The Vapor Technology Association's Comment

in Response to FDA's

Proposed Tobacco Product Standard for Menthol in Cigarettes

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I. INTRODUCTION

As a leading voice of the vapor products industry, the Vapor Technology Association has weighed in and offered constructive recommendations on every major issue that has confronted the vapor products industry since 2015. We have valued our engagement with the FDA's Center for Tobacco Products and are grateful for the opportunity to present data and information to and comment on the FDA's Proposed Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 86, 26454 (May 4, 2022) (the "Menthol Cigarette Rule").

The Menthol Cigarette Rule could be the most significant step that the FDA has taken to protect public health in the United States. This bold move could have a dramatic impact on reducing cigarette smoking – the leading cause of death and disease of Americans – particularly if the Agency also heeds the scientists' warnings that menthol smokers need to have access to less harmful vaping and other alternative nicotine products.

A. The Vapor Technology Association

The Vapor Technology Association is the national non-profit industry trade association whose members are dedicated to developing and selling high quality vapor products that provide adult consumers with a safer alternative to traditional combustible cigarettes. Our trade association includes the leading manufacturers of vaping devices – commonly known as e-cigarettes – manufacturers of e-liquids, flavorings, and components, as well as wholesalers, importers, and brick-and-mortar vape shop retailers. Under a deluge of both federal and state laws and regulations, the vapor industry has been challenged but still remains strong due primarily to the dedication of adult smokers and former smokers who continue to demand access to a wide variety of vapor products to help them quit and stay quit.

VTA's mission is to foster a U.S. marketplace with a variety of vaping and other less harmful nicotine products which can provide adult smokers real alternatives and accelerate their movement away from cigarettes. VTA promotes regulation that can hasten the reduction in smoking cigarettes and that focuses on the critical importance of tobacco harm reduction as an essential public policy objective for reducing the death and disease associated with combustible cigarettes which continue to dominate the market.

B. Summary of Considerations

The FDA has issued its proposed tobacco product standard to ban the use of menthol in cigarettes. VTA has argued for years that vaping products provide adult smokers who are

desperately trying to quit smoking cigarettes a viable and meaningful way to do so. We have argued that ENDS products are a substantially less harmful alternative to combustible cigarettes. We have consistently taken the position that the Congressional and FDA approaches to date have wrongly focused almost exclusively on concerns related to less harmful non-combustible products, generally, and on youth use of ENDS, specifically, when it is cigarettes which are the direct cause of myriad diseases and the death for nearly half a million people in the U.S. every year.

The FDA's rule to ban menthol cigarettes is the single most dramatic step that it has taken to reduce cigarette smoking. Arguably, everything else the FDA has done in the past decade to address cigarette smoking pales in comparison. To be sure, the myopic focus on vaping, and particularly the attenuated risks associated with youth vaping, has been the ultimate representation of taking one's eye off of the ball. During this period of time, the steps taken have not prevented the deaths of 10 million Americans. For this reason, it is within VTA's mission to support the FDA's proposed ban on menthol cigarettes.

However, given that FDA's Menthol Cigarette Ban acknowledges that the banning of menthol cigarettes still will result in 55% of menthol smokers simply switching to the equally deadly non-mentholated cigarettes, this long overdue action is dangerously close to being, at best, a half measure. This is especially true since the FDA has used its regulatory power in the past five years to remove, not approve, less harmful nicotine vaping and other nicotine products from the marketplace.

II. **FDA's Proposed Product Standard for Eliminating Menthol in Cigarettes is Justified.**

Cigarettes are the only product sold in the U.S. that, when used as intended, cause disease and or death to the consumers using the product. According to the CDC, 1,300 Americans die every day from smoking, equating to almost 480,000 Americans dying annually. That is COVID scale event every two years! As noted in the Menthol Cigarette Rule, ""The Surgeon General has reported that about 30 individuals will suffer from at least one smoking-related disease for every person that dies from smoking each year (Ref. 245)." (87 Fed. Reg. at 26482, citing Smoking Cessation: A Report of the Surgeon General). That's another 14 million Americans who suffer from debilitating smoking-related illnesses every year imposing billions of dollars of costs to an already taxed health care system.

Worse, the death and disease directly linked to smoking cigarettes disproportionately affects communities of color, particularly the African American community, people of lower incomes, and members of the LGBTQ community. (87 Fed. Reg. at 26458)

Congress knew the truth about cigarettes in 2009 when it passed the Family Smoking Prevention and Tobacco Control Act (the "Tobacco Control Act) in which it gave the FDA new powers to regulate all tobacco products.

Yet, in the Tobacco Control Act Congress hog-tied the FDA by barring the agency from removing cigarettes from the marketplace. At the same time, Congress gave cigarettes, and the companies that manufacture them, the biggest gift possible: exempting them from all pre-market tobacco regulatory requirements. Due to this massive Congressional exemption, cigarette companies never have had to justify the appropriateness of their products for public health or otherwise present to the FDA any justification, much less any data or science, for the continued marketing and sale of their deadly cigarettes. Congress gave this gift to cigarette companies for both their tobacco and menthol flavored products knowing full well that such products could never meet the appropriateness for the protection of public health standard created under the Tobacco Control Act which was limited to only new tobacco products.

As a result, over 10 million Americans have died from smoking since the passage of the TCA in 2009. At least another 2 million Americans will suffer the same fate in the years it will take to finalize the Menthol Cigarette Rule, implement it, and resolve the likely litigation that will be filed by manufacturers and sellers of menthol cigarettes. Also during that time, another 60 million Americans will contract and suffer from debilitating smoking-related illnesses which will continue to burden America's health care system with the enormous associated health care costs.

Hence, the FDA's proposed rule to ban menthol cigarettes is the first material action taken by the agency to directly address the death and disease caused by cigarettes and to challenge the continued dominance of the marketplace otherwise directly by cigarette companies. In this respect, the Menthol Cigarette Rule could be the most significant step the Agency has taken to protect public health despite the unjustifiable limitations placed upon it by Congress to ensure the continued sale of cigarettes.

After recognizing the death and disease associated with smoking cigarettes, in Section IV of the Menthol Cigarette Rule the FDA lays out the significant adverse impacts of menthol cigarette smoking on adults, including its impact on reducing cessation efforts. Additionally, the FDA lays out the disproportionate impact that menthol smoking has on youth, young adults, and other vulnerable populations, including initiation.

Importantly, the Menthol Cigarette Rule represents a welcome change from the seemingly exclusive focus that Congress and the Agency has had on youth use of less harmful non-combustible products, like vaping products, to the detriment of the more than 10 million American smokers have been relying on vaping products to quit and stay quit. For this reason

and others, the Vapor Technology Association, which has called on the Agency to take dramatic action to focus on the adult smoker and offer them less harmful non-combustible products, supports the Menthol Cigarette Rule.

Our support, however, comes with serious red flags raised by the very scientists, on whom the FDA relies, about the likely success of this initiative: namely, in the absence of dramatic action by the FDA to use its PMTA process to create a regulated marketplace for products that are appropriate for the protection of public health, specifically less harmful vaping and modern oral nicotine products, the majority of menthol smokers will be left with options that are bad and worse – turn to smoking other combustibles or turn to the illicit market. Very simply, if FDA continues to refuse to build a credible, robust off-ramp from smoking, all of the "countervailing considerations" it describes in the Menthol Cigarette Rule will be realized to an extent greater than FDA predicts.

III. Dangers of the Menthol Cigarette Rule Becoming No Better Than a Half Measure.

FDA is required to consider "all other information submitted in connection with a proposed standard, including 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." 21 U.S.C. § 387g(b)(2).

In the Menthol Cigarette Rule, the FDA acknowledges, but downplays, serious limitations with its proposed rule. The limitations threaten to take what should be a dramatic move to improve public health and convert it into a half measure that, in the absence of other decisive action from the FDA, will fall short of the Agency's claimed benefits of the Menthol Cigarette Rule. VTA contends that without concerted action to mitigate these limitations, the effectiveness of the Menthol Cigarette Rule will be muted and will lead to only incremental change in combustible smoking, where geometric change is demanded to best serve the public health.

A. Fifty Percent of Menthol Cigarette Smokers Will Simply Switch to Tobacco Flavored Cigarettes & Other Combustible Products, Per FDA.

