Juul Labs OMB 12866 Meeting

Tobacco Product Standard for Menthol in Cigarettes

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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



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

David T Levy 0, Rafael Meza 0, Zhe Yuan, Yameng Li, Christopher Cadham, Luz Maria Sanchez-Romero o, 1 Nargiz Travis o, 1 Marie Knoll, 1 Alex C Liber o Ritesh Mistry O, Jana L Hirschtick, Nancy L Fleischer O, Sarah Skolnick, Andrew F Brouwer , 2 Cliff Douglas , 2 Jihyoun Jeon, 2 Steven Cook, 3 Kenneth E Warner 0 2

Introduction The US Food and Drug Administration most recently announced its intention to ban menthol cigarettes and cigars nationwide in April 2021. Implementation of the ban will require evidence that it would improve public health. This paper simulates the potential public health impact of a ban on menthol in cigarettes and cigars through its impacts on smoking initiation, smoking cessation and switching to nicotine

Methods After calibrating an established US simulation nodel to reflect recent use trends in cigarette and NVP use, we extended the model to incorporate menthol and non-menthol cigarette use under a status quo scenario. Applying estimates from a recent expert elicitation on the behavioural impacts of a menthol ban, we developed a menthol ban scenario with the ban starting in 2021. We estimated the public health impact as the difference between smoking and vaping-attributable deaths and life-years lost in the status guo scenario and the menthol ban scenario from 2021 to 2060.

Results As a result of the ban, overall smoking was estimated to decline by 15% as early as 2026 due to menthol smokers quitting both NVP and combustible use or switching to NVPs. These transitions are projected to reduce cumulative smoking and vaping-attributable deaths from 2021 to 2060 by 5% (650 000 in total) and analyses showed appreciable public health benefits

Conclusions and relevance Our findings strongly support the implementation of a ban on menthol in cigarettes and cigars.

While US cigarette smoking prevalence has declined substantially in the past decade, the prevalence of menthol smoking has remained constant. 1-5 Menthol cigarettes now represent 35% of cigarette sales6 and are disproportionately used by youth, young adults, women and African-Americans.³⁷ Menthol cigarette use has been associ-ated with increased smoking initiation and reduced smoking cessation. s-11 In response, the European Union, Canada, Brazil, Ethiopia and Turkey have file 1. banned menthol in cigarettes. ¹² In the USA, more than 20 localities and the state of Massachusetts have

Status quo scenario

cigarettes and cigars.¹⁴ A stronger evidence base is urgently needed about whether such a ban would improve public health.¹⁵ ¹⁶

A small body of research has examined the potential impact of banning menthol in cigarettes. A simulation model¹⁷ 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 vapin products (NVPs, also known as e-cigarettes). Addi tionally, recent evidence finds that a menthol bar limited evidence of reducing smoking initiation and switching from smoking to other products. 18 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 cessa tion and on NVP use.19

This paper applies the results of our expert elic tation to evaluate a US menthol ban on all combus-tibles, including cigarettes and cigars. We use the previously developed smoking and vaping mode (SAVM)²⁰ to simulate the impact of the ban on ciga rette and NVP use. We extend that model to distin to estimate the public health impact of a mentho ban on combustible tobacco products.

The SAVM is a compartmental model that simu lates the public health impact of cigarette and NVP use over time for a specific set of birth cohorts in a given population.20 The model is publicly available as a Microsoft Excel file with a user manual.²¹ W extend SAVM to project menthol and non-mentho scenario) and in the presence of a ban (menthol bar scenario). We estimate the public health impact as the difference in smoking and vaping-attributable deaths (SVADs) and life-years lost (LYLs) between scenarios. Further description of the model and model equations are found in online supplementa

banned menthol cigarettes. 13 Recently, the Food The SAVM 20 first projects never, current and forme and Drug Administration announced its intention smoking prevalence using age and sex-specific

Leve DT et al. Teh Control 2023;32:e37:e44. doi:10.1136/tehacroccostrol.2021.056604

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	-		
<u> </u>			0.7	0.9%
Switch to non-menthol cigars, especially little cigars, filtered cigars or cigarillos (exclusively or with other products, but not cigarettes)	-	4.1		(0.7/71.2)
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 in Age 35-54 100 menthol smokers in the status quo)

