Juul Labs®

Parker D. Kasmer
Senior Vice President
Regulatory Affairs

August 2, 2022

Electronic Submission

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. FDA-2021-N-1349; Comment on Tobacco Product Standard for Menthol in Cigarettes

To whom it may concern:

Juul Labs, Inc. (JLI or the Company; we or our)[1] appreciates the opportunity to provide comment to the Food and Drug Administration (FDA or the Agency) on its proposed rule that would prohibit menthol as a characterizing flavor in combustible cigarettes (Proposed Rule).[2]

While our comment provides data and analysis below, we summarize our position here: We support a science- and evidence-based approach to reduce the use of combustible tobacco products, including menthol cigarettes, as part of a comprehensive framework to advance tobacco harm reduction and reduce tobacco-related death and disease. To fully realize the public-health benefits of this measure, we believe it is critical to have a marketplace of viable, scientifically-substantiated, less harmful alternatives to move adult smokers (who have not or will not quit) down the continuum of risk. And this should include electronic nicotine delivery system (ENDS) products when supported by the data, particularly in options that appeal to menthol smokers as an effective off-ramp from combustible use.

[1] JLI is the manufacturer of the JUUL System, a closed, cartridge-based electronic nicotine delivery system (ENDS) that utilizes proprietary heating technology to aerosolize and deliver nicotine without combustion. The JUUL System is composed of the JUUL Device and JUULpods. JUULpods are pre-filled with a nicotine-containing e-liquid formulation, which varies by tobacco or menthol flavor and nicotine concentration. The JUUL System is marketed as an alternative for adult smokers to transition and completely switch them from combustible cigarettes.

[2] 87 Fed. Reg. 26454 (May 4, 2022).

I. INTRODUCTION

There are approximately 12 million adult menthol cigarette smokers in the United States, representing 37% of the adult-smoker population.[3] Should FDA determine, based on the science and evidence, that a tobacco product standard prohibiting menthol as a characterizing flavor in cigarettes is appropriate for the protection of public health, it could result in a historic public-health opportunity to reduce combustible use and shift the trajectory of tobacco-related death and disease. We support this approach. But we also believe that a robust marketplace of scientifically-substantiated, reduced-risk products is necessary to realize the public-health benefits of implementing this measure.

The Proposed Rule is an important step to further FDA's comprehensive framework for tobacco and nicotine regulation. Announced in 2017, the Agency sought to implement regulatory policies and programs to "better protect kids and significantly reduce tobacco-related disease and death" — a pillar of which is to "make tobacco products less toxic, appealing and addictive."[4] This framework also recognizes the need for an off-ramp of potentially less harmful, noncombustible alternatives for adult smokers and commits to "encouraging innovations that have the potential to make a notable public health difference and inform policies and efforts that will best protect kids and help smokers quit cigarettes."[5] That is, advancing tobacco harm reduction through product innovation and regulation.

In laying out the principles of its comprehensive framework — founded on the role of nicotine and a continuum of risk for tobacco and nicotine products — FDA made clear that its success required that "all of these steps must be done in concert and not in isolation."[6] Regulatory policies to *pull* currently addicted adult smokers from combustible products and, for those that have not or will not quit, *push* them towards noncombustible alternatives, while also mitigating the potential for underage use. Naturally, effectively communicating the differential health risks between noncombustible and combustible products is integral to this comprehensive and interconnected approach.

The public-health impact of the Proposed Rule depends, in part, on how adult menthol smokers respond to the removal of menthol cigarettes from the market.[7] These

---

[3] Centers for Disease Control and Prevention, Menthol Tobacco Products, http://bitly.ws/t4ju (last accessed July 31, 2022).

[4] FDA, Press Release, FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death (July 27, 2017), available at https://bit.ly/3jcCGhT.

[5] *Id.*

[6] *Id.*; S. Gottlieb & M. Zeller, A Nicotine-Focused Framework for Public Health, New England J Med (2017) ("In working toward this vision, the FDA is committed to striking an appropriate balance between protecting the public and fostering innovation in less harmful nicotine delivery.").

[7] For brevity throughout, we use the term "menthol cigarettes" to denote combustible cigarettes with menthol as a characterizing flavor. We recognize that it is possible for cigarettes to contain menthol as an ingredient which may not be characterizing.

smokers would be "in the wind" and faced with a variety of behavioral options. These include:

- Quit the use of all tobacco and nicotine-containing products;
- Switch to potentially less harmful, noncombustible alternatives;
- Smoke nonmenthol combustible cigarettes; or
- Continue smoking menthol cigarettes obtained through illicit sources.

The best option would be for adult menthol smokers to quit using tobacco and nicotine altogether. And many will, but many others will not. Those who are unable or unwilling to quit will either choose to smoke other combustible products or can switch to less harmful, noncombustible alternatives. To *push* the latter and preferred public-health option of the two, these smokers need available and appealing noncombustible products, so that they are *pulled* from more harmful combustible use.

The concern that many adult menthol smokers will continue using combustible products is real and substantiated by real-world data. In the face of a potential ban on menthol cigarettes, studies show that many adult menthol smokers intend to use nonmenthol cigarettes instead.[8] Following the implementation of a menthol ban, other studies show that menthol smokers do just that and more: They not only smoke nonmenthol cigarettes but they do so at higher rates than predicted by behavioral-intention studies.[9]

Thus, the potential public-health benefit of ENDS and other noncombustible alternatives for adult menthol smokers. Here, studies show interest in and switching to ENDS products among adult menthol smokers — eliminating or significantly reducing combustible use.[10] More notably, while flavored products appeal across adult smokers, menthol-/mint-flavored ENDS products are differentially preferred by adult menthol smokers and positively impact switching from combustible cigarettes.[11]

The availability of appealing, scientifically-substantiated, noncombustible alternatives as an off-ramp for adult menthol smokers is critical. As critical though, these

---

[8] C. Cadham, et al., The Actual and Anticipated Effects of a Menthol Cigarette Ban: A Scoping Review, BMC Public Health, 20(1):1055 (2020).

[9] O. Wackowski, et al., Switching to E-Cigarettes in the Event of a Menthol Cigarette Ban, Nicotine Tob Res 17, 1286 (2015); C. Carpenter & H. Nguyen, Intended and Unintended Effects of Banning Menthol Cigarettes, J Law Econ (2021).

[10] C. Shang, et al., E-cigarette Product Preferences Among Adult Smokers: A Discrete Choice Experiment, Tob Reg Sci 6, 66 (2020).

[11] B. Rostron, et al., ENDS Flavor Preference by Menthol Cigarette Smoking Status Among US Adults, 2018–2019, Int J Environ Res Public Health 18, 240 (2020).

smokers — who otherwise may continue combustible use — need clear, accurate, science-based information on the role of nicotine and relative health risks between noncombustible and combustible products. Otherwise, why would an adult menthol smoker change their entrenched tobacco-use behavior and switch to a different product if there is no benefit to be gained?

Common sense dictates, and research bears out, that adult smokers are unlikely to switch to a less harmful product if they do not perceive such products to be, in fact, less harmful. For example, adult smokers who misperceive ENDS to be *as or more harmful* than cigarettes are far less likely to switch to these noncombustible products compared to those who correctly perceive ENDS *as less harmful* than cigarettes.[12] These misperceptions are not in the abstract. Today, the majority of adult smokers incorrectly believe that ENDS products are as or more harmful than the combustible cigarettes they are currently using.[13] Risk misperceptions negatively impact switching to less harmful alternatives; correcting these perceptions can have a positive effect and move adult smokers down the continuum of risk.[14] The same applies to menthol smokers.

Below we provide data, evidence, and analysis in support of the Proposed Rule as part of a science-based, comprehensive framework to advance tobacco harm reduction and reduce tobacco-related death and disease. First, we highlight how, with a menthol ban, many adult menthol smokers may move to other combustible products like nonmenthol cigarettes. Second, we detail the real-world impact of ENDS products for adult smokers generally. Third, we discuss the effect of ENDS products for menthol smokers specifically, particularly the importance of menthol-/mint-flavored products to transition and completely switch them from combustible use. And fourth, we assess the role of misperceptions on nicotine and relative risk and their impediment to changing tobacco-use behaviors and realizing public-health goals shared by the Proposed Rule.