The most significant limitation of the potential effectiveness of the Menthol Cigarette Rule is that the FDA's proffered scientific support acknowledges that at least 50%, and in some cases a larger percentage, of smokers will continue to smoke cigarettes or other combustible products after the Menthol Cigarette Rule is put into effect. Specifically, FDA explains the results of studies that it has funded. "Some menthol cigarette smokers may switch to non-

menthol cigarettes. The expert elicitation study suggested that among menthol smokers age 35 to 54, 45.7 percent would become non-menthol cigarette smokers (compared to 4.6 percent under the status quo) while 3.7 percent would become non-menthol cigar smokers (compared to no change under the status quo) (Ref. 211)." (87 Fed. Reg. at 26473, citing Levy, et al 2021a). Further, the FDA noted, "In an expert elicitation study estimating effects of a menthol ban on transitions in use, the panel of experts estimated that among menthol smokers aged 35 to 54 years, 55.1 percent would remain combustible tobacco users (Ref. 211) [and] among those aged 12 to 24 years who would have initiated as menthol cigarette smokers, under the menthol ban, 41.1 percent would still initiate combustible tobacco use (including non-menthol cigarettes, cigars, or illegal menthol cigarettes) (Ref. 211)." (87 Fed. Reg. at 26479, citing Levy, et al., 2021a)

FDA also cited an expert simulation study which concluded, "Among current menthol smokers aged 18–24, 10.1% switch to illicit menthol combustibles, [and] 48.0% switch to non-menthol combustibles, 24.2% switch to NVPs and 17.7% quit all product use. These transitions are applied to menthol smokers through age 30. Among current menthol smokers aged 35–54, 8.8% switch to illicit menthol cigarettes and cigars, 59.1% switch to non- menthol tobacco use, 17.3% switch to NVPs and 14.7% quit all product use. These transitions are applied to menthol smokers above age 30." (Levy, et al 2021b) Thus, under the Menthol Cigarette Ran, amongst the younger demographic, 59.1% would continue smoking combustible tobacco (illicit menthol or legal tobacco), while in the older demographic 67.8% would continue smoking combustible tobacco.

Hence, the FDA is acknowledging that the Menthol Cigarette Rule may only marginally reduce combustible tobacco use as a majority of menthol smokers simply switch to smoking traditional cigarettes. In real numbers, under the Menthol Cigarette Rule nearly 2 billion more packs of traditional cigarettes would be sold in the legal marketplace. See, Economic Impact of the Proposed Ban on Menthol Cigarettes, John Dunham & Associates, July 28, 2022, attached hereto as Appendix 1 ("Dunham Analysis"). As further explained in Section IV below, even that success is dependent on the availability of alternative nicotine products, such as electronic nicotine delivery systems and other less harmful nicotine delivery mechanisms.

B. FDA's Projected Smoking Cessation Rates Under the Menthol Cigarette Rule is Contingent on the FDA the Unlikely Banning of Menthol Cigars.

The cessation studies cited by the FDA to justify banning menthol cigarettes make clear that the failure of FDA to also ban menthol cigars raises serious questions about the effectiveness of the Menthol Cigarette Rule. The problem for FDA is that its justification of the

separate proposed product standard for banning menthol in cigars is substantially less compelling than the justification for banning menthol cigarettes, from both an initiation and cessation standpoint, making the likelihood of a menthol cigar ban highly suspect. According to the Levy, et al. expert simulation on which the FDA heavily relies to support its Menthol Cigarette Rule, "Were cigars (especially little cigars) exempted, many preban menthol cigarette smokers would likely switch to menthol cigars." (Levy, et al. 2021b) According to Levy, "We did, however, ask the experts about the impact of a menthol ban on just cigarettes, which the experts indicated would have substantially less impact." *Id*.

Given the limited and highly questionable justifications for banning menthol in cigars and given the unique place that cigars occupy in the tobacco products realm, the likelihood of simultaneous adoption of a menthol cigar product standard remains low. As a result, there is a strong likelihood that the adoption of the Menthol Cigarette Rule will result in the continued high rates of combustible smoking as menthol cigarette smokers switch to tobacco cigarettes, as described in Section III. A above, and other combustible products.

C. The Illicit Market for Menthol Cigarettes Will Surge Beyond That Predicted by FDA.

The banning of any popular consumer product has virtually always led to a robust illicit or black market. Since prohibition, the only similarly situated product as popular with consumers but banned federally has been cannabis. Countless years and billions of dollars were spent on an ill-advised war on drugs, which did little to change behavior or restrict illicit sales. Interestingly, however, even with the majority of US states legalizing and regulating cannabis sales, a black market continues to flourish. "From California, where there are more than three times as many illicit cannabis dispensaries than licit ones, to Oregon, where the State Police Sergeant laments a growing problem with illegal marijuana, the black market for weed has persisted in states that have legalized the drug." (Walsh 2020)

Like all markets, black markets are driven by demand and opportunity. FDA justifies its action against menthol cigarettes particularly because of their popularity in the U.S. amongst "vulnerable populations". Given their popularity and given what FDA notes is the uniquely addictive properties of menthol cigarettes, the high demand for menthol cigarettes will not be curtailed simply by their being made unlawful.

To be sure, in the Menthol Cigarette Rule, the experts on which FDA relies find that of those menthol smokers between the ages of 18 and 30, "10.1% switch to illicit menthol combustibles," while of those above 30, "8.8% switch to illicit menthol combustibles." However, according to an analysis completed by John Dunham & Associates, the change would be even

greater and that "approximately 20 percent of the current menthol cigarette market would move from normal legal channels to some form of illicit channel as a result of the proposed rule" (Dunham Analysis, Appendix 1).

Strikingly, the Dunham Analysis finds that of the 3.7 billion packs of menthol cigarettes sold in this U.S., 738.8 million packs would be procured from the black market after implementation of the Menthol Cigarette Rule (Dunham Analysis, Appendix 1).

While FDA has cited certain studies which downplay the likelihood of a black market, most of those studies involve the sale of all flavored tobacco products (not simply menthol cigarettes) and none of those studies take into account the fact that a key aspect of FDA's announced Menthol Cigarette Rule is that FDA has hamstrung its own enforcement efforts of such a ban.

Importantly, what makes the promise of a black market so much greater in the U.S. is that, in its effort to demonstrate the equity of its approach to ameliorate political concerns of the largest population of menthol smokers being targeted by law enforcement, the FDA has made clear that the proposed rule does not prohibit use or possession. Moreover, FDA has declared loudly and repeatedly its intention *not* to enforce a menthol cigarette ban against individuals for either use *or* possession (terms which remain undefined and unexplored in the Menthol Cigarette Rule).

In doing so, the FDA has told population of menthol smokers (who are addicted to this format of smoking) that they are "safe" from prosecution and, therefore, have no risk associated with and no disincentive for continuing to seek out, purchase and smoke menthol cigarettes. While the marijuana black market thrived (and still thrives) despite the threat of serial prosecution for use and possession, VTA contends that FDA's absolution of a consumer's use and possession of menthol cigarettes will dramatically seed the ground for the growth of a new black market for menthol cigarettes.

To complicate matters, there already exists a substantial grey market of cigarettes in the United States. (Dunham Analysis, Appendix 1). Cigarettes, including menthol cigarettes, produced in the U.S. for export regularly never leave U.S. soil and find their way back into illicit channels of commerce. Thus, the infrastructure for a burgeoning black market already exists and the banning of menthol cigarettes will only create the impetus for growth of that grey market and will create a new illicit or black market.

IV. The "Countervailing Effects" of the Menthol Cigarette Rule Can Only Be Solved by the Creation of a Robust Marketplace of Less Harmful Menthol and Other Flavored Vaping and Nicotine Products.

The countervailing effects that FDA admits will inhibit the effectiveness of the Menthol Cigarette Rule could be solved if FDA demonstrates the same level of commitment to providing menthol smokers access to less harmful alternative vaping and other novel nicotine products as it is to removing menthol cigarettes from the market. Importantly, while the marketplace of dramatically less harmful alternatives was just starting to emerge when the Tobacco Control Act was passed and when FDA first considered banning menthol cigarettes a decade ago, it most certainly does today. Less harmful ENDS products and oral nicotine products offer today's smokers real and effective alternatives to the certain death of smoking cigarettes. Thus, a robust regulated marketplace of legal nicotine alternatives (particularly those that have menthol and other flavors) will help ensure that menthol smokers have options other than smoking traditional cigarettes, smoking cigars, turning to an unregulated black market of menthol cigarettes and/or menthol work arounds (like menthol strips and drops).

A. FDA's Projections on Reduced Menthol Cigarette Use Are Dependent on the Availability of Less Harmful Vaping and Other Alternatives to Smoking.

The FDA has explicitly recognized a continuum of risk for all tobacco products. On that continuum, combustible products (cigarettes, cigars, cigarillos) sit at the riskiest (i.e., most toxic) end of the continuum, while medicinal nicotine replacement therapies (NRT) sit at the lowest end of the risk continuum. Since innumerable scientific studies have concluded that NRTs, while safest, are simply not effective tools for smoking cessation, renewed priority needs to be placed on ENDS and other non-combustible nicotine products that FDA recognizes sit near the lower end of the risk continuum. Even in the proposed rule, FDA spends considerable time justifying the Menthol Cigarette Rule by noting in numerous places that, upon banning menthol cigarettes, a considerable number of menthol smokers would switch to less harmful ENDS products.

