoke menthol cigarettes were significantly more likely than people who smoke non-menthol cigarettes to have quit smoking for at least six months (12.1% vs. 5.9%).¹⁷⁷ People who smoked menthol cigarettes daily (the group most likely to turn to illicit sources of menthol cigarettes) were significantly more likely than people who smoked non-menthol cigarettes daily to have quit for at least six

¹⁷⁴ Stoklosa, M., “No surge in illicit cigarettes after implementation of menthol ban in Nova Scotia,” *Tobacco Control* 28:702-794, 2018.

¹⁷⁵ Chung-Hall J, *supra* note 147.

¹⁷⁶ Fong, GT, *The Canada-Wide Menthol Cigarette Ban did NOT Increase Illicit Purchases*, ITC PROJECT AT ONTARIO INSTITUTE FOR CANCER RESEARCH, 2021, <https://itcproject.s3.amazonaws.com/uploads/documents/ITC-Menthol-Ban-No-Increase-in-Illicit-Purchases-Apr52021.pdf>.

¹⁷⁷ Chung-Hall, *supra* note 147, at 5.

months (12.7% vs. 5.2%).¹⁷⁸ Thus, whatever illicit market has developed in Canada, the menthol prohibition is having its intended effect of causing people who smoke to stop.

Furthermore, 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 Section 920(b) of the Tobacco Control Act to adopt a “track and trace” system that should include 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, 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 the legally-required identifier would do so.

It is noteworthy that the inclusion of Section 920(b) shows 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. Nine years ago, several of the groups joining this Comment joined the New York City Department of Health & Mental Hygiene in filing a Citizen Petition calling on FDA to establish the required “track and trace” system.¹⁷⁹ It is revealing that Altria, which has opposed a prohibition of menthol cigarettes in part because of the risk of an illicit market, filed an opposition to the Citizen Petition.¹⁸⁰

Finally, the argument that product standards should not be imposed at all because it will lead to a market in illicit product sales hypocritically ignores the fact that for decades the industry’s marketing strategy focused on the importance of attracting and addicting buyers too young to purchase them legally. Yet no one could credibly argue that the prohibition on sales to youth should be repealed because it has led to illegal sales. One of the central purposes of prohibiting menthol as a characterizing flavor in cigarettes is to curtail use by, and sales to youth, and thus eliminate this illicit market. In this context, it is ironic that product standards are opposed with the argument that they would “create” illicit markets. The market for illicit sales to minors is, in effect, a result of the absence of product standards. Prohibiting menthol as a characterizing flavor in cigarettes would sharply reduce this illicit market by making tobacco products less addictive and appealing to young people. Moreover, those who argue most vociferously against product standards because of concerns about illicit markets are the very

¹⁷⁸ *Id.*

¹⁷⁹ New York City Department of Health & Mental Hygiene, et. al., Comment in Docket #FDA-2013-P-0285, “Citizen Petition”, (March 6, 2013), <https://www.regulations.gov/document/FDA-2013-P-0285-0001>.

¹⁸⁰ Altria Client Services, Comment in Docket #FDA-2013-P-0285, (Sept. 6, 2013), <https://www.regulations.gov/comment/FDA-2013-P-0285-0018>.

companies whose conduct has been found to have created and sustained the illicit marketing of tobacco products to youth and who continue to derive their customer base from that market.¹⁸¹

In summary, we fully support the conclusion of the Attorneys General in their comments filed in support of the menthol Citizen Petition: “There is little reason to suggest that prohibiting menthol cigarettes will cause the emergence of an illicit market that will threaten the public health gains from prohibiting menthol cigarettes The FDA should not be swayed by the tobacco industry’s doomsday predictions of an increase in illegal trade.”

B. Prohibiting Menthol Cigarettes Will Not Increase the Likelihood of Police Abuse in Black and Other Communities of Color.

FDA recognizes that concerns have been expressed that, given the high prevalence of menthol cigarette use in the Black community, a prohibition of menthol cigarettes will exacerbate the problem of police abuse in that community by criminalizing the conduct of Black people who smoke. Thus, the agency has requested comments on “policy considerations related to potential racial or social justice implications of this rule,” including comments on “any potential for this proposed rule to result, directly or indirectly, in disparate impacts within particular underserved communities of vulnerable populations” and on “the existence, nature and degree of any change in police activity or community encounters with State or local law enforcement . . . following implementation of a prohibition of menthol cigarettes.” 87 Fed. Reg. at 26,486.

