SRNT Comment on Tobacco Product Standard for Menthol in Cigarettes

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This letter is on behalf of the Board of Directors of the Society for Research on Nicotine and Tobacco (SRNT), in response to the invitation for public comment on a Tobacco Product Standard for Menthol in Cigarettes from the U.S. Food and Drug Administration (FDA), May 4, 2022. SRNT is the largest scientific organization dedicated to interdisciplinary nicotine and tobacco research from molecular to societal levels and has an international membership of more than 1,000 members worldwide. The work of many of our members have contributed to the scientific evidence on commercial menthol cigarettes and our members’ work is heavily cited in the evidence underpinning the proposed rule. Importantly, we distinguish commercial tobacco throughout this comment from ceremonial tobacco—plants which are used by many indigenous populations for ceremonial and cultural purposes.¹ SRNT strongly supports swift implementation of a final rule prohibiting the sale, distribution, and manufacture of menthol cigarettes in the US. We offer the following points for consideration in finalizing the rule.
Summary

SRNT Comment on Tobacco Product Standard for Menthol in Cigarettes

SRNT strongly supports a menthol ban. The science on menthol cigarettes is clear and supports the FDA’s conclusions that a menthol ban is appropriate for the protection of public health and will reduce tobacco-related health disparities.

- Menthol in cigarettes increases smoking initiation
- Menthol in cigarettes is associated with progression to regular use
- Menthol exacerbates the addictiveness of cigarettes
- Menthol in cigarettes contributes to nicotine dependence and makes quitting smoking more difficult, especially for non-Hispanic Black/African American individuals
- The health effects of menthol cigarettes are substantial
- A national menthol ban is projected to decrease the overall number of cigarette smokers, increase the number of cigarette smokers who quit smoking, and decrease initiation
- Menthol cigarettes contribute to tobacco-related health disparities and a menthol ban is likely to reduce these disparities

Comments on specific provisions of the Proposed Rules

1. SRNT strongly supports applying the proposed rule to all retailers including “adult-only” and online retailers with no exemptions
2. SRNT strongly urges the FDA to do everything in its powers to support cessation by individuals who smoke menthol
3. SRNT strongly supports ensuring that nothing in the final rule would preempt state/localities from applying more comprehensive sales restrictions on flavored tobacco products beyond menthol cigarettes
4. SRNT strongly supports no further extensions of the comment period
5. SRNT strongly supports ensuring that any products or accessories sold to add flavors to cigarettes should be subject to enforcement under the rule
6. SRNT urges FDA to make clear in the final rule that marketing of menthol cigarettes is also prohibited
7. SRNT encourages FDA to vigorously conduct post-product standard surveillance and enforcement of the final rule
8. SRNT provides comments on allowing for any potential exemptions for modified risk tobacco products
9. SRNT supports the use of broad application of ‘characterizing flavor’ as the basis of the product standard and urges FDA to enforce the standard against products intended to circumvent a menthol ban

REFERENCES CITED
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A. Menthol in cigarettes increases smoking initiation

The addition of menthol to tobacco products like cigarettes makes them more appealing, easier to smoke, and facilitates the addictive effects of nicotine in the brain.\textsuperscript{2} Menthol tobacco has been dubbed a "starter product" for its ability to get nonsmokers to start smoking.\textsuperscript{3,4} Ample evidence from cohort studies conducted among youth and young adults suggests a correlation between menthol cigarette smoking and youth smoking initiation.\textsuperscript{5} Nearly half of ever cigarette smoking youth (43\%) first used a menthol cigarette.\textsuperscript{6} Similar results were found from a systematic review, including 46 studies on menthol cigarette initiation.\textsuperscript{7} This review found sufficient consistent evidence of a relationship between menthol cigarette use, youth smoking initiation, and nicotine dependence.