The Proposed Rule, if implemented, should not exist in a vacuum. Doing so would marginalize its potential and significant public-health opportunity. Such a measure should be driven by the science and evidence and supported by both a robust marketplace of viable, noncombustible alternatives and effective communications on their differential

---

[12] A. Persoskie, et al., Perceived Relative Harm of Using E-cigarettes Predicts Future Product Switching Among US Adult Cigarette and E-cigarette Dual Users, Addiction 114, 2197 (2019).

[13] L. Malt, et al., Perception of the Relative Harm of Electronic Cigarettes Compared to Cigarettes Amongst US Adults from 2013 to 2016: Analysis of the Population Assessment of Tobacco and Health (PATH) Study Data, Harm Reduction J 17:65 (2020); J. Huang, et al., Changing Perceptions of Harm of E-cigarette vs Cigarette Use Among Adults in 2 US National Surveys from 2012 to 2017, JAMA Network 2(3):e191047 (2019).

[14] S. Shiffman, et al., Perceived Safety and Efficacy of Nicotine Replacement Therapies Among US Smokers and Ex-smokers: Relationship with Use and Compliance, Addiction 103(8):1371(2008); S. Ferguson, et al., Providing Accurate Safety Information May Increase a Smoker's Willingness to Use Nicotine Replacement Therapy as Part of a Quit Attempt, Addictive Behaviors 36(7):713 (2011).

health risks compared to combustible products. This comprehensive, pull-push strategy will ensure the public-health benefits of implementing the Proposed Rule are realized and set us on a path to an endgame in which combustible-cigarette use no longer exists in the United States.

II. THE EFFECT OF PROHIBITING MENTHOL CIGARETTES OUTSIDE A COMPREHENSIVE FRAMEWORK

A. Many Adult Menthol Smokers Intend to Use Nonmenthol Cigarettes If Menthol Cigarettes Were Banned

The intent of the Proposed Rule is to decrease initiation and increase cessation of a combustible product by reducing the appeal of a combustible cigarette.[15] Various studies, however, show that when confronted with a potential menthol ban in cigarettes, adult menthol smokers intend to continue using combustible products and, more often, simply smoke nonmenthol cigarettes instead. These include surveys, discreet-choice experiment, structured interviews, and interventions — all assessing the intended tobacco-use behaviors if menthol cigarettes were removed from the market.

For example, using the Truth initiative Young Adult Cohort from 2011–2016, Rose et al. surveyed young adult menthol smokers (aged 18–34 years) and asked the question "If menthol cigarettes were no longer sold, which of the following would you most likely do?"[16] Across several waves of the survey, an average of 32.3% of respondents said that they would smoke nonmenthol cigarettes. This was the most frequent response, followed by "don't know," which comprised 30.8% of respondents. 25.3% of respondents indicated an intention to quit all tobacco products and 10.7% indicated they would switch to another tobacco product. The researchers found that the proportion of respondents intending to switch to another tobacco product in response to a menthol ban increased over the survey.[17]

The researchers stated: "Food and Drug Administration review and regulation of products such as e-cigarettes is critical so that, should a menthol ban take effect, smokers who cannot quit will move to less harmful alternatives rather than other combustibles."[18]

Wackowski et al. conducted a survey among 519 adult menthol smokers, drawn from a nationally-representative panel, on tobacco-use intentions in light of a potential

---

[15] 87 Fed. Reg. at 26455.

[16] S. Rose, et al., Longitudinal Response to Restrictions on Menthol Cigarettes Among Young Adult US Menthol Smokers, 2011–2016, Am J Public Health 109, 1400 (2019).

[17] *Id.*

[18] *Id.*

menthol ban.[19] When respondents were asked "If menthol cigarettes were no longer sold, which of the following would you most likely do" almost half (45.9%) indicated that they would smoke nonmenthol cigarettes and 28.4% stated an intention to quit all tobacco products. 15.1% of respondents stated that they would "switch to menthol e-cigarettes."[20]

The researchers concluded:

> [W]hile quitting all tobacco products would be an ideal policy effect, switching to e-cigarettes could still provide a public health benefit from a harm reduction perspective. Furthermore, given the cessation difficulty associated with menthol cigarettes, it is possible that menthol e-cigarettes may make quitting menthol tobacco cigarettes easier and help prevent switching to some more harmful form of tobacco.[21]

In its "Review of Studies Assessing the Potential Impact of Prohibiting Menthol as a Characterizing Flavor in Cigarettes," FDA conducted a thorough review of the scientific evidence on the behavioral intentions of adult menthol smokers if menthol cigarettes were banned.[22] The Agency identified ten studies evaluating the intentions of menthol smokers to smoke nonmenthol cigarettes should menthol cigarettes be prohibited. FDA summarized the data stating "that fewer than 50% (estimates from 14.7%–45.9%) of menthol cigarette smokers intend to switch to non-menthol cigarettes in the event of a menthol cigarette ban."[23]

"Fewer than 50%" equates to millions of adult menthol smokers. Based on the Agency's review of tobacco-use intentions, with approximately 12 million adult current menthol smokers in the United States, between 1.8–5.6 million of them intend to smoke nonmenthol cigarettes following the implementation of a ban for menthol cigarettes.

B. Many Adult Smokers Would Smoke Nonmenthol Cigarettes If Menthol Cigarettes Were Banned

The above research on tobacco-use intentions if a menthol ban were implemented show smoker intent to move to nonmenthol cigarettes. Real-world data following the implementation of similar menthol bans confirm this intent with actual use of nonmenthol cigarettes.

---

[19] O. Wackowski, et al., Switching to E-Cigarettes in the Event of a Menthol Cigarette Ban, Nicotine Tob Res 17, 1286 (2015).

[20] *Id.*

[21] *Id.*

[22] FDA, Review of Studies Assessing the Potential Impact of Prohibiting Menthol as a Characterizing Flavor in Cigarettes (April 2022), available at https://www.fda.gov/media/157643/download.

[23] *Id.*

Bans on the sale of menthol cigarettes have been enacted in certain U.S. states and localities, as well as outside the United States. Studies have assessed the effect of these policies on smoking prevalence and cigarette-sales volumes to estimate their public-health impact. In turn, these findings provide real-world data on how adult menthol smokers responded to menthol bans and inform projections of what adult menthol smokers would do if a ban were implemented nationally in the United States. Generally, these data show that, following a menthol ban, many smokers would still use combustible products, particularly nonmenthol cigarettes.

For example, in June 2020, Massachusetts banned the sale of all "flavored" tobacco products, including menthol cigarettes. Asare et al. estimated the impact of this policy on cigarette sales, comparing sales trends among Massachusetts and surrounding states that did not implement similar bans.[24] The researchers reported a significant decline in cigarette-sales volumes in Massachusetts: 282.65 packs per 1,000 people relative to comparator states in the year following the Massachusetts policy.[25]

But the researchers also found that "[n]onflavored cigarette sales in Massachusetts vs the comparison states increased after the ban, suggesting the potential substitution of nonflavored cigarettes for menthol cigarettes." Specifically, nonflavored cigarette sales in Massachusetts were 120.25 packs per 1,000 people higher than in comparator states.[26] Over the same period, menthol cigarette sales in Massachusetts declined by 372.27 packs per 1,000 people, suggesting that 32% of the menthol cigarette-sales volumes in Massachusetts shifted to nonmenthol cigarettes.

The researchers identified limitations of their analysis, including that "cross-border or online cigarette sales in Massachusetts were not accounted for." [27] Apart from the study, Massachusetts' Multi-Agency Illegal Tobacco Task Force (Task Force) believed that the volume of illicit tobacco products, including menthol cigarettes, entering Massachusetts from neighboring states could be significant.[28] In its 2022 annual report, the Task Force found that:

> The increase in seizures of flavored ENDS products and menthol cigarettes combined with the decrease in revenue for cigarettes and [other tobacco products] likely indicates increased cross-border smuggling of these products. Several neighboring states, including New Hampshire, Rhode Island, and Vermont, have reported an increase in tobacco revenue related to cigarettes

---

[24] S. Asare, et al., Association of Cigarette Sales with Comprehensive Menthol Flavor Ban in Massachusetts, JAMA Internal Med 182, 231 (2022).

[25] *Id.*

[26] *Id.*

[27] *Id.*

[28] Multi-Agency Illegal Tobacco Task Force, Annual Report of Multi-Agency Illegal Tobacco Task Force (March 2022), available at https://www.mass.gov/doc/task-force-fy22-annual-report/download.

