Juul Labs

Juul Labs Position: Tobacco Product Standard for Menthol In Cigarettes – Remarks As Delivered to OMB

December 5, 2023

Overview

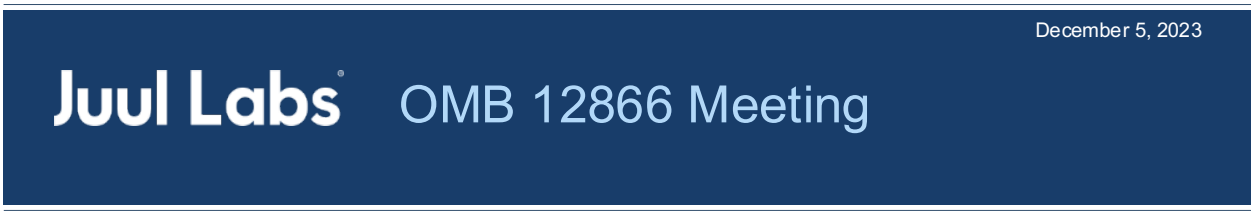
On December 5, 2023, representatives from Juul Labs, Inc. met with representatives from the Office of Management and Budget (OMB) and the Food and Drug Administration (FDA) regarding the proposed product standard to ban menthol as a characterizing flavor in cigarettes.

Attendees from Juul Labs included:

- Dr. Michael Fisher, Senior Director of Regulatory Strategy
- Jason Robinson, Director of Regulatory Engagement
- Kaitlyn Boecker, Head of Federal Affairs

Below is the script, as prepared, which accompanied the slides presented.

Slide 1: Introduction



Tobacco Product Standard for Menthol in Cigarettes

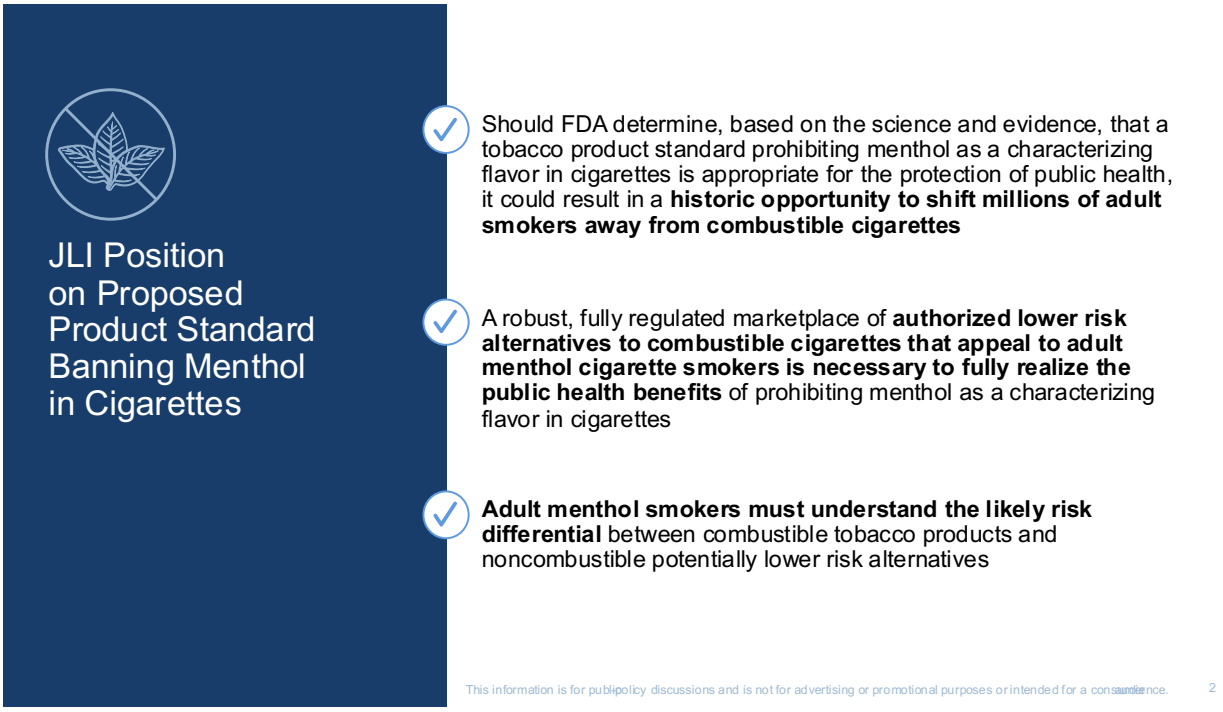
Dr. Michael Fisher
Jason Robinson
Kaitlyn Boecker

Good morning and thank you very much for taking the time to speak with us. I'm Michael Fisher, Senior Director of Regulatory Strategy at JUUL Labs and I have with me my colleagues Jason Robinson, our Director of Regulatory Engagement and Kaitlyn Boecker who leads Federal Affairs for JUUL Labs. As I'm sure you're aware, JUUL Labs is a leading manufacturer of electronic nicotine delivery systems, which I'll abbreviate as ENDS.

