

December 5, 2023

# Juul Labs<sup>®</sup> OMB 12866 Meeting

## **Tobacco Product Standard for Menthol in Cigarettes**

**Dr. Michael Fisher**  
**Jason Robinson**  
**Kaitlyn Boecker**



## JLI Position on Proposed Product Standard Banning Menthol in Cigarettes



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 opportunity to shift millions of adult smokers away from combustible cigarettes**



A robust, fully regulated marketplace of **authorized lower risk alternatives to combustible cigarettes that appeal to adult menthol cigarette smokers is necessary to fully realize the public health benefits** of prohibiting menthol as a characterizing flavor in cigarettes



**Adult menthol smokers must understand the likely risk differential** between combustible tobacco products and noncombustible potentially lower risk alternatives

# 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



The public health gains predicted in the model rely upon  
**MANY MENTHOL SMOKERS 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 S.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.

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

Public comments submitted to the docket for the Proposed Rule banning menthol cigarettes

“Based on our research, as cited, the population level impact of a cigarette menthol ban is expected to be greatest in a scenario in which menthol smokers have the **ability to switch to a menthol flavored NVPs**. ”

“Moreover, implicit in this expert opinion, and the Buckell et al. study results, is that menthol smokers who switch to NVPs **are likely to select menthol-flavored NVPs rather than tobacco-flavored NVPs**. ”

“However, if there are no authorized menthol NVPs on the market, **the percentage of switching to NVPs is likely to be lower** and a significant portion of the switching to ENDS/NVPs that does occur will be to **unauthorized and potentially illicit products**... ”

Regulations.gov  
*Your Voice in Federal Decision Making*

August 2, 2022

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

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

To Whom It May Concern:

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

Comment available at: <https://www.regulations.gov/comment/FDA-2021-N-1349-175692>



# 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  
and Public Health*

[https://www.mdpi.com/  
journal/ijerph](https://www.mdpi.com/journal/ijerph)



Drug and Alcohol Dependence  
Volume 236, 1 July 2022, 109475



## Article

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

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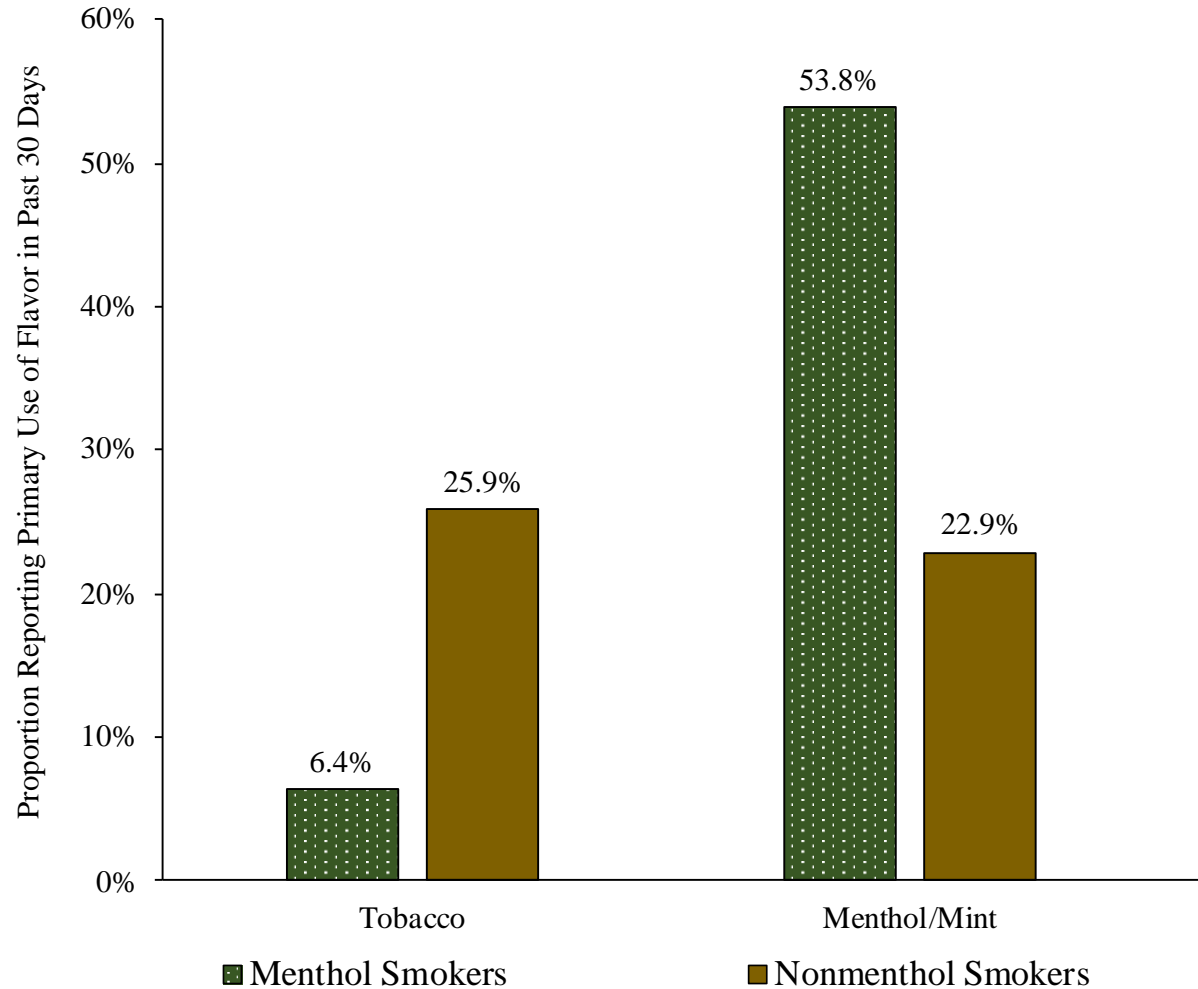
\* Correspondence: [brian.rostron@fda.hhs.gov](mailto:brian.rostron@fda.hhs.gov)

