PUBLIC HEALTH
LAW CENTER
at Mitchell Hamline School of Law

August 2, 2022

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

Re: Tobacco Product Standard for Menthol in Cigarettes

Docket No. FDA-2021-N-1349

Dear Commissioner Califf:

The Public Health Law Center is pleased to submit these comments to the U.S. Food and Drug Administration (FDA) on the need for a product standard prohibiting menthol in cigarettes. The Public Health Law Center (the Center) is a public interest legal resource center dedicated to improving health through the power of law and policy, grounded in the belief that everyone deserves to be healthy. Located at the Mitchell Hamline School of Law in Saint Paul, Minnesota, the Center helps local, state, national, Tribal, and global leaders promote health by strengthening public policies. For over twenty years, the Center has worked with public officials and community leaders to develop, implement, and defend effective public health laws and policies, including those designed to reduce commercial tobacco use, improve the nation's diet, encourage physical activity, protect the nation's public health infrastructure, and promote health equity.

The Center, with many partner organizations, filed a citizen petition in 2013 requesting that the FDA prohibit menthol as a characterizing flavor in cigarettes.[1] While we are disappointed that it has taken almost ten years for the agency to finally begin the process of establishing the rule for which we petitioned, we congratulate the FDA for taking this step and we fully support a product standard that will protect public health.

[1] TOBACCO CONTROL LEGAL CONSORTIUM, *Citizen Petition to Food & Drug Administration: Prohibiting Menthol as a Characterizing Flavor in Cigarettes* (Apr. 12, 2013), http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fdacitizenpetition-menthol-2013.pdf; *see also* FDA, Prohibit Menthol as a Characterizing Flavoring of Cigarettes and Cigarette Smoke (2013), https://www.regulations.gov/docket?D=FDA-2013-P-0435.

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Despite the possession of abundant evidence that the elimination of menthol would save hundreds of thousands of lives, the FDA has continued to gather additional evidence, confirming what has been known for decades. The evidence gathered by the FDA includes: 1) the FDA's commissioned scientific review from the Tobacco Products Scientific Advisory Committee (TPSAC) concluding that the "[r]emoval of menthol cigarettes from the marketplace would benefit public health in the United States";[2] 2) the FDA's own internal scientific review of menthol, which concludes that menthol plays a key role in youth and young adult initiation, that mentholated [3]tobacco use is associated with a deeper level of addiction, and that these factors point to a greater overall health risk when compared to non-menthol cigarettes; 3) the above-mentioned citizen petition demonstrating tremendous support for the elimination of menthol to address the health harms imposed by menthol[4] cigarettes and to address the historic and intentional targeting of specific vulnerable populations by the tobacco[5] The FDA's latest compilation of scientific research completed by the agency's Tobacco Regulatory Science Research Program also echoes these past conclusions: that menthol increases initiation, facilitates addiction through suppressing the irritation of cigarette smoke, decreases cessation, and affects vulnerable populations at higher rates.[6] The FDA's latest compilation of scientific research completed by the agency's Tobacco Regulatory Science Research Program also echoes these past conclusions: that menthol increases initiation, facilitates addiction through suppressing the irritation of cigarette smoke, decreases cessation, and affects vulnerable populations at higher rates.[7]

While we must credit the FDA for finally acting to remove menthol, this is only the first step in a multi-step process that is likely to end with the government defending such action against multiple lawsuits. This comment will offer some additional sources of scientific information, not referenced by the FDA, as well as some potential changes to the language and structure of the FDA's proposed rule. We also offer some suggestions for actions that the FDA can take outside of this rulemaking

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[2] TOBACCO PROD. SCI. ADVISORY COMM., FDA, *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations* (2011), https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf.

[3] FDA, *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes* (2013), https://www.fda.gov/downloads/ucm361598.pdf.

[4] TOBACCO CONTROL LEGAL CONSORTIUM, *supra* note 1; *see also* FDA, *supra* note 1.

[5] FDA, *Menthol in Cigarettes, Tobacco Products; Request for Comments*, FDA-2013-N-0521 (2014), https://www.regulations.gov/docket?D=FDA-2013-N-0521.

[6] FDA, *Regulation of Flavors in Tobacco Products,* FDA-2017-N-6565 (2018), https://www.regulations.gov/docket/FDA-2017-N-6565.

[7] CTR. FOR TOBACCO PROD., FDA, *Tobacco Regulatory Science Research Program at FDA s Center for Tobacco Products: Summary and Highlights,* https://www.fda.gov/downloads/TobaccoProducts/PublicHealthScienceResearch/UCM613046.pdf.

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that will further improve the public health benefits of the product standard. Perhaps, most importantly, this comment begins with a discussion of one of the most important aspects of this rule: the amount of time that it takes to move from this proposal to the day when menthol cigarettes are no longer sitting on store shelves all over the country.

I. The decision to establish a product standard is based solely on whether the standard will protect public health and to provide the most protection.

In proposing a product standard, the FDA has initiated a process with only two possible outcomes: a final rule implementing the proposed standard or a notice of a termination of the development of the standard. The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act, the Act, or TCA) requires the FDA to either finalize a rule or explain why it is not doing so after it has read and considered the public comments.[8] Unfortunately, the statute does not establish a timeframe for this step, so this is left to the agency's discretion. What is clear is that after considering the comments, the FDA is required to decide to finalize the rule or not.

It is also clear from the statute that if the FDA determines that the proposed standard would protect public health, the standard must be finalized. The FDA is obligated to accept comments that discuss the technical achievability of the proposed standard and consider any countervailing effects of the standard. At the same time, the decision to finalize the standard is ultimately based on whether the product standard will advance public health. If the proposed standard will protect the public health, then the standard must be finalized.[9]

A comprehensive reading of the statute shows that the FDA can propose a standard after the agency has considered the public health impacts. 21 U.S.C. § 387g(a)(3)(B)(i). The proposal is published in the Federal Register (21 U.S.C. § 387g(c)) and the agency accepts comments. 21 U.S.C. § 387g(d)(1) describes the next step in the process, which requires the FDA to decide either to finalize or terminate the proposal. The agency must consider comments submitted under 21 U.S.C. § 387g(b), which relates to technical achievability and countervailing effects, as well as 21 U.S.C. § 387g(c), which relates to the protection of public health, the potential to advantage foreign-grown tobacco over domestically grown tobacco, and any information the Secretary of Agriculture deems relevant to the standard.

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[8] 21 U.S.C. § 387g(d)(1).

[9] *Id.* ("[T]he Secretary shall . . . if the Secretary determines that the standard would be appropriate for the protection of the public health, promulgate a regulation establishing a tobacco product standard . . . .").

However, it is absolutely critical that, if the FDA determines that the standard "would be appropriate for the protection of public health," [10] the agency must finalize the standard.[11] The FDA is required to analyze issues that are not directly health-related, such as technical achievability and countervailing effects, but because the decision on whether to finalize the standard is based on the appropriateness of the protection of public health, the FDA's focus must be on the health effects of the issues that are not directly health-related.

As a health-focused agency and an expert on the health consequences of the products it regulates, the FDA – when proposing a product standard, the FDA must focus its own analysis on the three prongs of the public health standard. When it accepts comments on its proposal, it must solicit information on the abovementioned issues that are not directly related to health, but as it considers those comments, it is only the *health* consequences of those issues that the FDA must examine. For example, if a commenter raises an issue about the technical feasibility of a proposed standard and concludes that because of technical limitations, achieving the standard will be difficult and costly to the regulated industry, then in analyzing that comment, if the information is accurate, the FDA cannot adjust the standard to accommodate the difficulty if that means that the standard is less protective of health. The FDA can only make changes to the proposed standard if those changes make the proposed standard more health protective, not less. Furthermore, if the weight of the evidence relevant to the public health standard establishes that the rule will protect public health, even if costly or challenging, the FDA is *required* to finalize the rule.

II. Delay in the implementation of a final rule can be measured in additional lives lost and so the FDA must finalize this rule quickly with a short implementation period.

The evidence base demonstrating the need for the rule is clear and the FDA has reviewed the evidence thoroughly over a period of years. As with most actions that the agency can take to regulate tobacco products, the public health benefits are well-documented. If action saves lives, inaction costs lives, and so it is absolutely incumbent on the FDA to act as quickly as possible to finalize life-saving rules.

The purpose of the public comment period is to allow the agency to gather information it may not possess and to hear perspectives on the regulatory issue that it may not have heard. Because of the amount of time that has been devoted to this issue and the number of opportunities for formal and informal engagement with the

[10] 21 U.S.C. § 387g(d)(1)(A).
[11] *Id.* ("the Secretary shall").

FDA, it is incredibly unlikely that any comment that the agency receives will provide any new information or perspective that the FDA has not already analyzed thoroughly. The volume of information that is already known makes it all but impossible that any new information would so significantly change the FDA's analysis as to require a delay for additional analysis.

The agency has already analyzed the potential impacts of the standard and has addressed all relevant substantive issues in its proposal. It should be very simple for the agency to draft a final rule even if it chooses to modify the proposed standard. The analysis under the Public Health Standard should not change significantly from the proposal which means that the analysis in the final rule should look essentially the same. Addressing issues raised in comments that are already substantively addressed in the proposal should also take little time for the FDA to draft. The final version of this product standard should be written and published shortly after the close of the comment period.

Similarly, there is no reason the FDA cannot establish a short implementation period for the final rule. The only two relevant issues that could impact the timeline for implementation are the statutory requirements and the logistics of implementing and enforcing a rule.

The TCA has specific and clear standards for the process of implementing a product standard. The statute sets a default implementation date of not more than one year "unless the Secretary determines that an earlier date is necessary for the protection of the public health."[12] It is clear from this provision that when establishing a product standard, Congress intended to provide the FDA discretion to shorten the period of time for implementation when it would create a public health benefit. The TCA envisions some standards where the need would not be so great as to warrant an implementation period of less than one year.[13] However, when there is a need and no need could be greater than saving lives - Congress gave the FDA the ability to act more quickly. There could be no better time for the FDA to seize that opportunity.

