MODELING A MENTHOL BAN USING THE MENTHOL SAVM (SMOKING AND VAPING MODEL)

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Funding and Conflicts of Interest

Requirements of the FDA

- Pursuant to the Family Smoking Prevention and Tobacco Control Act (TCA), FDA may not issue a new rule to regulate the marketing and sale of tobacco products or to regulate the characteristics of the tobacco product unless FDA determines that the rule is "appropriate for the protection of the public health" [TCA, Sec. 906(d)(1) & 907(a)(3)]. Our TCORS focuses on modeling public health implications of policies.

- A ban on menthol in cigarettes was previously attempted by the FDA and failed, due to court challenge citing lack of evidence of public health effects. Hence, our model.

- Recently, the FDA promulgated a new proposal for a ban on menthol in cigarettes and all flavors of cigars. The expert elicitation and model presented today were featured prominently in the report, see https://www.fda.gov/media/158012/download

Elements of Modeling a Menthol Ban

- Define the menthol ban framework and the potential role of flavors in cigarettes (i.e., menthol) and ENDS

- Evidence:
  - Literature review- studies of actual and hypothetical use related to menthol cigarette ban
  - Expert Elicitation- framed to the needs of our model

- Model
  - Development of the model
  - Model calibration and validation
  - Base results
  - Sensitivity analysis

Scoping Review: Impact of actual and hypothetical menthol and flavor bans (Cadham et a., BMC Pub Health 2020)

	Implemented Menthol Ban (Actual)	Hypothetical Menthol Ban (Hypothetical)	Implemented Flavor Ban – Cigarettes Only	Implemented Flavor Ban – All Tobacco
Sales change (ban)	~100% reduction	NA	NA	39% reduction sales
Sales change (all tobacco products)	11% reduction	NA	Increase in cigar sales cigar sales	27% reduction in all cigar sales
Quit Attempt	29%-63%	24%-64%	NA	NA
Successful Quit	24%	NA	NA	NA
Switch to other tobacco products	28%-76%	11%-46%	14%	0%-11%
Switch and attempt to quit	NA	20-25%	NA	NA
Switch to ENDS	29%	12-30%	NA	NA
Illicit use under a ban	NA	9-25%	NA	NA
Odds of Trying Any Tobacco Product	NA	NA	-6%	NA
Reduced Odds of Trying Cigars	NA	NA	NA	5%

Issues based on the review

- The impact of a menthol ban varied considerably across studies, seemingly independent of the quality of studies.

- Information on the relationship of switching from menthol cigarette use to ENDS use was limited. While some hypothetical studies considered the impact of ENDS, the potential impact of ENDS had likely changed with newer brands (Juul).

- Studies of a menthol cigarette ban did not explicitly consider the role of cigar use. A separate literature has considered the high rate of substitutability between cigar and cigarette use, suggesting their potentially importance.

For the above reasons, we conducted an expert elicitation which explicitly considered ENDS and the difference between a ban on menthol cigarettes alone and a ban on both menthol cigarettes and cigars

Expert Elicitation (EE) focused on Menthol Ban

- Similar to the methodology employed by FDA is modeling a nicotine reduction standard (Apelberg, NEJM, 2018)

- Worked with an EE expert and conducted extensive discussion in our TCORS on framework and potential transitions

- Used 11 experts (chosen based on expertise in the area and publications) and provided them with recent prevalence data and our scoping review of the literature on menthol bans. Two rounds (Delphi method) conducted over the internet.

- Scenarios: 1) ban on menthol only in cigarettes, 2) ban only on menthol in cigarettes and cigars, 3) menthol cigarette and ENDS flavor restrictions

- Considered four target groups
  - Age 12-24- initiation
  - Age 18-24- prevalence of menthol smokers
  - Ages 35-54- prevalence of menthol smokers
  - Ages 35-54- prevalence of non-menthol smokers

See *Levy et al. Nicotine and Tobacco Research, 2021 for further information*

Transition over two year period of menthol smokers age 35-54 in the status quo with a ban on menthol in cigarettes and cigars

Product Type	Before ban Mean	With ban Mean	Min	Max	Absolute difference
Continue to be menthol cigarette smokers (exclusively or with other products)	67.9	0.0			-67.9
Switch to non-menthol cigarettes (exclusively or with other products, except menthol cigarettes)	4.5	45.7	60	90	41.2
Switch to cigars, especially little cigars, filtered cigars, or cigarillos (exclusively or with other products, but not cigarettes)	2.7				
Switch to non-menthol cigars, especially little or filtered cigars or cigarillos (exclusively or w? other products, but not cigarettes)		3.7	0	10	1.0
Switch to illicit menthol cigarette or cigar use	0.0	5.7	0	12	5.7
Total Combustible	75.2	55.2			
Switch to exclusive smokeless tobacco or other oral tobacco products	2.6	2.4	0	5	-0.2
Switch to novel nicotine delivery products (NNDP), such as ENDS or heated tobacco products (exclusively or in combination with other products, but not cigarettes or cigars)	9.7	20.0	6	33	10.3
Quit regular use of all tobacco or novel nicotine delivery products	12.5	22.5	10	65	10.0