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 <sup>a b</sup>  , Eugenia Buta <sup>c</sup>, Patricia Simon <sup>a</sup>, Ralitza Gueorguieva <sup>a c</sup>,  
Asti Jackson <sup>a</sup>, Sakinah C. Suttiratana <sup>d</sup>, Suchitra Krishnan-Sarin <sup>a</sup>, Stephanie S. O'Malley <sup>a b</sup>

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.

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



Contents lists available at [ScienceDirect](https://www.sciencedirect.com)

**Drug and Alcohol Dependence**

journal homepage: [www.elsevier.com/locate/drugalcdep](https://www.elsevier.com/locate/drugalcdep)

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<sup>a,\*,1</sup>, Erik M. Augustson<sup>a</sup>, Saul Shiffman<sup>b</sup>

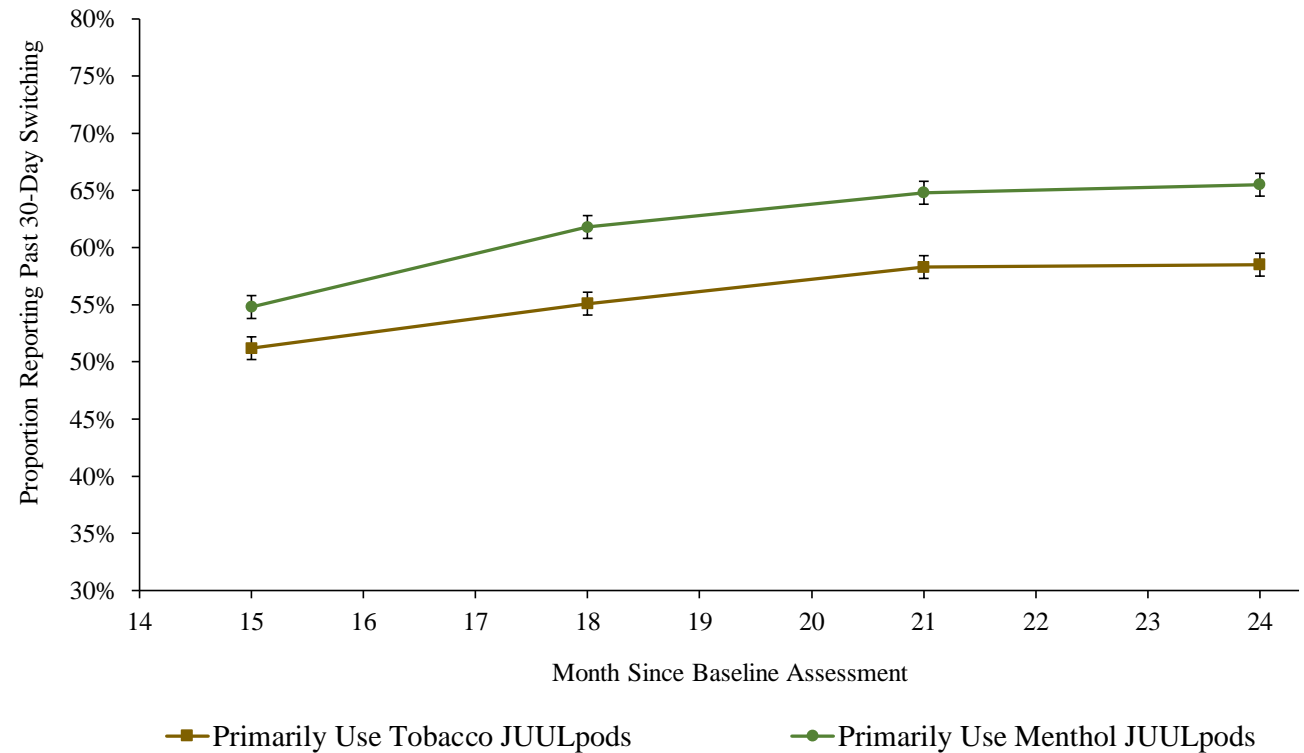
<sup>a</sup> Juul Labs, Inc., USA

<sup>b</sup> 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.