B. Menthol in cigarettes is associated with progression to regular use

Data from a nationally representative, longitudinal study of youth (Evaluation of Public Education Campaign on Teen Tobacco Cohort Study) found that youth who initiate smoking with menthol cigarettes are more likely to progress from experimental to established, current smoking (e.g., using 100 or more cigarettes while continuing use), compared to those who initiated with nonmenthol cigarettes.\textsuperscript{3} For example, a recent cohort study found that the first use of menthol cigarettes is associated with subsequent cigarette use among young people aged 12-24.\textsuperscript{6} Also, first use of menthol/mint cigarettes and cigars is associated with subsequent cigarette and cigar use in young people aged 12-24, according to a recent study using longitudinal data from the Population Assessment of Tobacco and Health (PATH) Study.\textsuperscript{8} First use of menthol cigarettes was associated with greater past 12-month cigarette use and new use of menthol/mint-flavored cigars was associated with past 30-day cigar use in youth and young adults.\textsuperscript{5}

C. Menthol exacerbates the addictiveness of cigarettes

Addiction is characterized by a constellation of physiological, behavioral and cognitive symptoms including dependence, withdrawal, cravings, tolerance, compulsive use or continued use despite consequences, and difficulty with cessation.\textsuperscript{9,10} Menthol amplifies the effects of nicotine, the primary chemical driver of addiction to cigarettes.\textsuperscript{9} Menthol acts on the brain’s nicotinic acetylcholine receptors,\textsuperscript{11,12} which, when activated, promote the release of neurotransmitters such as dopamine that reward and reinforce substance use behaviors.\textsuperscript{9,13} When paired with nicotine, menthol slows nicotine metabolism\textsuperscript{14} and facilitates greater nicotinic receptor upregulation (i.e.,
increases in total receptors with repeated activation) and dopamine release than nicotine alone, further enhancing the bioavailability and reinforcing effects of nicotine.

Animal studies demonstrate that menthol increases nicotine self-administration behavior. Menthol also serves as an additional cue to reinforce smoking-related behavior, both through its sensory characteristics (taste, smell, cooling sensation) and through visual stimuli such as the green and blue color used in most menthol cigarette packaging. These mechanisms provide an explanation for the numerous studies reporting that menthol cigarette smokers score higher than non-menthol smokers on measures of nicotine/tobacco dependence. Recent evidence from national surveys suggests that adult menthol cigarette smokers are more likely to smoke daily and to smoke within 30 minutes of waking (a key measure of dependence) and adolescent menthol smokers have stronger emotional attachments to cigarettes than their non-menthol smoking peers.

Compared to non-menthol smokers, menthol smokers find their cigarettes more subjectively appealing, rating them higher on factors such as reward, satisfaction, and craving reduction. In sum, a multidisciplinary body of evidence illustrates that menthol exacerbates the addictiveness of combustible tobacco cigarettes and explains the mechanism by which it does so.

D. Menthol in cigarettes contributes to nicotine dependence and makes quitting smoking more difficult, especially for non-Hispanic Black/African American individuals

People who smoke menthol cigarettes are more prone to develop nicotine dependence and less likely to quit effectively than those who use nonmenthol cigarettes, particularly for Black/African American smokers. A systematic review including 10 studies on cessation linked menthol cigarette smoking with reduced smoking cessation success at follow-up. A review of the scientific evidence by the FDA and recommendations by the FDA Tobacco Products Scientific Advisory Committee (TPSAC) concluded that cigarettes containing menthol can make quitting smoking more difficult. However, the effects of menthol on cessation are not due to differences in motivation to quit or differences in making quit attempts. For example, among a sample of young adults (aged 18-34 years), menthol smokers were more likely to report intention to quit, but did not differ in making quit attempts when compared to non-menthol smokers. The effects of menthol on making quitting cigarettes more difficult may be most pronounced for non-Hispanic Black/African American smokers. A meta-analysis of cessation studies found that the odds of quitting smoking were 12% lower for Black/African American smokers who used menthol vs. non-menthol. Another study using four waves of the PATH Study found in stratified analyses that African American daily menthol vs. daily non-menthol adult smokers had 53% lower odds of quitting, and they had lower odds of quitting compared with White adult daily menthol smokers. In another PATH study, the rate of discontinuing smoking was much lower for African American menthol vs. non-menthol smokers.

