August 2, 2022

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

RE: Tobacco Product Standard for Menthol in Cigarettes (FDA-2021-N-1349)

To Whom It May Concern:

The purpose of this comment is to address the relationship between the anticipated public health benefit of the Proposed Tobacco Product Standard for Menthol in Cigarettes (Proposed Rule) and the availability or lack of availability of PMTA-authorized, menthol-flavored electronic nicotine delivery system (ENDS) products. By way of brief background, to this point the Food and Drug Administration (FDA) has issued marketing granted orders (MGOs) for a small number of tobacco-flavored ENDS products and issued marketing denied orders affecting more than five million flavored ENDS products. The FDA has withheld any decision on menthol-flavored ENDS products on the grounds that these raise "unique considerations," given the continued availability of menthol cigarettes in the marketplace.

The Proposed Rule directly implicates the "unique considerations" referenced by the FDA in its menthol ENDS marketing decisions to this point. The focus of this comment is, therefore, on the relevance of authorized menthol ENDS products to the ability of a combustible menthol ban to achieve the full public health benefit outlined in the Proposed Rule. It also addresses the relevance of such availability on the ability of a final menthol cigarette rule to withstand an expected legal challenge by one or more of the manufacturers of combustible menthol cigarettes – given that the Proposed Rule fails to consider a scenario in which authorized menthol ENDS are *not* available to menthol smokers post-ban.

Consistent with the FDA's Comprehensive Plan for Tobacco and Nicotine Regulation, it is critical that the FDA authorize, as it has begun to do, products that will allow adult smokers who are otherwise unable or unwilling to quit smoking combustible tobacco products to transition off of them by moving down the continuum of risk for nicotine containing products. Any science-based, responsibly-implemented regulation that will further optimize the migration of smokers down the continuum of risk – and, critically, that is capable of withstanding legal challenge – is desirable.

As set forth in Section III(C) of the Proposed Rule, the legal standard governing the FDA's exercise of its product standard authority is found in Section 907(a)(3) of the Family Smoking Prevention and Tobacco Control Act, which permits the adoption of standards if they are "appropriate for the protection of public health" (APPH). To make this determination, the FDA is required to consider "scientific evidence" regarding:

> 1. The "risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard";

> 2. The "increased or decreased likelihood that existing users of tobacco products will stop using such products"; and
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> 3. The "increased or decreased likelihood that those who do not use tobacco products will start using such products."

The FDA's discussion of the application of this standard to the Proposed Rule is contained in Section V, including particularly in Section V(C)(5), titled "Results from Simulation Models Are Consistent With the Findings That Prohibiting Menthol Cigarettes Would Benefit the Population's Health." The simulation models to which the FDA refers identify four primary responses by current menthol cigarette smokers to the implementation of a menthol cigarette ban: (a) some will switch to non-menthol combustibles; (b) some will switch to illicit menthol combustibles; (c) some will switch to ENDS (also referred to in the literature as Nicotine Vaping Products or "NVPs"); and (d) some will quit all product use. The FDA's estimates of the levels of each of the four primary responses, for different demographic groups, comes from a series of population models, informed in part by our peer-reviewed research on the anticipated impact of a menthol cigarette ban. Primarily, these estimates are based on three Levy, et al. studies cited at footnotes 45[1], 46[2] and 211[3] to the Proposed Rule – with our 2021 study cited at footnote 46 receiving the greatest reliance.

The 2021 Levy, et al. expert elicitation cited in footnote 46 (hereafter "Levy/46") provides the following estimates of the levels of the four primary responses for individuals through age 30 and for individuals above age 30. For the younger group, the experts predict the following for current menthol smokers in response to a menthol cigarette ban: (a) 10% will switch to illicit menthol combustibles; (b) 48% will switch to non-menthol combustibles; (c) 24% will switch to ENDS/HTPs (heated tobacco products); and (d) 18% will quit all product use. For the older group, the experts predict the following: (a) 9% will switch to illicit menthol combustibles; (b) 59% will switch to non-menthol combustibles; (c) 17% will switch to ENDS/NVPs; and (d) 15% will quit all product use. Translating these percentage estimates into expected public health impact, Levy/46 predicts that a menthol ban will result in 650,000 deaths averted and 11.3 million life years gained. The FDA's Proposed Rule explicitly relies upon these numbers and thereby endorses the Levy/46 methodology and conclusions:

> "In conclusion, population health models simulating menthol ban policies are consistent with a substantial public health benefit. The 2021 simulation by Levy et al., using the

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[1] Levy, D.T., J. Pearson, A. Villanti, et al. ''Modeling the Future Effects of a Menthol Ban on Smoking Prevalence and Smoking-Attributable Deaths in the United States.'' American Journal of Public Health, 101:1236–1240, 2011. Available at https://doi.org/10.2105/AJPH.2011.300179.