FDA explains that half of its projected menthol smoking cessation rate is dependent upon those smokers switching to ENDS products. "FDA expects that, if this proposed rule is finalized and menthol is prohibited as a characterizing flavor in cigarettes, many menthol cigarette smokers will either quit smoking or switch to a non-combusted tobacco product, such as ENDS. In an expert elicitation study estimating transitions in use under both menthol ban and status quo scenarios, the panel of experts estimated that an additional 20.1 percent of menthol smokers ages 35 to 54 would cease combustible tobacco use over 2 years under a

menthol ban compared to the status quo, with about half (10.3 percent) switching to ENDS and about half (10 percent) quitting all tobacco use (Ref. 211). The expert panel also estimated that an additional 30.1 percent of menthol smokers ages 18 to 24 would cease combustible tobacco use over 2 years, with 15.6 percent switching to ENDS and 12.3 percent quitting all tobacco use (Ref. 211)." (87 Fed. Reg. at 26473)

FDA further explained that, "the panel of experts estimated that among menthol smokers aged 35 to 54 years, 55.1 percent would remain combustible tobacco users (a reduction of 20.1 percent from the status quo), with another 20 percent switching to a "novel nicotine delivery product," defined in the study as ENDS or heated tobacco products (HTPs) (a 10.3 percent increase from the status quo), and about 22.5 percent quitting all tobacco use (a 10.0 percent increase from the status quo) (Ref. 211)." (87 Fed. Reg. at 26479) Thus, in these examples, at least half of the quitting potential FDA seeks to achieve through the Menthol Cigarette Rule is dependent on menthol smokers switching to ENDS products.

B. Studies Conclude that ENDS Products Are "Especially Important" to Helping Menthol Smokers Quit and That Menthol Cigarette Rule Will Be "Particularly Effective" if Menthol/Mint Vaping Products Are Available.

Importantly, a recent study not cited in the Menthol Cigarette Rule concluded that not only are "menthol smokers who use e-cigarettes … more likely to quit smoking," but "a menthol smoking ban may be *more effective* if menthol smokers have access to e-cigarettes as a way to quit cigarette use or as a way to transition to exclusive e-cigarette use." (Cook, et al., 2021) Relying on "nationally representative longitudinal data among adult smokers," this study made important findings:

> We also found that current e-cigarette use was associated with a higher odds of smoking cessation among both menthol and non-menthol adult smokers. These findings are consistent with research showing that many smokers use e-cigarettes as an aid to help them quit smoking (Biener and Hargraves, 2015; Levy et al., 2018; Zhu et al., 2017), at least in the short-term (Everard et al., 2020). However, **a key finding in our study was that the association between e-cigarette use and smoking cessation was stronger for menthol smokers than for non-menthol smokers, even after adjusting for racial/ethnic and other determinants of menthol smoking**. We also examined this association using a measure of regular e-cigarette use (10+ days used in the past 30 days) as a sensitivity analysis and we obtained similar results for the effect modification. **These results suggest that e-cigarettes may be an especially important cessation aid for menthol smokers who want to quit smoking.** E-cigarettes may

> be an alternative product for menthol smokers, and their availability to current smokers may help to reduce the public health harms associated with tobacco use. Furthermore, **a menthol ban may be particularly effective in reducing smoking among menthol smokers, especially if mint and menthol flavored e-cigarettes are available as an option for menthol smokers affected by such a ban.**

(Cook, et al. 2022) (emphasis added).

Though FDA did not cite Cook, et al, FDA did recognize the importance of ENDS to menthol cigarette smokers trying to quit. "A recent literature review examined such surveys and based on responses from U.S. menthol smokers, concluded that banning menthol cigarettes would increase quit attempts and switching to potentially less harmful tobacco products (Ref. 218)." (87 Fed. Reg. at 26474) "In surveys, some menthol cigarette smokers and some dual users of menthol cigarettes and ENDS report intending to use ENDS if menthol cigarettes were no longer available (Refs. 221, 272, and 222). Experimental marketplace studies also suggest that, in addition to taking other actions, some menthol smokers may switch partially or fully to ENDS in the event of a menthol cigarette ban (Refs. 273 and 225). These empirical findings are consistent with the 2020 Surgeon General's Report, titled "Smoking Cessation," and several systematic reviews, which suggest that some adult cigarette smokers report using ENDS to try to reduce or quit smoking (Refs. 245, 274-276)." (87 Fed. Reg. at 26479) Thus, menthol smokers have already indicated their intention to convert to ENDS use in the event of a menthol cigarette ban. But, they will not be able to do so unless FDA approves menthol and other flavored vaping products.

C. The Goal Must Be to Encourage Switching to Non-Combustible Products.

FDA explains that for smokers, switching to less harmful nicotine delivery systems could "significantly reduce their risk of tobacco-related disease" which, of course, cannot be said for that large percentage of menthol smokers which FDA expects to continue smoking combustibles even after the implementation of the Menthol Cigarette Rule. "FDA recognizes that smokers who choose to switch completely to a potentially less harmful nicotine delivery product to maintain their nicotine dose also could, to the extent that those products result in less harm, significantly reduce their risk of tobacco-related death and disease (Ref. 271). The least harmful nicotine delivery products available to smokers are the pharmaceutical nicotine replacement therapies already approved by FDA as both safe and effective cessation tools, many of which are available in a variety of flavors, including mint, which could appeal to menthol smokers. However, smokers may also transition to tobacco products which utilize other forms of nicotine

delivery in place of smoking combusted cigarettes. These include smokeless tobacco, dissolvable products, and ENDS products, among others." (87 Fed. Reg. at 26479)

All of the potential benefits cited by FDA to support its ban on menthol cigarettes assumes that the legal marketplace actually offers adult smokers meaningful and attractive less harmful nicotine alternatives such as "smokeless tobacco, dissolvable products, and ENDS products, among others." (87 Fed. Reg. at 26479) However, the existence of an orderly and regulated marketplace filled with less harmful nicotine alternatives is seriously in doubt given FDA's recent actions limiting, if not extinguishing, the less harmful ENDS market.

D. FDA's Current Trajectory of Declining to Approve Less Harmful Flavored Vaping Products, Including Menthol, Will Doom the Expected Results of the Menthol Cigarette Rule.

The dearth of approved mentholated ENDS products will hobble the Menthol Cigarette Rule even before it is implemented. The FDA explains, "In the expert elicitation study, it is likely that when the experts were answering survey questions around tobacco use behaviors under a future menthol ban, they considered the products available in the market at the time. The marketplace of products may change over time due to a variety of reasons, and it is possible that changes in the marketplace, if known, may impact experts' judgements about how menthol smokers and non-users at risk for initiation may act in response to a menthol ban." (87 Fed. Reg. at 26481, citing Levy, et al. 2021a)

In this case, the marketplace has changed dramatically since the expert elicitation study. Today, the FDA has effectively denied, through its refusal to approve, adult smokers' access to approved menthol and other flavored ENDS products. As explained by the Dunham Analysis, based on FDA records, the FDA has approved only 41 of the millions of PMTAs filed for new or novel non-combustible tobacco products, only 23 of which are for ENDS products. Dunham Analysis, p. 3. Importantly, the 23 approved ENDS PMTAs include only 7 device options – two of which have/had little or no market presence – that are available only with tobacco-flavored e-liquids.

While it is true that a variety of menthol vaping products remain on the market due to administrative or judicial stay orders, or FDA placing all mentholated PMTAs in a separate bucket for later consideration, the fact is that the marketplace FDA has shaped thus far is one without mentholated or other options. In fact, recently, the FDA announced its Marketing Denial Order ("MDO") in connection with JUUL Labs, Inc.'s ("JLI") menthol pod product PMTAs. This was significant as it was the first of the innumerable menthol PMTAs filed on which the FDA has even made a decision. (As the agency is aware, upon the issuance of the MDOs for

JLI's PMTAs, JLI sought a stay pending its appeal in the D.C. Circuit Court of Appeals and shortly thereafter, the FDA decided to administratively stay its enforcement of the JLI MDO indefinitely.) With respect to every other PMTA filed, FDA has either failed or refused to approve any of the millions of mentholated or mint vaping product PMTAs that were filed with the FDA on or before September 9, 2020 (for tobacco-derived PMTAs), or on or before May 14, 2022 (for synthetic or non-tobacco nicotine PMTAs). Thus, as it stands today, FDA has created a marketplace devoid of menthol or mint, or any other flavored, vaping products.

To be clear, the danger of the FDA's continued removal of flavored vaping products (including menthol) from the market will harm adults trying to quit smoking. In a first of its kind "analysis using nationally representative, longitudinal data to evaluate associations between e-cigarette flavor preferences and subsequent smoking behavior by age group," Friedman, et al. (2020) found that, "Favoring flavored e-cigarettes was not associated with greater youth smoking initiation but was associated with greater adult smoking cessation; specifically, among adults who smoked and began vaping, the odds of cessation for those favoring nontobacco flavors were 2.3 times that of those who used tobacco-flavored e-cigarettes. Because early smoking cessation has substantial health benefits, with those who quit smoking before age 35 years experiencing a life expectancy similar to that of those who never smoked, increased cessation among individuals aged 18 to 54 years has substantive implications for population health." (Friedman 2020).

Further, a discrete choice experiment by Buckell, et al. (2018) attempted to predict the impact of various potential ENDS flavor bans on preferences and demand for combustible cigarettes in both adult smokers and recent quitters. The authors employed a "best-best" discrete choice experiment to elicit smokers' and recent quitters' preferences with respect to flavors and other tobacco product characteristics. A sample of 2,031 adult smokers and recent quitters completed the online survey and discrete choice experiment. The discrete choice experiment resulted in predictions by the authors that a ban on all non-tobacco flavors in e-cigarettes, while allowing menthol in cigarettes, would result in an 8.3% increase in demand for cigarettes and an 11.1% decrease in demand for e-cigarettes. A ban on all non-tobacco flavors in e-cigarettes (i.e., the near status quo) and menthol in cigarettes would similarly increase cigarette demand by 2.7% and decrease choice of e-cigarettes by 7.9%.

