

July 22, 2022,

Dr. Robert Califf

Commissioner, Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, MD 20993

RE: Docket No. FDA-2021-N-1349 Tobacco Product Standard for Menthol in Cigarettes

Dear Dr. Califf:

Reason Foundation is grateful for the opportunity to submit comments on the proposed rule to prohibit the use of menthol as a characterizing flavor in cigarettes. Reason Foundation's nonpartisan public policy research promotes choice, competition, and a dynamic market economy as the foundation for human dignity and progress. Reason produces rigorous, peer-reviewed research and directly engages the policy process, seeking strategies that emphasize cooperation, flexibility, local knowledge, transparency, accountability, and results.

The available evidence suggests prohibition of menthol cigarettes will not present significant public health benefits to the population as a whole and will produce a suite of negative consequences undermining the FDA's goals. While studied for decades, the evidence is either conflicted or directly contrary as to whether menthol cigarettes pose greater risks for smoking initiation, progression to regular smoking, increased dependence, and reduced cessation, particularly among African Americans, compared to non-menthol cigarettes.

The FDA has not sufficiently considered the effectiveness of menthol bans and tobacco prohibitions from other jurisdictions, the severe limitations on and public misperceptions of safer alternatives such as e-cigarettes, or the unintended consequences of possible increased cigarette consumption among those menthol smokers who switch to a non-menthol product. The FDA has also not accounted for the extremely low levels of youth cigarette use, for which menthol remains the least favored option. Furthermore, such a prohibition will result in a host of unintended consequences, including increased tobacco smuggling, burdens on law enforcement, and more frequent interactions between law enforcement and minority communities.

INITIATION

While menthol smoking among youth has been shown to be somewhat elevated compared to adult smokers, menthols have been consistently less popular than non-menthol cigarettes.

Whether menthol can be convincingly shown to increase youth initiation relative to non-menthol is a key part of the FDA's rationale for restricting menthol. In its 2021 scientific review of the effects of menthol cigarettes on tobacco addiction, the FDA stated that menthol is "likely associated with increased smoking initiation."¹

But the FDA relies exclusively on its 2013 preliminary scientific evaluation of menthol and reference addendum to reach this conclusion. The FDA's evaluation asserted menthol is likely associated with increased initiation, but the breadth of evidence reviewed was not strong enough to support this position, with FDA saying there "...is no indication that menthol smokers first experience cigarette smoking any earlier or later than nonmenthol smokers (Pletcher et al., 2006; Okuyemi et al., 2004; Gandhi et al., 2009)." ² The FDA adds: "Data that appear to indicate that menthol smokers start smoking later than nonmenthol smokers are difficult to interpret because differences may be driven by racial or ethnic differences."

The FDA is referencing research showing African American smokers, who disproportionately choose menthol products, start later, not earlier, than white smokers. The data is, in fact, not difficult to interpret. If menthol is a clear contributor to youth initiation in and of itself, it should be clearly observable that menthol cigarette smokers should start earlier than non-menthol smokers across demographics. It should not be surprising that tobacco naïve smokers are more likely to experiment with menthol than adult smokers who have established taste preferences and brand loyalties. There is no convincing evidence that in the absence of menthol, those who initiated with menthol wouldn't have initiated smoking at all, especially as many who start with menthol reject it in favor of non-menthol, which is substantially more popular among adults.

In its 2013 reference addendum, three studies were added that used different methodologies to examine menthol's impact on smoking initiation.^{3,4,5} The first study by Dauphinee et al. examined the relationship between brand recognition and smoking initiation. The authors found students

¹ "Scientific Review of the Effects of Menthol in Cigarettes on Tobacco Addiction: 1980-2021," Food and Drug Administration. April 2022. <https://www.fda.gov/media/157642/download>

² "Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes," Food and Drug Administration, Center for Tobacco Products. 2013. <https://www.fda.gov/media/86497/download>

³ Dauphinee, A.L., Doxey, J.R., Schleicher, N.C. *et al.* "Racial differences in cigarette brand recognition and impact on youth smoking." BMC Public Health. February 2013. <https://bmcpublichealth.biomedcentral.com/articles/10.1186/1471-2458-13-170>

⁴ Rosenbloom J, Rees VW, Reid K, Wong J, Kinnunen T. "A cross-sectional study on tobacco use and dependence among women: Does menthol matter?" Tobacco Induced Diseases. November 2012. <https://pubmed.ncbi.nlm.nih.gov/23181980/>

⁵ Faseru B, Nollen NL, Mayo MS, Krebill R, Choi WS, Benowitz NL, Tyndale RF, Okuyemi KS, Ahluwalia JS, Sanderson Cox L. "Predictors of cessation in African American light smokers enrolled in a bupropion clinical trial." Addiction Behaviors. March 2013.