It should be understood that the tobacco industry, in recent years, has adopted the cynical strategy of using legitimate concerns of communities of color about law enforcement abuse to protect industry profits from the targeted marketing of those same communities with menthol cigarettes. Thus, RAI Services Co, an R.J. Reynolds affiliate, in comments to FDA, wrote that “any differential regulation of menthol cigarettes will wrongly criminalize adult smoking preferences, with a disproportionate impact on African-American smokers.”¹⁸² The comments noted that “menthol cigarettes are more popular among African-American smokers,” with no mention of the decades of predatory industry marketing that yielded this “popularity,” nor of the disproportionate burden of addiction, disease and mortality in the Black community that this marketing has caused.

There is no question that police abuse of Black people and other communities of color is a matter of urgent national concern, and one that we share. However, the need for police reform

¹⁸¹ *U.S. v. Philip Morris USA Inc.*, 449 F.Supp.2d 1, 561-691 (D.D.C. 2006), *aff’d in relevant part*, 595 F.3d 1095 (D.C. Cir. 2009).

¹⁸² RAI Services Co., Comments in Docket No. FDA-2017-N-6565 (83 Fed. Reg. 12,294, March 21, 2018) “Regulations of Flavors in Tobacco Products,” at 31, (July 18, 2018), <https://www.regulations.gov/comment/FDA-2017-N-6565-18265>.

is not a sound basis to oppose a product standard that will save many thousands of Black lives by preventing Black youth from beginning to smoke and helping Black adults to quit. We need not choose between protecting the health of Black people against the purveyors of deadly and addictive menthol cigarettes and protecting their safety against police violence. As Carol McGruder of the African American Tobacco Control Leadership Council put it so eloquently, “. . . we’re not going to wait and let the biggest predator and profiler of our Black men and boys roam in our neighborhoods and addict another generation of our children while we get . . . police reform under control. We’re going to do both of those things simultaneously.”¹⁸³

Two states¹⁸⁴ and over 150 localities nationwide, have prohibited or restricted menthol cigarettes,¹⁸⁵ and there are no indications that these laws have been enforced through abusive police tactics directed Black Americans and other people of color. Moreover, nothing in the proposed rule itself will function to increase the risk of such police abuse. First, the rule does not criminalize the conduct of Black people who smoke. As FDA has made clear, “this regulation does not include a prohibition on individual consumer possession or use” and thus “FDA cannot and will not enforce against individual consumer possession or use of menthol cigarettes.” 87 Fed. Reg. at 26,486. Instead, the rule provides that, “No person may manufacture, distribute, sell, or offer for distribution or sale” menthol cigarettes or their components or parts. 87 Fed. Reg. at 26,501 (proposed 21 CFR 1162.1(b)). Thus, “FDA’s enforcement will only address manufacturers, distributors, wholesalers, importers, and retailers.” 87 Fed. Reg. at 26,484. In addition, FDA has stated unequivocally that “State and local law enforcement agencies do not independently enforce the FD&C Act. These entities do not and cannot take enforcement actions against any violation of chapter IX of the Act or this regulation on FDA’s behalf.” *Id.*

The proposed rule, therefore, will protect the health of Black people without increasing the risk of police harassment and abuse in the Black community. For this reason, organizations and individual leaders in the Black community, all intensely committed to ending police violence and other misconduct in that community, strongly support ending the manufacture, promotion, and sale of menthol cigarettes. For example, an overwhelming majority of the Congressional Black Caucus (CBC) voted for H.R. 2339, the “Protecting American Lungs and Reversing the Youth Epidemic Act of 2020,” legislation that would prohibit both menthol cigarettes and flavored cigars.¹⁸⁶ Moreover, in April of last year, 34 CBC members sent a letter to HHS Secretary Becerra urging the Administration to “remove menthol cigarettes from the marketplace.”¹⁸⁷ On April 20 of this year, in a letter to the FDA, NAACP President and CEO Derrick Johnson called on the agency to move forward with this rulemaking, rejecting the

¹⁸³ AshOrgUSA, *Post FDA Lawsuit Decision - Plaintiffs & Partners Discussion*, YouTube (Apr. 20, 2021), https://www.youtube.com/watch?v=oBvNShBZU-w&t=93s&ab_channel=AshOrgUSA.