If FDA continues on this trajectory, it will, according to the very experts on whom FDA relies, further reduce the likelihood of menthol smokers' quitting. "We also asked experts about the impact of a menthol ban that is extended to all nicotine delivery products, including NVPs [nicotine vaping products], and they indicated that menthol smokers were 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." (Levy, et al., 2021b)

Thus, the effectiveness of the Menthol Cigarette Rule will be dramatically impaired by the FDA's tacit ban on flavored vaping products. FDA's refusal to approve any mentholated or other flavored vaping product, according to the science, will jeopardize menthol smokers' switching or, as noted above, will drive them to the black market.

E. An FDA Course Correction to Embrace Vaping is Desperately Needed to Ensure the Success of the Menthol Cigarette Rule and to Secure a Future that is Devoid of Cigarettes, Including Menthol Cigarettes.

Given the experts considered view that "menthol smokers would be especially likely to switch to menthol [nicotine vaping products]", (Levy, et al. 2021a), and that "a menthol ban may be particularly effective in reducing smoking among menthol smokers, especially if mint and menthol flavored e-cigarettes are available as an option for menthol smokers affected by such a ban," (Cook et al., 2022) a dramatic course correction is required to ensure that the marketplace is filled with menthol, mint and, arguably, other flavored vaping alternatives if the Menthol Cigarette Rule is going to have the FDA's desired effects. In what should be considered a seminal peer-reviewed analytic essay entitled "Balancing Consideration of the Risks and Benefits of E-Cigarettes," fifteen of the past presidents of the revered academic group, the Society for Research on Nicotine and Tobacco ("SRNT"), called for a serious course correction with respect to US ENDS policies. (Balfour, David, et al. 2021)

1. Vaping can save lives and balanced policies must be implemented to commit to protect adult smokers.

Despite the case-by-case approach taken by FDA in reviewing PMTAs which has resulted in a dearth of vaping products being approved for sale in the U.S., the 15 past presidents of SRNT expressed their science-based understanding that vaping can save lives. "Many, including this article's authors, believe that vaping can benefit public health, given substantial evidence supporting the potential of vaping to reduce smoking's toll. Our objective is to encourage more balanced consideration of vaping within public health and in the media and policy circles." *Id.,* p. 1666. The absence of a balanced consideration of e-cigarettes is sorely lacking both at the agency level and amongst U.S. politicians.

The danger as described by the 15 past presidents of SRNT is the adult smoker is not being given due consideration under current US regulatory actions and statements. "We agree with former Surgeon General C. Everett Koop who, in 1998, urged that '[A]s we take every

action to save our children from the ravages of tobacco, we should demonstrate that our commitment to those who are already addicted . . . will never expire.' The latter appears at risk today." *Id.* While the FDA's Menthol Cigarette Rule can be considered a serious attempt to address the adult smoker, for all the reasons cited above, that attempt will be foiled without a serious commitment to ensuring the broad availability of a diverse array of less harmful vaping and other non-combustible nicotine products.

2. The focus on initiation, particularly the overstatement of risk to youth, is jeopardizing the lives and well-being of adult smokers.

The 15 past presidents of SRNT noted that US regulators must change their focus from preventing vaping product initiation, primarily amongst youth, to providing adult smokers legal options to switch from deadly cigarettes to less harmful nicotine alternatives. These icons of tobacco control starkly declared, "We believe the potential lifesaving benefits of e-cigarettes for adult smokers deserve attention equal to the risks to youth. Millions of middle-aged and older smokers are at high risk of near-future disease and death. Quitting reduces risk. Young people will not experience smoking-related (and conceivably vaping-related) chronic disease for 3 decades, and likely not at all if they quit within a decade or 2. Social pressures to quit smoking will probably remain strong, and quitting aids may improve. Furthermore, as noted previously, the rate of smoking among young people has declined while vaping has increased. Vaping may addict some youths to nicotine, but many fewer than popularly believed." *Id.*

With this dose of reality, the 15 past presidents of SRNT warned, "To date, the singular focus of US policies on decreasing youth vaping may well have reduced vaping's potential contribution to reducing adult smoking. … The public health objective should be to develop policies and interventions that both reduce youth vaping and increase adult smoking cessation." *Id.*

Further, the FDA needs to speak clearly about the risks associated with nicotine both for youth and adults. While the Menthol Cigarette Rule emphasizes that "the adolescent brain is particularly vulnerable to the effects of nicotine." It is telling that the 15 past presidents of SRNT suggest otherwise and call on regulators to speak accurately about the relative risks of smoking and vaping. Referring to studies raising concerns about nicotine on the developing brain, these esteemed experts explain, "However, given species differences and questions about the relevance of experimental animal nicotine patterns, the validity of extrapolation to humans is speculative. Whether impaired brain development with behavioral consequences occurs in young nicotine consumers is difficult to determine because of potential confounding of genetic and socioeconomic favors, the influence of other substance abuse, and the role of

preexisting neuropsychiatric problems associated with youth smoking. Research has yet to isolate nicotine use in the adolescent years and then examine later sequelae." *Id. at* 1665.

Importantly, given that the rate of youth usage of ENDS products has dropped precipitously by 62% in the last two years, the FDA must heed the warnings of the 15 past presidents of SRNT and refocus its efforts on approving less harmful vaping products for adult smokers -particularly those menthol smokers which FDA is about to deprive of their favored format of nicotine consumption.

3. Restricting the sale of flavored vaping products to adult only stores can preserve adult menthol smokers' access to alternatives while at the same time protect youth.

The current policies about which the 15 past presidents of SRNT raise concern "include taxing e-cigarettes at rates comparable to cigarette taxes, decreasing adult access to flavored e-cigarettes that may facilitate smoking cessation, and convincing the public—including smokers—that vaping is as dangerous as smoking." *Id.* at 1666. The fact that these anti-tobacco research leaders have questioned the continuing reduction in adult access to flavored e-cigarettes that could facilitate smoking cessation is directly applicable here where FDA has, to date, refused to approve a single flavored vaping product, including mentholated vaping products.

The experts recommend, "Because both youth and adult smokers find e-cigarette flavors attractive, banning all (or most) flavors risks reducing smokers' use of e-cigarettes to quit smoking at the same time that it reduces youth vaping. An alternative would be to limit the retail sale of flavored e-cigarettes to adult-only outlets such as vape shops. An imperfect policy for either goal, this approach could benefit both." *Id.,* p. 1666. VTA strongly endorses this sound policy recommendation that the FDA could implement through its considered regulatory authority or that Congress could impose via legislation that VTA is currently promoting which would simultaneously impose significant new marketing restrictions on flavored vaping products and require their sale in adult only stores as recommended by the leading anti-tobacco experts.

4. FDA's equity concerns expressed in the Menthol Cigarette Rule can be addressed by ensuring the availability of vaping products.

Given the emphasis that the FDA places on equity considerations, namely how menthol cigarettes disproportionately affect what FDA calls "vulnerable populations", a course correction is required. "FDA anticipates the proposed product standard also will improve health outcomes among vulnerable populations. As previously described, menthol cigarette

use, and the disease and death linked to such use, is disproportionately high among members of vulnerable populations such as African Americans and other racial and ethnic groups, those with lower household income, and those who identify as LGBTQ+ (Refs. 55-57, 21-24, 44)." (87 Fed. Reg. 26485)

Again, the failure of the agency to approve vaping products will confound its efforts to protect these vulnerable populations which the 15 past presidents agree need additional attention. In fact, in calling for a reformed view of e-cigarettes, the 15 past presidents emphasize, ""The need to pay attention to adult smokers is particularly important from a social justice perspective. African Americans suffer disproportionately from smoking-related deaths, a disparity that, a new clinical trial shows, vaping could reduce. Today's smokers come disproportionately from lower education and income groups, the LGBTQ (lesbian, gay, bisexual, transgender, and queer or questioning) community, and populations suffering from mental health conditions and from other drug addictions. Smoking accounts for a significant proportion of the large life expectancy difference between affluent and poorer Americans. For smokers with serious psychological distress, two thirds of their 15-year loss of life expectancy compared with nonsmokers without serious psychological distress may be attributable to their smoking. Vaping might assist more of these smokers to quit." (Balfour, et al. 2021)

However, it is critical to vulnerable populations and all populations that the FDA also speak clearly about the relative risks of ENDS products if switching to less harmful products is going to be realized. Regarding the need to speak clearly about risks, the 15 past presidents recommend that, "Government agencies [i.e., FDA] and health organizations should develop nuanced, targeted communications that emphasize the realistic concerns about youth vaping and, separately, the potential benefits of e-cigarettes as less-risky (but not risk-free) alternatives for adult smokers otherwise unable or unwilling to quit smoking." *Id.,* p. 1666. To date, complicating the fact that the FDA's communications to date have been anything but targeted or nuanced and have not raised realistic concerns about youth vaping, the FDA's communications about e-cigarettes being less-risky alternatives for adults to use to quit have been virtually non-existent. While, as noted above, FDA's Menthol Cigarette Rule uses the potential for transitioning to less-risky vaping as a rationale for the proposed rule itself, the language used by the agency continues to reflect a lukewarm belief in vaping, directly contrary to some of the worlds' most staunchly anti-tobacco scientists.