> and [other tobacco products] during the past year. For example, cigarette excise tax revenue increased approximately 15% between FY20 and FY21 in New Hampshire.[29]

Collectively, the data show that many adult menthol smokers continued using combustible products (nonmenthol cigarettes or illicit menthol cigarettes) following the implementation of Massachusetts' flavor ban that included menthol cigarettes. Sales of nonmenthol cigarettes increased in Massachusetts compared to surrounding states and cross-border smuggling of menthol cigarettes into Massachusetts increased from surrounding states.

Outside the United States, the Canadian province of Ontario banned menthol cigarettes in January 2017. To evaluate the policy's impact on smoking cessation, Chaiton et al. prospectively followed a cohort of Ontario residents aged 16-years and older who reported current smoking at baseline in late 2016 and were evaluated for smoking outcomes at follow-up in 2018 after the menthol ban took effect.[30] Smoking outcomes included quit attempts and quitting (quit for approximately one-year post-ban).[31] These outcomes are summarized in Table 1 below.

Table 1 Proportion of Smokers Reporting Quit Attempts and Quitting After Ontario's Ban of Menthol Cigarettes

Baseline Menthol Status	Attempted to Quit	Quit 1-Year Post-Ban
Daily menthol	63%	24%
Occasional menthol	62%	20%
Nonmenthol	43%	14%

The researchers also conducted regression models between menthol-smoking status and reported quitting following the menthol ban. In the model adjusted for factors impacting smoking cessation, the adjusted rate ratio for daily menthol smokers compared to nonmenthol smokers was 1.62. The researchers concluded that there was a "significantly higher rate of reported smoking cessation one year after the menthol ban for baseline daily menthol smokers when compared to nonmenthol smokers."[32]

These results are consistent with a public-health benefit resulting from prohibiting the sale of menthol cigarettes — facilitating quit attempts and actual quitting of combustible use. The study, however, highlighted that the vast majority of menthol

[29] *Id.*

[30] M. Chaiton, et al., Ban on Menthol-Flavoured Tobacco Products Predicts Cigarette Cessation at 1 Year: A Population Cohort Study, Tob Control 29, 341 (2020).

[31] *Id.*

[32] *Id.*

smokers did not actually quit smoking: 76% of menthol smokers continued smoking combustible products (either nonmenthol cigarettes or menthol cigarettes largely obtained from First Nations Reserves).[33]

By 2018, all Canadian provinces prohibited the sale of menthol cigarettes, with a national ban implemented in 2017 to cover the remaining provinces. Since then, economic analysis of smoking prevalence in Canada show that most adult menthol smokers continued smoking cigarettes following these measures.

Carpenter and Nguyen used a difference-in-differences analysis to compare smoking prevalence in Canadian provinces that prohibited the sale of menthol cigarettes before the national ban in 2017 with those provinces that did not. [34] Smoking-prevalence data at the provincial level was obtained through the Canadian Tobacco, Alcohol and Drugs Survey (CTADS), which is administered biannually and representative. The researchers noted that "[d]ifference-in-differences models using national survey data return no evidence that provincial menthol cigarette bans affected overall smoking rates for youths or adults."[35]

The researchers also found "no evidence of substitution from menthol to nonmenthol cigarette smoking or substitution to e-cigarettes in response to provincial menthol bans."[36] Rather, the results indicated that many adult menthol smokers obtained menthol cigarettes from First Nations Reserves (where the ban did not apply). The researchers stated that:

> Menthol bans are associated with statistically significant increases in the likelihood that a respondent reported purchasing cigarettes on or from a First Nations reserve in the previous 6 months, an effect on the order of 4.3 percentage points. This is very large relative to the prereform mean and is most consistent with substitution behavior from regulated to unregulated sources.[37]

The European Union (EU) implemented a ban on the sale of menthol cigarettes in May 2020. Liber et al. used monthly Nielsen cigarette sales data collected between May 2018 and April 2021 to evaluate the impact of the menthol ban on cigarette sales in

---

[33] *Id.*

[34] C. Carpenter & H. Nguyen, Intended and Unintended Effects of Banning Menthol Cigarettes, J Law Econ (2021).

[35] *Id.*

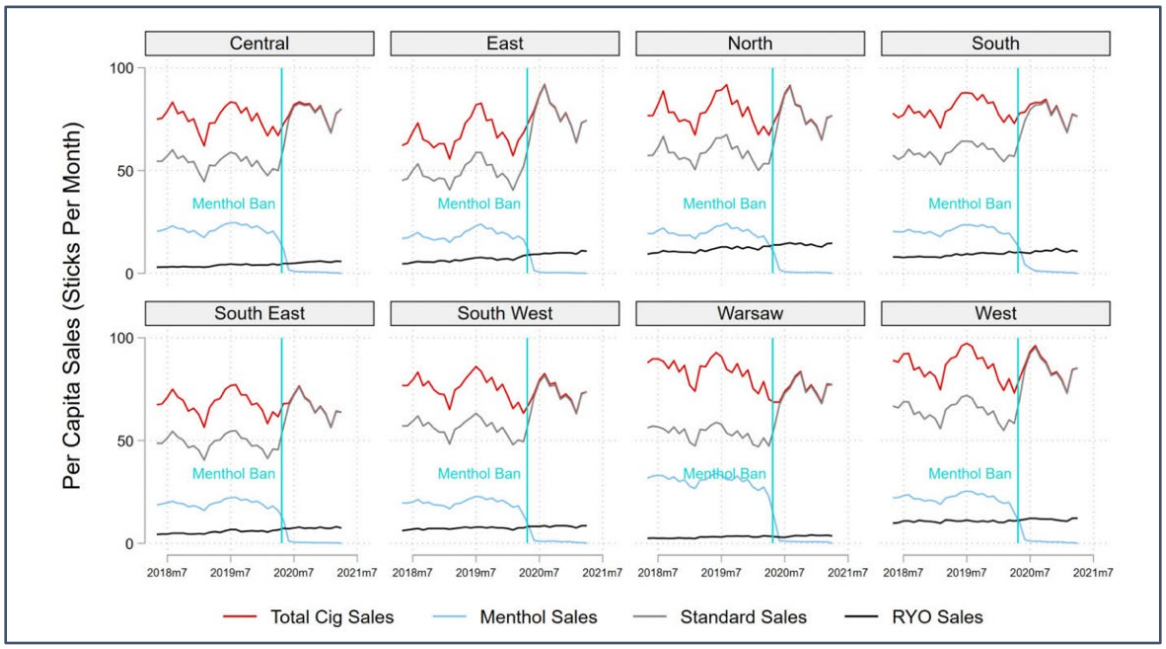
[36] *Id.*

[37] *Id.*

Poland.[38] Before the ban, Poland had the highest prevalence of menthol smokers (30%) among EU member nations and 28% of cigarettes sold in Poland were menthol.[39]

The researchers found that, following implementation of the menthol ban, menthol cigarette sales declined by 97% but total cigarette sales declined by only 2.9%, which was not statistically significant.[40] The changes in the sales of all cigarettes — menthol, nonmenthol, and roll-your-own (RYO) — in Poland following the menthol ban are shown by region in Figure 1 below. The researchers concluded that "total cigarette sales have not significantly changed" in Poland — presumably the country expected to see the most significant impact given its high prevalence of menthol cigarettes.[41]

Figure 1 Trends in Cigarette Sales by Region in Poland Following Implementation of a Ban on Menthol Cigarettes



Real-world data following the implementation of menthol bans provide both directional insights and evidence of actual impact. While a nationwide menthol ban in the United States should decrease initiation of menthol cigarettes and increase smoking cessation, we will fall far short of realizing the full public-health potential absent a comprehensive approach that accounts for noncombustible alternatives. As the data show,

[38] A. Liber, et al., An Analysis of Cigarette Sales During Poland's Menthol Cigarette Sales Ban: Small Effects with Large Policy Implications, European J Public Health, 1–6 (2022).

[39] *Id.*

[40] *Id.*

[41] *Id.*

many adult menthol smokers will continue using combustible products — more often smoking nonmenthol cigarettes instead.

Implementing the Proposed Rule within a comprehensive framework that not only pulls adult smokers from combustible use but pushes "non-quitters" to potentially less harmful alternatives advances this public-health opportunity.