If you have questions during the presentation, please don't hesitate to ask.

So we're here to talk about FDA's proposed product standard to ban menthol as a characterizing flavor in cigarettes and the role that menthol-flavored ENDS have in fully realizing the public health benefit of the proposed product standard. I will discuss the population model FDA has cited to substantiate the proposed product standard's public health benefit and highlight the importance of ENDS in the model's projections. I will then present data showing that menthol-flavored ENDS are particularly important as alternatives for adults who smoke menthol cigarettes.

Slide 2: JLI Position on Proposed Product Standard Banning Menthol in Cigarettes



First, I want to be clear JLI supports the proposed product standard. If FDA determines, based on the science and evidence, that banning menthol as a characterizing flavor in cigarettes is appropriate for the protection of public health, it will present an enormous opportunity to shift adults who smoke away from combustible cigarettes.

However, the data I'll share with you today suggest that without a robust marketplace of authorized menthol-flavored ENDS products available as alternatives for menthol cigarette smokers, the positive public health impact of the proposed product standard will not be fully realized.

Another barrier to fully realizing the potential public health benefit of the proposed product standard is the misperceptions among adult smokers about the relative risks of ENDS compared to cigarettes. The vast majority of adult smokers incorrectly believe that ENDS are as harmful or more harmful than cigarettes. While the long-term health effects of ENDS use are not formally known, data from chemical analysis, risk assessment and clinical studies of biomarkers of exposure and biomarkers of potential harm strongly suggest that any health effects of ENDS use are likely to be vastly lower than those resulting from cigarette smoking.

Risk perceptions matter because adult smokers' perceptions of ENDS risks are predictive of the likelihood that adult smokers will switch to ENDS from combustible cigarettes. The fact the majority of people who smoke menthol cigarettes also perceive that ENDS are as or more harmful than cigarettes reduces the likelihood that these people will switch to ENDS following a menthol cigarette ban, and increases the

likelihood that these people will switch to nonmenthol cigarettes. FDA should take action to address the significant misperceptions of ENDS risk to maximize the public health benefit of the proposed product standard.

Slide 3: FDA's Proposed Rule to Ban Menthol Cigarettes Relies on Population Modeling that Anticipates Significant Switching to ENDS and other NVPs

FDA's Proposed Rule to Ban Menthol Cigarettes Relies on Population Modeling that Anticipates Significant Switching to ENDS and other NVPs

Model predicts the proposed rule will AVERT
324,000 to 654,000 smoking attributable deaths* overall
(92,000 to 238,000 among African Americans)
*model predictions are over 40 years

Population Modeling
- Led by Dr. David Levy of Georgetown University and colleagues
- Funded by the FDA CTP's Tobacco Centers of Regulatory Science (TCORS) grant

TCORS grant: ***"Public health impact of a U.S. ban on menthol in cigarettes and cigars: a simulation study"***
- Looks at scenarios possible after implementing the proposed rule to ban menthol in cigarettes


Public health impact of a US ban on menthol in cigarettes and cigars: a simulation study

The public health gains predicted in the model rely upon
MANY MENTHOL SMOKERS SWITCHING to ENDS

http://dx.doi.org/10.1136/tobaccocontrol-2021-056604
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Now let's turn to the population model FDA cites to substantiate the public health benefit of the proposed product standard. This model was developed and published by a team led by Dr. David Levy at Georgetown University with funding provided by FDA through its Tobacco Centers of Regulatory Science grant program. The model projects that the proposed product standard will avert between 324,000 to 654,000 smoking-attributable deaths over a 40-year timeframe, beginning in 2021. What's critical is that the model's projections rely upon many current menthol cigarette smokers switching to ENDS.

Now I want to take an aside: FDA also mentions in the proposed product standard a previous population model of the impact of a menthol cigarette ban. This model was also produced by Dr. Levy and colleagues and published in 2011. This model begins in 2010 and projects that a menthol cigarette ban implemented in 2011 would avert between 323,000 to 633,000 smoking attributable deaths by 2050. This model assumes that a menthol cigarette ban would increase the quit rate among menthol smokers by between 10 to 30% and would decrease the smoking initiation rate by between 10-30%.