Further, given the sizeable black market that will thrive after the implementation of the Menthol Cigarette Rule, the creation of a legal, orderly and regulated marketplace filled with menthol, mint and other flavored vaping products will give menthol smokers legal products to which they can turn in the absence of menthol cigarettes. A robust legal marketplace of less harmful ENDS products will curtail the need for vulnerable populations to seek out products

from the illicit market and will limit the real dangers associated with local efforts to enforce the menthol ban with all of its inequitable consequences.

V. The Availability of Flavored (Including Menthol) Vaping Products, Properly Regulated, Will Give Adult Smokers The Products That Are Aiding Cessation.

As explained in detail below, the existing peer reviewed scientific research regarding the role of flavors in ENDS products does not provide a sound basis for limiting access to any flavors—including non-tobacco flavors—in ENDS. Rather, the existing science supports continuing to allow adult consumers, including current and former smokers, full access to such flavors to support their efforts at smoking cessation.

A. Adult Consumers Use and Rely Upon a Wide Variety of Non-Tobacco-Flavored ENDS Products.

In order to fully understand the beneficial impact of flavors in ENDS products, it is important to recognize that a wide diversity of flavors are popular with adult consumers of nicotine products. Unlike the limited product range and market for flavored cigarettes prior to 2009, today there is a broad selection of non-tobacco-flavored e-liquids available to and popular with adult consumers of all ages. It is scientifically unacceptable to suggest that flavors are solely intended to attract or appeal to youth when the evidence suggests that adults of all ages like many categories of flavors – including fruits, sweets, and cool flavors – and tend to dislike harsh and bitter flavors (Zare, et al., 2018; Harrell, et al., 2017). These findings are borne out in surveys (Bonhomme, et al., 2016; Berg, 2016; Bowler, et al., 2017; and Krishan-Sarin, et al., 2014), experimental studies (Goldenson, et al., 2016; Kim, et al., 2016; Garrison, et al., 2018), and focus groups (Soule, et al., 2016; Kim, et al., 2017).

Studies have found no demonstrable differences in ENDS flavor preferences between people of different races (i.e., Harrell, et al., 2017; Ashford, et al., 2017; Kim, et al., 2016), while others have suggested that African Americans prefer menthol flavor (Bowler, et al., 2017; Bonhomme, et al., 2016) and Caucasians prefer fruit and candy flavors (Bonhomme, et al., 2016.) What is certain, however, is that adults enjoy and use a wide variety of ENDS flavors.

Most important to the Menthol Cigarette Rule, given the importance of the availability of menthol flavored alternatives to menthol cigarettes, as set forth in greater detail in Section V.B., below, both anecdotal evidence and a growing body of literature suggest that, as smokers transition from combustible cigarettes to use of ENDS products, they first tend to use tobacco and menthol-flavored e-liquids, but eventually transition to non-tobacco flavors as their dependency on combustible cigarettes decreases. In part, this trend may be due to the fact that many ENDS products sold as kits include tobacco-flavored e-liquids, so it is thus probable that an existing smoker's first exposure to an ENDS product is more likely to involve a tobacco-flavored e-liquid. However, as also discussed below, the existing literature demonstrates that, as smokers

of all ages wean themselves off of cigarettes, they tend to gravitate toward non-tobacco flavors to avoid the taste sensations associated with tobacco flavors. Thus, the continued availability of non-tobacco flavors is critical to encourage cessation in existing smokers, to prevent relapse into combustible cigarettes, and to increase harm reduction as a matter of public health policy.

B. The Existing Reliable Literature Strongly Supports the Role of Non-Tobacco ENDS Flavors as Valuable Smoking Cessation Tools.

The existing reliable scientific literature on flavors and ENDS products—including longitudinal analyses, survey data, and experimental studies—trends strongly in favor of the conclusion that access to a wide variety of flavors—and particularly non-tobacco flavors—plays a critical role in encouraging cessation among existing smokers and preventing relapse. Thus, any move by FDA to restrict access to such flavors has the potential to significantly impede smoking cessation efforts for millions of current and former smokers and consign them to the adverse health effects that accompany continued smoker status.

1. Two Longitudinal Studies Based on PATH Study Data Found Users of Non-Tobacco-Flavored ENDS Are More Likely to Reduce Cigarette Use or Quit Altogether.

Two reliable longitudinal analyses of data from the Population Assessment of Tobacco and Health (PATH) Study have studied the role of non-tobacco flavors in e-liquids and determined that users of such flavors were more likely to have reduced their cigarette consumption or have quit smoking altogether.

One longitudinal study analysis by Chen (2018) found that users of e-cigarettes with one or more non-tobacco / non-menthol flavors were *significantly more likely* to have reduced or quit smoking over time than non-e-cigarette users, thus suggesting that the continued availability of such flavors is important to support smoking cessation efforts. The data collected between Wave 1 and Wave 2 indicated that "*25.9% of respondents either reduced or quit smoking,"* with 6.7% currently using e-cigarettes with tobacco / menthol flavors and 11.5% currently using e-cigarettes with one or multiple non-tobacco flavors. In that analysis, the author examined longitudinal data from the PATH Study to examine differences in smoking reduction / cessation among young adult smokers (age 18-34) who: (1) did not use e-cigarettes; (2) used e-cigarettes with tobacco and/or menthol flavors; and (3) used e-cigarettes with other flavors. Of the 4,645 smokers in Wave 1 who responded to the e-cigarette flavor questions in Wave 2, 844 were current e-cigarette users, approximately one-third of whom used tobacco and/or menthol flavors and approximately two-thirds of whom used other flavors. Adjusted logistic regression showed that subjects who used e-cigarettes at Wave 2 with either one "other" flavor (AOR = 2.5, $p<0.001$) or multiple "other" flavors (AOR = 3.0, $p<0.001$) were significantly more likely to have reduced or quit smoking in the past year than non-e-cigarette users. The study also demonstrates that proper understanding and access to flavors is important to those reducing smoking or quitting.

With respect to their reasons for using e-cigarettes, subjects who reported that e-cigarettes "help people quit smoking" (OR = 2.3, p<0.001) and "come in flavors I like" (OR = 2.1, p = 0.007) were more than twice as likely to have reduced or quit smoking in the past year compared to those who did not endorse those reasons.

A second important longitudinal analysis by Buu, et al., (2018) demonstrated the harm reduction potential of access to a variety of non-tobacco flavors by finding use of non-tobacco flavored e-cigarettes to be positively associated with a lower quantity of combustible cigarette use over time. In this analysis, 2,727 subjects who reported at Wave 1 of the PATH Study that they were exclusively smokers (i.e., had smoked more than 100 cigarettes in their lifetime and had smoked in the last 12 months) and had not used an e-cigarette in the past 12 months were re-examined at Wave 2 to determine if e-cigarette use was associated with changes in smoking behavior. Users of e-cigarettes at Wave 2 were defined as subjects who used e-cigarettes some days or every day in the last 30 days. The use of flavoring was measured by the subjects' responses to the question: "In the past 30 days, was any of the e-cigarettes / e-cigarette cartridges / e-liquid you used flavored to taste like menthol, mint, clove, spice, fruit, chocolate, alcohol drinks, candy, or other sweets?" Notably, the use of non-tobacco flavored e-cigarettes (i.e., a positive response to the foregoing question) was positively associated with a lower quantity of combustible cigarette use at Wave 2 (p<0.05).

2. Survey Data Also Strongly Correlate Use of Non-Tobacco Flavors in ENDS Products With Successful Cigarette Quit Attempts.

In addition to the two longitudinal studies noted above, an extensive body of survey data also reflects statistically significant associations between the use of non-tobacco flavors in ENDS products and successful attempts to quit smoking combustible cigarettes. The literature recognizes that dual use of cigarettes and e-cigarettes among existing smokers is common and is often a necessary step toward total "switching" and complete smoking cessation.

Beginning this trend in the literature, an early internet survey study by Farsalinos, et al., (2013) found that of 4,618 e-cigarette users, 91.9% of the participants were former smokers. The survey found that the remaining participants reporting smoker status had, on average, reduced their consumption of combustible cigarettes from 20 per day to 4 per day. The respondents reported using an average of three different flavors of e-liquids on a regular basis, with former smokers switching between flavors more frequently than current smokers, with over 69% of former smokers doing so on at least a daily basis. More than 50% of the participants reported that the taste of an e-liquid gets "blunt" with long-term use of the same flavor. Fruit and sweet flavors were found to be more popular among former smokers, while tobacco flavors were more popular at the time of initiation of electronic cigarette use.