III. A SUMMARY OF THE REAL-WORLD IMPACT OF ENDS PRODUCTS FOR ADULT SMOKERS

Noncombustible alternatives, substantiated by science and evidence, can provide currently addicted adult smokers an off-ramp from combustible use. And the public-health benefits of pushing these smokers to a less harmful form of nicotine delivery can be significant. One out of every two long-term smokers will die prematurely from tobacco-related disease.[42] Currently, there are approximately 38 million users of combustible products, 31 million users of combustible cigarettes, and 12 million users of menthol cigarettes.[43]

ENDS products are one example among other noncombustible options, including smokeless tobacco products, heated tobacco products, and oral tobacco-derived nicotine products (e.g., nicotine pouches), in addition to FDA-approved nicotine-containing cessation products. Although relative risk is product specific, the current state of evidence (and FDA marketing authorizations) shows that adult smokers who switch to ENDS products substantially reduce their exposure to harmful chemicals compared to combustible cigarettes. But that is only step one. A reduction in individual health risk has limited public-health benefit unless adult smokers are actually using these products to transition and switch completely from cigarettes.

Through evolving in-market data and research, we are starting to see just that. Specifically, four lines of evidence are converging and showing the real-world impact of ENDS products for adult smokers:

- Market data show accelerated declines in cigarette sales following the growth of ENDS;
- Population-level data show adult smokers transitioning and completely switching from cigarettes to ENDS;
- Behavioral and economic data show ENDS as substitutes for cigarettes; and

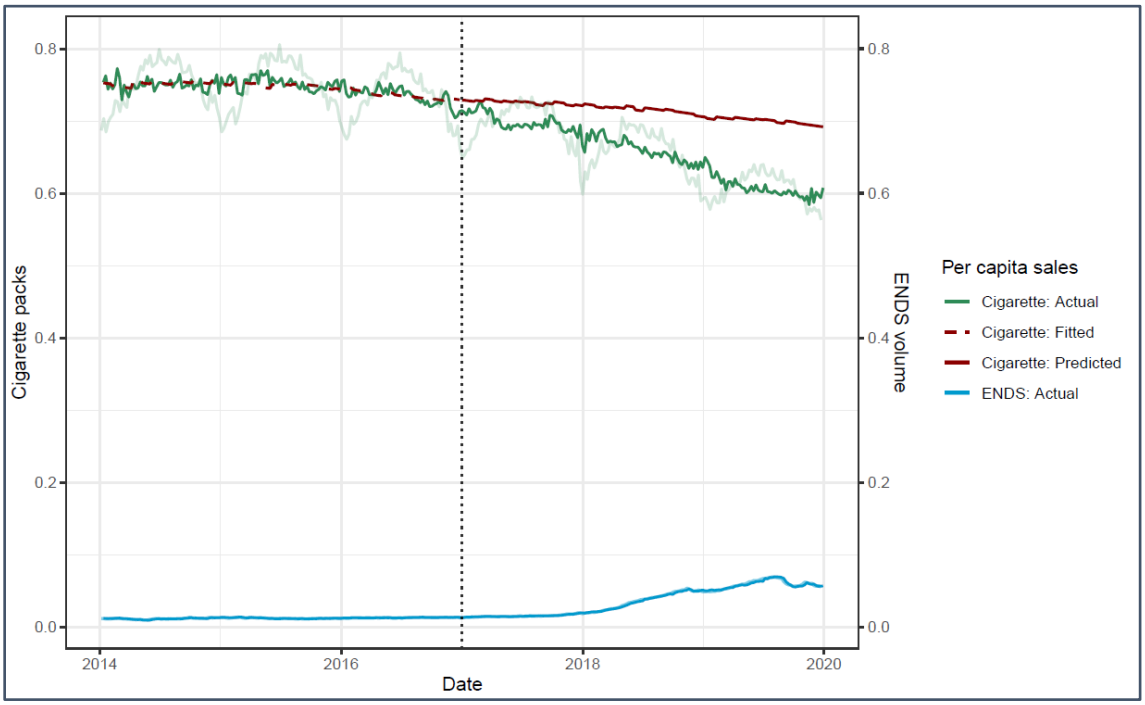
[42] U.S. Department of Health and Human Services, The Health Consequences of Smoking: 50 Years of Progress, A Report of the Surgeon General, Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014. Printed with corrections, Jan. 2014.

[43] M. Cornelius, et al., Tobacco Product Use Among Adults – United States, 2020, 71 Morbidity and Mortality Weekly Report 397, 398 (March 18, 2022).

- Population models show ENDS accelerating the decline of cigarette smoking — resulting in a net-population benefit.

First, analysis of U.S. sales data is consistent with the growth of ENDS sales resulting in significant and measurable declines in cigarette-sales volumes. Selya et al. used Information Resources, Inc. (IRI) data, capturing cigarette and ENDS sales from a national sample of retail outlets, to correlate the changes in cigarette sales with changes in ENDS sales from 2014–2019 (Figure 2 below).[44] The researchers calculated that every unit of ENDS sold displaced the sale of 1.4–1.5 cigarette packs and show that cigarette sales are 16% lower than would be expected following the growth of ENDS sales between 2017–2019.[45]

Figure 2 Actual Sales of Cigarette Packs and ENDS Units Per Capita and Projected Cigarette Sales



Second, the finding that ENDS sales are displacing cigarette sales is supported by population-level data demonstrating that adult smokers are transitioning and completely switching from combustible cigarettes to ENDS products. An analysis of the ITC Four Country Smoking and Vaping Survey showed that, among adult current smokers and recent

[44] A. Selya, et al., US Sales of Electronic Nicotine Delivery Systems (ENDS) Are Associated with Declines in Cigarette Sales, J Consumer Policy (2022), *in review.*

[45] *Id.*

former smokers, 11.4% reported current use of ENDS products.[46] Among recent former smokers aggregated across the four countries surveyed (U.S., Canada, England, and Australia), 21.3% reported current use of ENDS products.[47]

A more recent analysis of the ITC Four Country Smoking and Vaping Survey showed that daily ENDS use was associated with a greater likelihood of quit attempts and cigarette-smoking cessation among adults.[48] Here, the researchers conducted a longitudinal analysis across three waves (2016, 2018, and 2020) among respondents who, at baseline, were daily cigarette smokers and had not used an ENDS product (i.e., exclusive cigarette smokers). Findings included:

- "Respondents who initiated vaping between surveys (at any frequency) were more likely to have made a quit attempt . . . compared to those who did not initiate vaping."

- "Based on frequency of vaping, those who initiated daily vaping and made a quit attempt, were significantly more likely to have quit smoking . . . compared to those who made a quit attempt but did not initiate vaping."

- "Regardless of whether respondents made a quit attempt or not, those who initiated (at any frequency) vaping were more likely to have quit smoking by follow-up . . . compared to those who did not initiate vaping."

- "Respondents who initiated daily vaping were significantly more likely to have quit smoking . . . than those who did not . . . ."[49]

The researchers concluded: "[A]mong adults who smoke daily, and are likely highly dependent on nicotine, the initiation of daily [ENDS] use was associated with increased quit attempts and abstinence from smoking. Those who continued to vape daily across time, were the most successful at quitting smoking."[50]

Use of ENDS products also is strongly associated with increased odds of cigarette-smoking cessation among adults *who had no intentions to quit cigarettes*. Using Waves 2–5 of FDA's Population Assessment of Tobacco and Health (PATH) Study, Kasza et al. identified

---

[46] L. Lin, et al., Patterns of Non-Cigarette Tobacco and Nicotine Use Among Current Cigarette Smokers and Recent Quitters: Findings From the 2020 ITC Four Country Smoking and Vaping Survey, Nicotine Tob Res, 23(9):1611–1616 (2021).

[47] *Id.*

[48] S. Gravely, et al., Differences in Cigarette Smoking Quit Attempts and Cessation Between Adults Who Did and Did Not Take Up Nicotine Vaping: Findings from the ITC Four Country Smoking and Vaping Surveys, Addictive Behaviors (2022).