This earlier model is outdated for two reasons. First, the model projections rely in part on the smoking initiation rate in 2010, which is very different from this rate today. I don't have specific data on the number of smoking initiates by year, but, as a proxy, 12.8% of 8th, 10th, and 12th graders reported past 30-day smoking in 2010, according to the Monitoring the Future survey. By 2021, the rate of past 30-day smoking among these groups was 2.3%. Clearly, projections of the impact of a menthol ban on smoking initiation based on 2010 smoking initiation rates will be very different from projections based on current rates of smoking initiation. Second, Dr. Levy's 2011 model does not include ENDS products. There is a substantial body of literature showing significant interplay between cigarettes and ENDS, with impacts on both smoking initiation and smoking cessation rates.

Dr. Levy noted the limitations of his 2011 model in the publication of his 2021 model. He says:

"A simulation model projected that a menthol ban would have major impacts on smoking prevalence and smoking-attributable deaths. However, that model simulated a ban starting in 2010 and did not consider the impact of switching to nicotine vaping products (NVPs, also known as e-cigarettes) … To better gauge the potential impact of a menthol cigarette and cigar ban in the vaping era, we conducted an expert elicitation to explicitly consider the impact of the ban on smoking initiation and cessation and on NVP use."

So the fact that the projected smoking attributable deaths averted is similar between Dr. Levy's 2011 and 2021 models is happenstance. FDA should base its substantiation of the proposed product standard on Dr. Levy's 2021 model, which considers ENDS, and not on his 2011 model, which omits them entirely.

Slide 4: Transitions Among Adults Who Smoke Menthol Cigarettes in the Levy Model Demonstrate the Majority of Benefit is in Switching to ENDS

Transitions Among Adults Who Smoke Menthol Cigarettes in the Levy Model Demonstrate the Majority of Benefit is in Switching to ENDS

Negative outcomes include transitioning to non-menthol cigarettes and entering the illicit market

Table 5.2.2. Transitions of age 18-24 Menthol Smokers in the Status Quo and Menthol Ban Scenarios in Pe
100 age 18-24 menthol smokers in the Status Quo)

Population	Status Quo	Menthol Cigarette and Cigar Ban	Net Effect	Final Transition as a Percent of Menthol Smokers in the Status Quo
Product Type	Mean	Mean	Absolute difference	Percent of 71.2%
Continue to be menthol cigarette smokers (exclusively or with other products)	71.2	-	-71.2	
Switch to non-menthol cigarettes (exclusively or with other products, except menthol cigarettes)	5.6	36.8	31.2	43.8% (31.2/71.2)
Switch to cigars, especially little cigars, filtered cigars, or cigarillos (exclusively or with other products, but not cigarettes)	3.4	-	0.7	0.9% (0.7/71.2)
Switch to non-menthol cigars, especially little cigars, filtered cigars or cigarillos (exclusively or with other products, but not cigarettes)	-	4.1		
Switch to illicit menthol cigarette or cigar use	-	7.2	7.2	10.1% (7.2/71.2)
Switch to exclusive smokeless tobacco or other oral tobacco products	1.7	4.1	2.4	3.3% (2.4/71.2)
Switch to novel nicotine delivery products (NNDP), such as e-cigarettes or heated tobacco products (exclusively or in combination with other products, but not cigarettes or cigars)	8.3	25.5	17.2	24.2% (17.2/71.2)
Quit all tobacco product use	9.8	22.4	12.6	17.7% (12.6/71.2)

Table S2.3. Transitions of Age 35-54 Menthol Smokers in the Status Quo and Menthol Ban Scenarios i
Age 35-54 100 menthol smokers in the status quo)

Population	Status Quo	Menthol Cigarette and Cigar Ban	Net Effect	Final Transition as a Percent of Menthol Smokers in the Status Quo
Product Type	Mean	Mean	Absolute difference	Percent of 71.2%
Continue to be menthol cigarette smokers (exclusively or with other products)	71.2	-	-71.2	
Switch to non-menthol cigarettes (exclusively or with other products, except menthol cigarettes)	4.5	43.3	38.8	54.5% (38.8/71.2)
Switch to cigars, especially little cigars, filtered cigars, or cigarillos (exclusively or with other products, but not cigarettes)	1.5	-		
Switch to non-menthol cigars, especially little cigars, filtered cigars or cigarillos (exclusively or with other products, but not cigarettes)	-	4.1	2.6	3.7% (2.6/71.2)
Switch to illicit menthol cigarette or cigar use	0.0	6.3	6.3	8.8% (6.3/71.2)
Switch to exclusive smokeless tobacco or other oral tobacco products	1.9	2.6	0.7	1.0% (0.7/71.2)
Switch to novel nicotine delivery products (NNDP), such as e-cigarettes or heated tobacco products (exclusively or in combination with other products, but not cigarettes or cigars)	8.2	20.5	12.3	17.3% (12.3/71.2)
Quit regular use of all tobacco or novel nicotine delivery products	12.7	23.2	10.5	14.7% (10.5/71.2)

Levy DT, Meza R, Yuan Z, *et al.* Public health impact of a US ban on menthol in cigarettes and cigars: a simulation study. *Tobacco Control* 2023; **32**:e37-e44.