Importantly, the Farsalinos survey suggested that restricting the availability of flavors would have a negative effect on reducing smoking or quitting altogether. Significantly, 48.5% of

the survey respondents reported that restricting the availability of non-tobacco flavors would increase their cravings for combustible cigarettes, while 39.7% reported that they would have been less likely to reduce or quit smoking if non-tobacco flavors were not available to them. Binary logistic regression analysis showed that a greater number of flavors regularly used was independently associated (B = 0.089, p = 0.038) with complete smoking abstinence in the survey population of dedicated, long-term vapers. Flavor availability was rated as "very important" (4 on a scale of 1 to 5) with respect to reducing or quitting combustible cigarettes. These results led the study authors to conclude that variability in flavors both resulted in reduced cigarette cravings and promoted smoking cessation in the population of smokers studied. Moreover, they hypothesized that the switch away from tobacco flavors over time may have reflected a desire by users to reduce their cravings for combustible cigarettes. (Farsalinos, 2013)

The increasing popularity of non-tobacco flavors among adult smokers for harm reduction and smoking cessation efforts is also supported by very recent survey results. In a survey conducted by Russell, et al., (2018) of 20,836 adult e-cigarette users that had used an e-cigarette on at least 20 out of the last 30 days, 15,807, or *76.4%, had completely substituted e-cigarettes for conventional cigarettes*. The researchers found that the number of smokers who had used a non-tobacco flavor as their first ENDS flavor increased substantially over time. Among the survey participants that were either "switchers," dual users, or former smokers, the percentage who had first used a tobacco flavor with their first ENDS product decreased from 46.0% prior to 2011 to 24.0% between 2015 and 2016. Meanwhile, first purchases of fruit-flavored e-liquids increased from 17.8% to 33.5% during that same time. Among these current and former smokers, tobacco and menthol flavors, which were the two most popular flavors for initiating e-cigarette use prior to 2013, are now the fifth and sixth most popular currently used flavors, behind (1) fruit / fruit beverage, (2) dessert/pastry, and (3) candy/chocolate/sweets.

The researchers concluded that "[a]ccess to a variety of non-tobacco flavored e-liquid may be important for encouraging and assisting adults to use e-cigarettes in place of conventional cigarettes" and that "[r]estricting access to non-tobacco e-cigarette flavors may discourage smokers from attempting to switch to e-cigarettes." To be sure, this conclusion is bolstered by an earlier online survey conducted by Russell, et al. (2017). In that survey, 4,192 ENDS users who were former smokers that quit by using e-cigarettes were asked what advice they would provide to smokers who are considering using ENDS to quit smoking. One of the primary themes was that such smokers should "find a combination of vaping device, flavors of e-liquids, and nicotine strength that works for you."

Several other survey studies have also demonstrated that smokers tend to begin e-cigarette use with the tobacco and menthol flavors that most closely resemble the cigarette flavors to which they are accustomed and that they then transition to other flavors over time—particularly as they cease use of combustible cigarettes altogether. An online survey (Truman, et al., 2018) of 218 vapers in New Zealand found that 23% both vaped and smoked. The results of the survey were consistent with a progression from initially both vaping and smoking using less effective electronic cigarette types, then moving to more powerful devices, and moving away

from tobacco and menthol flavors (which 42% of respondents reported having used at one time) to experiment with other flavors (as only 10% of respondents were still using tobacco and menthol flavors at the time of the survey). The authors concluded that smokers' experimentation with non-tobacco flavors was consistent with reducing or stopping combustible tobacco use.

Another online survey (Adriaens, et al., 2017) of 215 vapers that were both smokers and ex-smokers found that while 19% were dual users, 81% had completely switched to vaping. Both groups had been vaping for an average of 22 months and used flavors other than tobacco. In contrast, at the time of e-cigarette initiation, tobacco was the flavor primarily used by the respondents. Similarly, a focus group study of electronic e-cigarettes users by Simmons, et al. (2016) also concluded that it is plausible that e-cigarette users may use tobacco and menthol flavors to ease the transition to e-cigarettes and then switch to a contrasting flavor to prevent the tobacco flavor from serving as a cue to resume combustible cigarettes.

Still other surveys have similarly found statistically significant associations between cessation and the preference for non-tobacco flavors in electronic cigarettes. A study authored by Tackett, et al., (2015) that analyzed data collected in-person from 215 vape shop customers found that the respondents had, on average, used ENDS for seven months, that two-thirds (66%) had quit smoking altogether (a finding that was biochemically verified through exhaled CO readings) and that those who continued to smoke had reduced their daily cigarette usage from a mean of 22.1 to a mean of 7.5 ($p<0.001$), an overall average decline of almost 15 cigarettes per day. The study also found that 72% of the subjects used non-tobacco / non-menthol flavors and that subjects who used these flavors were significantly more likely ($p=0.035$) to quit smoking entirely than those who relied on tobacco or menthol flavors. In fact, quitting was two and a half times more likely among respondents using fruity, candy, or bakery-flavored e-liquids than those using tobacco or menthol-flavored e-liquids. The study authors concluded that "regulators should carefully examine the cost-benefit of banning flavors," as "the current available science would not support a decision to do so."

More descriptive surveys also support the conclusion that the availability and desirability of non-tobacco flavors supports smoking cessation efforts. An early online survey conducted in 2011-2012 of 1,347 vapers from 33 countries found that 1,123 – 83.3% - of them had stopped smoking and that, while tobacco was the most popular flavor identified, when allowed to choose more than one "preferred" flavor, significant proportions of ex-smokers selected "fruit," "chocolate / sweet flavor," "coffee," and "vanilla" flavors in addition to tobacco and mint/menthol flavors. (Dawkins, et al., 2013.) Similarly, a very early survey by Etter (2010) found that of 81 electronic cigarette users, 63% were former smokers. The positive feature of electronic cigarettes most frequently identified by the respondents was the *taste and variety of flavors*.

3. Study Demonstrates the Harm Reduction Potential of Flavored ENDS, Even Absent Any Subjective Intent to Quit Smoking.

An experimental study reported by Litt, et al., (2016) also powerfully underscores the potential for flavored ENDS to reduce reliance on cigarettes, even in the absence of subjective intent to quit smoking. In that study, 88 current smokers were asked to adopt e-cigarettes for a period of six weeks. To minimize the confounder effect that a desire to quit smoking might result in reduced use of all tobacco products, the study authors recruited only participants that reported no subjective intent to quit using combustible cigarettes. Study participants were allowed to taste and smell e-liquids flavored with tobacco, menthol, cherry, and chocolate and were provided with an ENDS product with either their preferred flavor or a randomly assigned control flavor.

Significantly, during the six-week period, cigarette smoking rates dropped from an average of approximately 16 cigarettes per day to 7 cigarettes per day. The largest drop in smoking rates (to 4.0 cigarettes per day) occurred among those participants using menthol e-cigarettes, while the smallest reduction (to 9.8 cigarettes per day) occurred among those using chocolate-flavored e-liquids, thus reinforcing the notion that menthol flavor plays an important role in early smoking cessation efforts involving ENDS products. Interestingly, smokers assigned the menthol e-cigarette tended to reduce their use of both the e-cigarette and combustible cigarettes. What is remarkable about this study is that, even in the absence of any desire or intent to quit, the use of flavored e-liquids resulted in a dramatic reduction in cigarette smoking.

C. The FDA's Articulated Concern About Dual Use Impeding or Delaying Cessation is Misplaced and Inconsistent with Existing FDA Policy.

FDA has often raised the potential concern of "dual use" of ENDS products and combustible cigarettes, suggesting that ENDS are being used as a crutch to extend the time that a person continues to smoke. This assertion has been used by some to question and by others to undercut the role that ENDS play in cessation efforts. In examining the appropriate policy with respect to ENDS products, the United Kingdom's Department of Public Health clearly explained why the dual use concern is illogical:

> It has been suggested that there is a risk of sustained dual use among smokers who might otherwise have quit smoking completely, representing missed opportunities to achieve complete cessation. This concern clearly applies equally to NRT, which is licensed for what is in effect dual use and recommended on the grounds that dual use is likely to increase quit attempts. The concern is therefore inconsistent; if dual use is good as a pathway to quitting, that surely applies to dual use involving either NRT or electronic cigarettes.

(Britton and Bogdanovica, 2014.)

In addition to the fact that there is simply no evidence to support such a concern for either adults or youth, FDA already has declared that continuing to use non-combustible nicotine products, *even if* one continues to smoke cigarettes, is appropriate. To be sure, in 2013 (and

prior to first raising "dual use" concerns in the proposed Deeming Regulation), FDA recognized the inherent contradiction between arguing against dual use and for public health, and amended its policy pertaining to the dual or poly-use of nicotine replacement products and tobacco products. *See* Modifications to Labeling of Nicotine Replacement Therapy Products for Over-the-Counter Human Use, 78 Fed. Reg. 19,718 (Apr. 2, 2013).

Despite the hyperbolic claims that we hear from some today regarding the "addictiveness" and the "dangers" of nicotine, the FDA reported to Congress in 2013 that, "[w]e also note that although any nicotine-containing product has the potential to be addicting, based on the available evidence, currently marketed OTC NRT products do not appear to have significant potential for abuse or dependence." *Id*. at 19,720. Interestingly, FDA made this statement because it was asked to change the warning labels in 2013 on over-the-counter nicotine replacement therapies ("NRTs"), including fruit, mint, cinnamon, and other flavored NRTs. At that time, NRTs included a stark dual use warning to smokers instructing them never to dual use:

> "**Do not use** if you continue to smoke, chew tobacco, use snuff, or use [a different NRT product] or other nicotine containing products." "Stop smoking completely when you begin using the [NRT product]."