¹⁸⁴ Implementation of California’s law pending a November 2022 referendum vote.

¹⁸⁵ Campaign for Tobacco-Free Kids, *States & Localities That Have Restricted The Sale of Flavored Tobacco Products*, April 19, 2022, <https://www.tobaccofreekids.org/assets/factsheets/0398.pdf>.

¹⁸⁶ <https://www.congress.gov/116/bills/hr2339/BILLS-116hr2339rfs.pdf>

¹⁸⁷ https://www.tobaccofreekids.org/assets/content/press_office/2021/CBCletter.pdf

message that prohibiting menthol cigarettes “would be discriminatory.” Instead, “[t]he failure to prohibit the sale of menthol cigarettes and products would be discriminatory and counter the goal and function of the FDA to protect and promote public health for all, including the African-American community.”¹⁸⁸ In April of last year, ten Black civil rights, medical, and public health organizations, including the NAACP, wrote to HHS Secretary Becerra urging him to support commencement of this rulemaking because “further delays will cost Black/African American lives.” The letter directly addresses the argument that the enforcement burden of the rule will fall disproportionately on the Black community:

The tobacco industry’s spokespeople have attempted to stoke fears that prohibiting menthol cigarettes is discriminatory, but this could not be further from the truth. The industry has mischaracterized a prohibition on menthol cigarettes as criminalizing Black/African American smokers when the tobacco industry is directly responsible for this disparity in menthol use. Therein lies the true injustice. There are undoubtedly racial injustices in our criminal justice system, but FDA’s rulemaking process should clarify that just as it enforces other tobacco regulations, a prohibition of menthol cigarettes will focus enforcement efforts on manufacturers and retailers, not individual consumers.¹⁸⁹

As noted above, the proposed rule makes it clear that, as with other tobacco regulations, enforcement will necessarily be directed at commercial entities, not individuals.

U.S. Rep. Karen Bass (D-CA) has made the case against allowing tobacco companies to exploit legitimate concerns about police abuse to oppose life-saving action to end the suffering, disease, and death inflicted by menthol cigarettes on the Black community:

Recent incidents of police brutality against Black Americans have forced our nation to confront racism and injustice in its many forms . . . As we continue to protect Black lives, we must put an end to one of the most pernicious destroyers of Black health and lives: deadly menthol cigarettes and the tobacco industry’s decades-long targeted marketing to our kids and communities.¹⁹⁰

We urge FDA to heed the wisdom of these words. It is difficult to imagine an action FDA could take that would more directly and substantially advance the goals of decreasing existing tobacco-related health disparities than the adoption of the proposed menthol rule. The agency must not allow this historic opportunity to advance health equity to pass without final action to issue and implement this rule.

¹⁸⁸ <https://naacp.org/articles/naacp-writes-letter-urging-fda-ban-menthol-flavored-cigarettes-and-flavored-cigar-products>

¹⁸⁹ bna.org/files/2021/AA%20group%20letter%20to%20Becerra%20re%20Menthol%20Cigarettes%204_14_21.pdf

¹⁹⁰ Karen Bass, *California must ban menthol cigarettes to protect Black lives from Big Tobacco’s greed*, THE SACRAMENTO BEE, July 16, 2020, <https://www.sacbee.com/opinion/op-ed/article244221177.html>.

C. The Need to Provide Sufficient Resources to Help People Stop Smoking Does Not Justify Continuing to Permit the Manufacture and Sale of Menthol Cigarettes.

As discussed previously, there is every reason to believe that implementation of the proposed rule will lead hundreds of thousands of people who smoke menthol cigarettes to make quit attempts, with enormous public health benefits if those attempts are successful. Indeed, some have raised the concern that resources to help menthol smokers quit will be insufficient, leaving those who want to quit without adequate cessation support. While we support the benefit of taking steps to increase assistance for smokers who want to quit, this is not a persuasive argument against the proposed rule; indeed, it recognizes that the rule will have the salutary effect of inducing many thousands of people who smoke menthol cigarettes to make serious quit attempts.

We are supportive of a comprehensive effort designed to provide strong cessation support to menthol smokers. We encourage FDA and others to 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 people who formerly smoked menthol cigarettes. Such a campaign should prioritize reaching communities where the usage of menthol cigarettes is high.