E. The health effects of menthol cigarettes are substantial

Menthol is characterized by its anesthetic, analgesic, antibacterial, antifungal, immunomodulating, and enhanced skin penetration effects. Menthol is used as a flavor in
tobacco products to minimize the harshness and discomfort of inhaled tobacco smoke by promoting a cooling sensation in the tongue and throat.\textsuperscript{35,36} Menthol may also decrease the coughing response and relieve respiratory irritation, making cigarette smoke inhalation more bearable.\textsuperscript{37} This cooling sensation, as well as historic marketing of menthol, lead to consumer perceptions that smoking menthol was healthier than nonmenthol smoking.\textsuperscript{38} Menthol cigarettes are also seen as easier to smoke among adolescents who smoke them.\textsuperscript{6} There is considerable evidence that menthol smokers have higher plasma and urine cotinine per cigarette smoked.\textsuperscript{39} As a result, menthol promotes deep inhaling and increased toxicity exposure per cigarette smoked. As with nonmenthol smokers, menthol smokers are at elevated risk of cancer and noncancer disorders compared with non-smokers.\textsuperscript{29,40}

Thus, despite lower harm perceptions by some consumers\textsuperscript{41} and historical marketing of menthol as a lower harm product,\textsuperscript{42} menthol cigarettes are no safer than non-menthol cigarettes and have substantial individual health harms. Additionally, menthol smoking has been associated with significant excess harms on the population level. A recent analysis of National Health Interview survey data from 1980-2018 found that menthol cigarette smoking was attributable for slowing the decline in smoking prevalence by 2.6 percentage points and contributing to 10.1 million additional smokers, 3 million life years lost, and almost 400,000 premature deaths over that time period compared with menthol cigarettes not being available in the first place.\textsuperscript{43}

F. A national menthol ban is projected to decrease the overall number of cigarette smokers, increase the number of cigarette smokers who quit smoking, and decrease initiation

Pre-post studies in Canada found that those who were menthol smokers before the ban were more likely to have made a quit attempt and to successfully quit smoking after the ban compared to non-menthol smokers.\textsuperscript{44-46} In Canada, after the menthol cigarette ban, menthol smokers were more likely than non-menthol smokers to have quit smoking among daily smokers (difference=8.0%; 95% CI: 2.4% to 13.7%,\textit{p}=0.005) and all (daily+non-daily) smokers (difference=7.3%; 95% CI: 2.1% to 12.5%,\textit{p}=0.006). Using these estimates, the projected number of smokers who would quit after a US menthol ban would be 789 724 daily smokers (including 199 732 African Americans) and 1 337 988 daily and non-daily smokers (including 381 272 African Americans).\textsuperscript{45} A systematic review of studies on the anticipated and actual effects of a menthol ban found that an estimated 25-64\% of menthol smokers would consider quitting.\textsuperscript{47} Studies of flavor bans also indicate a 6\% reduction in smoking initiation.\textsuperscript{47} Flavor bans in the US have also been associated with decreased availability of flavored tobacco, decreased marketing, and decreased sales, and reduced youth and adult use of banned products sales.\textsuperscript{48} Expert elicitation of the potential effects of a menthol ban in the US estimate that under a menthol ban, up to 39\% of youth and young adults who would otherwise initiate with menthol would be discouraged from using tobacco.\textsuperscript{49}

G. Menthol cigarettes contribute to tobacco-related health disparities and a menthol ban is likely to reduce these disparities

Menthol cigarette use is more prevalent among individuals from racially/ethnically minoritized backgrounds and socioeconomically disadvantaged groups.\textsuperscript{50,51} Compared with non-Hispanic
White cigarette smokers (25.4%), non-Hispanic Black/African American (88.4%), Hispanic (38.1%), Asian (30.1%), multi-racial (42.2%), and non-Hispanic smokers of other race (45.2%) have higher prevalence of using menthol cigarettes. Additionally, the proportion of menthol smokers has increased over time particularly in non-Hispanic White, Asian, and Hispanic groups. There is also a reverse income gradient in menthol cigarette use, with 43.7% of smokers in the lowest income households using menthol cigarettes, followed by those in middle income households (37.2%), and then those in the highest income households (32%). Menthol cigarette use is also disproportionately used at higher rates among sexual minority individuals versus heterosexuals.