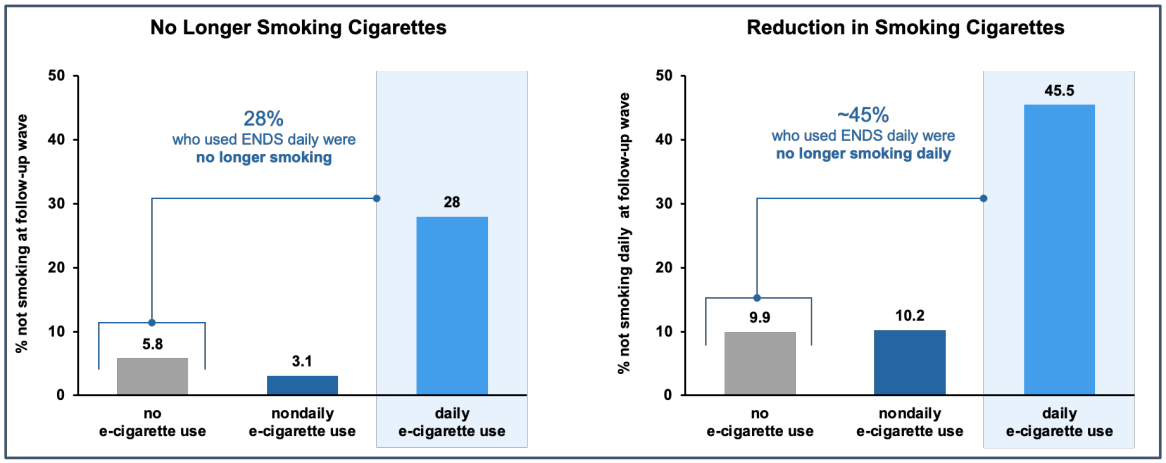
[49] *Id.*

[50] *Id.*

adult daily smokers who, at baseline, did not use ENDS products and answered "No" to the question "Do you plan to ever quit [cigarettes/tobacco] for good?"[51] In subsequent waves of this longitudinal study, the researchers assessed smoking cessation and current ENDS use among this group.[52]

Among baseline adult smokers who did not plan to quit and who subsequently began using ENDS daily, 28.0% quit smoking cigarettes. In contrast, among those who reported no subsequent use of ENDS, only 5.8% quit smoking cigarettes. The researchers found that those adult smokers not planning to quit who subsequently used ENDS daily were eight times as likely to quit smoking cigarettes as those who did not use ENDS products. Further, those who used ENDS daily were almost ten times as likely to no longer smoke cigarettes daily as those who did not use ENDS products (Figure 3 below).[53]

Figure 3 Daily ENDS Use Increases Cigarette-Smoking Cessation and Reduces Cigarette Consumption Among Adult Smokers Not Planning to Quit



Third, modeling of population-level data show that the availability and uptake of ENDS products has resulted in significant declines in cigarette sales and smoking prevalence — resulting in a net-population benefit. Levy et al. used their Smoking and Vaping Model (SAVM) to estimate the impact of ENDS products on cigarette-smoking rates and smoking/vaping attributable mortality in the United States by comparing model outcomes under scenarios with and without ENDS products in the U.S. market.[54] The National Health Interview Survey (NHIS) provided cigarette-smoking and ENDS use

[51] K. Kasza, et al., E-Cigarette Flavors and Frequency of E-Cigarette Use Among Adult Dual Users Who Attempt to Quit Cigarette Smoking in the United States: Longitudinal Findings from the PATH Study 2015/16–2016/17, Int J Environ Res Public Health, 18(8):4373 (2021).

[52] *Id.*

[53] *Id.*

[54] D. Levy, et al., Public Health Implications of Vaping in the USA: The Smoking and Vaping Simulation Model, Population Health Metrics 19 (2021).

prevalence inputs and FDA's PATH Study provided age-group specific transition probabilities between ENDS products and combustible cigarettes.[55]

The researchers estimated that, without ENDS products, adult smoking prevalence in 2023 would be 17.4% for males and 12.7% for females. In the model specification with ENDS products, adult smoking prevalence in 2023 would drop to 12.9% for males and 10.1% for females. The lower smoking prevalence under the scenario with ENDS products resulted in an estimated 7,050 fewer smoking and vaping attributable deaths in 2023 alone compared to the model scenario without ENDS in the U.S. market. As referenced by FDA in the Proposed Rule, extending the models from 2013 to 2060 with ENDS products in the market projects "654,000 premature deaths and 11,300,000 life-years lost averted by 2060."[56]

Real-world data and evidence show that ENDS products are viable alternatives for adult smokers, displace cigarette sales and use, and can have a significant public-health benefit by reducing tobacco-related mortality and morbidity. By implementing the Proposed Rule, the real-world impact of ENDS products for adult smokers can be further realized and accelerated if they are available in offerings that appeal to menthol smokers.

IV. THE ROLE OF ENDS PRODUCTS FOR ADULT MENTHOL SMOKERS

A. Data Show Adult Menthol Smokers Transitioning and Completely Switching from Combustible Cigarettes to ENDS Products

The available science and evidence demonstrate that adult menthol smokers switch from combustible cigarettes to ENDS products. For example, Cook et al. analyzed longitudinal data from Waves 1–4 of FDA's PATH Study to evaluate the association between cigarette-smoking cessation and ENDS use among adult menthol smokers.[57] Relative to nonmenthol-cigarette use, menthol-cigarette smoking was significantly associated with lower odds of smoking cessation. Among all smokers, however, current ENDS use was associated with significantly increased odds of smoking cessation. The relationship between menthol-cigarette smoking and ENDS use was significant and positive, indicating that adult menthol smokers who currently used ENDS products were more likely to quit smoking cigarettes than nonmenthol smokers/current ENDS users (Figure 4 below).[58]

The researchers concluded: "Our results suggest that a menthol smoking ban may have a favorable impact on smoking cessation for [non-Hispanic] Black adults. In addition,

---

[55] *Id.*

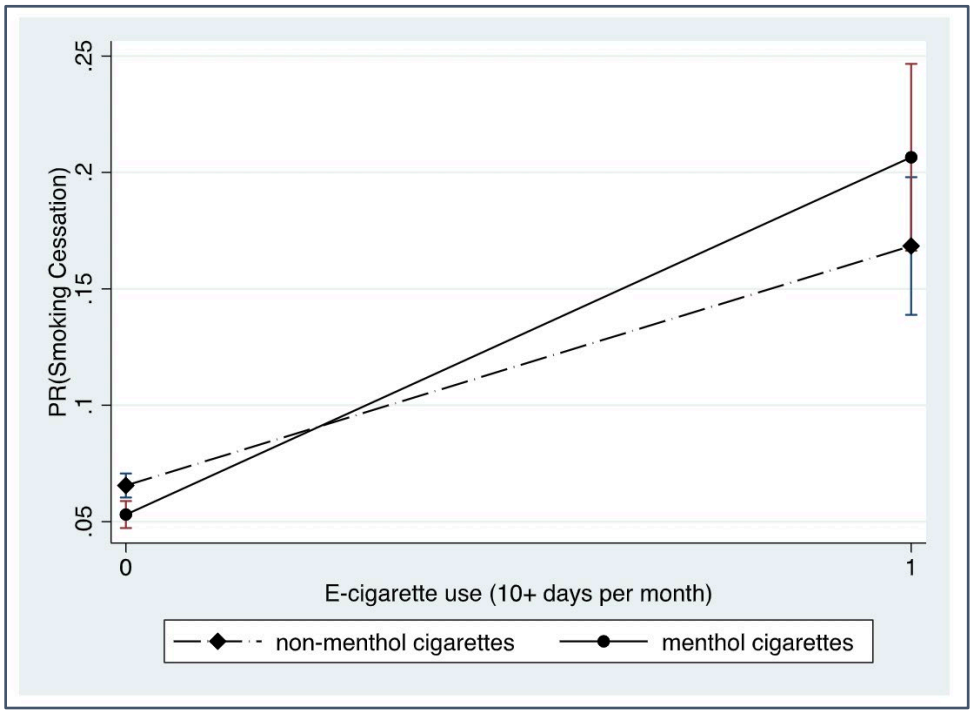
[56] *Id.*; 87 Fed. Reg. at 26481.

[57] S. Cook, et al., A Longitudinal Study of Menthol Cigarette Use and Smoking Cessation Among Adult Smokers in the US: Assessing the Roles of Racial Disparities and E-cigarette Use, Prev Med 154:106882 (2022).