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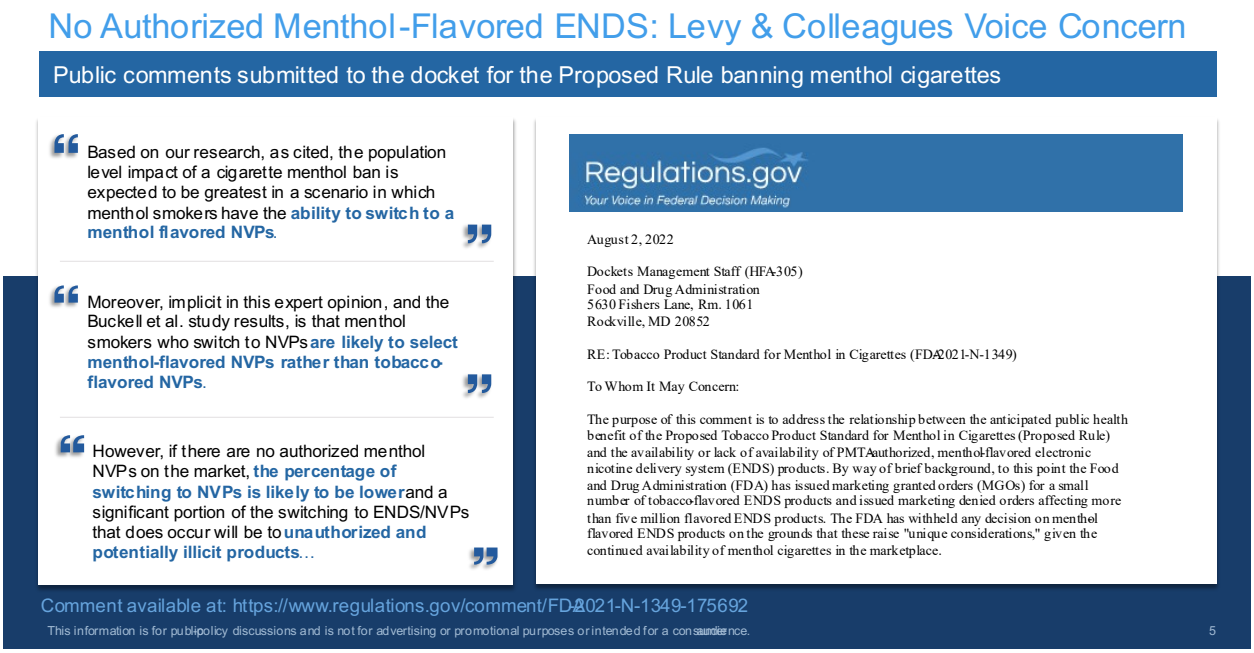
Now I'd like to look at Dr. Levy's 2021 model, and specifically the role that ENDS have as an alternative for menthol cigarette smokers in the event of a menthol cigarette ban. The two tables are taken from the supplemental material for the publication of the 2021 model. The first table are the transitions for menthol smokers aged 18-24. The first column shows the estimated transitions for menthol smokers aged 18-24 without a menthol ban and the second column shows the estimated transitions following a menthol ban. The third column shows the difference between the two scenarios for each transition. I've emphasized in red the transitions which are bad for public health and highlighted in green those transitions which are good for public health.

Essentially, the model projects that about half of menthol smokers aged 18-24 will continue to smoke in some form, about a quarter will quit all tobacco product use and about a quarter will quit smoking and switch to noncombustible nicotine products, predominantly ENDS. The projected transitions are similar for menthol smokers aged 35-54, shown in the second table, although more continue to smoke and fewer quit or switch to noncombustible nicotine products. For both age cohorts, approximately half of the beneficial transitions following a menthol cigarette ban are to ENDS. This is shown in the final column of each table. This makes clear the importance that ENDS have as a "landing place" for displaced menthol smokers in the model FDA uses to substantiate the public health benefit of the proposed product standard. And, FDA's reliance on this model implicitly accepts the importance of ENDS to achieve this public health benefit.

Slide 5: No Authorized Menthol-Flavored ENDS: Levy & Colleagues Voice Concern



Now, while the model highlights the important role of ENDS in realizing the public health benefit of banning menthol cigarettes, it does not speak to the role of menthol-flavored ENDS specifically. So now I'm going to present data showing, that a robust marketplace of menthol-flavored ENDS is needed to maximize the number of displaced menthol smokers who cease smoking cigarettes after a menthol cigarette ban.

