



The Consumer Advocates for Smoke-free Alternatives Association

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To: U.S. Food and Drug Administration

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VIA REGULATIONS.GOV

Re: CASAA Comments on FDA's Proposed Product Standard for Menthol in Cigarettes.

The following comments are submitted on behalf of The Consumer Advocates for Smoke-free Alternatives Association ("CASAA") in opposition to the Food and Drug Administration's (FDA) proposed Tobacco Product Standard for Menthol in Cigarettes (RIN 0910-AI60, Docket No. FDA-2021-N-1349). CASAA is a 501(c)(4) nonprofit public health and education NGO and is the leading representative of consumers who use, or might in the future use smoke-free tobacco and nicotine products. It is a U.S. membership organization with over 250,000 members. CASAA advocates on behalf of consumers, and does not represent the interests of industry.

While there is no denying that the use of menthol as a characterizing flavor in cigarettes is for the sole purpose of selling more cigarettes, simply banning the flavor will not eliminate, or even meaningfully reduce consumer demand. Moreover, the estimated public health gains cited in FDA's justification for this product standard will probably not outweigh the social and racial justice harms of enforcing this standard at the state and local levels. Instead, CASAA is urging the FDA to take a more humane harm reduction approach that includes authorizing and

promoting a meaningful variety of safer alternatives to smoking that will expedite benefits to public health and support long-term gains for social, racial, and health justice.

INTRODUCTION

Since their humble introduction in the 1920s¹, credited to Lloyd “Spud” Hughes, menthol cigarettes have grown in popularity to make up more than 35% of cigarette sales in the United States.² What, according to legend, started as an accidental discovery that simply storing cigarettes overnight in the same tin as mint would give them a minty taste³ has grown into a multi-billion dollar juggernaut in tobacco sales.

For almost 100 years, menthol has been added to cigarettes to enhance their appeal. From the earliest marketing campaigns, it is clear that menthol is used to soften or mask the sting of nicotine and the harsh flavors associated with burning tobacco. Until the 1950s, cigarette marketers also got away with making claims reinforcing consumer perception that menthol may even have medicinal qualities. This misperception led many to believe that menthol cigarettes were safer than those without menthol. Like many other chemicals in cigarettes, menthol is an optional additive that has always been used to sell more cigarettes to more people who otherwise would not start smoking, or may quit smoking regular cigarettes.⁴

There are reasons for why people choose to use drugs, including nicotine. Whether a person uses for the purpose of self-soothing, marking time, relaxation, or a pick-me-up, the underlying reasons for substance use are more diverse and run deeper than simply exposure to marketing and/or peer-pressure. While it may be convenient to focus on marketing by way of flavors as a root cause of smoking tobacco, a ban on menthol is a short-sighted approach with immediate consequences that ignores the greater nuance and complexity of why people choose to use nicotine.

¹ Tabler, D., 2022. *Light up a Spud!*. [online] Appalachian History. Available at: <<https://www.appalachianhistory.net/2018/07/light-up-spud.html>> [Accessed 2 August 2022].

² cdc.gov. 2022. *Menthol Tobacco Products*. [online] Available at: <https://www.cdc.gov/tobacco/basic_information/menthol/index.html> [Accessed 2 August 2022].

³ Perma.cc. 2022. *Menthol Cigarettes - SPUD Menthol Cigarettes*. [online] Available at: <<https://perma.cc/XM26-AFM2>> [Accessed 2 August 2022].

⁴ CASAA. 2022. *CASAA: Think Bigger Than a Menthol Ban*. [online] Available at: <<https://casaa.org/think-bigger-than-a-menthol-ban/>> [Accessed 2 August 2022].

ANTICIPATED GAINS DO NOT OUTWEIGH THE HARM OF A BAN

Although bans on menthol, or all tobacco products, are not new ideas, there is limited data on outcomes from recent implementation of such prohibitions. In 2017, Canada, followed by Poland in 2020, both banned sales of menthol cigarettes, but neither has experienced a meaningful decline in smoking as a result. In both countries, people who lost access to legal sales of menthol cigarettes mostly just substituted with regular cigarettes.⁵ In Poland where the percentage of sales of menthol cigarettes is similar to the U.S., researchers found that youth initiation with regular cigarettes actually increased in response to the ban⁶ thereby offsetting any reduction in smoking among adults.