[2] Levy, D.T., R. Meza, Z. Yuan, et al. ''Public Health Impact of a US Ban on Menthol in Cigarettes and Cigars: A Simulation Study.'' Tobacco Control, 2021. Available at https://doi.org/10.1136/tobaccocontrol-2021-056604.

[3] Levy, D.T., C.J. Cadham, L.M. Sanchez-Romero, et al. ''An Expert Elicitation on the Effects of a Ban on Menthol Cigarettes and Cigars in the United States.'' Nicotine & Tobacco Research, 23(11): 1911–1920, 2021. Available at https://doi.org/10.1093/ntr/ntab121.

> SAVM model, estimated approximately 650,000 premature deaths averted and 11.3 million life-years lost averted in the first 40 years of a menthol cigarette and cigar ban beginning in 2021 (Refs. 46, 211, and 291)."

Levy/46 also asked the participating experts to consider the potential impact of a menthol ban that "is extended to all nicotine delivery products, including NVPs." The experts "indicated that menthol smokers would be less likely to switch out of menthol cigarette use (ie, into NVPs or no regular use) in that scenario compared with a ban limited to cigarettes and cigars. This outcome is consistent with expectations that menthol smokers would be especially likely to switch to menthol NVPs."

This assessment is also consistent with the findings of a study by Buckell et al. that estimated the potential impact of a menthol ban via discrete choice experiments in a sample of smokers and recent quitters.[4] The authors concluded that, "A ban on flavoured e-cigarettes alone would likely increase the choice of cigarettes in smokers, arguably the more harmful way of obtaining nicotine, whereas a ban on menthol cigarettes alone would likely be more effective in reducing the choice of cigarettes. A ban on all flavours in both products would likely reduce the smoking/vaping rates, but the use of cigarettes would be higher than in the status quo."

Based on our research, as cited, the population level impact of a cigarette menthol ban is expected to be greatest in a scenario in which menthol smokers have the ability to switch to a menthol flavored NVPs. The availability of certain other flavors, especially mint, may also increase the likelihood of menthol cigarette smokers finding a desirable alternative to smoking. This might specifically be the case with the availability of products that are the subject of an MGO. Moreover, implicit in this expert opinion, and the Buckell et al. study results, is that menthol smokers who switch to NVPs are likely to select *menthol-flavored* NVPs rather than tobacco-flavored NVPs.

The Proposed Rule implicitly assumes, by its reliance on Levy/46, that lawful menthol ENDS/NVPs are available post-ban. However, if there are no authorized menthol NVPs on the market, the percentage of switching to NVPs is likely to be lower and a significant portion of the switching to ENDS/NVPs that does occur will be to unauthorized and potentially illicit products – a clearly non-optimal public health outcome that would fundamentally undermine the public health analysis contained in the Proposed Rule. Critically, this scenario is neither addressed nor modeled in the Proposed Rule. Unless authorized menthol ENDS/NVPs are fully available at the time a menthol cigarette ban is implemented – based on careful scientific review and application of the APPH standard – we believe that the failure to address a scenario in which there are no authorized menthol ENDS/NVPs post-ban may violate Section 907(b) of the statute, which provides that the Secretary "shall" consider "information concerning the *countervailing* effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter and the significance of such demand." In such context, this omission risks contributing to a successful legal challenge to the

[4] Buckell J, Marti J, Sindelar JL. Should flavours be banned in cigarettes and e-cigarettes? Evidence on adult smokers and recent quitters from a discrete choice experiment. Tob Control. 2018 May 28:tobaccocontrol-2017-054165. doi: 10.1136/tobaccocontrol-2017-054165. Epub ahead of print. PMID: 29807947; PMCID: PMC6261708.

Proposed Rule – with the result that a menthol cigarette ban could ultimately not become enforceable law, at the loss of the significant public health benefits that would otherwise occur.

We encourage the FDA to carefully consider this vulnerability in the public health analysis underpinning the Proposed Rule. If, as we anticipate, the science supports the authorization of some carefully reviewed mentholated ENDS products, and the agency grants MGOs for such products in advance of the publication of a final rule banning menthol combustible cigarettes, the rule will be more likely to be upheld and ultimately have the intended effect of significantly reducing smoking prevalence and its deleterious health consequences.

Sincerely,

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