In fact, Congress gave the FDA a very clear model to work from. The TCA established the very first tobacco product standard by prohibiting all flavors in cigarettes except tobacco and menthol. This standard was implemented just three months after the TCA became law, at a time when the FDA's Center for Tobacco Products had few staff and the Center was working on meeting numerous other congressional

[12] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 907(d)(2), 123 Stat. 1776, 1802 (2009).
[13] *See id.* § 907(a)(4)(B)(ii) ("provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the tobacco product").

deadlines. Given the Center's size in 2022, the robust enforcement infrastructure, and the agency's years of experience enforcing a prohibition on flavors in cigarettes, there is no reason the FDA could not establish a similar three-month, or shorter, implementation period for this standard. Because Congress did not establish a one-year implementation period for the existing product standard for flavors in cigarettes, it seems likely that this is exactly the type of standard that was intended to have a shorter implementation period.

It is also worth noting that tobacco product manufacturers have been on notice for several years that such a standard was a possibility. Any loss of revenue due to inflexible manufacturing and distribution mechanisms is a result of failing to adapt to a changing regulatory environment which is not a concern for the FDA. Because this standard would prohibit the addition of something to a product that is not inherent to the product, it is hard to imagine that the standard would be difficult to implement at the manufacturing level. There should be no reason that manufacturers could not simply stop adding flavor constituents on the day that a final rule is published or shortly thereafter and the inventory of non-compliant products would run out quickly. This is a standard easy for manufacturers to implement and will save a tremendous number of lives. It is difficult to imagine a situation more suited to the FDA using its discretion to shorten the implementation period for a product standard.

III. While the FDA has failed to act, research on the effects of menthol on public health has continued to accumulate.

This proposed rule provides an extensive review of the harms of menthol cigarettes and public health rationale for banning menthol. The following information serves to support FDA's decision to ban menthol and provides further evidence of the importance of that action.

The Center applauds the FDA for its recognition of health equity as an integral part of the consideration of what is best for the population as a whole. The Center agrees that "advancement of health equity is integral to the reduction and elimination of tobacco-related health disparities, which result from denied opportunity and access to economic, political, and social participation."[14] Banning menthol is a necessary step for the advancement of health equity. Vast disparities in menthol use and menthol-related harms exist among various communities. Therefore, this comment centers around the importance of health equity.

[14] Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26,454, 26,458 (proposed May 4, 2022) (to be codified at 21 C.F.R. pt. 1162).

A. The presence of menthol facilitates initiation.

Menthol has been a significant factor in tobacco product initiation, and its removal as a characterizing flavor is likely to have a great impact on cigarette and other tobacco product uptake and continued use. Flavored tobacco products, especially menthol, are important in attracting new consumers and maintaining current tobacco product users. As noted in our 2021 supplement to our 2013 citizen petition and recognized in the proposed rule, the tobacco industry has known that menthol-flavor cigarettes are "good starter products" for new consumers, and especially youth.[15]

TPSAC estimated that between 2010 and 2020, an estimated 2.28 million more people would begin smoking than would have been expected to start if menthol cigarettes were not available.[16] This represents 2.28 million additional sources of exposure to secondhand and thirdhand smoke for nonusers and the concomitant health consequences of those exposures. Recent research underscores TPSAC's estimation; between 1980 and 2018, menthol cigarettes were responsible for slowing down the decline in smoking prevalence by 2.6 percentage points, and were responsible for 10.1 million extra smokers, 3 million life years lost, and 378,000 premature deaths.[17]

1. Youth are particularly susceptible to initiation of tobacco products via menthol cigarettes.

The evidence is clear and has continually been reaffirmed that menthol plays an outsized role in youth and young adult tobacco initiation.[18] Menthol's presence in cigarettes has contributed to youth misconceptions about the harm of consuming

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[15] PUB. HEALTH L. CTR., *Supplement to Citizen Petition: Prohibit Menthol as a Characterizing Flavoring of Cigarettes and Cigarette Smoke* (Jan. 15, 2021), https://www.publichealthlawcenter.org/sites/default/files/resources/Supplement-to-Menthol-Citizen-Petition.pdf (citing Brown & Williamson Tobacco Corp., *Kool Isn't Getting the Starters*, TRUTH TOBACCO INDUS. DOCUMENTS 621079918-621079921 (Feb. 17, 1987), https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=mnbd0132).

[16] TOBACCO PROD. SCI. ADVISORY COMM., *supra* note 2.

[17] Thuy T.T. Le & David Mendez, *An Estimation of the Harm of Menthol Cigarettes in the United States from 1980 to 2018*, 31 TOBACCO CONTROL 564 (2021), https://tobaccocontrol.bmj.com/content/tobaccocontrol/early/2021/02/09/tobaccocontrol-2020-056256.full.pdf.

[18] James Nonnemaker et al., *Initiation with Menthol Cigarettes and Youth Smoking Update*, 108 ADDICTION 171 (2013), https://pubmed.ncbi.nlm.nih.gov/22862154/; Andrea C. Villanti et al., *Menthol and Mint Cigarettes and Cigars: Initiation and Progression in Youth, Young Adults and Adults in Waves 1-4 of the PATH Study, 2013-2017*, 23 NICOTINE & TOBACCO RSCH. 1318 (2021), https://pubmed.ncbi.nlm.nih.gov/33159209/.

cigarettes,[19] while also increasing perceptions of pleasure and enjoyment from use - the combination of which contributes to uptake and sustained use.

The tobacco industry has a long history of manipulating menthol in cigarettes as a "starter" product for youth. Historical industry documents state, "menthol brands have been said to be good starter products because new smokers appear to know that menthol covers up some of the tobacco taste and they already know what menthol tastes like, vis-à-vis candy."[20] These troves of documents also reveal the industry's recognition that youth are the key to success for menthol brands: "the success of Newport has been fantastic during the past few years. Our profile taken locally shows this brand being purchased by [B]lack people (all ages), young adults (usually college age), but the base of our business is the high school student."[21] Marketplace data confirms this reality – although youth smoking continues to decline, menthol cigarettes continue to dominate the youth market share.[22] Encouragingly, the FDA has likewise reached these conclusions as it notes in the proposed rule.[23]

Multiple studies have shown over the past decade that youth initiation with menthol-flavored cigarettes or other tobacco products carries a higher risk for continued use than starting with non-menthol tobacco products.[24] The finding, as to menthol's particular risk in tobacco product use, was most recently reaffirmed in February, 2022, where cohort data from two studies assessing continued tobacco use between 2013 and 2018/2019 found that youth and young adults who initiated with menthol-flavored tobacco products were more likely to be still using tobacco products, at increased frequency, and have greater nicotine dependence, than those youth and young adults who initiated with unflavored or tobacco-flavored tobacco products.[25] Additionally, a 2018 study found that youth who initiate with menthol

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[19] PUB. HEALTH L. CTR., *supra* note 15, at 44–46.
[20] Brown & Williamson Tobacco Corp., *Kool Isn't Getting the Starters*, TRUTH TOBACCO INDUS. DOCUMENTS 621079918-621079921 (1987), https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=mnbd0132.
[21] Lorillard Tobacco Co., *Product Information - Memo from T. L. Achey Providing Sales Figures and Stating That Newport King Size is the #1 Selling Lorillard Brand and Newport Box is the #6 Selling Lorillard Brand in Field 3*, INDUS. DOCUMENTS LIBR. 3990695747-3990695748 (Aug. 30, 1978), https://www.industrydocuments.ucsf.edu/docs/yqyl0190.
[22] Andrea C. Villanti et al., *Menthol Cigarettes and the Public Health Standard: A Systematic Review*, 17 BMC PUB. HEALTH 983 (2017), https://doi.org/10.1186/s12889-017-4987-z.
[23] *E.g.*, Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26,454, 26,464 (proposed May 4, 2022) (to be codified at 21 C.F.R. pt. 1162).
[24] PUB. HEALTH L. CTR., *supra* note 15, at 52–54.
[25] James D. Sargent et al., *First E-Cigarette Flavor and Device Type Used: Associations with Vaping Persistence, Frequency, and Dependence in Young Adults*, 24 NICOTINE & TOBACCO RSCH. 380 (2022), https://pubmed.ncbi.nlm.nih.gov/34460934/.

compared to non-menthol cigarettes were less likely to report feeling nauseated when first using.[26] Potential explanations for the initiation and usage rates among youth include that flavors mask the harshness of tobacco, youth are targeted by media campaigns, and youth perceive lower harm and more pleasure from menthol products.[27]

FDA is correct in noting that if the proposed rule is finalized, the unavailability of menthol flavoring in cigarettes will likely result in significant reductions in youth initiation and youth tobacco use prevalence.[28] Research continues to affirm this likely outcome, with expected decreases in initiation and, consequently, smoking rates.[29]

2. Due to purposeful targeting by the tobacco industry, Black and African American people initiate and use menthol at higher rates than other racial and ethnic groups.

In Section IV.E of the proposed rule, the FDA recognizes that tobacco companies market menthol more in neighborhoods that have more Black and low-income residents.[30] These patterns have been repeatedly observed at the local level.[31] In California, cigarette stores in neighborhoods with greater proportions of Black residents are significantly more likely to advertise menthol cigarettes.[32]

Tobacco companies also make menthol cheaper for Black people, decreasing the price barrier to tobacco and making it more likely that Black people will smoke

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[26] Joanne D'Silva et al., *Differences in Subjective Experiences to First Use of Menthol and Nonmenthol Cigarettes in a National Sample of Young Adult Cigarette Smokers*, 20 NICOTINE & TOBACCO RSCH. 1062 (2018), https://pubmed.ncbi.nlm.nih.gov/29059351/.
[27] Cristine D. Delnevo et al., *Banning Menthol Cigarettes: A Social Justice Issue Long Overdue*, 22 NICOTINE & TOBACCO RSCH. 1673 (2020), https://academic.oup.com/ntr/article/22/10/1673/5906409; *see also* Cristine D. Delnevo et al., *Assessment of Menthol and Nonmenthol Cigarette Consumption in the US, 2000 to 2018*, 3 JAMA e2013601 (2020), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2769132.
[28] Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. at 26,470.
[29] David T. Levy et al., *An Expert Elicitation on the Effects of a Ban on Menthol Cigarettes and Cigars in the United States*, 23 NICOTINE & TOBACCO RSCH. 1911 (2021), https://academic.oup.com/ntr/article-abstract/23/11/1911/6294188.
[30] Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. at 26,468.
[31] Sabrina L Smiley, *Retail Marketing of Menthol Cigarettes in Los Angeles, California: A Challenge to Health Equity*, 18 PREVENTING CHRONIC DISEASE E11 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7879965/.
[32] Lisa Henriksen et al., *Menthol Cigarettes in Black Neighbourhoods: Still Cheaper After All These Years*, 0 TOBACCO CONTROL 1 (2021), https://tobaccocontrol.bmj.com/content/tobaccocontrol/early/2021/08/11/tobaccocontrol-2021-056758.full.pdf.

menthol. The same California study found that Newport menthol cigarettes cost on average $0.25 less per pack in neighborhoods with higher proportions of Black residents.[33] Even on an international level, Black smokers receive significantly more price discounts for menthol cigarettes, compared to white smokers.[34] These tactics have resulted in disproportionately high menthol usage rates among Black smokers.