Additionally, there are clear disparities in the marketing of menthol cigarettes, as revealed in tobacco industry documents that highlight how the industry targets specific subpopulations (i.e., according to race/ethnicity, gender, and socioeconomic status). Several expert reviews causally link marketing exposure with tobacco use. The 2012 Surgeon General’s report concludes: “there is a causal relationship between advertising and promotional efforts of the tobacco companies and the initiation and progression of tobacco use among young people.” As such, reasons driving the appeal and use of menthol cigarettes among young tobacco users and various groups that experience tobacco-related health disparities are that tobacco products are marketed more heavily, and are widely available in neighborhoods where these groups reside. African American audiences have long been targeted with menthol marketing, particularly African American neighborhoods, often accompanied by price promotions. African-American adolescents are more likely to recognize Newport (a leading menthol brand) than other youth, and Newport recognition is associated with increased smoking initiation. Differential point-of-sale advertising exposure, particularly for menthol cigarettes are likely to increase tobacco use disparities.

Non-Hispanic Black/African American populations also experience disproportionate amounts of tobacco-related morbidity and mortality due to menthol use. Cancer mortality is higher for both males and females from Black vs. those from White backgrounds. Lung cancer is the leading cause of cancer death, and tobacco use contributes to 2 of the top 4 causes of cancer for non-Hispanic Black/African American populations. As noted, use of menthol cigarettes is 2-3 times higher among non-Hispanic Black/African American individuals who smoke (88.5% of Black smokers use menthol) compared with other racial/ethnic groups. A recent analyses of National Health Interview survey data from 1980-2018 found that among Black/African American populations, menthol smoking contributed to 1.5 million additional people initiating smoking, 156,000 additional deaths, and 1.5 million life-years lost. This study found the menthol burden has been disproportionately borne by African Americans who are only 12% of the population but comprise 15% of excess initiators, 41% of the excess deaths, and 50% of excess life-years lost due to menthol use.

As a result of these disparities in use and the role menthol plays in initiation, progression to regular use, addiction/nicotine dependence, and lack of success in quitting, menthol bans are likely to reduce disparities in tobacco use and work to ameliorate the harms of tobacco on populations that have been disproportionately affected. Achieving health equity in tobacco, as in other fields, can be defined as “the absence of systematic disparities in health (or in the major social determinants of health) between social groups who have different levels of underlying social advantage/disadvantage.” One modeling study found that banning menthol cigarettes in 2011 would have resulted in over 600,000 deaths averted by 2050 with, over one-third of deaths averted among African Americans, disproportionate to their percent of the population. A more recent simulation study found that a menthol ban in 2021 would decrease smoking prevalence by 15%
by 2026 and avert 654,000 deaths by 2060.\textsuperscript{77} Recent data on Canada’s menthol ban found that after one year, daily menthol smokers were significantly more likely to have quit than non-menthol smokers (ARR=1.25 95%CI 1.03-1.50).\textsuperscript{46} Additional data from the International Tobacco Control (ITC) Canada arm of the four-country survey showed that post-ban, 21.5% of pre-ban menthol smokers had quit.\textsuperscript{44} Pooling data from the ITC study and the Ontario Menthol Ban Study, it was estimated that applying these effect sizes to the US context would result in an additional 1.3 million smokers quitting with 28% of new quitting among African American smokers.\textsuperscript{45} This would mean greater proportional benefit among African American smokers – i.e., a potential equity impact.

**Comments on specific provisions of the Proposed Rules**

SRNT provides the following comments regarding specific provisions of the Proposed rule.

1. SRNT strongly supports applying the proposed rule to all retailers including “adult-only” and online retailers with no exemptions.

Exempting any retailer types in a menthol ban would lead to loopholes that could undermine the effectiveness of the rule and increase disparities. Currently, while over 300 localities have restrictions on the sale of flavored tobacco, only 100 localities in the US and one state have comprehensive restrictions on the sale of flavored tobacco products including menthol cigarettes and without significant retail exemptions.\textsuperscript{78}

Analyses of potential impacts of retailer type exemptions on a national basis found that retailer exemptions of liquor stores and tobacco stores (i.e., “adult only” retailers) may differentially exempt more retailers in urban communities where more racial/ethnic minority populations reside, potentially increasing disparities.\textsuperscript{79} Additionally, local policies that exempted such adult-only retailers, led to significant increases in new ‘tobacco shop’ licenses after the ban with existing retailers changing their space by adding an additional door or window to create a way to circumvent the intent of the regulations and to continue to sell menthol cigarettes and flavored tobacco.\textsuperscript{80} Online retailers have also served as a source of tobacco products which has been relatively easy to access for youth even after policy actions.\textsuperscript{81} As such, making sure that all retailers, manufacturers, distributors, and wholesalers are subject to the menthol ban will allow FDA to enforce the policy as intended and is more likely to reduce tobacco use and sales across all populations.\textsuperscript{82}

