



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 ig 8.04 201004 T

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 FD-33.0amendaendaed ()T (i,

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

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

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

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

.”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.

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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

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,"

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African Americans who smoke, those who smoked menthol cigarettes had 12% lower odds of

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

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

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(1)0.5 (1)0ID 6h (uni)-26.

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.

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—

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 /T-2 (i)-2 (ng tl)-6 (ab)-pt s

likely to try to quit than people who smoked non-

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 (a)4 (1)4 (1a)-1 5 ()JTJ 04 Tc -0.004 >>BDC /7(r)-12/()Te

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 VLN™ 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 VLN™ 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 VLN™ 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

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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 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

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,

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.

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 the rule.

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

First, at the manufacturing level, the impact of the proposed rule

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

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

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