Consequently, Black smokers have disproportionate usage rates of commercial tobacco products. The proposed rule discusses that "African American smokers, regardless of age, are disproportionately more likely to smoke menthol cigarettes than smokers of any other race," but does not specify the rates. Of African American smokers, 73.2% prefer menthol, compared to 52.4% of white smokers.[35] Additionally, rates of exclusive menthol cigarette use are higher among non-Hispanic Black people, compared to non-Hispanic white people (11.8% and 3.3%, respectively).[36]

The disparities among Black youth are even worse than for the Black population as a whole. The proposed rule compares the proportion of non-Hispanic Black and Hispanic students who smoke to the proportion of non-Hispanic white students, finding "significant differences" that are consistent over time.[37] Importantly, we add that these "significant differences" are also found throughout all levels of socioeconomic status. Unlike the findings from past research that has suggested cigarette smoking is higher among adolescents of lower socioeconomic status, Black and Hispanic youth of higher socioeconomic status actually have higher smoking rates than Black and Hispanic youth of lower socioeconomic status.[38]

3. Other communities that have been marginalized also experience disproportionate usage rates.

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[33] *Id.*
[34] Hyunchul Kim & Dongwon Lee, *Tax Incidence for Menthol Cigarettes Across Race: Evidence from Nielsen Homescan Data* (2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3884717.
[35] Amy M. Cohn et al., *Affirming the Abuse Liability and Addiction Potential of Menthol: Differences in Subjective Appeal to Smoking Menthol Versus Non-Menthol Cigarettes Across African American and White Young Adult Smokers*, 24 NICOTINE & TOBACCO RSCH. 20 (2021), https://academic.oup.com/ntr/article-abstract/24/1/20/6354067.
[36] Bukola Usidame, *Exclusive and Dual Menthol/Non-Menthol Cigarette Use with ENDS Among Adults, 2013–2019*, 24 PREVENTIVE MED. REPS. 101566 (2021), https://www.sciencedirect.com/science/article/pii/S2211335521002564.
[37] Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. at 26,462.
[38] Anna E. Epperson et al., *Challenging Assumptions About Race/Ethnicity, Socioeconomic Status, and Cigarette Smoking Among Adolescents*, J. RACIAL & ETHNIC HEALTH DISPARITIES (2021), https://ncpc.ucmerced.edu/sites/ncpc.ucmerced.edu/files/page/documents/eppersonanna-challengingassumptionsaboutrace.pdf.

While the Black community and youth are particularly important in the discussion of menthol, they are not the only communities disproportionately impacted. The FDA details the disparities among individuals who identify as LGBTQ+, pregnant people, those with lower household income or educational attainment, and individuals with behavioral health disorders.[39]

The FDA details the disparate menthol usage rates between lesbian, gay, bisexual, and transgender smokers in the proposed rule.[40] Studies have consistently reaffirmed that LGBTQ+ individuals smoke menthol at higher rates than heterosexual individuals. The FDA also details the disparate menthol usage rates by females. The Center adds an intersectional lens to these findings. Women who identify as a sexual minority are more likely to initiate smoking with a menthol cigarette and are more likely to report past 30-day menthol use compared to heterosexual women.[41] A menthol ban would address the individual disparities these groups face as well as the intersection of the disparities.

The FDA also discusses the smoking rates among people with behavioral health conditions.[42] We add that the disparate usage rates are especially apparent among people with opioid use disorder. Among smokers with opioid use disorder, 88.4% smoke menthol.[43] Considering the disparities discussed in the proposed rule and here, a menthol ban will decrease disparities for people with behavioral health conditions.

We would also like to stress the disparity of menthol use among pregnant people. The proposed rule mentions that "[h]igh levels of menthol cigarette smoking have also been reported in pregnant smokers."[44] We add to the record a study with a possible explanation. Among pregnant women who smoke, menthol cigarettes were perceived as more likable and less harmful than non-menthol cigarettes.[45] A

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[39] Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. at 26,458.
[40] *Id.* at 26,463.
[41] Sarah J. Ehlke et al., *Differences Between Adult Sexual Minority Females and Heterosexual Females on Menthol Smoking and Other Smoking Behaviors: Findings from Wave 4 (2016–2018) of the Population Assessment of Tobacco and Health Study*, 129 ADDICTIVE BEHAVS. 107265 (2022), https://www.sciencedirect.com/science/article/abs/pii/S0306460322000314.
[42] Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. at 26,463.
[43] Danusha Selva Kumar et al., *The Impact of Menthol Cigarette Use on Quit Attempts and Abstinence Among Smokers with Opioid Use Disorder*, 118 ADDICTIVE BEHAVS. 106880 (2021), https://www.sciencedirect.com/science/article/abs/pii/S0306460321000654.
[44] Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. at 26,463.
[45] Nancy C. Jao et al., *Use and Perceptions of Menthol Versus Non-Menthol Cigarettes Among Pregnant Women*, 40 J. ADDICTIVE DISEASES 247 (2022), https://www.tandfonline.com/doi/abs/10.1080/10550887.2021.1981123.

menthol ban has the potential to increase perceptions of harm from menthol cigarettes, and therefore reduce usage rates among pregnant women.

B. The presence of menthol suppresses cessation.

As stated in the Supplement to the Citizen Petition in 2021, it is well-understood that menthol makes it harder for smokers to quit using tobacco products and continues to exacerbate disparate cessation rates for certain populations, especially African American smokers. Since this submission, studies have continued to support that menthol flavored products make cessation attempts more difficult and less successful.[46]

Recent review of PATH data compared quit attempts among menthol smokers in several cohorts and results suggest that there is a lower probability of both quit attempts and cessation for menthol users than for those who use non-menthol products. These trends hold true for youth as well, according to a 2021 review of NYTS data, adolescents who smoke menthol cigarettes have lower intentions of quitting smoking.[47] Findings continue to suggest that removing menthol may contribute to cessation and improve menthol smokers' quit attempts. Completed in 2021, an international literature review of menthol bans around the world was used to estimate the impact a ban would have on the United States and indicates that a sizable number of American smokers', anywhere from 25% to 64% would attempt to quit smoking.[48] In a study recently completed in Canada after implementation of their menthol ban, a significant number of smokers quit (21.5%).[49] The menthol ban was also significantly associated with higher rates of quit attempts and quit success among menthol smokers compared with non-menthol smokers, which may have helped to prevent relapse among menthol smokers who had quit smoking before the

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[46] *E.g.*, Steven Cook et al., *A Longitudinal Study of Menthol Cigarette Use and Smoking Cessation Among Adult Smokers in the US: Assessing the Roles of Racial Disparities and E-cigarette Use*, 154 PREVENTIVE MED. 106882 (2022), https://www.sciencedirect.com/science/article/pii/S0091743521004552.

[47] Dale S. Mantey 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)*, 121 ADDICTIVE BEHAVS. 106986 (2021), https://www.sciencedirect.com/science/article/abs/pii/S0306460321001714?casa_token=8GNXX4e5At4AAAAA:MEennHnuV39AeBK4otbOyA0Yn8RIy_RSlqWP0gTXw5oFDf2wXkWTiFV4lM8XOh2eQVRvtIzSDQ.

[48] Christopher J. Cadham et al., *The Actual and Anticipated Effects of a Menthol Cigarette Ban: A Scoping Review*, 20 BMC PUB. HEALTH 1055 (2020), https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-020-09055-z.

[49] Janet 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*, 31 TOBACCO CONTROL 556 (2022), https://tobaccocontrol.bmj.com/content/31/4/556?int_source=trendmd&int_medium=cpc&int_campaign=usage-042019.

ban. The prohibition of menthol cigarettes will undoubtedly act as leverage for American smokers to quit.

1. Rates of cessation are especially low for Black menthol smokers.

As the proposed rule discusses, "the effect of menthol on reduced cessation success is particularly evident among Black smokers."[50] We add further evidence that Black menthol smokers have lower rates of cessation. This disparity was confirmed in a more recent longitudinal study of smoking cessation among U.S. adults. The study found that "adults who smoke menthol cigarettes had lower odds of smoking cessation, but the effect was modified by race/ethnicity as non-Hispanic (NH) Black menthol smokers had lower odds of quitting smoking than NH White or Hispanic menthol smokers."[51] Specifically, non-Hispanic Black menthol smokers are 23% less likely to cease smoking than their white counterparts.[52] A menthol ban would support Black smokers in quitting, reducing this disparity.

2. A significant reason that menthol smokers have lower cessation rates is because menthol creates heightened dependence.