Transition of would-be menthol smokers by age 24 with a ban on menthol in cigarettes and cigars (meant to capture initiation)

| Population	Status Quo	Menthol Ban			
Product Type	Mean/ Median	Mean	Median	Min	Max
Become non-menthol cigarette users (exclusively or with other products)	-	33.0	30.0	1.9	79.0
Become non-menthol cigar users (exclusively or with other products, but not cigarettes)	-	5.5	2.0	0.0	20.0
Become illicit menthol cigarette or cigar user	-	2.6	1.0	0.0	10.0
Total combustible use (status quo all menthol cigarettes)	100.0	41.1	46.0	3.5	83.0
Become exclusive smokeless tobacco or other oral tobacco product users	-	2.2	2.0	0.0	5.0
Become novel nicotine delivery product users (NNDP), such as ENDS or heated tobacco products (exclusively or in combination with other products, but not cigarettes or cigars)	-	17.6	20.0	3.4	25.0
No tobacco or novel nicotine delivery product use	-	39.1	30.0	6.0	92.3

Menthol Model: Basic Strategy

- We used the Smoking and Vaping Model (SAVM), with an underlying age-period-cohort analysis, incorporating ENDS and validated by gender and age over the period 2013-2020 (Levy et al., Population Metrics 2021). Different than previous model by Levy et al. (2011) which used SimSmoke (no ENDS).

- *The Menthol Status Quo Scenario d*istinguishes menthol and non-menthol cigarettes use and trajectories absent a ban. We calibrated the model menthol vs. non-menthol smoking rates to trends in actual rates.

- The *Menthol Ban Scenario* transitions are based primarily on the expert elicitation. We assumed that the ban includes a ban on menthol in cigarettes and cigars, but we did not explicitly model cigar impacts. The ban alters status quo trajectories of menthol cigarette use towards non-menthol combustible, ENDS or non-use.

- Calculate the public health effects = difference in attributable deaths and life years lost (LYL) between the Menthol Status Quo and the Menthol Ban Scenario

ibed in more detail in Levy et al., Tobacco Control, 2021.

Smoking and ENDS Prevalence, Smoking and Vaping Attributable Deaths, Life-Years Lost and Public Health Impact for Both Genders Combined, Ages 18 and Above, 2021-2060

Menthol Status Quo				
Category/Year	**2021**	**2026**	**2060**	**Cumulative (2022-2060)**
Menthol smoker	5.4%	4.5%	2.4%	-56%
Nonmenthol smoker	7.2%	5.7%	2.7%	-63%
All Smokers	12.6%	10.2%	5.1%	-60%
Exclusive ENDS user	3.5%	4.7%	5.8%	64.4%
Former smoker	19.4%	18.4%	9.2%	-53%
Former ENDS user	0.2%	0.6%	4.6%	1973%
Total SADs	380,525	377,046	282,457	14,217,294
Total LYL	4,694,635	4,425,092	2,401,706	143,238,275
Menthol Ban Scenario				
Category/Year	**2021**	**2026**	**2060**	**Cumulative Impact**
Menthol smoker	5.4%	0.3%	0.1%	-98%
Nonmenthol smoker	7.2%	8.4%	4.2%	-41%
All Smokers	12.6%	8.7%	4.3%	-66%
Exclusive ENDS user	3.5%	5.7%	7.4%	108.0%
Total Smoking-Attrib. Deaths	380,525	359,958	268,435	13,563,073
Total life years lost	4,694,635	4,113,651	2,182,890	131,927,198
Public Health Impact				
Menthol Smoker	-	-92%	-97%	-
Nonmenthol Smoker	-	47%	58%	-
All Smokers	-	-15%	-15%	-
Exclusive ENDS use	-	23%	27%	-
Averted Deaths	-	17,088	14,022	654,221
Averted life-years lost	-	311,441	218,817	11,311,077