We also support the expansion of coverage of tobacco cessation treatments, including under the Affordable Care Act (ACA). Under the ACA, all non-grandfathered group and individual insurance plans—including insurers and plans required to cover essential health benefits—are required to cover recommended tobacco cessation services with no cost sharing. The ACA also: required state Medicaid programs to cover evidence-based tobacco cessation treatments with no cost sharing for pregnant women; prevented Medicaid programs from excluding tobacco cessation medications from their drug coverage; and required coverage of essential benefits, including tobacco cessation treatments and other preventive services recommended by the U.S. Preventive Services Task Force, for persons newly eligible for Medicaid through Medicaid expansion. These provisions must be vigorously enforced.

Further, we support HHS expanding telephone cessation support that can be accessed 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. Smokers who use these state quitlines are at least two to three times more likely to succeed in quitting compared to those who try to quit on their own.¹⁹¹ New ways of accessing tobacco cessation services, such as online cessation services, should also be developed and implemented. In addition, CDC's Tips from Former Smokers media campaign, which has been highly successful in helping people who smoke to quit, should be expanded and adapted to maximize its impact on populations most

¹⁹¹ Fiore, MC, et al., *Treating Tobacco Use and Dependence: 2008 Update – Clinical Practice Guideline*, U.S. PUBLIC HEALTH SERVICE, 2008, http://www.surgeongeneral.gov/tobacco/treating_tobacco_use08.pdf.

affected by menthol cigarettes. Finally, states—through the tobacco prevention and cessation programs they fund—can play an important role in assisting people who smoke menthol cigarettes and who attempt to quit as a result of the rule.

FDA has proposed to adopt the statutory one-year implementation period but has requested comment on whether a shorter period would be necessary for the protection of the public health. 87 Fed. Reg. at 26,489. The one-year implementation period gives the agency ample time to work with other federal agencies and non-governmental organizations to plan how to assist people who smoke but would like to quit. However, in no event should FDA consider an implementation period of more than one year to accommodate industry concerns. Given that industry compliance is simply a matter of taking menthol cigarettes off the market, or no longer using characterizing flavors in the manufacture of cigarettes, the statutory one-year period is more than sufficient to permit the industry to comply with the rule in an orderly fashion.

FDA also has asked for comment on whether it should provide for a “sell-off” period—for example, 30 days after the effective date of a final rule—for retailers to sell through their current inventory of menthol cigarettes. 87 Fed. Reg. at 26,489. Given FDA’s proposed implementation period of one year prior to the effective date, retailers will be given sufficient time to plan for the removal of menthol cigarettes from their inventory and to minimize any adverse financial impact of such removal. There is, therefore, no justification for an additional 30 days to continue to sell products that cause such substantial public health harm.

Finally, as part of a longer-term strategy, we encourage FDA to take steps to have its Center for Tobacco Products and its Center for Drug Evaluation and Research work together to maximize the potential benefits of current FDA-approved nicotine replacement products and to encourage the availability of new and innovative cessation products. Almost 70% of people who smoke report they want to quit,¹⁹² and studies continue to show higher success in quitting among those who use some form of approved medication,¹⁹³ but only one-third of smokers use any of those medications when making a quit attempt.¹⁹⁴

IX. OTHER IMPACTS OF THE PROPOSED RULE

A. Impact on Small Business Entities and Retailers

Although the Regulatory Flexibility Act requires FDA to analyze regulatory options that would minimize any significant impact of a rule on small entities, there is no requirement that the impact on small entities be reduced at a cost to public health. FDA’s analysis of the impact of

¹⁹² Babb S, et al., “Quitting Smoking Among Adults—United States, 2000–2015,” *MMWR* 65:1457–1464, 2017.

¹⁹³ Siu, AL, “Behavioral and Pharmacotherapy Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Women: U.S. Preventive Services Task Force Recommendation Statement,” *Annals of Internal Medicine* 163(8):622-34, 2015; Cahill, K, et al., “Pharmacological interventions for smoking cessation: an overview and network meta-analysis,” *Cochrane Database of Systematic Reviews* 4:CD009329, 2013.

¹⁹⁴ Babb, S, *supra* note 192.

the proposed rule on small entities includes several observations of particular importance.