Additionally, FDA should ensure that all retailers receive education on the new regulation and conduct enforcement with fines and penalties for violations including no-tobacco-sales orders of sufficient magnitude and regularity to ensure that retailers, manufacturers, wholesalers, and distributors who are violating the policy are addressed as quickly as possible.
2. SRNT strongly urges the FDA do everything in its powers to support cessation by individuals who smoke menthol

Those who use tobacco need support and effective cessation resources to quit – support that SRNT members have provided for many years. SRNT supports the FDA’s intention to apply enforcement of the proposed rule only to retailers, distributors, wholesalers, importers, and manufacturers of tobacco and NOT individual consumers. No consumer of tobacco products should be subject to penalties under a menthol ban. As a cautionary tale, possession, use and purchase (PUP) laws (as were in place in many states for minor’s access prior to raising the national age of sale to 21 (Tobacco21) were unjust in shifting the policy impact to youth and away from the tobacco industry and were also largely ineffective.\textsuperscript{53,84} As such, we support the actions of FDA to focus attention for enforcement on the tobacco industry and their marketing, sales, and distribution practices.

In addition to making it clear that enforcement of the product standard is not to be directed at individual consumers, we also urge the FDA to use all other tools at its disposal to support quitting among menthol smokers so as to maximize the product standard’s likely benefit of increased cessation. This includes actions through FDA’s public education programs, partnerships, and promotion of smoking cessation products. We encourage FDA to ensure that they pair the implementation of the rule with effective cessation messaging, promotion of quitlines, free access to NRT, and cessation medication, and tailored cessation programming to different communities most affected by a menthol ban. Furthermore, we urge the FDA to ensure that all partners across and beyond the Federal government and the FDA are primed and ready to support and engage menthol smokers to quit when the ban is implemented.\textsuperscript{72}

3. SRNT strongly supports ensuring that nothing in the final rule would preempt state/localities from applying more comprehensive sales restrictions on flavored tobacco products beyond menthol cigarettes

One state and over 150 municipalities across 8 other states have implemented restrictions on menthol cigarette sales.\textsuperscript{78} State and local policies can inform federal tobacco control efforts as demonstrated by the proposed rule’s analysis of evaluation studies from localities across the country. As the proposed rule states, the Tobacco Control Act does not preempt states and localities from implementing their own sale and distribution policies on menthol cigarettes and other flavored tobacco products, and both the final rule and subsequent regulations should avoid restricting that authority.

4. SRNT strongly supports no further extensions of the comment period

All interested parties have had years to comment on a menthol cigarette product standard, including two prior comment periods on Advanced Notices of Proposed Rulemaking in 2013 and 2018. The FDA has already extended the comment period to 90 days. No additional extension to the comment period should be granted beyond August 2, 2022.
5. SRNT strongly supports ensuring that any products or accessories sold to add flavors to cigarettes should be subject to enforcement under the rule

The evidence from the menthol bans in other countries show that the tobacco industry has developed accessories that could be used to add menthol to non-menthol cigarettes such as but not limited to drops, capsules, flavor cards, filter tips, RYO tobacco, or flavor cards. Even without substantial marketing in Canada, 14% of daily menthol smokers used these accessories to add menthol to cigarettes after the Canadian ban. The introduction of such accessories in the UK may also be related to any use of a menthol or capsule cigarette by 44% of youth smokers after the ban, though usual menthol brand use declined to 3%. Extending the product standard to apply to these accessories, as FDA has proposed, will help to ensure that the benefits of the proposed rule are achieved.

Additionally, FDA should ensure that there is active pre-and post-product standard surveillance of these types of accessories since the industry should be required to subject these accessories to the same pre-market authorization process as other tobacco products to ensure whether they are appropriate for the protection of public health. Otherwise any product used to add a characterizing flavor or other similar taste, smell, or sensory characteristics to cigarettes should not be allowed (or allowed to remain) on the market without such authorization.