Prevalence Rates: Pre- and Post-Menthol Ban
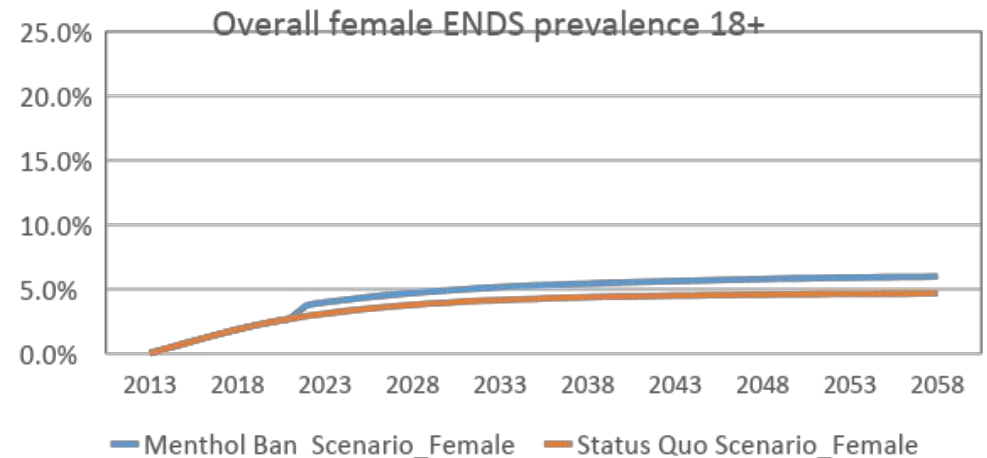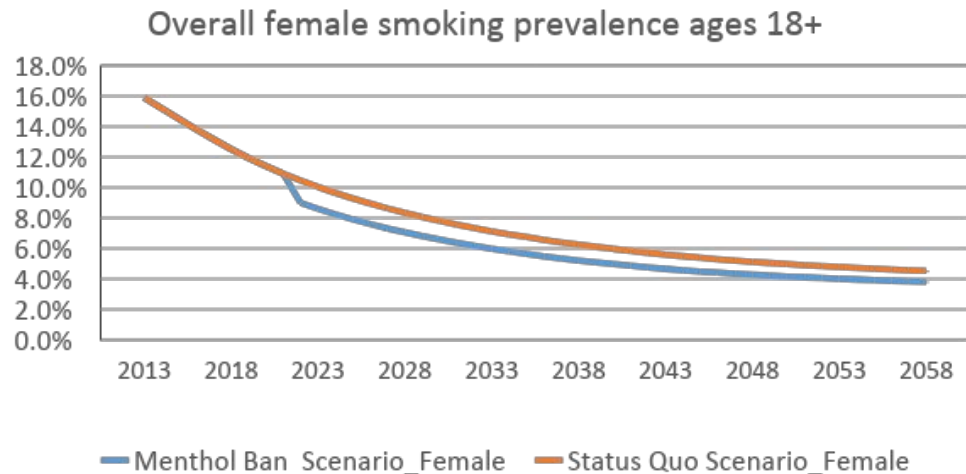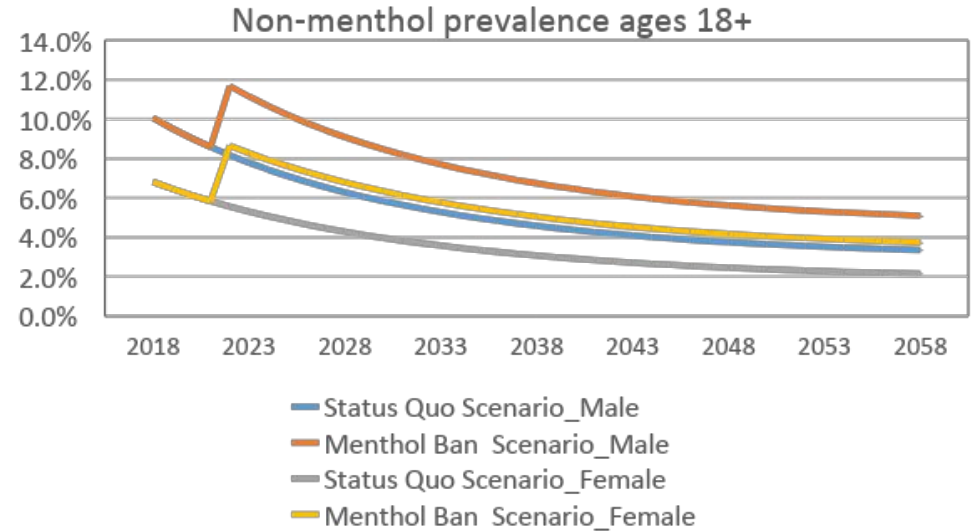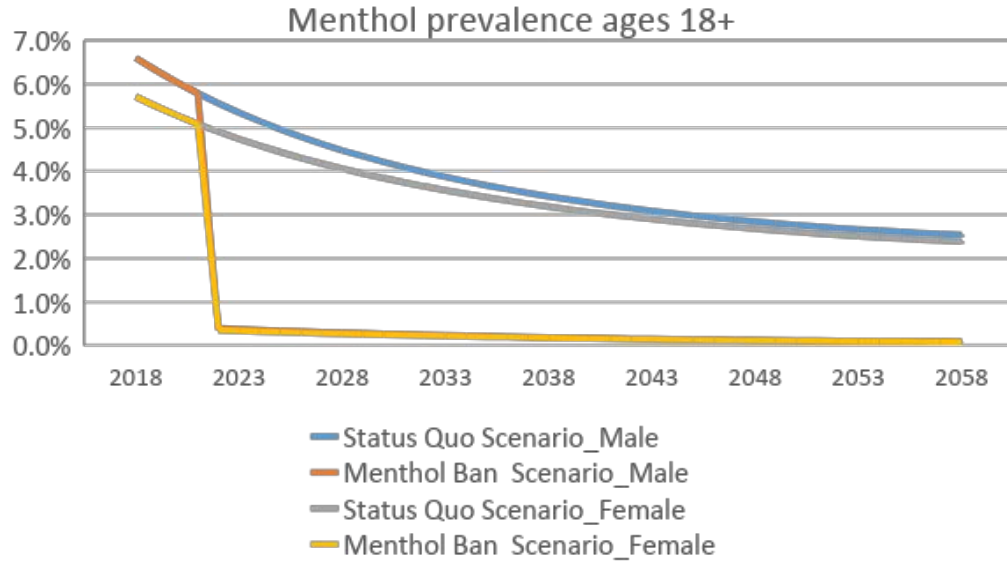
Sensitivity Analysis of Averted Smoking- and Vaping-Attributable Deaths (ASVADs) to ENDS Excess Risks and Individual Transition Parameters