Recent studies show that menthol specifically facilitates deeper addiction and dependency in both youth and adult smokers. Research published in 2022 reaffirms what older studies have found: menthol is more appealing than the flavor of tobacco, especially among youth, which contributes to smoking intensity and risks for nicotine dependency.[53] Multiple studies show that youth menthol smokers have a significantly shorter time between waking and smoking their first cigarette compared to those that smoke non-menthol cigarettes.[54] The time between waking and smoking one's first cigarette is a recognized and established measure of nicotine dependency.[55] Other studies indicate that youth menthol smokers are more likely to report withdrawal symptoms, higher feelings of craving, and more irritability and restlessness after not smoking for a few hours.[56] Several studies, incorporating recent NYTS data, reveal that youth menthol smokers have higher

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[50] Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26,454, 26,467 (proposed May 4, 2022) (to be codified at 21 C.F.R. pt. 1162).
[51] Cook et al., *supra* note 46.
[52] *Id.*
[53] Cohn et al., *supra* note 35.
[54] *E.g.*, Mantey et al., *supra* note 47.
[55] James C. Hersey et al., *Menthol Cigarettes Contribute to the Appeal and Addiction Potential of Smoking for Youth*, 12 NICOTINE & TOBACCO RSCH. S136 (2010), https://pubmed.ncbi.nlm.nih.gov/21177370/.
[56] Villanti et al., *supra* note 22.

scores on nicotine dependence scales than those that smoke non-menthol cigarettes.[57] For adults, the most recent research shows that for adult daily smokers, those that smoke menthol cigarettes are significantly more likely to report reluctance to give up their first morning cigarette and to report more difficulty refraining from smoking in places where smoking is prohibited.[58] Importantly, multiple studies reaffirm findings that dependence may be greater for female adults and African American adults who use menthol than for menthol cigarette smokers in other demographics.[59]

At the biological and physiological level, animal studies show that menthol increases dependence by interacting with nicotine to produce additional nicotine-specific receptors in the brain, increasing the sensitivity and preventing desensitization of nicotine specific receptors, and by increasing dopamine release due to greater dopamine neuron excitability.[60] Additionally, because menthol has a distinct and recognizable odor, research in mice shows that menthol can increase relapse and drive nicotine-seeking behaviors.[61] Research into tobacco industry documents establishes that the industry has long been studying these physiological impacts and has used this knowledge to manipulate menthol in cigarettes to promote addiction.[62]

C. Menthol Poses a Risk to Users and Nonusers

A 2021 study reaffirms what earlier research and FDA has determined: menthol has contributed to the continued use of cigarettes despite increasing awareness of the harms of smoking, impacting both initiation and cessation, and ultimately contributing to tobacco-related health disparities and negative health outcomes. Between 1980 and 2018, menthol cigarettes alone slowed down the decline in smoking by 2.6% and led to over 10 million *new* smokers, 3 million life-years lost, and 378,000 premature deaths.[63] As FDA states in the proposed rule: "FDA expects a significant reduction in youth initiation and progression to regular cigarette smoking, which would ultimately protect youth from a lifetime of addiction and

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[57] *Id.*; Mantey et al., *supra* note 47; Nonnemaker et al., *supra* note 18.
[58] Pebbles Fagan et al., *Comparisons of Three Nicotine Dependence Scales in a Multiethnic Sample of Young Adult Menthol and Non-menthol Smokers*, 149 DRUG & ALCOHOL DEPENDENCE 203 (2015), https://pubmed.ncbi.nlm.nih.gov/25744873/.
[59] Villanti et al., *supra* note 22; Mantey et al., *supra* note 47.
[60] Robert J. Wickman, *The Biological Impact of Menthol on Tobacco Dependence*, 22 NICOTINE & TOBACCO RSCH. 1676 (2020), https://academic.oup.com/ntr/article/22/10/1676/5684935.
[61] *Id.*
[62] Geoffrey Ferris Wayne & Gregory N. Connolly, *Application, Function, and Effects of Menthol in Cigarettes: A Survey of Tobacco Industry Documents*, 6 NICOTINE & TOBACCO RSCH. S43 (2004), https://pubmed.ncbi.nlm.nih.gov/14982708/.
[63] Le & Mendez, *supra* note 17.

disease, and premature death, attributable to cigarette smoking."[64] The impact of the rule would result in a reduction in the number of current users and a reduction in the number of future users,[65] either of which, on their own, would be a tremendous public health benefit and collectively will significantly reduce disease and death into the future.

The disproportionate usage and cessation rates among Black smokers result in disproportionate health outcomes. The proposed rule rightfully acknowledges the "disproportionate burden of tobacco-related morbidity and mortality" faced by Black smokers, including higher rates of mortality from cancer, heart disease, stroke, and hypertension.[66] However, the proposed rule does not quantify this burden. A simulation study based on data from 1980–2018 did quantify these harms, finding that 1.5 million new smokers, 157,000 premature deaths, and 1.5 million life years lost among African Americans were traced to smoking. These figures represent a "staggering . . . 41% and 50% of the total menthol related harm," while African Americans made up only 12% of the population.[67]

D. Prohibiting menthol creates significant public health benefits.

FDA cites research exploring how prohibitions on flavored tobacco product sales, including for menthol products, have affected users, with that research broadly supporting the argument that bans reduce current consumption and improve cessation.[68] Related work published in 2022—and recognized in FDA's proposed rule—suggests that the impact of the ban would see significant declines in current smoking as well as current tobacco use of any kind, especially among youth and young people. Because, according to the CDC nearly 40% of current middle and high school smokers use menthol cigarettes, the immediate effect of the ban could lead to a precipitous decline in youth tobacco consumption.[69] Similarly, research published in May 2022, comparing menthol cigarette sales bans in England and Canada to current use of menthol cigarettes in the U.S., suggests that effective

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[64] Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26,454, 26,470 (proposed May 4, 2022) (to be codified at 21 C.F.R. pt. 1162).
[65] Cadham et al., *supra* note 48.
[66] Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. at 26,478.
[67] David Mendez & Thuy T.T. Le, *Consequences of a Match Made in Hell: The Harm Caused by Menthol Smoking to the African American Population over 1980–2018*, 0 TOBACCO CONTROL 1 (2021), https://tobaccocontrol.bmj.com/content/tobaccocontrol/early/2021/09/16/tobaccocontrol-2021-056748.full.pdf.
[68] Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. at 26,471.
[69] Andrea S. Gentzke et al., *Tobacco Product Use and Associated Factors Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021*, 71 MORBIDITY & MORTALITY WKLY. REP. 1 (2022), https://www.cdc.gov/mmwr/volumes/71/ss/ss7105a1.htm?s_cid=ss7105a1_w.

implementation could substantially reduce youth smoking.[70] A ban could yield an almost 60% reduction in initiation, especially within the African American community.[71] The ban could result in almost one-third of overall smoking in the African American community ending by 2026, and half the current user population quitting by 2060.[72] Put differently, research shows that a ban may save 255,000 Black lives from premature death and decrease the lives-lost from smoking menthol tobacco products by almost 20%.

1. Prohibiting menthol benefits health equity.

As with the African American community, the impact of the proposed rule on the health prospects for other demographics like the sexual minority population is very likely to be significant and beneficial. A 2021 study, analyzing menthol use among sexual minorities, demonstrates that LGBT+ people are more likely to initiate and sustain with menthol-flavored cigarettes and tobacco products, with female-identifying LGBT+ especially likely to initiate and sustain their tobacco use with menthol when compared to heterosexual females.[73] The proposed rule could have a significant impact on these populations similar to its impact on the African American population and youth generally; even where tobacco use is sustained in the form of other tobacco products, such as non-combustible products, the decline in smoking is likely to impart outsized benefit.[74] Noted earlier, real world evidence suggests that the proposed prohibition would result in some current users continuing to smoke non-menthol cigarettes, while many current users quit smoking altogether or switch to non-combustible products, and fewer people tend to start smoking.[75]

The vast evidence of disproportionate harm to the Black community supports the conclusion that a menthol ban will be especially beneficial for Black smokers. A simulation study on the impact of a menthol ban on the Non-Hispanic Black

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[70] Katherine A. East et al., *Evaluating the Outcomes of the Menthol Cigarette Ban in England by Comparing Menthol Cigarette Smoking Among Youth in England, Canada, and the US, 2018-2020*, 5 JAMA e2210029 (2022), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2791805.

[71] Levy et al., *supra* note 29; Yan Li et al., *Assessing the Health and Economic Impact of a Potential Menthol Cigarette Ban in New York City: A Modeling Study*, 98 J. URB. HEALTH 742 (2021), https://link.springer.com/article/10.1007/s11524-021-00581-8.

[72] Mona Issabakhsh et al., *The Public Health Impact of a US Menthol Cigarette Ban on the Non-Hispanic Black Population: A Simulation Study*, TOBACCO CONTROL (2022), https://tobaccocontrol.bmj.com/content/early/2022/06/12/tobaccocontrol-2022-057298.

[73] Ehlke et al., *supra* note 41.

[74] Brian L. Rostron et al., *ENDS Flavor Preference by Menthol Cigarette Smoking Status Among US Adults, 2018–2019*, 18 INT'L J. ENV'T RSCH. & PUB. HEALTH 240 (2021), https://www.mdpi.com/1660-4601/18/1/240/htm.

[75] Chung-Hall et al., *supra* note 49.

population in the United States supports just how impactful this proposed rule would be. The study found that a menthol ban would save 255,000 premature deaths and 3.9 million life-years for Black people over 40 years.[76]

Black menthol smokers are more likely to quit smoking compared to white smokers under a menthol ban, closing the outcome gaps faced by the community. The FDA provides evidence of this in the proposed rule: "the proposed product standard will improve smoking cessation outcomes among vulnerable populations, in particular, Black smokers, leading to a reduction in adverse tobacco-related health effects in these populations."[77] Under a menthol ban, Black menthol smokers are less likely to initiate smoking, more likely to quit smoking, and less likely to switch to other products. An expert elicitation study estimating the specific effects of a menthol ban on current and future tobacco use, research cited multiple times by the FDA in the proposed rule, establishes this.[78] Under a ban, African Americans ages 12-24 are predicted to be less likely to initiate nonmenthol cigarettes and more likely to become nonusers. Also, African American menthol smokers ages 12-24 are predicted to be less likely to switch to nonmenthol cigarettes and more likely to quit regular use.[79] Additionally, the likelihood of Black smokers switching to other products under a menthol ban is 31% lower than white smokers.[80] A menthol ban is especially beneficial for Black smokers, closing the gap between Black and white smoker health outcomes.

A study on a potential menthol ban in New York City found that reduction in adverse cardiovascular disease outcomes would be significant.[81] These benefits were predicted to be strongest among Black women, reducing both racial and gender disparities.[82] Under a menthol ban, there is the possibility that some Black menthol smokers will switch to non-menthol cigarettes. While any cigarette is clearly harmful, switching to non-menthol cigarettes could be beneficial for cessation. A study which looked at the ability to quit between African American menthol smokers and African American menthol smokers who switched to non-menthol cigarettes, found that those who switched to non-menthol cigarettes smoked fewer

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[76] Issabakhsh et al., *supra* note 72.
[77] Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26,454, 26,479 (proposed May 4, 2022) (to be codified at 21 C.F.R. pt. 1162).
[78] Levy et al., *supra* note 29.
[79] *Id.*
[80] Yong Yang et al., *How Smokers of Menthol Cigarettes and Flavored Cigars Might Respond to FDA's Proposed Bans*, NICOTINE & TOBACCO RSCH. (2022), https://academic.oup.com/ntr/advance-article-abstract/doi/10.1093/ntr/ntac078/6556048.
[81] Li et al., *supra* note 71.
[82] *Id.*

times per day, reported lower withdrawal symptoms, and had higher perceived effectiveness of their ability to quit smoking altogether.[83]

These positive impacts are likely why Black people are more supportive of a menthol ban. Both Black smokers and non-smokers express stronger support for a menthol ban than their white counterparts.[84] In total, 60.5% of non-Hispanic African Americans support a government policy to ban menthol cigarette sales.[85] Among Black smokers, 27% express support for a menthol ban (which was the highest among all racial/ethnic groups studied).[86] A menthol ban is beneficial for Black smokers and is widely supported by Black individuals.