Id. at 19,719.

But, FDA abandoned the dual use warnings altogether, removing the "Stop use" warning, removing the requirement that the user "quit" first, and even permitting new instructions to continue ingesting nicotine *even after* the end of the recommended period without having to speak to a physician. Thus, based solely on the "safety" of continually ingesting the pharmaceutical grade nicotine, FDA had no concerns about any adverse implications toward continued cigarette use or, for that matter, the continued poly-use of any other tobacco products.

In so doing, FDA expressly encouraged dual use. Given that e-cigarettes contain the same or lower levels of nicotine that most NRTs, and given the fact that FDA lifted the dual use restriction for other nicotine-containing products that contain no tobacco, the FDA has acknowledged that alternative nicotine consumption, even if it involves continued cigarette smoking, is preferable to individuals no longer using those alternatives.

Going forward, policies adopted by FDA in connection with ENDS should advance the potential for encouraging and enabling smokers to reduce consumption or quit altogether. FDA already has recognized that it should not discourage individuals trying to quit smoking using alternative nicotine products by instructing them that dual use is wrong. Hence, that consideration is equally true for ENDS, including flavored ENDS.

VI. CONCLUSION

Given that Congress under the Tobacco Control Act prevented the FDA from banning cigarettes, thereby protecting the legal sale of the only consumer product sold in the U.S. that, when used as intended, is the leading cause of death and disease in the U.S., the FDA's Menthol Cigarette Rule can be the most significant step the Agency has taken to protect public health. As difficult as the development and implementation of this proposed tobacco product standard has been and will be, the FDA should not be content with the incremental change in smoking rates promised under this proposed product standard.

Instead, the FDA must act aggressively to approve PMTAs for the less harmful vaping and other novel nicotine products that it is currently reviewing. For the reasons cited in this comment, the FDA can only fully realize the potential of reducing smoking and saving lives if the FDA uses its regulatory power under existing law to create a well-regulated market for less harmful products, such as vaping devices and novel oral nicotine products.

Leading tobacco control scientists, including many of the scientists on whose work the FDA relies in justifying the Menthol Cigarette Rule, have declared that, among other things, for FDA's menthol cigarette ban to be effective, menthol smokers must have access to meaningful and desirable vaping alternatives. In fact, the scientists on which the Agency heavily relies warn that half of the anticipated smoking cessation rate involves menthol smokers switching to vaping. However, today the FDA has not yet created a marketplace with any approved mentholated or other flavored vaping products.

As set forth in this comment, the opportunity under the Menthol Cigarette Rule to dramatically reduce smoking could be squandered if the FDA does not ensure that mentholated and other flavored vaping products are available to menthol smokers looking for an off-ramp from their addiction to deadly cigarettes. While these vaping alternatives did not exist when FDA first considered banning menthol cigarettes a decade ago, they most certainly do now.

VTA supports the Menthol Cigarette Rule and calls on the FDA to accelerate its PMTA approvals for less harmful nicotine products, the existence of which in a legal marketplace will save lives, reduce disease, and will eliminate the allure of menthol smokers resorting to smoking traditional cigarettes or otherwise satisfy their desires through illicit markets. The opportunity for new and concerted course correction on vaping that will hasten the removal of cigarettes from the legal marketplace is now. Americans, particularly those in vulnerable populations, addicted to smoking menthol cigarettes deserve more than restrictions that will confound and complicate their daily lives, they deserve access to a diverse set of legal harmful options that will give them a real chance to quit smoking.

Respectfully submitted,

VAPOR TECHNOLOGY ASSOCIATION

Tony Abboud, Executive Director

APPENDIX 1 – DUNHAM ECONOMIC IMPACT ANALYSIS

JOHN DUNHAM & ASSOCIATES

MEMORANDUM

TO: Vapor Technology Association

FROM: John Dunham

DATE: July 28, 2022

RE: Economic Impact of the Proposed Ban on Menthol Cigarettes

As per your request, I have analyzed the probable economic impact to the tobacco industry resulting from the Proposed Regulations to Establish Tobacco Product Standards for Menthol in Cigarettes,[1] as well as the Preliminary Regulatory Impact Analysis (RIA) developed by the Food and Drug Administration (FDA).[2]

The proposed rule would essentially ban the manufacture, distribution, and sale of cigarettes in the US market that have menthol as a "characterizing flavor." Manufacturers would still be able to sell these products to foreign markets.

In addition, the FDA will have sole determination as to what is meant by a characterizing flavor.

According to the FDA, in 2020, 11.13 billion packs of cigarettes were sold in the United States, of which 3.9 billion packs, or 35.0 percent, were menthol.[3] This is just slightly below the industry standard, *Tax Burden on Tobacco*, which suggests 11.14 billion packs were sold.[4]

According to the RIA, these cigarettes sold for $94,173,300,000, of which $32,923,000,000 represented menthol cigarettes. Based on JDA's projected 2022 data, cigarette

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1 *Tobacco Product Standard for Menthol in Cigarettes*, Department of Health and Human Services, Food and Drug Administration [Docket No. FDA–2021–N–1349], Federal Register, Vol. 87, No. 86, May 4, 2022, at: https://www.govinfo.gov/content/pkg/FR-2022-05-04/pdf/2022-08994.pdf.

2 *Tobacco Product Standard for Menthol in Cigarettes [Docket No. FDA-2021-N-1349]: Preliminary Regulatory Impact Analysis; Initial Regulatory Flexibility Analysis; Unfunded Mandates Reform Act Analysis*, US Food and Drug Administration, Economics Staff, Center for Tobacco Products, undated, at: https://www.fda.gov/media/158012/download

3 Op. Cit., Footnote 2.

4 *The Tax Burden on Tobacco: Volume 56*, Orzechowski & Walker, April 2022.

sales are expected to be $94,735,500,000, of which $33,951,600,000 (35.8 percent) will be generated through the sale of 3.7 billion packs of menthol cigarettes.[5]

The proposed rule calls for a complete ban on the sale of cigarettes in the United States where menthol is a characterizing flavor. In effect, all 3.7 billion packs of menthol cigarettes that JDA estimates will likely be sold in 2022 could no longer be legally sold in the US market. According to the RIA, this will lead to changes in demand for both cigarettes and menthol cigarettes.[6] In effect, the FDA states that *Current Menthol Smokers* would either stop smoking, switch to non-menthol cigarettes, switch to vapor products, or purchase illegal menthol cigarettes.

The RIA uses a model based on a single paper published in the journal *Tobacco Control* in 2021 to determine how the market would react to the proposed ban.[7] This paper, which is the entire basis of the FDA's benefits analysis, was funded by the Agency.

The Levy model funded by FDA suggests that currently just 5.4 percent of the population smokes menthol cigarettes. The model suggests that even with no ban, this would fall to just 2.4 percent by 2060, and that only 5.1 percent of the population would smoke at all.

The Levy model also suggests that prevalence of vapor products use would increase from 3.5 to 5.8 percent of the population with no ban. This would increase to 7.4 percent of the population with a ban. In effect, the menthol ban would encourage more than twice the number of people who stop smoking to start vaping, with 5.7 percent of menthol smokers switching to vaping products.[8] Interestingly, this differs from other papers by the same author that suggested switching rates to vapor products of as much as 8.0 percent.[9]

Based on a model developed by John Dunham & Associates (JDA) for the Vapor Technology Association (VTA), the effects on the sale of tobacco products following a ban on menthol cigarettes, the switch to vapor products is less dramatic.[10]

This model shows that in 2022, 10.2 billion packs of cigarettes will be sold in the United States, of which 3.7 billion (36.2 percent) will be menthol. Once a ban on menthol cigarettes is enacted, the number of menthol cigarettes sold legally in the country would fall to zero.

The JDA model finds that of the lost menthol sales, 1.7 billion packs (46.0 percent) would be replaced by legally sold non-menthol cigarettes. At the same time, the equivalent of

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5 Note that this estimate shows that fewer cigarettes would be sold in 2022 no matter if a ban is enacted or not. Prices are also expected to be higher.

6 Op. Cit., Footnote 2.

7 Levy, D.T., Meza, R., Yuan, Z., et al., *Public Health Impact of a U.S. Ban on Menthol in Cigarettes and Cigars: A Simulation Study*, Tobacco Control, September 2021, at: https://doi.org/10.1136/tobaccocontrol-2021-056604.

8 Ibid.

9 Levy, David T., et. al., *Public health implications of vaping in the USA: the smoking and vaping simulation Model*, Population Health Metrics, April 17, 2021, at: https://link.springer.com/article/10.1186/s12963-021-00250-7

10 See Methodology section.

299.2 million packs (8.1 percent) would be replaced through increased consumption of vapor products.[11]

In addition, 738.8 million packs of lost menthol sales (20.0 percent) would be made up for cigarettes sold on the black market, from purchases made in jurisdictions where menthol cigarettes were still legal, or from some form of self-production. About 956.7 million fewer packs of cigarettes would be sold overall, accounting for 25.9 percent of current menthol cigarette purchases, and about 9.4 percent of overall cigarette purchases. Based on these figures, Federal revenues from cigarette excise taxes would fall by roughly $1.3 billion annually.