6. SRNT urges FDA to make clear in the final rule that marketing of menthol cigarettes is also prohibited

As we noted above, marketing of tobacco products has been causally linked with tobacco use especially among youth and young adults. Studies of local menthol policies find that while marketing for menthol products declined in retail stores after the policy, they did not decline to the same extent as menthol sales. This means that stores that may be compliant with a menthol sales ban may still have menthol marketing, which could undercut the rule’s intended benefits. Thus, FDA should make clear in the final rule that marketing of menthol cigarettes is also prohibited by the product standard.

7. SRNT encourages FDA to vigorously conduct post-product standard surveillance and enforcement of the final rule

Research conducted around various national and local flavor and menthol bans has shown multiple strategies used by the tobacco industry to change descriptors, packaging, and marketing claims in ways that may indicate a menthol substitute to consumers. Research around the recent menthol flavor ban in Canada has shown that the tobacco industry uses marketing tactics to circumvent the public health impact of such policies. Some of these tactics include changing the taste descriptor from “menthol” to “fresh” or “smooth”, or packaging tobacco with ‘menthol-suggestive’ colors, like blue or green.

Several local evaluations of flavor restriction policies show that after flavor bans, sales of ‘concept’ flavored products without an explicit flavor name increased. In fact, there has also been a growth of ‘ice’ flavor names in e-cigarettes indicating a cooling sensation like that found in menthol
cigarettes.92 ‘Ice’ descriptors are also in use in menthol cigarette products currently on the market (e.g., ‘Marlboro Ice’). After the 2020 European Union Tobacco Products Directive ban on menthol cigarettes, the tobacco industry utilized among other things, flavor capsules, which consist of a gelatin capsule filled with a flavoring liquid (commonly menthol, although other flavors are available) to exploit loopholes in the EU ban.93-96 The capsule (or multiple capsules) is embedded into the cigarette filter, then crushed by the consumer to release the flavor when inhaling on the cigarette.

The tobacco industry is also starting to “capitalize on the plant-based movement” by using novel packaging and advertising developed by one tobacco company which promotes ‘100% plant-based menthol’.97

Consequently, the FDA’s implementation of the menthol ban should ensure post-policy surveillance is in place to monitor tobacco industry behavior and consumer perceptions of menthol substitutes (including but not limited to repackaging, label changes, descriptor changes, and potential product reformulation). FDA should be prepared to quickly step in and enforce against such industry tactics.

8. SRNT provides comments on allowing for any potential exemptions for modified risk tobacco products

The current proposed rule applies to all products meeting the definition of a cigarette. However, FDA requested additional comments on whether the proposed product standard should cover tobacco products that meet the regulatory definition of a “cigarette” but have been granted “Modified Risk Tobacco Product” (MRTPs) status. Such products, authorized to use claims of “reduced exposure” only, include certain Very Low Nicotine Cigarettes (VLNCs) (e.g., “VLN King”) and HTPs (e.g., IQOS tobacco heating system/HeatSticks) – each of which comes in a menthol-flavored variety.98 Regulators must consider the tradeoff between retaining mentholated versions of these products against the possibility that those same products could promote initiation among tobacco-naïve individuals or deter complete cessation on the part of current smokers.

There is limited direct-evidence on this question. A critical shortcoming in much of the extant literature that informed the MRTP authorization that these products received is that in the trials demonstrating their potential utility, participants were able to use the products in the flavor of their choosing. It is unclear how findings may have differed if, instead, all participants were required to use the tobacco-flavored version (i.e., simulating the conditions of a comprehensive menthol ban).

Despite these limitations, the existing literature provides insights into the appeal of menthol-flavored MRTPs and the potential tradeoffs between exempting versus including them in pending regulation.

With respect to VLNCs, one trial found that while a majority (55%) of participants opted to use a menthol VLNC, those who used a menthol VLNC were not more likely to completely switch from full-nicotine cigarettes than those who used a non-menthol VLNC.99 Moreover, in a trial of predominantly menthol smoking adolescents, VLNCs were viewed as less risky/harmful than full-nicotine cigarettes, but the menthol status of the product did not moderate this relationship.100 Notably though, among this same sample of adolescent smokers, menthol VLNCs were less effective at reducing cravings for cigarettes than non-menthol VLNCs.
With regards to IQOS, under standard puffing regimens, IQOS-Menthol and IQOS-Tobacco yield similar levels of nicotine nicotine\textsuperscript{101} – suggesting similar propensities to be used as cigarette substitutes on a pharmacologic basis.