2. Prohibiting menthol is proven to decrease initiation and increase cessation.

A menthol ban is clearly appropriate for the protection of public health, as it would dramatically decrease initiation rates. *An Expert Elicitation on the Effects of a Ban on Menthol Cigarettes and Cigars in the United States*, a study cited many times in the proposed rule, predicts that initiation will decrease substantially.[87] Total menthol smoking initiation is expected to be reduced by 59% under this ban.[88]

A menthol ban is likely to see a dramatic increase in rates of cessation of menthol products. The menthol ban in Canada proved extremely successful at helping smokers quit tobacco. The ban was significantly associated with higher quit rates – after the menthol ban, 21.5% quit smoking entirely.[89] While some menthol smokers switched to non-menthol cigarettes, only 19.5% of pre-ban menthol smokers still smoked menthol.[90] Additionally, quit rates were 7.5% higher in menthol smokers, compared to non-menthol smokers.[91] The Canadian menthol ban was also significantly associated with higher quit attempts. An ITC evaluation found that the

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[83] Michael Kotlyar et al., Effects on Smoking Behavior of Switching Menthol Smokers to Non-Menthol Cigarettes, 23 NICOTINE & TOBACCO RSCH. 1921 (2021), https://academic.oup.com/ntr/article-abstract/23/11/1921/6275269.
[84] Lauren Czaplicki et al., National Support for a Menthol Cigarette Sales Ban, 136 PUB. HEALTH REPS. 183 (2021), https://journals.sagepub.com/doi/full/10.1177/0033354920966004; Yang et al., *supra* note 80.
[85] Czaplicki et al., *supra* note 85.
[86] Yang et al., *supra* note 80.
[87] Levy et al., *supra* note 29.
[88] *Id.* at 1914.
[89] Chung-Hall et al., *supra* note 49.
[90] *Id.*
[91] Geoffrey T. Fong et al., *The Impact of Canada's Menthol Cigarette Ban on Quitting Among Menthol Smokers and Projections of Impact in the European Union: Findings from the ITC Project*, 7 TOBACCO PREVENTION & CESSATION (2021), http://www.tobaccopreventioncessation.com/The-Impact-of-Canada-s-Menthol-Cigarette-Ban-on-Quitting-Among-Menthol-Smokers-and,143653,0,2.html.

ban increased quit attempts by 9.7%.[92] Lastly, the ban likely helped prevent relapse of smokers who had quit smoking prior to the ban. Menthol smokers were significantly more likely to be long-term quitters after the ban and fewer pre-ban quitters relapsed.[93]

These results were consistent throughout jurisdictions in Canada. A study on the ban of menthol tobacco products in Ontario found that both daily menthol smokers and occasional menthol smokers were significantly more likely to quit smoking compared to non-menthol smokers.[94] Menthol smokers were also more likely to make quit attempts than their non-menthol counterparts.[95]

Applying these successes to a menthol ban in the United States, up to 64% of smokers would likely attempt to quit smoking.[96] A menthol ban is clearly appropriate for the protection of public health, as it would vastly increase cessation rates.

3. Prohibiting menthol promotes the health of users and nonusers.

In countries in which menthol bans have been implemented, smoking rates have decreased substantially. In England, within six months, smoking rates decreased among all menthol smokers by over 21% and decreased among youth by 7.5%.[97] Smoking rates also continue to decrease as time goes on. From February 2020 to August 2020, smoking rates in Canada continued to fall, despite the menthol ban being implemented almost three years prior.[98]

Similarly, a decrease in sales strongly suggests that fewer people are smoking menthol. Menthol bans have been proven time and again to significantly decrease cigarette sales.[99] As just one example we point to Ontario, where after the

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[92] *Id.*
[93] *Id.*; Chung-Hall et al., *supra* note 49.
[94] Michael Chaiton et al., *Prior Daily Menthol Smokers More Likely to Quit 2 Years After a Menthol Ban Than Non-Menthol Smokers: A Population Cohort Study*, 23 NICOTINE & TOBACCO RSCH. 1584 (2021), https://academic.oup.com/ntr/article-abstract/23/9/1584/6167587.
[95] *Id.*
[96] Cadham et al., *supra* note 48.
[97] East et al., *supra* note 70.
[98] *Id.*
[99] *See* Michael Chaiton et al., *Analysis of Wholesale Cigarette Sales in Canada After Menthol Cigarette Bans*, 4 JAMA e2133673 (2021), https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2785881; Elizabeth M. Brown et al., *Changes in Retail Sales of Tobacco Products in Ontario After a Menthol Sales Restriction*, 0 TOBACCO CONTROL 1 (2021), https://tobaccocontrol.bmj.com/content/tobaccocontrol/early/2021/07/12/tobaccocontrol-2021-056489.full.pdf; Samuel Asare et al., *Association of Cigarette Sales with Comprehensive Menthol Flavor*

implementation of its menthol ban, menthol cigarette sales decreased by 93%, from 596 to 40 packs per capita.[100]

4. Prohibiting menthol creates an economic benefit.

The FDA estimates that implementing a prohibition on the sale of menthol cigarettes could yield an incredible cost savings to the national economy.[101] The agency estimates that the sum of monetized benefits over 40 years could amount to between $1.3 and $8.2 *trillion* dollars. While FDA action relies solely on the benefit to public health, not monetary benefits, these values still present a compelling argument for quick and efficacious enactment of the prohibition.[102]

E. The FDA can learn lessons from the jurisdictions that have led on prohibiting menthol.

The ample evidence of the effectiveness of menthol bans provides insight for the FDA to tailor this proposed rule in the best interest of public health. The FDA's final rule should not include any exclusions or exemptions, as they decrease the effectiveness of the tobacco control policy.[103]

One such potential problem is banning menthol as a "characterizing flavor," but allowing some amount of menthol to continue to be added to cigarettes. The definition of "characterizing flavor" is unclear, despite the proposed rule's clarifying factors.[104] Unclear definitions increase the potential for restricted products to be sold and make enforcement more difficult.[105] In other jurisdictions with menthol bans, the tobacco industry has exploited the use of the term "characterizing flavor" by claiming that menthol is not the "characterizing flavor" of a product, effectively

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Ban in Massachusetts, 182 JAMA INTERNAL MED. 231 (2022), https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2787781?casa_token=y4YlW3rn6QQAAAAA:hPv0tEpcGy8EeNQMhSaqzApd05Oh5KvpMfUDUeJIED2AickrpB5bGX49NE_NAunYgLsjK0tZSA; Todd Rogers et al., *A Comprehensive Qualitative Review of Studies Evaluating the Impact of Local US Laws Restricting the Sale of Flavored and Menthol Tobacco Products*, 24 NICOTINE & TOBACCO RSCH. 433 (2022), https://academic.oup.com/ntr/article/24/4/433/6370828; Linda M. Bosma et al., *Restricting Sales of Menthol Tobacco Products: Lessons Learned from Policy Passage and Implementation in Minneapolis, St. Paul, and Duluth, Minnesota*, 5 HEALTH EQUITY 439 (2021), https://www.liebertpub.com/doi/full/10.1089/heq.2020.0137.

[100] Brown et al., *supra* note 100.

[101] Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26,454, 26,489 (proposed May 4, 2022) (to be codified at 21 C.F.R. pt. 1162).

[102] *Id.*

[103] Rogers et al., *supra* note 100.

[104] Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. at 26,455.

[105] Rogers et al., *supra* note 100.

keeping menthol on the market.[106] Further reasons for this change are discussed in depth in section IV(A) of this comment.

The largest lesson learned for other jurisdictions is that a national menthol ban is the greatest opportunity for the FDA to protect public health. Various studies show that the effectiveness of a local prohibition is impacted by the absence of prohibition in nearby jurisdictions.[107] A national ban would eliminate the issue of residents traveling to other states or cities for prohibited products. We strongly urge the FDA to take this positive step towards the protection of public health.

F. Examining the scientific evidence through the lens of health equity demands that the FDA prohibit menthol.

The expansive scientific evidence listed in the proposed rule paints an exceptionally clear picture: menthol cigarettes must be banned. The material listed in this comment adds to that evidence, leaving no room for doubt. A menthol ban would prevent countless tobacco-related harms to smokers and non-smokers. These benefits would be especially pronounced in marginalized communities, closing persistent disparities. The Center reiterates our appreciation of the FDA's recognition of health equity as inherent in the decision of what is "appropriate for the protection of the public health" and urges the FDA to ban menthol for health equity purposes.

IV. In order to maximize the benefits to public health, the FDA must strengthen the proposed rule.

While the FDA's proposed rule will create tremendous public health benefits and finally take steps towards mitigating the health disparities caused by the exemption of menthol from the TCA's prohibition on flavored cigarettes, the rule can still be strengthened to increase the benefits to public health. Some of these improvements

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[106] *Id.*; Anne-Line Brink et al., *Tobacco Companies' Exploitation of Loopholes in the EU Ban on Menthol Cigarettes: A Case Study from Denmark*, TOBACCO CONTROL (2021), https://tobaccocontrol.bmj.com/content/early/2022/03/20/tobaccocontrol-2021-057213; Adam Kulhánek et al., *Analysis of Tobacco Industry Marketing and Media Communication in Response to the Menthol Cigarette Ban in the Czech Republic in 2020*, 21 ADIKTOLOGIE 75 (2021), https://adiktologie-journal.eu/wp-content/uploads/2021/12/21_016_Kulhanek_WEB-FINAL.pdf; Michael O. Chaiton et al., *Taking Global Leadership in Banning Menthol and Other Flavours in Tobacco: Canada's Experience*, 31 TOBACCO CONTROL 202 (2022), https://tobaccocontrol.bmj.com/content/tobaccocontrol/31/2/202.full.pdf.

[107] Joseph R Guydish et al., *Menthol Cigarette Use in Substance Use Disorder Treatment Before and After Implementation of a County-Wide Flavoured Tobacco Ban*, 30 TOBACCO CONTROL 616 (2021), https://tobaccocontrol.bmj.com/content/30/6/616; Rogers et al., *supra* note 100.

require changes to the proposed rule and others can be done entirely outside the rulemaking process.