First, Dr. Levy and his colleagues have expressed in their comments to the public docket on the proposed product standard that "the population level impact of a cigarette menthol ban is expected to be greatest in a scenario in which menthol smokers have the ability to switch to menthol-flavored NVPs." These authors support their contention citing research showing that menthol cigarette smokers are more likely to choose menthol-flavored ENDS, as opposed to tobacco-flavored ENDS. They also note the complete absence of FDA-authorized menthol ENDS and suggest that some menthol smokers will seek out illicit ENDS products as a result.

Slide 6: US Adult Menthol Cigarette Smokers Express Strong Preference for Menthol-Flavored ENDS

US Adult Menthol Cigarette Smokers Express Strong Preference for Menthol-Flavored ENDS

Published data from national surveys (i.e., PATH, TUS-CPS) demonstrate that US adults who smoke mentholated cigarettes overwhelmingly prefer menthol-flavored ENDS products

International Journal of Environmental Research and Public Health

MDPI

Article

ENDS Flavor Preference by Menthol Cigarette Smoking Status among US Adults, 2018–2019

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Drug and Alcohol Dependence

Volume 236, 1 July 2022, 109475

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

Krysten W. Bold [a b], Eugenia Buta [c], Patricia Simon [c], Ralitza Gueorguieva [a c], Asti Jackson [a], Sakinah C. Suttiratana [d], Suchitra Krishnan-Sarin [a], Stephanie S. O'Malley [a b]

1. Rostron BL, Chang JT, Chang CM, Jackson RA, Ambrose BK. ENDS Flavor Preference by Menthol Cigarette Smoking Status among US Adults, 2018–2019. *International Journal of Environmental Research and Public Health*. 2021; 18(1):240. https://doi.org/10.3390/ijerph18010240
2. Bold KW, Buta E, Simon P, Gueorguieva R, Jackson A, Suttiratana SC, Krishnan-Sarin S, O'Malley SS. 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. 2022 Jul 1;236:109475. doi: 10.1016/j.drugalcdep.2022.109475. Epub 2022 Apr 27. PMID: 35594642; PMCID: PMC9248755.

Published data demonstrates that adults who smoke menthol cigarettes have a strong preference for menthol-flavored ENDS. This first publication from Dr. Rostron at the Center for Tobacco Products analyzed the 2018/2019 Tobacco Use Supplement to the Current Population Survey to assess ENDS flavor preferences among menthol cigarette smokers. They found that over 50% of menthol cigarette smokers who also used ENDS reported using mint or menthol-flavored ENDS. Among menthol smokers who switched completely, 41% reported using menthol ENDS. Critically, only about 7% of both groups reported using tobacco-flavored ENDS, with the remainder using some other flavor type, such as fruit. These data support that menthol smokers preferentially choose menthol-flavored ENDS and, as importantly, most do not choose tobacco-flavored ENDS. These authors conclude that this study provides evidence that "adult menthol 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."

The second study led by Dr. Bold at Yale assessed ENDS flavor preferences among adult cigarette smokers stratified by menthol cigarette status and race/ethnicity using Wave 4 of FDA's Population Assessment of Tobacco and Health survey. They reported that adults who smoked menthol cigarettes were significantly more likely to use mint or menthol-flavored ENDS compared to nonmenthol cigarette smokers. The adjusted odds ratio for this difference was 7.6. In contrast, adult menthol cigarette smokers were significantly less likely to use tobacco-flavored ENDS compared to nonmenthol cigarette smokers, with an adjusted odds ratio of 0.25.

In terms of race/ethnicity, the authors found that although non-Hispanic Black and Hispanic smokers were significantly less likely to use ENDS compared to non-Hispanic white smokers, those that did were significantly more likely to report use of mint or menthol-flavored ENDS.

The study also assessed reasons for ENDS use. Adult menthol cigarette smokers were significantly more likely to endorse "because they come in flavors I like" compared to nonmenthol smokers, further supporting the role of menthol flavor as a basis for their choice of ENDS.

These authors concluded "Understanding the potential role of e-cigarette flavors for reducing the harm associated with menthol cigarette use is important for informing regulatory policies, especially given planned policies to ban menthol cigarettes. … These data suggest that allowing menthol-flavored e-cigarettes may help reduce the harm associated with menthol cigarette use among adults, including adults from minoritized communities who smoke, if availability of this e-liquid flavor encourages switching and complete substitution for menthol cigarettes."