[58] *Id.*

our results also suggest that a menthol smoking ban may be more effective if menthol smokers have access to e-cigarettes as a way to quit cigarette use."[59]

Figure 4 Predicted Probability of Cigarette-Smoking Cessation for Menthol and Non-Menthol Smokers by Regular E-Cigarette Use (10+Days Per Month)



Additional analysis of the PATH Study (Wave 4) indicated that adult menthol smokers are significantly more likely to report current use of ENDS products than nonmenthol smokers.[60] Notably, researchers in this study reported striking differences in ENDS flavor preference between menthol and nonmenthol smokers. Compared to nonmenthol smokers who reported current ENDS use, menthol smokers who currently used ENDS products were far more likely to use menthol-/mint-flavored ENDS products and significantly less likely to use tobacco-flavored ENDS products. There also were differences in ENDS flavor preference among cigarette smokers by race/ethnicity, with Hispanics and non-Hispanic Blacks more likely than non-Hispanic Whites to use menthol-/mint-flavored ENDS products. Menthol smokers were significantly more likely than

[59] *Id.*

[60] K. Bold, et al., Examining the Potential Role of E-cigarettes to Reduce Health Disparities Associated with Menthol Cigarette Use: Characterizing E-cigarette Use, Flavors, and Reasons for Use Among US Adults Smoking Menthol Cigarettes, Drug Alcohol Depend, 236:109475 (2022).

nonmenthol smokers to endorse that they used ENDS products because they came "in flavors I like."[61]

The researchers concluded: "[M]enthol flavored e-cigarettes may be important for adults who smoke menthol cigarettes."[62]

Researchers from FDA's Center for Tobacco Products (CTP) used the 2018–2019 Tobacco Use Supplement to the Current Population Survey (TUS-CPS) to evaluate ENDS flavor preferences among recent former smokers (i.e., switchers).[63] They found that a large proportion (41.4%) of switchers who had previously smoked menthol cigarettes reported current use of menthol- or mint-flavored ENDS products. A much smaller proportion (18.4%) of these former menthol smokers reported use of tobacco-flavored ENDS products. Among switchers who had previously smoked nonmenthol cigarettes, 21.5% reported use of menthol- or mint-flavored ENDS products while 26.7% reported use of tobacco-flavored ENDS products.[64]

The researchers concluded: "[M]enthol cigarette smokers are particularly likely to use menthol or mint-flavored e-cigarettes compared to nonmenthol smokers. This association may inform efforts to identify product characteristics that encourage adult smokers to transition from combusted tobacco use."[65]

The results of a recently published randomized clinical trial conducted among Black and Hispanic adult smokers, over half of whom were menthol smokers, further supports that ENDS products facilitate switching from combustible cigarettes among these populations.[66] Study participants were randomized to either use JUUL ENDS products for six weeks or to continue smoking cigarettes as usual. Participants in the treatment group (JUUL-product use) were provided free product in the flavor of their choice. Over half of these participants selected menthol- or mint-flavored JUUL products. The primary outcome measure was reduction in exposure to cigarette smoke toxicants, measured by urinary 4-

[61] *Id.*

[62] *Id.*

[63] B. Rostron, et al., ENDS Flavor Preference by Menthol Cigarette Smoking Status Among US Adults, 2018-2019, Int J Environ Res Public Health 18, 240 (2020). Switchers were defined as respondents who had smoked 100 cigarettes in their life, had smoked in the past twelve months, and now reported smoking "not at all."

[64] For both former menthol and nonmenthol smokers, the remainder used flavors other than tobacco or menthol.

[65] *Id.*

[66] K. Pulvers, et al., Effect of Pod e-Cigarettes vs Cigarettes on Carcinogen Exposure Among African American and Latinx Smokers: A Randomized Clinical Trial, JAMA Network Open, 3(11) (2020).

(methylnitrosamino)-1-(3-pyridyl)-1-butanol (NNAL), a biomarker for the lung carcinogen 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK).[67]

After six weeks, study participants who had completely switched to JUUL products had statistically significant reductions in urinary NNAL, as well as fewer respiratory symptoms. Further, 24% of participants in the treatment group reported exclusive ENDS use after six months — meaning those who used JUUL products completely switched from combustible cigarettes.[68]

The researchers concluded: "Reduction in cigarettes and biomarkers of exposure in this study suggest potential of . . . e-cigarettes as a harm reduction strategy for members of the 2 largest minority groups in the US who face significant health disparities."[69]

Moreover, in JLI-sponsored research, Goldenson et al. evaluated use transitions and complete switching from combustible cigarettes to JUUL products between adult menthol and nonmenthol smokers.[70] The study was a one-year longitudinal assessment of adult smokers who were first-time purchasers of JUUL products. The analytic sample included 8,842 participants who reported smoking nonmenthol cigarettes and 6,194 who reported smoking menthol cigarettes at baseline.[71]

Clear differences were observed in flavor preference among JUUL products between smoking populations. Among adult menthol smokers, 53.8% reported primarily using menthol-/mint-flavored JUUL products and 6.4% reported primary use of tobacco-flavored JUUL products. Among nonmenthol smokers, 22.9% reported primary use of menthol-/mint- flavored JUUL products and 25.9% primarily used tobacco-flavored JUUL products.[72]

At the twelve-month follow-up assessment, 47.7% of adult menthol smokers reported completely switching from combustible cigarettes, defined as currently using JUUL products and not smoking cigarettes at all in the past 30 days.[73]

---

[67] *Id.*

[68] *Id.*

[69] *Id.*

[70] N. Goldenson, et al., Differences in Switching Away from Cigarettes and JUUL Use Characteristics Among Adult Menthol and Nonmenthol Smokers Who Purchased the JUUL System, Drug Alcohol Depend 231, 109238 (2022).

[71] *Id.*

[72] *Id.* The balance of both groups reported primary use of non-tobacco or -menthol flavors which are no longer available in the market.

[73] *Id.*

B. Data Show Adult Menthol Smokers Differentially Prefer Menthol-/Mint-Flavored ENDS Products

As the data above demonstrate, ENDS products can transition and completely switch adult menthol smokers from combustible cigarettes. With the Proposed Rule, the efficacy and speed at which non-quitting adult menthol smokers move down the continuum of risk following a menthol ban depends, largely, on the availability and appeal of ENDS products and other noncombustible options.

For ENDS products, relevant product characteristics and considerations on appeal include nicotine delivery and satisfaction, form factor, ease-of-use and convenience, and flavors. Given the unique considerations of menthol cigarettes, including being the only characterizing flavor remaining in cigarettes, we see how certain flavored ENDS products differentially appeal to menthol smokers across demographics. Not surprisingly, menthol-/mint-flavored ENDS products present a particular opportunity.

Evidence to date shows that adult menthol smokers prefer menthol-/mint-flavored ENDS products which, in turn, supports transitions and complete switching from combustible cigarettes.[74] Much of these real-world data come from a marketplace that predates FDA's decisions on premarket tobacco product applications (PMTAs) for ENDS products, where various flavored ENDS products have been available in addition to menthol/mint. Nonetheless, the data emphasize that adult menthol smokers differentially prefer menthol-/mint-flavored options.

For example, Rest et al. conducted a prospective observational study of dual users of combustible cigarettes and ENDS products.[75] These researchers found that 89.1% of adult dual users who smoked menthol cigarettes preferred menthol-flavored ENDS products. In contrast, 24% of adult menthol smokers reported a preference for tobacco-flavored ENDS products. Black dual users, who predominantly smoke menthol cigarettes, also preferred menthol-flavored ENDS products above all other flavor types.[76]

The researchers concluded that "regulations on ENDS flavors that include bans or limitations on menthol/mint flavors may disproportionately affect Black smokers" and "[w]hile menthol cigarettes remain legal and easily accessible, menthol/mint flavored ENDS may retain their importance as a harm reduction alternative."[77]

---

[74] B. Rostron, et al., ENDS Flavor Preference by Menthol Cigarette Smoking Status Among US Adults, 2018–2019, Int J Environ Res Public Health 18, 240 (2020).

[75] E. Rest, et al., Preferred Flavors and Tobacco Use Patterns in Adult Dual Users of Cigarettes and ENDS, Addictive Behav 125, 107168 (2021).