A. The FDA must entirely prohibit the addition of menthol to cigarettes.

While the FDA has proposed to prohibit menthol as a "characterizing flavor" in cigarettes, the public health benefits of this rule could be dramatically increased by entirely prohibiting the *addition* of menthol to *all* cigarettes. This version of the rule would also be easier for the FDA to implement and enforce.

Although, there is a higher level of menthol in cigarettes marketed specifically as "menthol," all cigarettes contain some menthol.[108] The menthol content of cigarettes that are not marketed as being menthol flavored ranges from 0.002 to 0.07 milligrams per cigarette.[109] For cigarettes that are marketed as being menthol-flavored, the content reaches as high as 19.6 milligrams per cigarette.[110] The menthol added to cigarettes that are not marketed as menthol cigarettes has an impact on smokers similar to the menthol in menthol flavored cigarettes, merely to a lesser degree.

An alarming body of evidence clearly and consistently demonstrates that the presence of menthol in commercial tobacco products is distinctly harmful at any level. Animal research has shown that menthol uniquely interacts with nicotine in the brain to make physiological changes and that the respiratory system is impacted at a molecular level. These findings undermine industry efforts to characterize menthol as a harmless flavoring that only impacts the smell, taste, and abrasiveness of cigarettes. A major reason the tobacco industry uses menthol in *every* cigarette is because menthol is a unique additive that facilitates and increases initiation, leads to a deeper level of addiction and dependency, and makes it much more difficult to quit smoking.[111]

To maximize the health benefits of this rule for all smokers, not just menthol smokers, the FDA should entirely prohibit the addition of menthol to all cigarettes. Because of the abundant evidence on the menthol content of cigarettes, to enforce

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[108] Sydney M. Gordon et al., *Effect of Cigarette Menthol Content on Mainstream Smoke Emissions*, 24 CHEM. RSCH. TOXICOLOGY 1744 (2011), https://pubs.acs.org/doi/10.1021/tx200285s.
[109] Jiu Ai et al., *Menthol Levels in Cigarettes from Eight Manufacturers*, 27 TOBACCO CONTROL 335 (2018), https://tobaccocontrol.bmj.com/content/27/3/335.
[110] *Id.*
[111] Stacey J. Anderson, *Menthol Cigarettes and Smoking Cessation Behaviour: A Review of Tobacco Industry Documents*, 20 TOBACCO CONTROL ii49 (2011), https://tobaccocontrol.bmj.com/content/20/Suppl_2/ii49.

such a rule, the FDA could set a maximum level of menthol, somewhere at or above 0.0005 milligrams and presume that any cigarettes with a higher menthol concentration have had menthol added to them.[112] Menthol naturally occurs in tobacco at a rate of only 0.00023 milligrams per cigarette.[113] However, all cigarettes on the market have at least 10 times that quantity. By using a concentration of 0.0005 milligrams per cigarette for enforcement, the FDA can ensure that all cigarettes have not had menthol added to them beyond what is naturally occurring in the tobacco.

1. The presence of *any* menthol in cigarettes facilitates initiation, increases dependency, and suppresses cessation.

As discussed in depth in section III of this comment, menthol contributes to tobacco initiation, dependency, and unsuccessful cessation. The role of menthol as an important precursor to initiation and dependency to the population as a whole has been well-documented. At the biological level, animal studies show that menthol increases dependence by interacting with nicotine to produce additional nicotine-specific receptors in the brain, increasing the sensitivity and preventing desensitization of nicotine specific receptors, and by increasing dopamine release due to greater dopamine neuron excitability.[114] Additionally, because menthol has a distinct and recognizable odor, research in mice shows that menthol can increase relapse and drive nicotine-seeking behaviors. [115] Research into tobacco industry documents establishes that the industry has long been studying these physiological impacts and has used this knowledge to manipulate menthol in cigarettes to promote addiction across its consumer base and the wider population.[116]

Menthol unequivocally makes it harder for smokers to quit smoking.[117] This remains true despite increased quit attempts or intention to quit by menthol smokers.[118] Animal studies focusing on the biological and physiological impact of menthol in successful cessation further revealed that menthol may impact the metabolism of nicotine and disrupt the mechanisms that pharmaceutical medications like varenicline and bupropion engage to help smokers quit.[119] This is consistent with past studies that show that African American menthol smokers have less success quitting using bupropion compared to their counterparts who do not

[112] This number is supported by the evidence available to the Center. However, a lower threshold may be appropriate.
[113] Ai et al., *supra* note 110.
[114] Anderson, *supra* note 112.
[115] Wickham, *supra* note 60.
[116] Wayne & Connolly, *supra* note 62.
[117] Villanti et al., *supra* note 22.
[118] *Id.*
[119] Wickham, *supra* note 60.

use menthol.[120] This leads to the inference that any amount of menthol in cigarettes suppresses cessation.

2. Enforcement of a prohibition of menthol as an additive is much easier than enforcement of a prohibition of merely "menthol as a characterizing flavor."

Enforcement of a prohibition of "menthol as a characterizing flavor" would be challenging. The Tobacco Control Act provides no clear definition of "characterizing flavor." The proposed rule also makes no attempt to provide a clear definition for this concept, and instead provides a list of factors relevant to determining whether a cigarette has a characterizing flavor. While these factors provide guidance, they still fail to define "characterizing flavor." This lack of a definition makes enforcement of a standard relying on said definition challenging at best. The FDA can look to information provided by state and local governments that have restricted sales of flavored products for information on the difficulty of enforcing this sort of standard.[121] The FDA's failure to define the term will inevitably see the agency adjudicating hundreds of brands on a case-by-case basis.

Instead, the FDA should prohibit the addition of menthol entirely. A product standard prohibiting the addition of any menthol to cigarettes is clear and easily enforceable. Because naturally occurring menthol in tobacco is significantly lower than the concentration of menthol even in cigarettes that are not marketed as menthol cigarettes, if the FDA tests a cigarette and the menthol content exceeds 0.0005 milligrams, there is no question that the product is in violation of this proposed rule; at the least, there is a rebuttable presumption that extraneous menthol was added to the cigarette. The FDA would not have to undergo the time-consuming task of weighing all relevant factors.

B. In order to maximize the public health benefits of the rule, the FDA must stringently enforce the new regulation.

While the proposed rule spends little time discussing how the new rule will be enforced, the FDA must ensure that the rule is enforced with fidelity in order to provide the most protection to the public. The tobacco industry has perennially

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[120] Kolawole S. Okuyemi et al., *Does Menthol Attenuate the Effect of Bupropion Among African American Smokers?*, 98 ADDICTION 1387 (2003), https://pubmed.ncbi.nlm.nih.gov/14519175/.
[121] Largely due to the risk of litigation from manufacturers, state, local, and Tribal governments have not attempted to establish a particular concentration of flavor additives as the threshold for "characterizing flavors." Lawsuits from industry challenging these policies have attempted to claim they are preempted because the policies are illegal product standards. The FDA does not have this same risk and can certainly avoid this issue entirely.

raised issues of illicit trade as a barrier to action. However, the FDA has enforcement tools that can mitigate and entirely prevent such activities from jeopardizing the benefits of the rule, if they represent a real threat to public health.

1. Illicit trade concerns are less significant than what the tobacco industry claims.

Illicit trade – the manufacture, distribution, and sale of prohibited products – does not undermine the public health benefits of the proposed rule and is less significant than industry claims. Moreover, the proposed rule will reduce the illegal selling of tobacco products to minors and youth. Even if illicit trade and illegal sales to minors occur because of a menthol ban, it should be easy to identify because it would require the manufacture, distribution, promotion, and sale of products that would not otherwise be legally sold.

The National Research Council and the Institute of Medicine (now known as the National Academies of Sciences, Engineering and Medicine) concluded in their 2015 report that "the 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."[122] In Canada, the federal government prohibited menthol in cigarettes. There was no evidence of a market for contraband menthol cigarettes.[123]

2. The most important illicit market is that which provides cigarettes to consumers too young to buy them legally.

The most significant consequence of the proposed rule is likely to be a substantial reduction in the illicit sale of combusted tobacco products to customers below the minimum legal sales age. The tobacco industry will argue that the FDA should not impose any rule eliminating menthol because, as it claims when any tobacco control measure is proposed, it would cause illicit sales. However, that argument ignores the fact that illegal sales to people under the minimum legal sales age has existed for decades. Yet one could not credibly argue that the ban on sales to youth should be repealed because it has led to some illegal sales. One of the central purposes of the proposed rule is to curtail use by and sales to youth, and thus eliminate illegal sales to youth by making tobacco products less appealing to young people. In this context, it is ironic that the tobacco industry would put forth the argument that the rule would "create" illicit markets. Given that virtually all smokers start in their youth,

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[122] NAT'L RSCH. COUNCIL & INST. MED., UNDERSTANDING THE U.S. ILLICIT TOBACCO MARKET 9 (National Academies Press ed., 2015).
[123] Michael Chaiton et al., *Association of Ontario's Ban on Menthol Cigarettes with Smoking Behavior 1 Month After Implementation*, 178 ADDICTION JAMA INTERNAL MED. 710 (2018), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2673373.

today's tobacco epidemic is in large measure the product of an existing illicit market that makes combusted tobacco products available to consumers too young to legally sell to. The rule has been proposed because of the recognition that this illicit market will continue to exist so long as products that are addictive and attractive to youth are allowed to be sold.

Moreover, those who argue most vociferously against a menthol ban because of concerns about illicit markets are the very 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.[124]

3. Enforcement measures must remain focused on manufacturers, importers, distributors, and retailers.

For illicit *trade* to exist in the United Sates, there must first be either illicit manufacturing or smuggling. Track-and-Trace authority allows the federal government to prevent both illicit manufacturing and smuggling in collaboration with other agencies. Track-and-Trace is an effective enforcement policy that will reduce the risk of illicit trade and is important to ensure the success of the proposed rule. Key elements to combat illicit trade and non-compliance include: frequent and unannounced inspection of manufacturers, retailer education, and inspection of products labeled for export. In other words, to identify illicit products and keep them off the market, the FDA should use its existing authority under the Tobacco Control Act to track the transportation of tobacco products at every level of the supply chain.