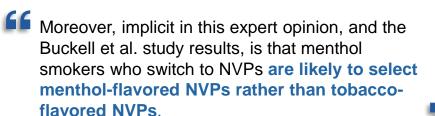
Population	Status Quo	Menthol Cigarette and Cigar Ban	Net Effect	Final Transition as a Percent of Menthol Smokers in the Status Quo
Product Type	Mean	Mean	Absolute difference	Percent of 71.2%
Continue to be menthol cigarette smokers (exclusively or with other products)	71.2	-	-71.2	
Switch to non-menthol 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				17.20/
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.



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...



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.

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







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Article

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

Brian L. Rostron *, Joanne T. Chang, Cindy M. Chang, Rebecca A. Jackson and Bridget K. Ambrose

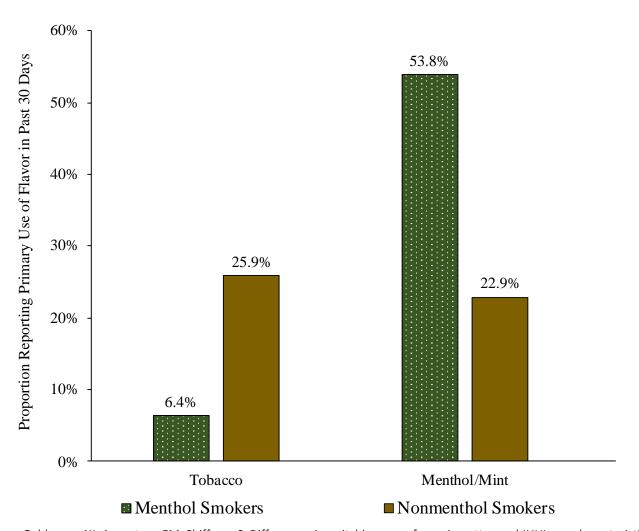
Center for Tobacco Products, US Food and Drug Administration, Silver Spring, MD 20993, USA; joanne.chang@fda.hhs.gov (J.T.C.); cindy.chang@fda.hhs.gov (C.M.C.); rebecca.jackson@fda.hhs.gov (R.A.J.); bridget.ambrose@fda.hhs.gov (B.K.A.)

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Examining the potential role of ecigarettes to reduce health disparities associated with menthol cigarette use: Characterizing e-cigarette use, flavors, and reasons for use among US adults smoking menthol cigarettes

- 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

Drug and Alcohol Dependence

journal homepage: 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 a,*,1, Erik M. Augustson a, Saul Shiffman b

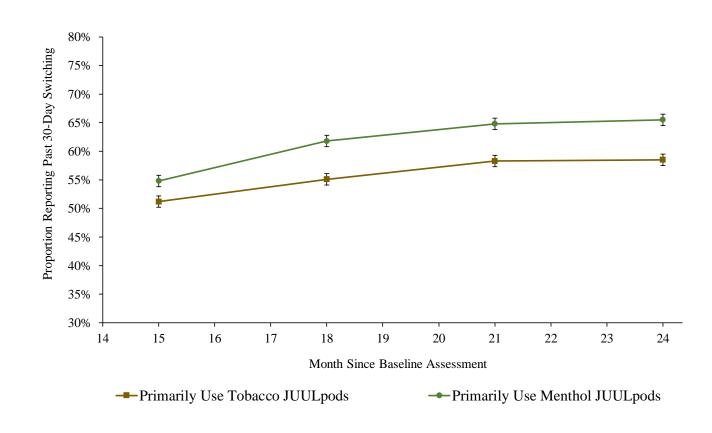
Goldenson NI, Augustson EM, Shiffman S. Differences in switching away from cigarettes and JUUL use characteristics among adult menthol and nonmenthol smokers who purchased the JUUL System. Drug Alcohol Depend. 2022 Feb 1;231:109238. doi: 10.1016/j.drugalcdep.2021.109238. Epub 2021 Dec 24. PMID: 34974269.