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

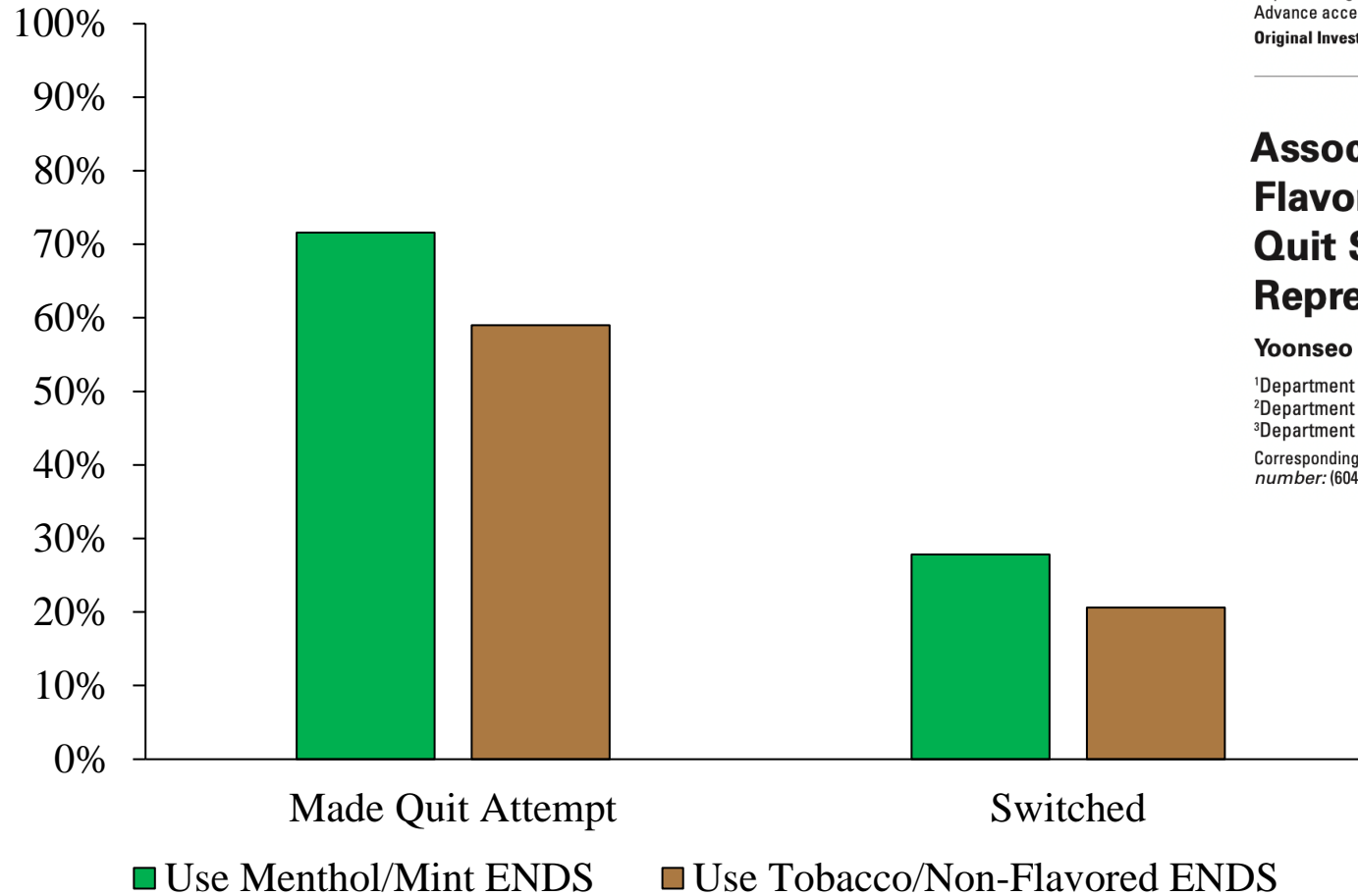
**Participants in the Adult JUUL Switching and Smoking Trajectories study who used Menthol (vs. Tobacco) flavored JUUL products had significantly higher rate rates of switching across the second year of follow-up.**



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.