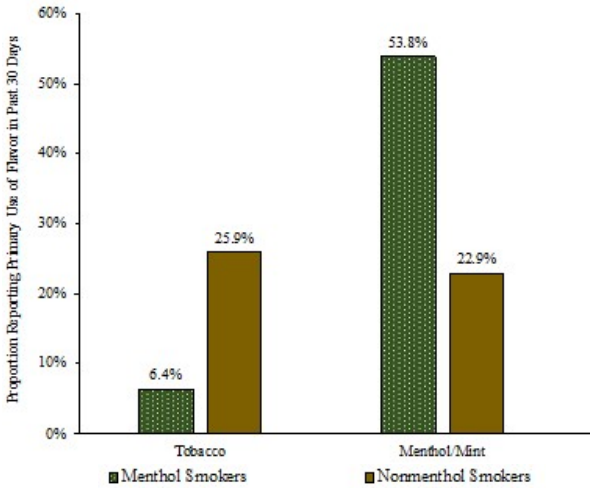
Both of these studies support that:

1. **Menthol cigarette smokers have a strong preference for menthol-flavored ENDS; and**
2. **Menthol cigarette smokers do not prefer tobacco-flavored ENDS**

These studies, and others, support Dr. Levy's and our concerns that the impact of the proposed product standard will be diminished if menthol-flavored ENDS are not available as an alternative for adult menthol cigarette smokers following a menthol cigarette ban.

Slide 7: US Adults Who Smoke Menthol Cigarettes Express a Strong Preference for Menthol-Flavored JUUL Product

US Adults Who Smoke Menthol Cigarettes Express a Strong Preference for Menthol-Flavored JUUL Products

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Short communication

Differences in switching away from cigarettes and JUUL use characteristics among adult menthol and nonmenthol smokers who purchased the JUUL System

Nicholas I. Goldenson [a,*,1], Erik M. Augustson [a], Saul Shiffman [b]

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[b] PinneyAssociates, Inc., USA

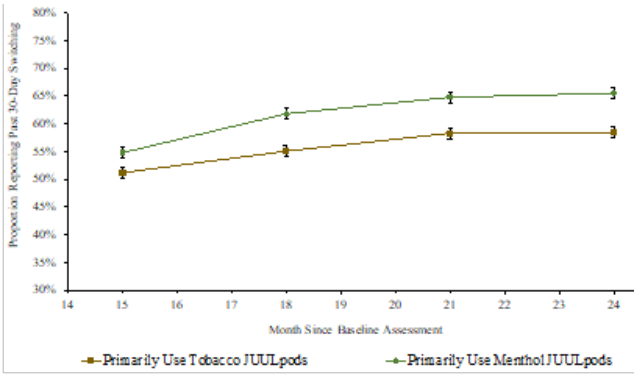
Goldenson NI, Augustson EM, Shiffman S. Differences in switching away from cigarettes and JUUL use characteristics among adult menthol and nonmenthol smokers who purchased the JUUL System. Drug Alcohol Depend. 2022 Feb 1;231:109238. doi: 10.1016/j.drugalcdep.2021.109238. Epub 2021 Dec 24. PMID: 34974269.

Our own data further substantiates the importance of menthol-flavored ENDS as alternatives for adult menthol cigarette smokers. These data from an analysis of our purchaser study which longitudinally followed first time purchasers of the JUUL System and assessed smoking status at regular intervals over one year. The analytic sample for this analysis includes approximately 4,000 menthol smokers and 6,000 nonmenthol smokers. Menthol smokers in this study showed a strong preference for menthol-flavored JUUL products, with over half reporting that they used menthol-flavored JUULpods. Less than 7% of menthol smokers reported using tobacco-flavored JUULpods and the remainder reported use of other JUUL flavors. Note that this study was conducted before JUUL voluntarily withdrew all non-tobacco or -menthol flavors from the market.

Slide 8: US Adults Who Smoke and Use Menthol-Flavored ENDS Products (vs. Tobacco) Have Higher Rates of Switching

US Adults Who Smoke and Use Menthol-Flavored ENDS Products (vs. Tobacco) Have Higher Rates of Switching

Participants in the Adult JUUL Switching and Smoking Trajectories study who used Menthol (vs. Tobacco) flavored JUUL products had significantly higher rate rates of switching across the second year of follow-up.