Illicit Sales

CASAA's opposition to banning menthol in combustible products is based on data and experience showing that drug prohibitions put pressure on people to buy products from an underground market. Rather than reducing demand, a menthol ban will contribute to more immediate public health consequences including a proliferation of counterfeit and adulterated products, an increase in unnecessary interactions between law enforcement and over-policed communities, and no accountability for sellers who will not verify the age of buyers, or the quality of products being sold. There is also a reasonable expectation that the ease with which consumers can alter their own cigarettes--either by home-spun means, or aftermarket products that will also be made illegal by the menthol standard--will ultimately undermine the effectiveness of any ban and erode FDA's credibility as a regulator.

State and Local Enforcement

FDA has routinely noted that its enforcement mandate is limited to manufacturers, distributors, and retailers. But where federal jurisdiction ends, states and municipalities are free to pick up the ball with regard to sales restrictions. Moreover, all states have criminal penalties for selling untaxed tobacco products which will ultimately include any menthol cigarettes banned by FDA. CASAA is echoing concerns expressed by the ACLU and a coalition of organizations⁷ that FDA's ban on menthol (and flavored cigars) will disproportionately affect black and brown communities while having a minimal effect on reducing overall smoking prevalence.

⁵ Chung-Hall J, Fong GT, Meng G, et al Evaluating the impact of menthol cigarette bans on cessation and smoking behaviours in Canada: longitudinal findings from the Canadian arm of the 2016–2018 ITC Four Country Smoking and Vaping Surveys *Tobacco Control* 2022;31:556-563.

⁶ Alex C Liber, Michal Stoklosa, David T Levy, Luz María Sánchez-Romero, Christopher J Cadham, Michael F Pesko, An analysis of cigarette sales during Poland's menthol cigarette sales ban: small effects with large policy implications, *European Journal of Public Health*, 2022;, ckac063, <https://doi.org/10.1093/eurpub/ckac063>

⁷ American Civil Liberties Union. 2022. *Coalition Letter of Concern to HHS on Menthol Cigarette Ban*. [online] Available at: <<https://www.aclu.org/letter/coalition-letter-concern-hhs-menthol-cigarette-ban>> [Accessed 2 August 2022].

More than two-thirds of states currently penalize purchase, use, and possession (PUP) of tobacco products by minors. Depending on the jurisdiction, the severity of punishment varies based on whether a person is under 21 or under 18. While supporters of policies such as, for example, flavor bans for all tobacco products often note state or municipal PUP laws and recommend changes, the opposition is often watered down in service of enacting further restrictions on access to tobacco. Virtually no progress is being made to ensure that communities already harmed by over-policing vis-à-vis America's failed drug war won't experience an increase in targeting by law enforcement as a result of a federal ban on menthol cigarettes and flavored cigars. It is simply not enough for FDA to restate that a *federal* prohibition on menthol will only be enforced on manufacturers and retailers when states and municipalities are free to enforce their own stricter laws. Federal laws and regulations do not exist in a vacuum, and ignoring that reality can have dangerous consequences.

HARM REDUCTION IS A WORKABLE ALTERNATIVE TO A MENTHOL CIGARETTE BAN

FDA must begin by correcting misperceptions of risk associated with vaping and other smoke-free alternatives--including nicotine replacement therapy (NRT).

FDA has acknowledged on several occasions that inaccurate beliefs about the risks associated with nicotine use are rampant among US Clinicians⁸, as well as the general public⁹. A probable consequence of this misalignment with reality is that even nicotine replacement products approved by the FDA are not being utilized and/or recommended to patients who smoke--thereby reducing the number of people making quit attempts. While FDA has suggested that a targeted messaging campaign is needed to correct the imbalance of knowledge, the agency has yet to take any meaningful action. Working to inform healthcare professionals about the real risks and benefits of nicotine use is just the start. FDA must also work to realign the broader public's beliefs about nicotine--in particular, nicotine from smoke-free sources.

To be clear, the lack of useful or even honest research was leveraged by the FDA and numerous lobbying campaigns to convince policy makers that vaping is unacceptably dangerous. Manifested as hyperbolic messaging about the dangers of vaping and nicotine, FDA admits that such campaigns are intended to resonate with children and adolescents, but are so wildly threatening and inaccurate that adults should not be exposed to them. At a fundamental level, the FDA's "Real Cost" campaign, for example, relies on a misinformed public to generate fear and panic that may prevent nicotine use. If the FDA chooses to sustain this degree of misinformation it is unlikely that a ban on menthol and flavored cigars will provide any real benefit to public health.

⁸ Steinberg, Michael B., Michelle T. Bover Manderski, Olivia A. Wackowski, Binu Singh, Andrew A. Strasser, and Cristine D. Delnevo. "Nicotine Risk Misperception Among US Physicians." *Journal of General Internal Medicine* 36, no. 12 (December 1, 2021): 3888–90. <https://doi.org/10.1007/s11606-020-06172-8>.