Specifically, Section 920 of the Tobacco Control Act already directs FDA to implement a Track-and-Trace system.[125] Such a system would permit the FDA and other law enforcement authorities to identify the source and distribution history of product packages and greatly increase the effectiveness of law enforcement. These systems have been most effective when they have included encrypted cigarette stamps.

Under a Track-and-Trace system, each tobacco product produced or sold in the United States would bear a unique, counterfeit-resistant identifying code that allows its origin to be identified and linked to a computer database of required records that would permit the product to be tracked and traced. Such a system would enable the FDA to track goods from manufacture or importation to the point of retail sale and provide it with the ability to trace back those goods to their point of origin. This kind

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[124] *United States 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).
[125] 21 U.S.C. § 387.

of system would be of great value in enforcing compliance with the rule, in addition to deterring smuggling and trafficking and preventing illegal diversion. To accomplish these goals, a national track and trace system should, at minimum, have the features outlined with much input and consideration by the World Health Organization's Framework Convention on Tobacco Control's (FCTC).[126]

In developing a policy for effective enforcement of the proposed rule, FDA must coordinate its activities with those of other federal agencies with experience in these areas. Measures the FDA can implement pursuant to the Tobacco Control Act, such as implementation of an effective Track-and-Trace system, can provide substantial assistance to other federal agencies in the performance of their functions, particularly in the identification of products on which taxes or import duties have not been paid. Effective coordination between the FDA and other federal enforcement agencies is essential. The FDA should also coordinate its enforcement efforts with those of state law enforcement agencies and those of indigenous Tribal governments.

Moreover, other federal agencies already exercise authority that is highly relevant to the task FDA will face. The Bureaus of Immigration and Customs Enforcement ("ICE") and Customs and Border Protection ("CBP"), agencies of the Department of Homeland Security, have been responsible for identifying imported tobacco products and ensuring that appropriate taxes and import duties are paid and the Department of Justice's Bureau of Alcohol, Tobacco, Firearms and Explosives ("ATF"), has been responsible for administration of the PACT Act. Similarly, for domestic products, the Alcohol and Tobacco Tax Bureau in the Department of the Treasury ("TTB") has been responsible for monitoring the shipment of domestically manufactured tobacco products and ensuring that taxes are paid. It is important that any track and trace system implemented by FDA to be under the direct management and control of the federal government. In addition, such a system should be designed to allow states and local jurisdictions shared access to data systems storing shipping and receiving information to and from local jurisdictions to ensure that required taxes have been paid and to assist with enforcement.

FDA should reject efforts by the tobacco industry to participate in the development of such a system or to use the industry-sponsored systems. In sum, the threat of an illicit market does not outweigh public health benefit.

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[126] World Health Org., *Framework Convention on Tobacco Control, Conference of the Parties, Intergovernmental Negotiating Body on a Protocol on Illicit Trade in Tobacco Products, fourth session*, Geneva, Switzerland (2010) (analysis of the available technology for unique markings in view of the global track-and-trace regime proposed).

4. The FDA should establish a "prohibited product list" or "permitted product list" with existing information to root out hidden flavors in commercial tobacco products because it is appropriate for the protection of public health.

The Tobacco Control Act grants the FDA wide-ranging authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public's health. Section 905(i)(1) of the FD&C Act requires that all tobacco product manufacturers "shall, at the time of registration . . . . file with [FDA] a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution." What this means in practice is that all commercial tobacco product manufacturers are required to file form 3741A, *Registration and Listing for Owners and Operators of Domestic Deemed Tobacco Product Establishment,*[127] or the electronic equivalent, every year, for every product they put into the stream of commerce. This document—filed under penalty of perjury—on page 7, section 7, requires manufacturers to list any flavor present, including menthol. The FDA could use this list to easily identify products that are currently marketed as having a characterizing flavor of menthol. Similarly, the FDA can use information gathered under Section 904(a) to determine which currently marketed cigarettes contain added menthol.

The time has come for the FDA to operationalize the data it routinely collects for the protection of public health. Here, it can do so by creating a "prohibited product list" or "permitted product list" with the information that manufacturers are required to report. In so doing, the FDA will be able to easily identify compliant and non-compliant products, making enforcement of this product standard exceptionally simple.

5. The FDA should take immediate action to remove menthol "components or parts" from the market because they lack marketing authorization and will be used to make an end run around the menthol prohibition.

The proposed rule would also prohibit menthol in cigarette "components or parts."[128] A product is a cigarette component or part if it: (1) alters or affects the performance, composition, constituencies, or characteristics of a cigarette; or (2)

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[127] U.S. DEP'T HEALTH & HUM. SERVS., FDA, *Registration and Listing for Owners and Operators of Domestic Deemed Tobacco Product Establishment*, Form 3741a, https://www.fda.gov/media/99863/download.

[128] Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26,454, 26,455 (proposed May 4, 2022) (to be codified at 21 C.F.R. pt. 1162).

can be used by humans to consume a cigarette.[129] Components or parts include products such as filters, papers, flavor cards, drops, oils, or other additives.[130] All cigarette components and parts are subject to FDA regulation and require marketing authorization. Under this rule, any menthol cigarette components and parts would not be compliant with the proposed product standard, and the FDA would have authority to remove them from the market.

This complete ban of menthol components or parts is the right course of action because the tobacco industry has a long and sordid history of exploiting regulatory loopholes. For example, the tobacco industry began to heavily market flavored cigars after the passage of the TCA in 2009, thereby undercutting the public health gains made by the TCA's ban on flavored cigarettes. More recently, the industry took advantage of defects in the European Union's menthol ban—the exemption of menthol accessories if they were sold outside the pack of cigarettes—to introduce separately sold components designed to reintroduce menthol into cigarettes.[131] By 2017, Imperial Brands had launched menthol flavor tips, and by 2020, menthol "Flavor Infusion" cards.[132] By mid-2021, Imperial reported selling 900,000 packs of flavor cards per week.[133] British American Tobacco and smaller tobacco brands followed the same business strategy, adding more flavored accessories to the market.[134] Therefore, because it is completely foreseeable that the industry will try to defang the menthol prohibition via the sale of components and parts, the FDA should ensure that enforcement of this rule includes enforcement action against manufacturers of components and parts designed to evade the product standard.

C. There is no legal authority or scientific justification for the FDA to create a waiver process to exempt products from the proposed standard.

The FDA has asked whether it should consider exempting some products from the product standard, including heated cigarettes and Very Low Nicotine (VLN) cigarettes, or whether the agency should set up a waiver process for any product

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[129] 21 C.F.R. § 1140.3.
[130] FDA, *Cigarettes* (Apr. 28, 2022), https://www.fda.gov/tobacco-products/products-ingredients-components/cigarettes.
[131] Brink et al., *supra* note 107; Ben Stockton et al., *'Impossible to Enforce': Big Tobacco Exploiting Loopholes in European Menthol Ban*, BUREAU INVESTIGATIVE JOURNALISM (Nov. 2, 2021), https://www.thebureauinvestigates.com/stories/2021-11-02/big-tobacco-exploiting-loopholes-in-european-menthol-ban; *Menthol Cigarettes: Industry Interference in the EU and UK*, TOBACCO TACTICS (Dec. 15, 2021), https://tobaccotactics.org/wiki/menthol-interference-eu-uk/; Rosemary Hiscock et al., *Tobacco Industry Tactics to Circumvent and Undermine the Menthol Cigarette Ban in the UK*, 29 TOBACCO CONTROL e138 (2020), https://tobaccocontrol.bmj.com/content/29/e1/e138.
[132] TOBACCO TACTICS, *supra* note 128.
[133] *Id.*
[134] Brink et al., *supra* note 107; Hiscock et al., *supra* note 128.

that a manufacturer wishes to receive an exemption for. This is a bad idea because it is not rooted in the law nor would it benefit public health.

First, there is no provision in the TCA that provides for waivers from product standards. Under section 907 of the FD&C Act, the FDA has the authority to establish tobacco product standards regarding the construction, components, ingredients, additives, constituents, and properties of tobacco products.[135] Nothing in this section allows the FDA to create a waiver process. Hence, creating a waiver process is outside the FDA's authority. Had Congress envisioned such a system, it would have specified so. Because it did not, it is clear that Congress intended a product standard to cover an entire class of products, a hallmark of a delegation of rulemaking authority - not to create an individualized application process, a hallmark of an adjudicatory authority. These two types of authorities are defined and governed differently under the Administrative Procedure Act. There is no question that Section 907 does not create any authority for some sort of adjudicatory waiver system. The creation of such a system would be squarely outside the FDA's authority.

Moreover, to establish a *new* tobacco product standard, the FDA must find that the standard is, "appropriate for the protection of the public health."[136] Thus, even if it were legal for the FDA to create a waiver process, the FDA has not made the prerequisite showing that such a waiver would be appropriate for the protection of public health.

V. There are actions that the FDA can take outside of this rulemaking that will further increase the public health benefits of this proposed rule.

The FDA can take important and immediate steps to ensure the protection of public health before this rule is finalized. The FDA is aware that cigarettes, especially menthol cigarettes, have led to disparate health impacts across varied marginalized groups - more prominent of which are African Americans, other communities of color, and young people. The Tobacco Control Act allows the FDA to make decisions regarding the regulation of commercial tobacco to advance public health.[137] In advancing public health, the FDA should pursue culturally specific services that prevent initiation and promote cessation of smoking in vulnerable populations. The FDA can also take a leadership role in coordinating with other government and non-government programs. One way it can do this is to provide localities and

[135] 21 U.S.C. § 387g.
[136] *Id.* § 387g(a)(3)(B)(i).
[137] 21 U.S.C. § 387g.

organizations with technical assistance as required by statute.[138] Finally, by working to promote other product standards for cigars and e-cigarettes, the FDA has several options to better protect public health that it can accomplish outside the rulemaking process. These actions do not require a finalized rule and can happen during the current rulemaking process. The FDA should not delay in taking these necessary actions.

A. Cessation Programs should emphasize cultural competence for better results

In the United States, studies show that menthol cigarettes were specifically marketed to African American communities in addition to other ethnic groups, LGBTQ+ communities and young people.[139] The industry intentionally targeted these groups knowing that menthol made it easier to take up smoking and harder to quit. The FDA's announcement of a rule to ban menthol in cigarettes is a welcome response to the industry's targeting. The FDA can do more outside the rulemaking process to continue to support smoking cessation before the rule is final.