First, at the manufacturing level, the impact of the proposed rule will mostly be on large manufacturers. Three manufacturers or brand owners account for over 91% of menthol cigarette sales by volume and almost all of the revenue (96.3%) generated by menthol cigarette sales.¹⁹⁵ As FDA noted, these three manufacturers/brand owners “would consequently bear a significant majority of the impact of the estimated revenue transfer from manufacturers to consumers.”¹⁹⁶

Second, as to the impact of the rule on retailers, FDA reasonably predicts that such an effect will be minimal, noting that “[c]onsumers are expected to use the transferred value of previous menthol cigarette product purchases to instead purchase other goods at retail, including both tobacco and non-tobacco products. These purchases may result in revenues for the same retailers that previously sold menthol cigarette products or may create new revenues for different retailers. We, therefore, do not estimate any additional changes in revenues for small retailers.”¹⁹⁷

FDA has asked for comment on whether it should provide a “sell-off” period of 30 days after the effective date of a final rule for retailers to sell their current inventory of menthol cigarettes. 87 Fed. Reg. at 26,489. Given FDA’s proposed implementation period of one year prior to the effective date, retailers will be given sufficient time to plan for removal of menthol cigarettes from their inventory, and to minimize any adverse financial impact of such removal. Therefore, there is no justification for an additional 30 days to continue to sell products that cause such substantial public health harm.

FDA analyzes two possible regulatory options to reduce the impact of the rule on small entities: (1) extending the effective date of the rule from 1 to 2 years, and (2) allowing exemption requests. Both should be rejected as undermining the public health goals of the rule. As to extending the effective date, as FDA states, “[a]dditional delay, past 1 year, would only increase the numbers of youth and young adults who experiment with menthol cigarettes and become regular smokers, delay cessation by current smokers, and exacerbate tobacco-related health disparities.” 87 Fed. Reg. at 26,489. As to allowing exemption requests, for such products as menthol heated tobacco products and very low nicotine menthol products, such exemptions would be harmful to public health, and an unwise use of FDA resources, for the reasons given in Section IV above.

B. Impact on Tobacco Farming and Manufacturing

As summarized in the RIA, by any measure, the role of tobacco farming in the nation’s economy has been shrinking steadily and significantly. In the meantime, tobacco growers have

¹⁹⁵ RIA at 227.

¹⁹⁶ *Id.*

¹⁹⁷ *Id.* at 226.

been able to shift to growing other crops in response to these trends.

Over the past five years, tobacco leaf production in the United States has decreased 40%, from 630 million pounds in 2016 to about 390 million pounds in 2020.¹⁹⁸ The number of U.S. tobacco farms has fallen sharply—from approximately 93,000 tobacco farms in 1997 to approximately 6,000 in 2017.¹⁹⁹ FDA attributed this long-term trend to the effect of the Master Settlement Agreement of 1998 and the elimination of the Federal Tobacco Price Support Program, which together provided over \$15 billion to tobacco growers to transition to growing other crops.²⁰⁰ The decline in tobacco farming has virtually eliminated the smaller family tobacco farms, as larger agribusinesses have taken their place.²⁰¹

Farmers have turned to other crops to replace tobacco. FDA’s RIA noted that some tobacco farmers are growing hemp.²⁰² In 2013, tobacco farmers in Virginia turned to chickpeas in response to reduced tobacco consumption and increased interest in hummus.²⁰³ A series of news articles on tobacco farming in North Carolina described growers’ transitions away from tobacco due to various reasons including higher costs and trade issues resulting from the Trump Administration’s tariffs on imported products from China. One featured long-time grower said that he was switching to soybeans, corn, and wheat,²⁰⁴ and another said this may be his last year growing tobacco.²⁰⁵

The decline in tobacco farming has been matched by a decline in tobacco manufacturing jobs. Those declines are entirely due to tobacco companies shutting down or moving factories, or otherwise restructuring. For instance, the *Winston-Salem Journal* reported that Reynolds American cut more than 10% of its employees, or more than 500 jobs, from 2020 to 2021,²⁰⁶ though not all of those jobs are in manufacturing. Between 1997 and 2020, overall tobacco manufacturing jobs declined by 68.2%; in 2020 those jobs made up less than 0.1% of all manufacturing jobs in the United States, and even in the two states with the most tobacco manufacturing (North Carolina & Virginia), related employment makes up less than 2% of all

¹⁹⁸ *Id.* at 199.

¹⁹⁹ *Id.* at 200.