⁹ Nguyen, Anh B., Xiaoquan Zhao, Leah Hoffman, Aura Lee Morse, and Janine Delahanty. "Nicotine and Addiction Beliefs and Perceptions among the US-Born and Foreign-Born Populations." *Preventive Medicine* 114 (September 1, 2018): 107–14. <https://doi.org/10.1016/j.ypmed.2018.06.018>.

Authorizing a Variety of Flavored Smoke-free Alternatives

Research shows that “a menthol smoking ban may be more effective if [people who smoke menthols] have access to e-cigarettes as a way to quit cigarette use.”¹⁰ This is consistent with FDA’s July 2017 announcement¹¹ laying out a path forward with new rules and standards for nicotine products which included a proposed product standard prohibiting the manufacture and sale of menthol cigarettes and reducing the nicotine content in cigarettes to minimally or non-addictive levels. Notably, in the same announcement FDA acknowledged the need for people affected by such extreme and coercive interventions to have a less risky product to switch to, including better access to existing smoking cessation products like NRT.

FDA has acknowledged that the availability of smoke-free products that may be similarly appealing to people who smoke menthol cigarettes, like vapor, oral tobacco, and alternative nicotine products may be beneficial to people who are motivated to switch in response to losing access to their preferred tobacco product. This suggestion was limited to mint, menthol, and wintergreen flavors, and falls short of ensuring that smoke-free alternatives will have broad appeal to anyone who smokes. In addition to providing a place for people who smoke menthol to land, a wide variety of flavors other than tobacco—particularly sweet flavors—are vital to helping more people who smoke transition away from combustible cigarettes.¹²

To date, no vapor products in flavors other than tobacco have been authorized for sale by the FDA. Observers and critics of the FDA (CASAA being one) speculate that this is mostly a political decision meant to appease anti-tobacco lobbying groups and their captured politicians. But while flavors may play a role in reinforcing habituation to tobacco and nicotine use, they remain secondary to primary drivers of youth initiation such as social and familial influences, young people’s willingness to take risks, and general curiosity about drugs.

CONCLUSION

CASAA does not see a need or a net benefit to prohibiting the use of menthol in combustible tobacco products at this time. The FDA has yet to authorize a meaningful variety of smoke-free

¹⁰ Steven Cook, Jana L. Hirschtick, Akash Patel, Andrew Brouwer, Jihyoun Jeon, David T. Levy, Rafael Meza, Nancy L. Fleischer, “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,” *Preventive Medicine*, Volume 154, 2022, 106882, ISSN 0091-7435, <https://doi.org/10.1016/j.ypmed.2021.106882>. (<https://www.sciencedirect.com/science/article/pii/S0091743521004552>)

¹¹ U.S. Food and Drug Administration. 2022. *FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death*. [online] Available at: <<https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death>> [Accessed 2 August 2022].

¹² Lin Li, PhD, Ron Borland, PhD, Kenneth Michael Cummings, PhD, Geoffrey T Fong, PhD, Shannon Gravely, PhD, Danielle M Smith, MPH, Maciej L Goniewicz, PhD, Richard J O’Connor, PhD, Mary E Thompson, PhD, Ann McNeill, PhD, How Does the Use of Flavored Nicotine Vaping Products Relate to Progression Toward Quitting Smoking? Findings From the 2016 and 2018 ITC 4CV Surveys, *Nicotine & Tobacco Research*, Volume 23, Issue 9, September 2021, Pages 1490–1497, <https://doi.org/10.1093/ntr/ntab033>

nicotine products in flavors other than tobacco, which can be reasonably expected to serve as attractive alternatives to combustible menthol cigarettes for many people and may increase both quit attempts and people making a complete transition away from smoking. While it is tempting to suggest that FDA will *eventually* authorize an acceptable diversity of alternative nicotine products that meets the needs of people switching away from menthol cigarettes, even then the risks of triggering an expansion of the illicit market poses risks to public health that are beyond the jurisdiction of FDA.

Casual supporters of a product standard prohibiting the use of menthol in combustible cigarettes may imagine such a rule taking effect expeditiously. But the FDA and industry observers acknowledge that the decision will probably be tied up by legal challenges for several years. The FDA will be defending both its authority to finalize such a standard and its waning reputation as a science-based regulator. Rather than commit millions of taxpayer dollars to defending yet another doomed-to-fail coercive approach to drug control, user fees collected by the Center for Tobacco Products (CTP) (not extracted from taxpayers) would be better used in promoting a more accurate understanding of nicotine and safer alternatives to combustible tobacco.

Thank you for considering our comments.

Respectfully,

Alex Clark,
CEO, CASAA