One way the FDA can advance culturally responsive cessation programs is to work closely with organizations like the Center for Black Health and Equity (CBHE), African American Tobacco Control Leadership Council, and Truth Initiative, among others. These entities work in communities of color and with young people to advance smoking cessation and tobacco control policies. The FDA can support their efforts by being present at their activities or by amplifying their work to promote public health. The FDA has stated that it intends to work with other federal, state, and local government entities and Tribal governments on similar programs.[140] The FDA should follow through on that intention by ensuring that the work it does is culturally specific to groups disproportionately harmed by menthol cigarettes.

The FDA has promoted culturally relevant smoking intervention ad campaigns in the past. These included campaigns like "The Real Cost", "Fresh Empire", "This Free Life", and "Every Quit Counts". These campaigns were developed with consultants to provide content that would speak directly to those communities to raise awareness of the dangers of smoking and provide resources to stop smoking. Currently the FDA

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[138] 21 U.S.C. § 387f-1(b)(2).
[139] Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26,454, 26,468 (proposed May 4, 2022) (to be codified at 21 C.F.R. pt. 1162); *The Fight Against Menthol, Our Position on the Issue of Menthol*, CTR. FOR BLACK HEALTH & EQUITY, https://www.centerforblackhealth.org/menthol (last visited Aug. 1, 2022).
[140] Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. at 26,477.

is running a new campaign, "Next Legends" to speak to Native American youth.[141] Next Legends appears to be the only demographic-specific active campaign. The FDA should continue conducting culturally responsive ad campaigns around menthol that speak to the African American community and young people. A revival of the "Pathways to Freedom: Winning the Fight Against Tobacco" program could be an opportunity for the FDA to engage the African American community about its proposed menthol rule and how the rule can help in the fight against harms caused by commercial tobacco products.[142]

CBHE is a national organization that offers cessation programs and support to help people stop smoking, with an emphasis on supporting members of the African American community. CBHE notes that 70 percent of menthol smokers want to quit. Yet most menthol smokers report an inability to stop smoking because the effects of menthol make it harder.[143] CBHE facilitates programs that are culturally appropriate for Black smokers. One is a program known as "No Menthol Sunday" to reach African Americans through their faith communities. The Black church holds an active place in African American society as a place to receive information, services, and resources, especially for those who may not have other options. Another program that CBHE developed was specific to the pandemic when people of color were disproportionally likely to be affected by the COVID-19 virus. COVID-19, also designated as SARS-COV-2, can manifest as a respiratory disease, and quitting was important for any smoker to prevent susceptibility to a worse COVID-19 outcome. CBHE provided resources that allowed people to join support groups, connect to quit coaches, help them enlist friends to keep them accountable, and that contained educational information about the harms of smoking and tactics the industry uses to keep African American communities smoking.[144] These are two examples of programs that the FDA can amplify and partner with - national organizations with a local reach to support their efforts.[145] The FDA can also provide CBHE with additional scientific or technical information that can enhance CBHE's media campaigns.

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[141] FDA, *Public Health Education Campaigns* (Mar. 11, 2022), https://www.fda.gov/tobacco-products/public-health-education/public-health-education-campaigns.
[142] Robert Robinson, *Pathways to Freedom*, https://sakai.unc.edu/access/content/user/vschoenb/Public%20Library/Big%20public%20health%20concerns/Control%20of%20non-communicable%20diseases/Tobacco/Pathways%20to%20Freedom (last visited Aug. 1, 2022).
[143] *70% Toolkit*, CTR. FOR BLACK HEALTH & EQUITY, https://www.centerforblackhealth.org/1-resources/70%25-toolkit (last visited Aug. 1, 2022).
[144] *COVID Big Quit*, CTR. FOR BLACK HEALTH & EQUITY, https://www.centerforblackhealth.org/1-resources/covid-big-quit (last visited Aug. 1, 2022).
[145] *No Menthol Sunday*, CTR. FOR BLACK HEALTH & EQUITY, https://www.centerforblackhealth.org/1-resources/no-menthol-sunday (last visited Aug. 1, 2022).

Another organization that has taken a dedicated approach to helping the Black community is the American Lung Association (ALA). In its engagement with the Black community, ALA advises that program facilitators listen to Black people, understand how to support them, and then follow through. ALA promotes public policy that would remove menthol cigarettes from the market as a health equity public policy. The FDA should continue working with organizations like ALA that are promoting public policy through a health equity lens and working directly with affected communities. ALA suggests that the best practice is to promote Community Champions who are reflective of the community they represent and can build trust to promote government interventions on tobacco control.[146] The FDA can help support and promote Community Champions that can offer culturally competent smoking interventions for marginalized communities and young people.

The 2020 Surgeon General's Report notes the importance of community work and how the federal government should be involved in local efforts to advance public health.[147] Whether this is done in a healthcare setting where people can get support to stop smoking or in a community setting to prevent smoking initiation, the FDA has opportunities to support community, health, and government efforts to advance tobacco control while the menthol rule is finalized. The FDA should be the leading government agency to advance commercial tobacco control across the country. Its work must also be specific to the needs of different marginalized populations in the country.

B. The FDA must provide technical assistance and collaborate with local governments and community groups.

The FDA has a responsibility to develop an action plan to enforce its rules on the regulation of commercial tobacco products.[148] In addition to the action plan, the law also states that the FDA must provide technical assistance to communities seeking support in "strategies to address the prevention of underage tobacco use in communities with a disproportionate use of menthol cigarettes by minors."[149] The FDA has had the authority to provide this resource, but it does not appear to do so.

It is unclear when or how the FDA offered this support to communities seeking assistance. If it has, the FDA should promote this support more broadly. This

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[146] Am. Lung Ass'n, *Addressing Tobacco Use in Black Communities*, https://www.lung.org/getmedia/a13f1949-8d58-4e99-bed0-f28bcd18acfc/addressing-tobacco-use-in-black-comm-toolkit.pdf.
[147] U.S. DEP'T HEALTH & HUM. SERVS., SMOKING CESSATION: A REPORT OF THE SURGEON GENERAL (2020), https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf.
[148] 21 U.S.C. § 387f-1(a).
[149] *Id.* § 387f-1(b)(2).

underutilized resource will provide tangible benefits to communities seeking to limit the use of menthol cigarettes by young people. The FDA must implement a program to offer technical assistance and instructions on how communities can seek this assistance from the FDA.

Advancing a technical assistance program can provide an avenue for the FDA to engage in greater collaboration with local governments and non-governmental organizations. FDA involvement in broad collaborations will also follow the recommendations of the 2020 Surgeon General's report.[150] For example, the FDA can focus on implementing community-wide interventions that promote smoking cessation and prevent initiation. The conclusions in the 2020 Surgeon General's report show that overall public health is improved with the use of mass media campaigns, promoting smoke-free policies by making more public and private spaces smoke-free, the use of quit lines, and coordinating efforts with state tobacco control programs.[151]

The recommendations in the Surgeon General's report are initiatives that the FDA can implement now to promote public health from a health equity lens before the menthol rule is finalized. The FDA, in partnership with local organizations, can promote anti-smoking measures that include technical assistance and close collaboration in a sustained manner that meets culturally specific needs to support quitting.

C. The FDA must implement other product standards to close all potential loopholes.

The next few months will have an outsized focus on the rules to ban menthol cigarettes and flavored cigars. As this is happening, the FDA should continue efforts to advance regulations for other tobacco products. The concurrent release of the flavored cigar rule is an example of how the FDA can advance new regulations at the same time. The menthol rule and the flavored cigar rule complement each other well and address smoking issues in marginalized communities. Removing menthol from cigarettes and flavors from cigars will decrease initiation and increase cessation.[152] This is a public health benefit worth pursuing.

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[150] U.S. DEP'T HEALTH & HUM. SERVS., *supra* note 147.

[151] *Id.*

[152] Baojiang Chen et al., *Age of Initiation of Cigarillos, Filtered Cigars and/or Traditional Cigars Among Youth: Findings from the Population Assessment of Tobacco and Health (PATH) Study, 2013–2017*, 15 PLOS ONE e0243372 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7725294/; Yang et al., *supra* note 80.

The FDA must also advance product standards related to e-cigarettes. E-cigarettes have increased in popularity and have some health risks similar to those of conventional cigarettes.[153] In a limited manner, the FDA has prevented some e-cigarettes from entering the market, but the industry continues to find ways to circumvent the FDA's premarket review process and to target young people in the sale of e-cigarettes.[154] The FDA took a first step in this arena by denying the market order for JUUL. Similar to the effort to decrease youth access to nicotine, the FDA announced that it will seek to lower the amount of nicotine in tobacco products. Following through on these product standards will have a significant impact on the addictiveness of tobacco products by decreasing the main addictive ingredient.

VI. Conclusion

While we congratulate the FDA for finally issuing this proposed rule, it has taken far too long to reach this step. The public health impact of the presence of menthol in cigarettes may be one of the most studied tobacco control issues in a generation. There was already more than enough information to support the removal of menthol when Congress chose to exempt it from the prohibition on flavored cigarettes in the Act. The amount of time spent contemplating action and gathering information and the resources spent continuing to study this issue is perhaps the greatest failure of the FDA's Center for Tobacco Products. The gravity of the agency's inaction on menthol outweighs almost all, if not all, of the positive steps taken to protect the public from commercial tobacco products since 2009. To salvage those resources and the reputation of the agency, this rule must be finalized as soon as possible.

When finalized, this rule will save hundreds of thousands of lives and save trillions of dollars in a very short time. The rule will do more to advance the health of Black Americans than perhaps any government action since the reforms that came out of the civil rights movement of the 1960s. All the benefits depend on the FDA finishing this work and not diluting the policy due to the influence of a corrupt industry that has preyed on communities that are already marginalized. The public health and medical communities are united in their support of this policy, as are some of the largest organizations representing the communities most in need of this policy. The time is now. Finish this work and finalize this rule with the sense of urgency that this policy deserves. Lives are at stake and those lives matter.

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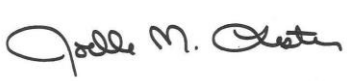
[153] *U.S. State and Local Issues: Ending the Sale of Flavored Tobacco Products*, CAMPAIGN FOR TOBACCO-FREE KIDS (Apr. 11, 2022), https://www.tobaccofreekids.org/what-we-do/us/flavored-tobacco-products.

[154] *Action Needed on E-Cigarettes*, TRUTH INITIATIVE (Nov. 13, 2020), https://truthinitiative.org/research-resources/emerging-tobacco-products/action-needed-e-cigarettes.

Respectfully,



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