a Juul Labs, Inc., USA

b PinneyAssociates, Inc., USA

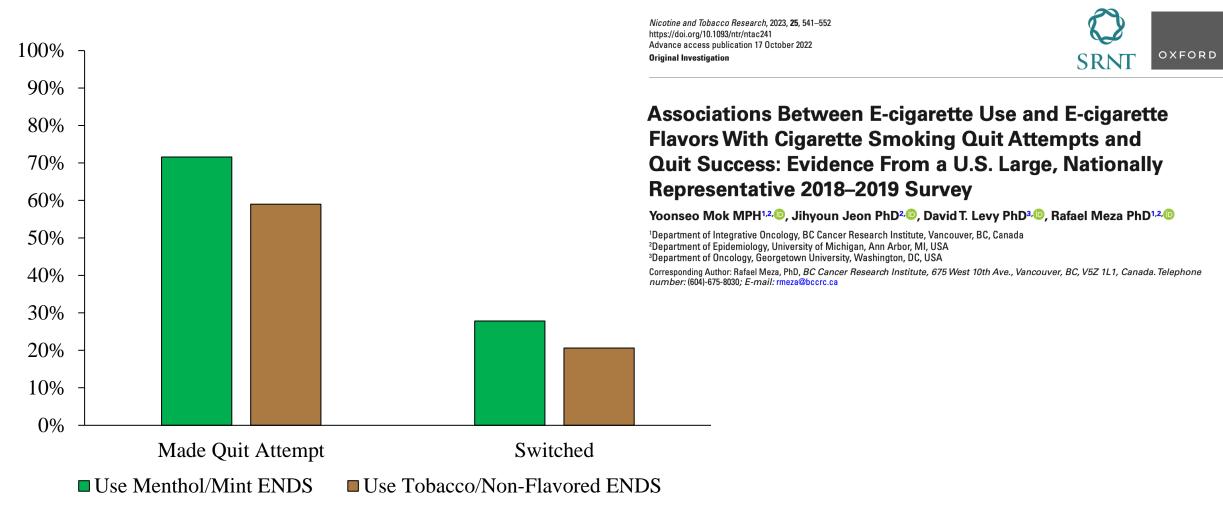
US Adults Who Smoke and Use Menthol-Flavored ENDS Products (vs. Tobacco) Have Higher Rates of Switching

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.



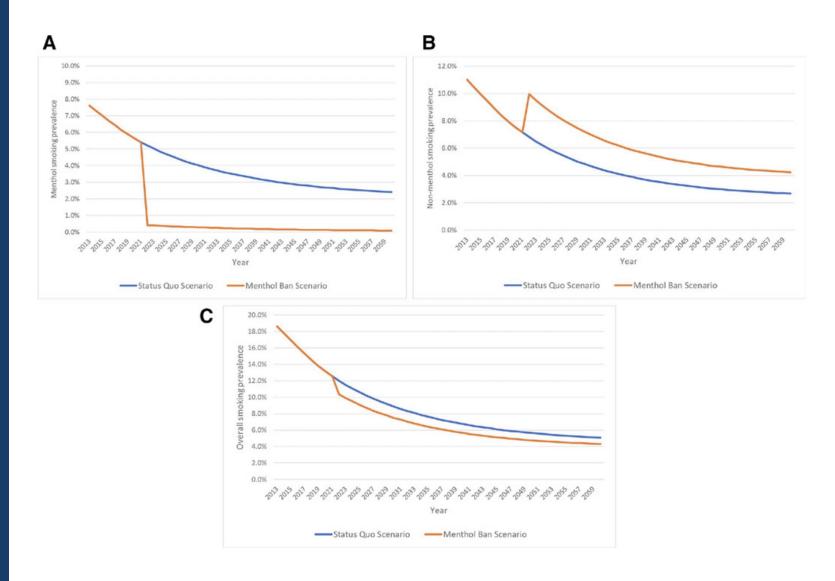
Shiffman S, Sembower MA, Augustson EM, Goldenson NI, Haseen F, McKeganey NP, Russell C. The Adult JUUL Switching and Smoking Trajectories (ADJUSST) Study: Methods and Analysis of Loss-to-Follow-up. Am J Health Behav. 2021 May 1;45(3):419-442. doi: 10.5993/AJHB.45.3.3. PMID: 33894793.

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



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.