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



*Nicotine and Tobacco Research*, 2023, **25**, 541–552  
<https://doi.org/10.1093/ntr/ntac241>  
Advance access publication 17 October 2022  
Original Investigation



## Associations Between E-cigarette Use and E-cigarette Flavors With Cigarette Smoking Quit Attempts and Quit Success: Evidence From a U.S. Large, Nationally Representative 2018–2019 Survey

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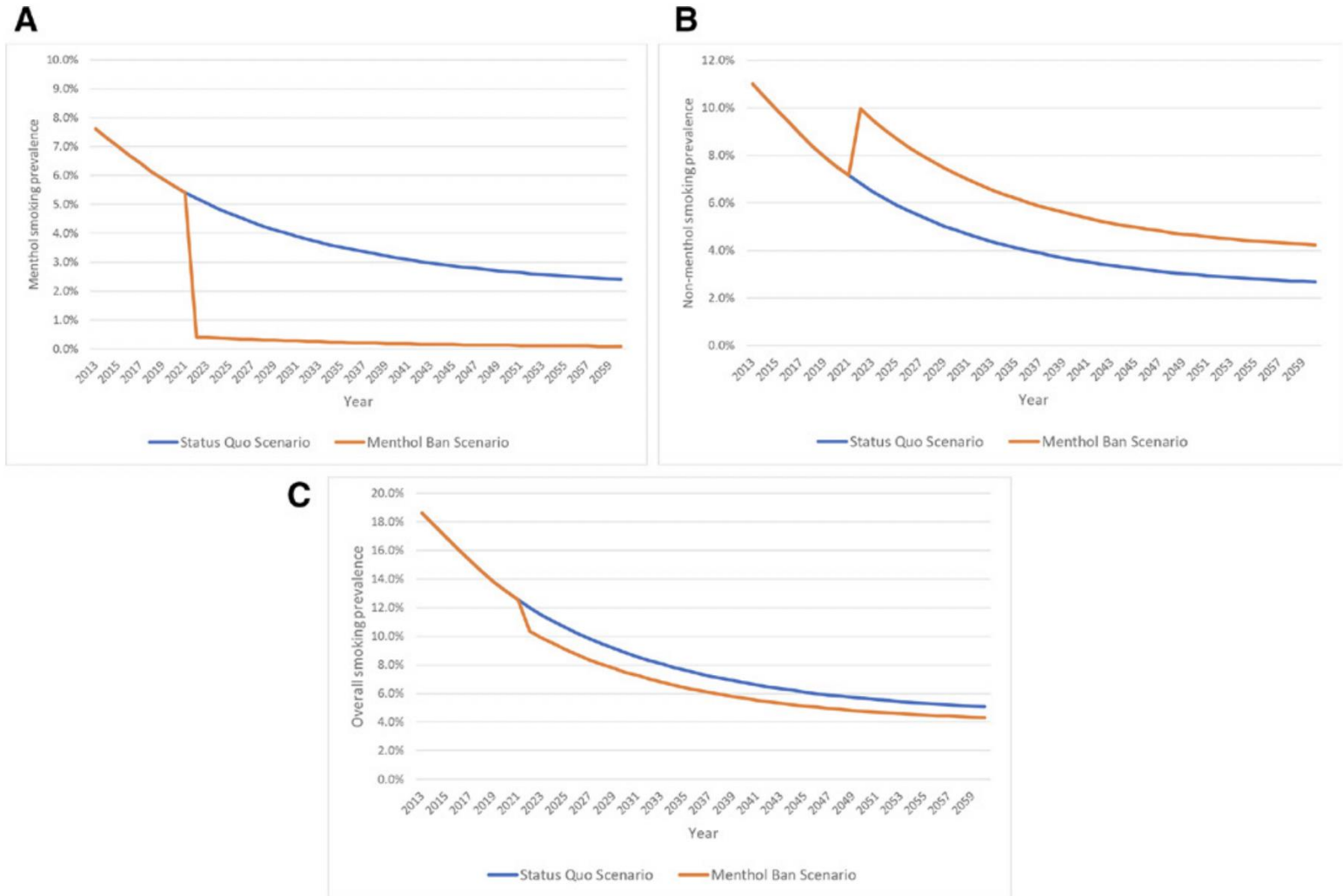
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Mok Y, Jeon J, Levy DT, Meza R. Associations Between E-cigarette Use and E-cigarette Flavors With Cigarette Smoking Quit Attempts and Quit Success: Evidence From a U.S. Large, Nationally Representative 2018–2019 Survey. *Nicotine Tob Res.* 2023 Feb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

# 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.