Table 1

Estimated Changes in Purchases Following Implementation of Proposed Rule (Packs or Pack Equivalents)

SALES IMPACT (PACKS)	Total Cigarettes	Non-Menthol Cigarettes	Menthol Cigarettes	Vapor Products
Current Taxable Cigarette Sales	10,217,383,532	6,523,517,648	3,693,865,883	n/a
Post-Ban Shifts - Cigarette Packs	(1,994,687,577)	1,699,178,306	(3,693,865,883)	299,203,137
Post-Ban Shifts - Illicit Sales	738,773,177		738,773,177	
Post-Ban Net Change in Sales	(956,711,264)	1,699,178,306	(2,955,092,706)	299,203,137

Effect of the Proposed Rule on the Vapor Industry

An increase in sales equivalent to 299.2 million packs of cigarettes will benefit the vapor industry, as long as substitute products are still available. The FDA has granted only 41 out of millions of Premarket Tobacco Marketing Applications (PMTAs) requested. Of these, only 23 are for vapor products (ENDS).[12]

According to JDA's most recent economic impact analysis, the vapor industry creates 133,573 jobs in the United States, paying just over $7.0 billion in wages. The overall impact of the industry is nearly $22.1 billion.[13]

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[11] There are a wide range of vapor products including closed-system vapor products such as pods or disposables and open-system vapor products, predominately e-liquids. These products have a wide range of nicotine levels. The model assumes that vapor products equivalent to 299.2 million packs will be substituted for menthol cigarettes.

[12] *Premarket Tobacco Product Marketing Granted Orders*, Food and Drug Administration, at: https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders. Accessed July 27, 2022.

[13] *The Vapor Industry Economic Impact Study 2021*, Prepared for the Vapor Technology Association, by John Dunham & Associates, September 20, 2021, at: https://vta.guerrillaeconomics.net/res/Methodology.pdf

The addition of sales equal to 299.2 million packs of cigarettes would have a positive, albeit minor impact on the vapor industry. Based on the model developed by JDA for the VTA, the additional sales would result in 79 additional vapor manufacturing jobs, and 257 vapor product wholesaling and retailing jobs for a total of 336 direct jobs. These jobs would pay workers roughly $28.5 million in additional wages.

Once the full impact on the vapor industry is accounted for (including new supplier impacts, and impacts "induced" by the spending of the additional employees, the overall benefit to the vapor industry from the menthol cigarette ban would be 2,056 full-time equivalent jobs, paying $159.5 million in new wages. The overall benefit of these new vapor sales to the US economy would be $461.9 million.

Table 2

Estimated Impact of the Proposed Menthol Cigarette Ban on the Vapor Industry

ECONOMIC IMPACT	Jobs	Wages	Output
Vapor Manufacturing	79	$4,477,468	$12,515,758
Vapor Wholesaling	80	$10,733,224	$51,357,830
Vapor Retailing	177	$13,285,267	$12,515,758
Total Direct Impact	336	$28,495,959	$118,153,597
Supplier Impact	719	$74,626,710	$165,335,534
Induced Impact	1,001	$56,416,804	$178,427,688
Total	**2,056**	**$159,539,473**	**$461,916,819**

Methodology

JDA's Regulatory Assessment Model is an updated version of a multi-market demand model first developed by the American Economics Group (AEG) under contract with Philip Morris. It was completely rebuilt by Dr. Hyeyeon Park in 2001, and its structure was updated by JDA in 2019. It is designed to measure product sales in a multi-state market structure with differential pricing. The general methodology is a two-stage estimation of the demand equation linked to a non-linear programming model of import and export patterns.

Data for the model comes from the 2021 Economic Impact Model of the Nicotine Vapor Industry, as well as from the US Census Bureau, the Bureau of Economic Analysis, the Bureau of Transportation Statistics Commodity Flow Survey and JDA research. Caliper Corporation estimated distances between states.

Estimates what sales should be in each state are developed first. In this case, both demand and prices come directly from the Impact model. If cross-border sales were observable, the calculations would be complete; however, since they are not, the model must estimate them through non-linear programming techniques that solve the 51 demand functions simultaneously. The model adjusts the cross-price elasticities between states to balance the actual sales with expected demand.

In the case of this particular model, cigarette demand elasticities are calculated using a logarithmic demand curve with a base of -0.80 which is an average for cigarettes. It uses a weight ratio of $225.92 dollars per kilogram to determine the shape of the demand curve. The demand elasticity for menthol cigarettes is -0.87, and the cross-elasticity between cigarettes and menthol cigarettes is 0.59, meaning that the products are complementary goods. In this case, however, when a ban is being imposed, a substitution effect of 46 percent is used.[14]

Offsetting Effects of the Proposed Rule on Menthol Vapor Products

In its RIA, the FDA calculates that the equivalent of 299.2 million packs of menthol cigarettes currently being sold would be replaced through increased consumption of vapor.[15] This, of course, assumes that the FDA has not already banned menthol and other flavored vapor products as part of its Premarket Tobacco Product Application (PMTA) process. To date, the FDA has not approved a single menthol/mint flavored vapor product. In fact, the FDA has already ruled that the vapor product producer with the largest market share in the country (JUUL) must stop selling all its products, including menthol, and has only approved a small fraction of all the other vapor products in the marketplace.

According to the journal article used by the FDA to model the effects of the menthol ban, about 17.4 percent of menthol smokers would switch to vapor products. However, based on Wackowski (2015), if a ban on menthol cigarettes were to be imposed, 15 percent of smokers would switch to vapor products, and 4 percent would switch to other tobacco products.[16] This equates to the equivalent of 299.2 million additional packs of cigarettes that would be converted to vapor products.

Offsetting Effects of the Proposed Rule on Un-Taxed or Illicit Sales

In its RIA, the FDA does not directly calculate the potential for current menthol cigarette smokers to transition to black market or other illicit untaxed cigarette sales or menthol

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14 Cadham, Christopher, et. al., *The actual and anticipated effects of a menthol cigarette ban: a scoping review,* BMC Public Health, July 9, 2020, citing, Wackowski OA, et. al. *Switching to E-cigarettes in the event of a menthol cigarette ban,* Nicotine and Tobacco Research, October 2015.

15 Op Cit. Footnote 2. Note that the EPA calculates shifts in users. This was translated into shifts in sales in the JDA model.

16 Cadham, Christopher, et. al., *The actual and anticipated effects of a menthol cigarette ban: a scoping review,* BMC Public Health, July 9, 2020, citing, Wackowski OA, et. al. *Switching to E-cigarettes in the event of a menthol cigarette ban,* Nicotine and Tobacco Research, October 2015.

components. The FDA does provide some data (also from Levy) [17] that suggests that between zero and 6.5 percent of current menthol cigarette smokers would find a way to work around the ban by purchasing illicit products.[18]

JDA's model estimates that approximately 20 percent of the current menthol cigarette market would move from normal legal channels to some form of illicit channel as a result of the proposed rule. This estimate is based on the results of research conducted by the non-partisan Tax Foundation.[19] The Tax Foundation has been researching cigarette smuggling since at least as far back as 2017.

Using this as an assumption the JDA model forecasts that in addition to the current illegal cigarette market, an additional 738.8 million packs of menthol cigarettes (20 percent of current sales) would transition to the illicit market. This would include so-called *grey market* cigarettes, which are manufactured in the United States for export markets but find their way back into domestic consumption.[20] It would include duty-free cigarettes, cigarettes brought into the country legally by travelers, and cigarettes produced by foreign manufacturers and then illegally imported into US consumption.

In addition, it is expected that many menthol cigarette smokers will find workarounds by adding their own menthol ingredients to legally purchased non-menthol cigarettes

Finally, there is already a large black market in tobacco products which are manufactured illegally abroad by operations in China, North Korea, and other countries with less than stellar trademark protections.

The 738.8 million packs would be divided across these non-taxed or illicit channels; however, data are not available to determine exactly how this volume would break across each segment.

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17 Levy, D.T., et al., *An Expert Elicitation on the Effects of a Ban on Menthol Cigarettes and Cigars in the United States*, Nicotine & Tobacco Research, November 2021, at: https://doi.org/10.1093/ntr/ntab121.

18 Op. Cit., Footnote 2.

19 See: Walczak, Jared, *Comments on Tobacco Product Standard for Menthol in Cigarettes*, Tax Foundation, May 18, 2022; Boesen, Ulrik, *Cigarette Taxes and Cigarette Smuggling by State, 2019*, Fiscal Fact Number 782, Tax Foundation, November 2021; and Boesen, Ulrik, *Federal Menthol Cigarette Ban May Cost Governments $6.6 Billion*, Tax Foundation, March 2, 2022.

20 For a discussion of grey market products, see for example Kelly, Richard B., *An overview of the influx of grey market goods into the United States*, North Carolina Journal of International Law and Commercial Regulation, 1986.

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