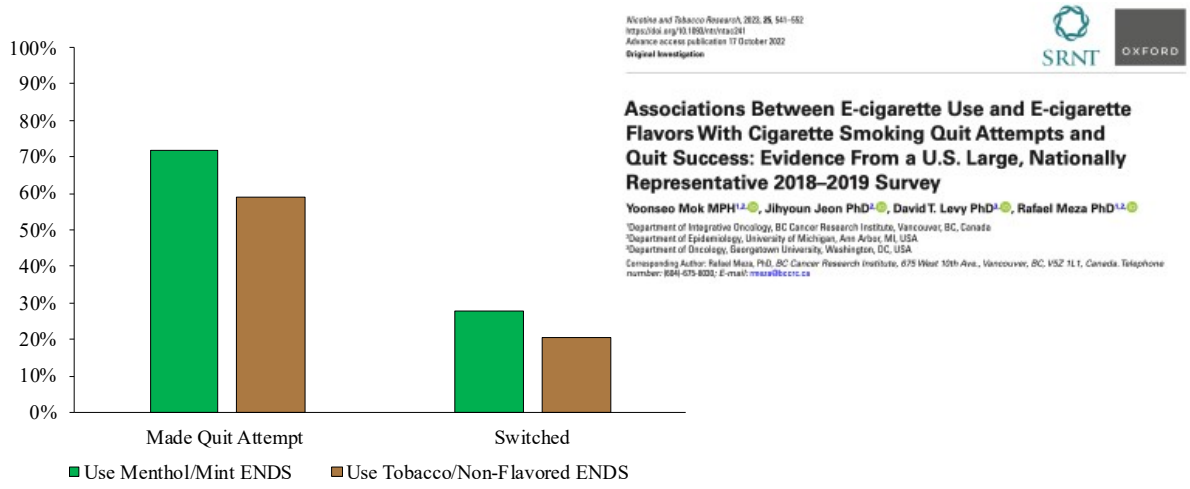


Shiffman S, Sembower MA, Augustson EM, Goldenson NI, Haseen F, McKeganey NP, Russell C. The Adult JUUL Switching and Smoking Trajectories (ADJUSST) Study: Methods and Analysis of Loss -to-Follow-up. Am J Health Behav. 2021 May 1;45(3):419 -442. doi: 10.5993/AJHB.45.3.3. PMID: 33894793.

Not only is it clear that menthol cigarette smokers prefer menthol ENDS, new analyses support that menthol-flavored ENDS may promote complete switching away from cigarettes at significantly higher rates than tobacco-flavored ENDS. As I'm sure you are aware, FDA has communicated that for a menthol-flavored ENDS to be granted market authorization under the Premarket Tobacco Product pathway, applicants are required to demonstrate that menthol-flavored ENDS provide an outsized benefit in switching adult smokers to offset the potential risk of increased use among underage people. The analysis shown here provides just that demonstration. This analysis is based on the 24-month follow-up for the JUUL purchaser study that I just discussed. These data come after JUUL voluntarily withdrew all non-tobacco and non-menthol flavors from the market and therefore enables a direct comparison of adult smoker switching between tobacco and menthol-flavored JUUL products.

At each follow-up time point, participants were asked if they smoked cigarettes in the past 30-days. Those that reported no past 30-day smoking were coded as switched. As you can see in the figure, switch rates were higher at all time points for those that primarily used menthol-flavored JUULpods compared to those that used tobacco-flavored JUULpods. When the results were aggregated across the four follow-up time points, switch rates were 63% among those who primarily used menthol JUULpods compared to 56% for those that used tobacco JUULpods. This difference was statistically significant with an odds ratio of 1.24 and remained significant after adjustment for sociodemographic and smoking covariates.

Slide 9: US Adult Smokers Who Use Menthol-Flavored ENDS have Higher Rates of Attempting to Quit Smoking and Switching

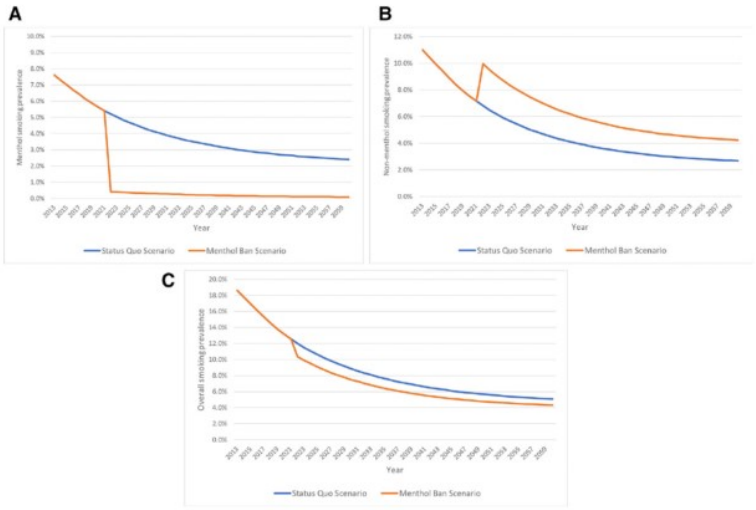


Mok Y, Jeon J, Levy DT, Meza R. Associations Between E -cigarette Use and E -cigarette Flavors With Cigarette Smoking Quit Attempt s and Quit Success: Evidence From a U.S. Large, Nationally Representative 2018 -2019 Survey. Nicotine Tob Res. 2023 Feb 9;25(3):541 -552. doi: 10.1093/ ntr/ntac241. PMID: 36250607; PMCID: PMC9910159.