[76] *Id.*

[77] *Id.*

Webb et al. surveyed a sample of adult current and former cigarette smokers comprised predominantly of Blacks and people of Hispanic ethnicity, 68% of whom smoked menthol cigarettes.[78] Although menthol smokers in this sample were less likely than nonmenthol smokers to have ever used an ENDS product, menthol smokers were more likely to consider using ENDS products to reduce or quit smoking cigarettes. Additionally, a greater proportion of menthol smokers reported use of menthol-flavored ENDS products compared to nonmenthol smokers.[79]

The researchers concluded:

> Our study may represent a signal that menthol cigarette smokers, relative to smokers of non-menthol cigarettes, may have particular interest in mentholated e-cigarettes to quit smoking. The harm reduction perspective would suggest that moving to menthol-flavored e-cigarettes vs mentholated combustible cigarettes could benefit public health.[80]

Using a discreet-choice experiment design, Shang et al. evaluated ENDS flavor preferences among adult current smokers and duals users of cigarettes and ENDS products.[81] In analyses stratified by menthol-smoking status, the researchers found that "menthol cigarette smokers preferred menthol flavored ENDS, whereas other smokers did not. These findings indicated that smokers prefer ENDS flavors that are same with their cigarette flavors."[82]

Population-level research from FDA's CTP is perhaps most telling on the differential appeal among menthol-/mint-flavored ENDS products for adult menthol smokers. As referenced above, Rostron et al. analyzed ENDS flavor preferences among dual users of cigarettes and ENDS products and ENDS users who reported recent cigarette-smoking cessation based on TUS-CPS.[83] These researchers found that dual users who smoked menthol cigarettes were more likely to use menthol-/mint-flavored ENDS products.[84]

Specifically, 52.2% of menthol-smoking dual users reported using menthol-/mint-flavored ENDS products compared to 10.3% of nonmenthol-smoking dual users. Among

---

[78] M. Webb Hooper & S. Smiley, Comparison of E-Cigarette Use Among Menthol and Non-Menthol Smokers: Findings from a Community Based Sample, Ethn Dis 12, 153 (2018)

[79] *Id.*

[80] *Id.*

[81] C. Shang, et al., E-cigarette Product Preferences Among Adult Smokers: A Discrete Choice Experiment, Tob Regul Sci 6, 66 (2020).

[82] *Id.*

[83] B. Rostron, et al., ENDS Flavor Preference by Menthol Cigarette Smoking Status among US Adults, 2018–2019, Int J Environ Res Public Health 18, 240 (2020).

[84] *Id.* Menthol and mint were combined as a single survey item in TUS-CPS, so an analysis specific to menthol-flavored ENDS products is unavailable.

ENDS users who reported quitting cigarettes while switching to ENDS products, 41.4% of former menthol smokers used mint-/menthol-flavored ENDS products compared to 21.5% of former nonmenthol smokers. The study also evaluated the use of tobacco-flavored ENDS products and found that few adult menthol smokers used tobacco-flavored ENDS products (28.9%) and very few (6.9%) reported exclusive use of tobacco-flavored ENDS products. In comparison, 45.1% of adult nonmenthol smokers reported use of tobacco-flavored ENDS products and 32.3% reported exclusive use of tobacco-flavored ENDS.[85]

The researchers concluded that "[m]enthol cigarette smokers are particularly likely to use menthol/mint-flavored e-cigarettes compared to nonmenthol smokers" and "[t]hese results can inform policy measures concerning flavored ENDS products."[86]

Data are increasingly clear that many adult menthol smokers prefer menthol-/mint-flavored ENDS products as an alternative to menthol cigarettes. The data also make clear that most adult menthol smokers do not prefer tobacco-flavored ENDS products and such products are unlikely to be a suitable less harmful substitute for menthol cigarettes. Taken together, the evidence affirms the importance of available and viable noncombustible alternatives that appeal to these specific smokers.

***

The data and analysis above focus on the role of ENDS products, particularly in menthol/mint flavors, to transition and completely switch adult menthol smokers from combustible cigarettes. Other noncombustible, reduced-risk options exist, including products that already have been authorized through FDA's PMTA and MRTPA processes as protecting and promoting public health.

In the Proposed Rule, the Agency requests comments on "whether the final rule should include a provision that allows for firms to request an exemption from the standard for specific products of certain types (e.g., noncombusted, reduced nicotine), on a case by-case basis."[87] We believe that FDA should exempt products that have or can be authorized through the PMTA process and demonstrate a net-benefit to public health.

Specifically, if the Proposed Rule were implemented, the Agency should include a provision that exempts products classified as a "cigarette" from the menthol ban if those products either already have received marketing authorization through the PMTA process (i.e., pre-ban authorized products) or can demonstrate that their marketing is appropriate for the protection of public health (i.e., post-ban authorized products). This science- and

[85] *Id.*

[86] *Id.*

[87] 87 Fed. Reg. at 26486.

evidence-based approach not only tracks the same standard for implementing the Proposed Rule but also encourages innovation and advances the same public-health goals.

For example, FDA already has authorized a heated tobacco product (IQOS System) in menthol flavors. Although classified as a "cigarette" by law, the IQOS System does not burn tobacco or produce smoke. Rather, it heats and aerosolizes a tobacco stick to deliver nicotine to the user. In the technical project lead memorandum accompanying its marketing authorization, the Agency found that the IQOS system (including menthol flavors) significantly reduced exposure to harmful and potentially harmful constituents (HPHCs) relative to combustible cigarettes and demonstrated the likelihood of adult smokers switching to these noncombustible products from combustible cigarettes.[88]

The standard of "appropriate for the protection of public health" is grounded in science and evidence. If an applicant can meet that standard, FDA has determined that the marketing of the product has a net-positive effect on public health. The benefits to adult smokers outweigh the risks to nonusers, including those underage. Products that have met or can meet that standard, even with menthol-flavored products, should not be subject to a policy that is intended to meet a similar public-health outcome.

V. THE IMPORTANCE OF CORRECTING RISK MISPERCEPTIONS TO ADVANCE PUBLIC-HEALTH OBJECTIVES WITH THE IMPLEMENTATION OF THE PROPOSED RULE

A robust marketplace of scientifically-substantiated, noncombustible alternatives, including ENDS products, that appeal to menthol smokers serves one aim of a comprehensive strategy to support the implementation of the Proposed Rule.

Currently, however, adult smokers harbor entrenched and worsening misperceptions of ENDS products. These misperceptions, in turn, impede positive changes in tobacco-use behavior, progress in tobacco harm reduction, and the realization of public-health objectives shared by the Proposed Rule. Today and through any implementation of a ban in menthol cigarettes, stakeholders, including FDA, should start to correct these misperceptions through clear, accurate, and science-based communications on nicotine and the relative risks between noncombustible and combustible products.

The current state of public (mis)understanding about the harms of nicotine and relative risk of noncombustible products highlights the need for research and messaging development to support accurate, non-misleading information for adult current users. Banning the sale of menthol cigarettes in this current (mis)information environment risks diluting the positive impact of such a policy because adult menthol smokers will not have the facts to make informed tobacco-use decisions.

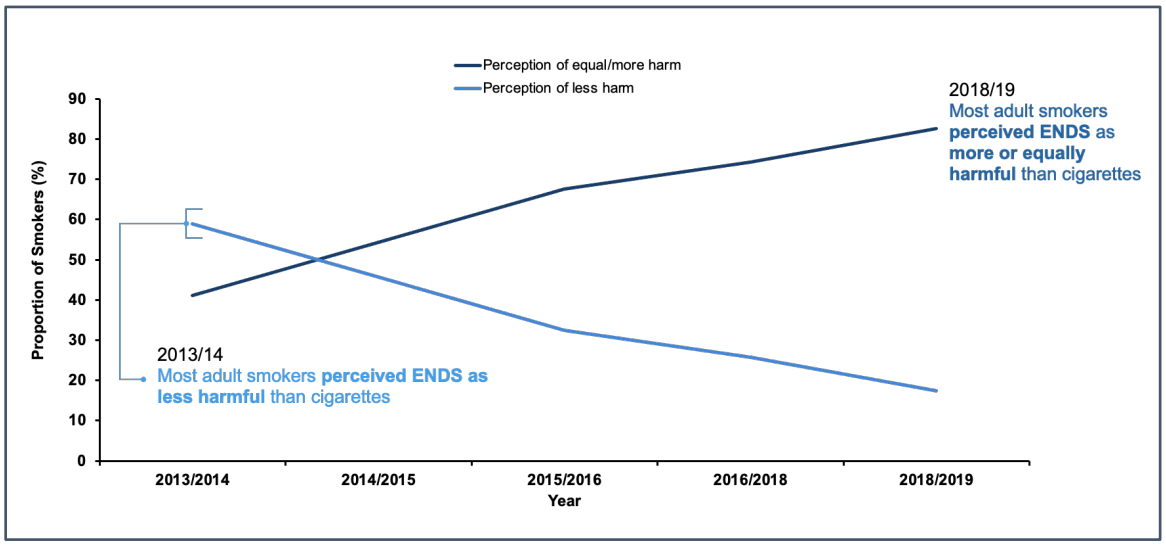
---

[88] FDA, PMTA Coversheet: Technical Project Lead Review (TPL) for PM0000425: Marlboro Smooth Menthol Heatsticks (April 29, 2019), available at https://www.fda.gov/media/124247/download.