A final consideration is that there is evidence that tobacco-naïve youth find IQOS\textsuperscript{102} and VLNCs appealing\textsuperscript{100} and menthol has been shown to further increase the appeal/palatability of cigarettes to youth.\textsuperscript{103,104} Taken together, there is insufficient evidence as to whether exempting cigarette MRTPs from the proposed product standards on menthol cigarettes is warranted. What evidence is available, however, suggests that there is not a clear added benefit at the population-level of the mentholated MRTPs, above and beyond what the tobacco-flavored versions offer. On an individual-by-individual basis, access to a menthol-flavored MRTP could potentially further encourage reductions in exposure to harmful chemicals from combustion (in the case of heated tobacco) or access to reduced nicotine products that could support quitting (in the case of VLNC), but there is insufficient evidence available to support this view either. We also note that neither product is authorized to make claims of ‘reduced risk.’

The current proposed product standard includes no exemptions for MRTP cigarettes. If FDA decides to offer exemptions to MRTP cigarettes, then like the MRTP authorizations themselves, the criteria to receive an exemption should be stringent and time-limited. Such exemptions should be stringent and only be granted if the benefits to users and non-users of menthol version of MRTP cigarettes would outweigh the benefits of the menthol cigarette ban itself. For instance, the potential public health benefit of VLN cigarettes is that they would reduce nicotine to non-addictive levels and support cessation. If the menthol cigarette ban itself would support quitting among menthol smokers, then potential use of menthol VLNC for quitting may just extend the quitting period, increasing lifetime tobacco use exposures with no additional benefits.

Additionally, any exemptions should be time limited. Any exemptions granted for menthol-flavored MRTPs should be only for a short time (e.g., ~1 year) with rigorous post-market surveillance and clear criteria for public health impact built in. If menthol MRTP cigarettes do not continue to meet standards for protection of the public health over time, any such exemptions should not be continued.

9. In particular, SRNT urges FDA to use a broad interpretation of ‘characterizing flavor’ as the basis of the product standard and quickly enforce against alternative “concept” and ambiguous descriptors

FDA finds that this proposed product standard, which would prohibit menthol as a ‘characterizing flavor’ in cigarettes, would be appropriate for the protection of the public health. This standard which includes the following relevant factors including:

- The presence and amount of artificial or natural flavor additives, compounds, constituents, or ingredients, or any other flavoring ingredient in a tobacco product, including its components or parts;

- The multisensory experience (i.e., taste, aroma, and cooling or burning sensations in the
magnify (or mouth and throat) of a flavor during use of a tobacco product, including its components or parts;

- Flavor representations (including descriptors), either explicit or implicit, in or on the labeling (including packaging) or advertising of tobacco products; and

- Any other means that impart flavor or represent that the tobacco products have a characterizing flavor.

SRNT agrees that these multifaceted factors are necessary to allow FDA to quickly address industry actions taken to circumvent the purpose of the menthol ban as we detail above. For example, if the FDA were to instead simply prohibit menthol as an additive rather than the broad definition proposed, many alternative chemicals could be substituted for menthol and have similar effects of reducing harshness and increasing ease of use of cigarettes.

In particular, we urge FDA to use a broad interpretation of ‘characterizing flavor’ and quickly enforce against alternative ‘concept’ and ambiguous descriptors that may be used as menthol substitute language after a ban. As noted above, ‘ice’ type descriptors are already used in menthol cigarette and in e-cigarettes to convey a menthol-like cooling sensation. Additionally, after bans on descriptors such as ‘light’ and ‘low tar’ were found to be misleading to the public and convey modified risk, alternative descriptors such as ‘mellow’ and ‘smooth’ took their place with similar consumer perceptions. These types of descriptors already convey reduced harm and appeal to the public as ‘modified risk’ language that is already under FDA authority. If they also become used as menthol substitute language, they should be enforced as violating both the MRTP requirements and the menthol cigarette product standard.

Overall, the science of menthol is clear. A ban on menthol cigarettes is both appropriate for the protection of public health and is long overdue given the strength and consistency of the evidence-base contributed to by many of our members over many years. SRNT strongly supports FDA in swiftly issuing and enforcing a final rule banning menthol cigarettes. This policy will save lives and reduce the disproportionate burden that menthol has placed on too many lives for too long.

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