The observation that menthol ENDS are associated with increased rates of switching is consistent with a recent publication by Mok et al., on which Dr. Levy is an author, in which they assessed the relationship between flavored ENDS use and smoking quit attempts and successful quitting using the 2018/2019 Tobacco Use Supplement to the Current Population Survey. They reported that "Current e-cigarette users of menthol or mint flavors had higher odds of making quit attempts and quit success versus current e-cigarette users of other non-tobacco flavors, although the differences were not statistically significant." It is possible that these results were not significant due to small sample size, as the analysis was based on approximately 400 tobacco-flavored ENDS users and 300 menthol-flavored ENDS users. These authors ultimately conclude that "This suggests that the potential for e-cigarettes to help people who currently smoke quit could be maintained with the availability of menthol or mint-flavored e-cigarettes, even if other nontobacco-flavored products, which are associated with e-cigarette use among youth, were removed from the market."

Slide 10: Dr. Levy's Projected Scenario Underscores Importance of Menthol-Flavored ENDS

Dr. Levy's Projected Scenario Underscores Importance of Menthol-Flavored ENDS



Levy DT, Meza R, Yuan Z, *et al.* Public health impact of a US ban on menthol in cigarettes and cigars: a simulation study. *Tobacco Control* 2023;**32:**e37-e44.

The data I've presented demonstrates that ENDS, and particularly menthol-flavored ENDS, are necessary to achieve the full benefit of the proposed product standard to ban menthol cigarettes. However, it may be helpful to conclude with a review of Levy's projected scenario for a menthol cigarette ban.

Panel A shows the impact of a menthol cigarette ban on menthol smoking prevalence and, unsurprisingly, the impact is instant and dramatic. Panel B, however, shows the impact of a menthol cigarette ban on non-menthol smoking prevalence and this impact is similarly instant and dramatic in the opposite direction, reflecting the fact that many displaced menthol smokers are projected to simply switch to non-menthol cigarettes. Finally, in Panel C, Dr. Levy presents the combined impact of these two projections on smoking prevalence and we see that the ultimate impact of a menthol cigarette ban is largely offset by switching to nonmenthol cigarettes. As discussed earlier, the public health benefit of a menthol cigarette ban depends on adult menthol smokers quitting cigarette smoking, so any factor that further impedes that dilutes the public health benefit of the proposed product standard to ban menthol cigarettes and should be taken very seriously.

As the figures depicting the projections of the model clearly demonstrate, the vast majority of the benefit of the proposed product standard occurs almost immediately. And, the fact the two lines in Figure C are essentially parallel, shows that the benefit of the proposed product standard following its initial implementation flow almost entirely from the displacement that occurs when the standard is implemented. Simply put, this is a one-shot opportunity. It would be a grave mistake to implement this

standard without the conditions in place envisioned for it to succeed and maximize its benefit.

If finalized and enacted, this product standard would be the most significant public health intervention since the prohibition of alcohol over 100 years ago. It is imperative for FDA to get this right and, as the data presented today demonstrate, it is apparent that this product standard will not fully succeed without a robust market of authorized menthol-flavored ENDS alternatives for menthol cigarette smokers.

Our recommendation is simple: The proposed product standard should not be implemented until the market conditions envisioned for it to succeed are in place.

CTP Director Dr. Brian King has acknowledged that ENDS are helping people quit cigarettes and has urged manufacturers to step up the "quality and rigor" of the science to meet the bar to demonstrate the differential benefit of flavors to adult smokers. Dr. King has also highlighted the importance of innovation with respect to age-gating technology that can address concerns about underage access to flavored ENDS, including menthol.

These innovations are imminent. Juul Labs is submitting a Premarket Tobacco Product Application (PMTA) this month for a menthol ENDS product that requires age-verification prior to use, an innovation FDA has said is sufficient to mitigate the risk of underage use of menthol ENDS products. Other responsible manufacturers have publicly shared their intentions to pursue similar innovations.

As FDA reviews these applications against the bar it has set for the science necessary to demonstrate a differential benefit of flavors, including menthol, for adult smokers, the Agency has the opportunity to provide adult menthol smokers a landing place in an environment that eventually bans menthol cigarettes.

List of References in Slides and Remarks

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Juul Labs, Inc.'s mission is to transition the world's billion adult smokers away from combustible cigarettes, eliminate their use, and combat underage usage of our products.

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