On perceptions of nicotine, FDA's own analysis of the Health Information National Trends Survey (HINTS) showed that among adult smokers planning to quit, 48% agreed or strongly agreed (incorrectly) that "The nicotine in cigarettes is the substance that causes most of the cancer caused by smoking."[89] 17% were unsure and only 35% disagreed or strongly disagreed.[90]

On perceptions of the relative risk of ENDS products, adult smokers harbor similar misperceptions and they are worsening. For example, in Wave 1 (2103–2014) of the PATH Study, the majority of current established smokers (54.4%) perceived ENDS products to be less harmful than cigarettes, 39.6% perceived ENDS products to be as harmful as cigarettes, and 6.0% perceived ENDS products to be more harmful than cigarettes. By Wave 5 (2018–2019), only 17.4% of current established smokers perceived ENDS products to less harmful than cigarettes, 70% perceived ENDS products to be as harmful as cigarettes, and 12.3% perceived ENDS products to be more harmful than cigarettes (Figure 5 below).[91]

Figure 5 Trends in ENDS Risk Perceptions Among Adult Smokers in the PATH Study Waves 1–5



These misperceptions have real and negative consequences for adult smokers' likelihood of switching to a less harmful form of nicotine delivery. The Agency's own analysis from the PATH Study of adult smokers and dual users of cigarettes and ENDS products concluded:

[89] E. O'Brien, et al., U.S. Adults' Addiction and Harm Beliefs About Nicotine and Low Nicotine Cigarettes, Prev Med 96, 94 (2017).

[90] *Id.*

[91] JLI's internal analysis of FDA's PATH Study, Waves 1–5.

> [T]hose who perceived e-cigarettes as less harmful than cigarettes were more likely to switch to exclusive e-cigarette use, more likely to remain dual users and less likely to switch to exclusive smoking 1 year later. Our findings highlight the concern that perceptions of e-cigarettes as equally or more harmful than cigarettes could potentially deter complete switching to e-cigarettes among some US adult smokers.[92]

Fortunately, adult smokers' perceptions of nicotine and ENDS relative risk are not immutable. In a recent study, adult daily smokers who did not use ENDS products were randomly assigned to one of three conditions before evaluating various aspects of nicotine and ENDS relative risk.[93] One group viewed a brief video (two minutes and thirty seconds) in which several experts provided information to address common misperceptions on ENDS risk (expert condition). The second group viewed a thirty-second, text-only video containing similar information and branded with the Cancer Research U.K. logo (CRUK condition). The third group received no information. All participants then completed a questionnaire on nicotine and ENDS risk perceptions.[94]

Participants in the expert condition demonstrated significantly improved perceptions on nicotine and ENDS relative risk compared to the control group (Figure 6 below). Behavioral intentions to try and use ENDS products in a future quit attempt for cigarettes also were assessed. In the expert condition, 59% of respondents indicated that they intended to try ENDS products and 67% indicated that they intended to use ENDS products in a future quit attempt. In the control condition, however, only 31% intended to try ENDS products and only 35% intended to use ENDS products in a future quit attempt.[95]

The researchers concluded that while "misinformation is often resistant to correction, we find that attitude change in this domain is possible, at least when we use carefully designed public health campaigns."[96]

---

[92] A. Persoskie, et al., Perceived Relative Harm of Using E-cigarettes Predicts Future Product Switching Among US Adult Cigarette and E-cigarette Dual Users, Addiction 114, 2197 (2019).

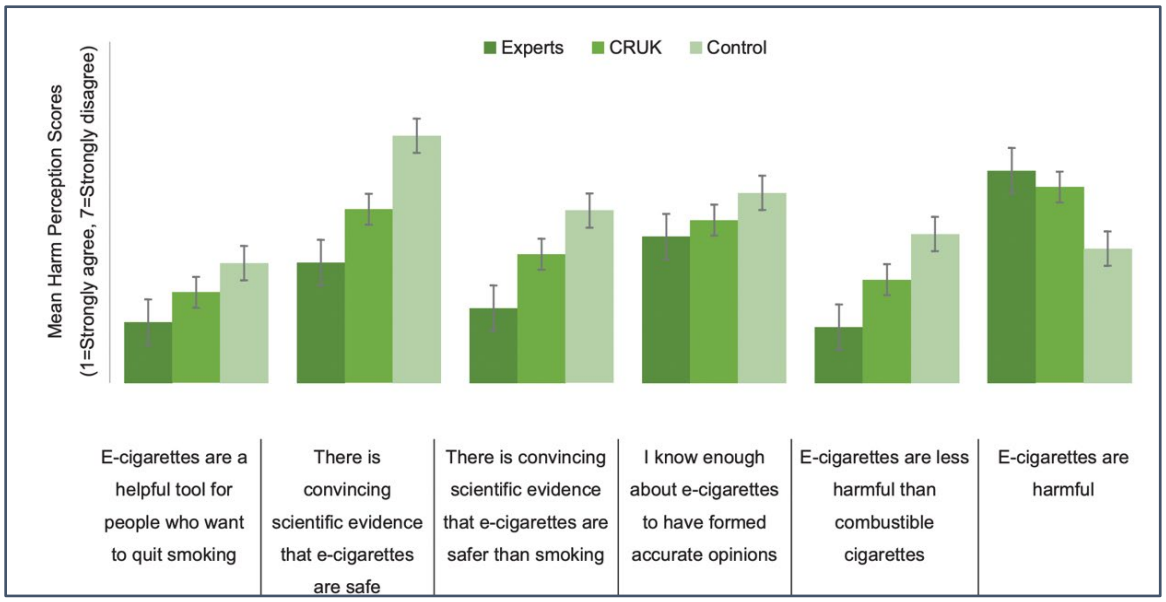
[93] M. Svenson, et al., Tackling Smoker Misperceptions About E-cigarettes Using Expert Videos, Nicotine Tob Res, 23(11) (2021).

[94] *Id.*

[95] *Id.*

[96] *Id.*

Figure 6 Mean Response to Risk-Perception Statements by Condition



Should FDA issue a final rule banning the sale of menthol cigarettes, it also should engage in significant efforts to correct the existing misperceptions of nicotine and the relative risks of ENDS products compared to combustible cigarettes. Such efforts will ensure that the menthol ban meets its public-health objectives — including by increasing the proportion of adult menthol smokers who will transition to less harmful, noncombustible alternatives and reducing the proportion who will continue smoking combustible products.

VI. CONCLUSION

The Proposed Rule has a straightforward objective: remove menthol cigarettes, decrease initiation, increase cessation, and thus reduce tobacco-related death and disease. Achieved to its fullest extent, this one policy can set in motion an end-game for combustible-cigarette use in the United States. But not in isolation and not without embracing and advancing tobacco harm reduction under a comprehensive framework.

This policy and its underlying public-health goals need to account for the real-world data and evidence demonstrating not just the positive impact of ENDS products for adult smokers but also the unique considerations for menthol smokers. By banning the sale of menthol cigarettes, many may quit but many others will not. Viable, scientifically-substantiated noncombustible alternatives, like ENDS products, provide that off-ramp. *Pulling* smokers from combustible cigarettes alone will not work; rather, for those that have not or will not quit, *pushing* these smokers to less harmful alternatives will.

But a pull-push strategy will be effective only if the same smokers understand — based on clear, accurate, and science-based information — that it is not the nicotine that

kills and ENDS and other noncombustible products can present significantly less risk than combustible cigarettes.

It is this comprehensive framework, based on science and evidence, that will ensure that the objectives and benefits of the Proposed Rule are realized.

Respectfully submitted,