- Increasing the ENDS excess risk from 15% to 25% reduced SVADs by 5% and reducing to 5% increased ASVADs by 5%

- Changing vaping or smoking initiation rates changed ASVADs $\leq$ 6%

- Increasing cessation rates, especially for menthol cigarette use, to non-product use increased ASVADS by almost 30%

- Increasing switching rates (to ENDS use) increased ASVADs by 11% to 23% depending how modelled.

Limitations

- The ban on menthol is assumed to apply to cigarettes and cigars (to reduce substitution into cigars), but does not explicitly model cigar use.
- Definitions of regular use are important to gauging public health impacts, but are not well-established. We do not model dual use, which is especially problematic.
- Does explicitly model variations across different subpopulations (e.g., Race and SES). We have extended to separately model for NHBs (Tobacco Control 2022).
- Stability of transitions is assumed, especially as related to ENDS (e.g., recent increases and declines in ENDs use, major changes in technology or surrounding events such as Covid).
- Does not incorporate smokeless tobacco/nicotine pouches (NPs; Zyn and On!) and heated tobacco products.
- Other non-menthol policies, including cigarette- and ENDS-oriented policies, are not considered and implicitly assumed be constant.

Conclusions

- Banning menthol flavors in cigarettes could
  - Reduce smoking by 15% by having smokers giving up tobacco products altogether or switching to ENDS and other nicotine vaping product
  - Prevents 650,000 premature deaths due to smoking in the next 40 years (16,250 tobacco-related deaths per year) and results in 11 million life-years gained (almost 300,000 per year) over the 40-year period
  - Can be expected to simultaneously provide health gains across all populations and especially among the Non-Hispanic Black (NHB) population, thus potentially reducing health disparities between the NHB and the rest of the US population

- We also conducted sensitivity analyses. Over the ranges considered, the impact of a menthol ban was sensitive to smoking cessation rates and rates of switching from cigarette to ENDS, but relatively insensitive to ENDS excess risks, and to cigarette and ENDS initiation parameters, and ENDS cessation parameters.

Future Projects

- Extending the Menthol SAVM model to examine how a menthol cigarette ban would be influenced by a policy restricting non-tobacco flavored ENDS. The role of an ENDS flavor restrictions is much less clear, especially in view of the impact of other potential cigarette substitutes (HTPs, NPs).

- Developing SAVM cigar models to consider switching between cigars and cigarettes and potential impact of a cigar flavor ban.

SAVM is meant to be a user-friendly model SAVM is available from the TCORS website with 100 page User Manual. We encourage others to use the model.

Thanks!