²⁰⁰ *Id.* at 201.

²⁰¹ See Campaign for Tobacco-Free Kids, *The Shrinking Role of Tobacco Farming and Tobacco Product Manufacturing in the United States Economy*, 2022 and data cited therein.

²⁰² RIA at 200-01.

²⁰³ Kesmodel, D & Fletcher, O, “Hummus Is Conquering America,” THE WALL STREET JOURNAL, April 30, 2013, [Hummus Is Conquering America - WSJ](https://www.wsj.com/articles/hummus-is-conquering-america-2013-04-30).

²⁰⁴ Quillin, M, “‘The point where there’s no money there’: Some have moved on to soybeans, corn and wheat,” THE NEWS & OBSERVER, February 27, 2022, <https://www.newsobserver.com/news/local/article257977483.html>.

²⁰⁵ Quillin, M, “‘I’m afraid this year’: NC without the golden leaf was once unimaginable. But no more,” THE NEWS & OBSERVER, February 27, 2022, <https://www.newsobserver.com/news/local/article257915918.html>.

²⁰⁶ Craver, R, “Reynolds has 10% workforce reduction during 2021; BAT chief executive’s total compensation jumps 51%,” WINSTON-SALEM JOURNAL, March 18, 2022, https://journalnow.com/business/local/reynolds-has-10-workforce-reduction-during-2021-bat-chief-executives-total-compensation-jumps-51/article_855797ae-a5e4-11ec-bcab-4f8877278bd9.html.

state manufacturing jobs, and even smaller fractions of total employment.²⁰⁷

Despite the decline in tobacco farms and tobacco manufacturing jobs, cigarettes still inflict huge costs on the American economy, with approximately \$220 billion in annual healthcare costs alone.²⁰⁸ The menthol rule will continue the decline in the role of tobacco in the American economy, but with enormous benefits to public health.

X. EFFECT OF THE RULE ON STATE AND LOCAL LAWS

As FDA observes, Section 916 of the TCA “broadly preserves the authority of states and localities to protect the public against the harms of tobacco use.” 87 Fed. Reg. at 26,491. Federal courts consistently have upheld local prohibitions on the sale of flavored tobacco products against industry lawsuits alleging that they are preempted by federal law.²⁰⁹ Thus, although Section 916(a) gives the FDA exclusive authority to issue product standards limiting the additives and other constituents that manufacturers may use in producing tobacco products, it preserves to states and localities the authority to restrict, or prohibit, the sale of those products within their jurisdictions. It thereby gives states and localities authority to protect the health of their residents against tobacco products, even though FDA has permitted their introduction into the stream of commerce. FDA concluded that “[s]tate and local prohibitions on the sale and distribution of flavored tobacco products, such as menthol cigarettes, would not be preempted by this rule, if finalized, because such prohibitions would be preserved by FD&C Act section 916(a)(1) or, as applicable, excepted from express preemption by FD&C Act section 916(a)(2)(B).” This conclusion is entirely consistent with the applicable case law.

XI. CONCLUSION: A PRODUCT STANDARD PROHIBITING MENTHOL AS A CHARACTERIZING FLAVOR IN CIGARETTES MEETS THE STATUTORY PUBLIC HEALTH STANDARD.

The proposed menthol product standard meets the statutory standard of being “appropriate for the protection of the public health,” considering the risks and benefits to the population as a whole, including users and nonusers of tobacco products.

As to nonusers of tobacco products, the proposed standard will significantly reduce youth smoking initiation and progression to regular use. For users of tobacco products, the proposed standard will substantially increase smoking cessation. The proposed rule will yield especially significant benefits for the Black community, which has, for decades, borne a disproportionate

²⁰⁷ U.S. Census Bureau, *Annual Survey of Manufactures*, 2020, <https://www.census.gov/programs-surveys/asm.html>.

²⁰⁸ Xu, X. et al., “US healthcare spending attributable to cigarette smoking in 2014,” *Preventive Medicine* 150:106529, 2021.

²⁰⁹ See *R.J. Reynolds Tobacco Co. v. County of Los Angeles*, 29 F.4th 542 (9th Cir. 2022); *National Association of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71 (1st Cir. 2013); *U.S. Smokeless Tobacco Mfg. Co. v. City of New York*, 708 F.3d 428 (2d Cir. 2013); *R.J. Reynolds Tobacco Co. v. City of Edina*, 482 F.Supp.3d 875 (D. Minn. 2020).

burden of disease and mortality from menthol cigarettes, due to decades of targeted marketing and promotion of menthol cigarettes directed at Black youth and Black people who smoke. The proposed rule would therefore reduce long-entrenched health disparities and lead to greater equity in health outcomes. As noted above and as reported by FDA, a published modeling study estimated that, if a menthol cigarette prohibition had been implemented in 2011, 324,000 to 634,000 smoking attributable deaths would have been prevented by 2050; of that number, 92,000 to 238,000 Black lives would have been saved. 87 Fed. Reg. at 26,481.

FDA's public health mission requires it to finalize the proposed rule to permit its life-saving benefits to be realized as quickly as possible.

Respectfully submitted,

AASA, The School Superintendents Association
Academic Pediatric Association
Academy of General Dentistry
Action on Smoking & Health
African American Tobacco Control Leadership Council
Allergy & Asthma Network
Alpha-1 Foundation
American Academy of Family Physicians
American Academy of Nursing
American Academy of Oral and Maxillofacial Pathology
American Academy of Oral and Maxillofacial Radiology
American Academy of Pediatrics
American Association for Cancer Research
American Association for Dental, Oral, and Craniofacial Research
American Association for Respiratory Care
American Cancer Society Cancer Action Network
American College Health Association
American College of Cardiology
American College of Physicians
American College of Preventive Medicine
American Dental Association
American Heart Association
American Lung Association
American Medical Association
American Pediatric Society
American Public Health Association
American Society of Addiction Medicine
American Thoracic Society

Americans for Nonsmokers' Rights
Asian Pacific Partners for Empowerment, Advocacy and Leadership (APPEAL)
Association for Clinical Oncology
Association for the Treatment of Tobacco Use and Dependence
Association of Black Cardiologists
Association of Black Women Physicians
Association of Medical School Pediatric Department Chairs
Association of Schools and Programs of Public Health
Association of Women's Health, Obstetric and Neonatal Nurses
Asthma and Allergy Foundation of America
ASTHO
Big Cities Health Coalition
Black Men's Health Initiative
Black Women's Health Imperative
Breathe Southern California
Campaign for Tobacco-Free Kids
CATCH Global Foundation
Catholic Health Association of the United States
Center for Black Equity
CenterLink: The Community of LGBT Centers
CHEST
Commissioned Officers Association of the USPHS
Common Sense Media
Community Anti-Drug Coalitions of America (CADCA)
COPD Foundation
Emphysema Foundation of America
First Focus on Children
GLMA: Health Professionals Advancing LGBTQ Equality
GO2 Foundation for Lung Cancer
HealthHIV
International Association for the Study of Lung Cancer
Islamic Society of North America (ISNA)
League of United Latin American Citizens (LULAC)
Mesothelioma Applied Research Foundation
National Alliance for Hispanic Health
National Association of County and City Health Officials
National Association of Hispanic Nurses
National Association of Pasifika Organizations (NAOPO)
National Association of Pediatric Nurse Practitioners
National Association of School Nurses

National Association of Secondary School Principals
National Black Church Initiative
National Black Nurses Association
National Center for Health Research
National Council of Asian Pacific Islander Physicians
National Education Association
National Eta Sigma Gamma
National Forum for Heart Disease & Stroke Prevention
National Hispanic Council on Aging
National Hispanic Medical Association
National LGBT Cancer Network
National Medical Association
National Network of Public Health Institutes
National Partnership for Women & Families
National Tongan American Society
North American Quitline Consortium
Oncology Nursing Society
Parents Against Vaping e-Cigarettes
Pediatric Policy Council
PHS Commissioned Officers Foundation for the Advancement of Public Health
Prevent Cancer Foundation
Preventing Tobacco Addiction Foundation/Tobacco 21
Preventive Cardiovascular Nurses Association
Respiratory Health Association
Save A Girl, Save A World
Society for Cardiovascular Angiography and Interventions
Society for Pediatric Research
Society for Research on Nicotine & Tobacco
Southern Black Policy & Advocacy Network
Students Against Destructive Decisions
The Center for Black Health and Equity
The National Alliance to Advance Adolescent Health
The Society of State Leaders of Health and Physical Education
The Society of Thoracic Surgeons
Truth Initiative
US PIRG