<https://www.sciencedirect.com/science/article/abs/pii/S0306460312003838?via%3Dihub>

who recognized Newport (menthol) at baseline were 49% more likely to initiate smoking. However, Camel's menthol brand was the most recognized of all three examined at 53%, with the second being a non-menthol Marlboro brand at 36%. Yet recognition of Camel and Marlboro did not predict smoking initiation. So while Camel was the most recognizable brand and also had a menthol flavor profile, it was not subject to significant interest in initiation. It is hard to maintain that menthol as a flavor profile is what is driving youth initiation as opposed to other influences over brand choice affecting the study's subjects which were selected from an urban, racially diverse California school district. Were the study replicated in a homogenous, rural Kentucky school district, you would likely observe the opposite result. The use of such a study to claim menthol is an independent driver of smoking initiation is inappropriate.

The following two studies found no difference between menthol and non-menthol smokers in the age of the first cigarette smoked. The FDA's assertion that menthol is likely associated with increased youth initiation was further undermined in 2014 by a peer-reviewed study by Reynolds American and Environ International.⁶ "Results from the analyses provided herein indicate that menthol cigarette use is not associated with an earlier age of initiating smoking or a greater likelihood of being a daily versus non-daily smoker; and, that menthol cigarette preference is not greater among new, less-experienced compared to more-established youth smokers," said the study's authors. More recently, the FDA's preliminary regulatory impact analysis attempts to make use of a host of studies examining youth initiation following menthol sales restrictions. In total, the FDA cites eight studies as directly relevant to the question of whether these restrictions impact youth initiation.

Two of these studies find youth tobacco use was either unchanged or increased following the bans on flavored tobacco, though the FDA challenges the findings of both, citing a separate study in one case. A further study simply examines the compliance of licensed tobacco retailers within San Francisco following a flavored tobacco ban, with no data on either sales or prevalence of tobacco use. Two studies only examined sales following flavored tobacco bans. One of these by Asare et al. studied the impact of Massachusetts's flavored tobacco ban, correctly identifies a dramatic fall in menthol sales within Massachusetts but is incorrect in claiming most neighboring states saw no increases in overall tobacco sales. A replication analysis by Reason Foundation's Jacob Rich found that in the year following the ban, Massachusetts sold 29.96 million fewer cigarette packs compared to the prior period. However, 33.36 million additional cigarette packs were sold during the same post-ban period in the

⁶ Curtin GM, Sulsky SI, Van Landingham C, Marano KM, Graves MJ, Ogden MW, Swauger JE. "Measures of initiation and progression to increased smoking among current menthol compared to non-menthol cigarette smokers based on data from four U.S. government surveys." *Regulatory Toxicology and Pharmacology*. November 2014.
<https://www.sciencedirect.com/science/article/pii/S0273230014001810>

counties bordering Massachusetts. Including all of the states bordering Massachusetts, the region saw a net increase in cigarette sales.

The second study focusing on San Francisco shows a sharp decline in flavored tobacco sales within the city relative to two other California cities with no flavor ban. But the study does not account for tobacco sales directly bordering San Francisco nor for youth prevalence of tobacco use within San Francisco. The FDA itself acknowledges the limitations of relying on aggregate tobacco sales information as a proxy for consumption, given that; “overall sales data are more likely to be driven by adult than adolescent use, given the larger size of the adult population as well as the tendency for youth to acquire tobacco via social sources.”

The final study examines youth tobacco use before and after sales restrictions in Minneapolis and St. Paul, Minnesota, finding an overall increase in youth tobacco after the menthol ban use largely driven by e-cigarette use. However, the increase was less than in the rest of the state. The authors’ conclusions are at best lukewarm on the effect of the policy, stating: “Policies restricting sales of all flavored and menthol tobacco products may be associated with attenuated increases in youth use of tobacco product categories.” Of all the studies cited in the FDA’s regulatory impact analysis, not even one actually examines the effects menthol has on youth smoking initiation, two contradict the FDA’s position on the effect of menthol bans, and one has failed to replicate. It is unclear why there is not more recent and clearer evidence for FDA to draw upon when claiming menthol is more likely to facilitate smoking initiation. Given the relative weight, initiation plays in modeling outcomes of a menthol ban the FDA should examine further how much evidence there truly is to associate menthol as a flavor profile with youth smoking initiation.

The assumption that there will be significant benefits from menthol prohibition by preventing youth initiation is also highly dubious, given that youth smoking rates have plummeted to almost negligible levels. Fortunately, current youth smoking rates in the United States are at a record low of 1.5%. The percentage of youth who smoke between 20-30 days of the month is just 0.28%, according to the 2021 National Youth Tobacco Survey.⁷ Of that small percentage, more than 60% of middle and high school students who are defined as current smokers use non-menthol cigarettes. Just 0.6% of middle and high school students used a menthol cigarette in the past 30 days. Many of the alleged future benefits of a menthol ban are predicated on the assumption that youth initiation will be severely diminished, but this is not supported by the current trends in youth smoking. According to an analysis of data from the Monitoring the

⁷ Gentzke AS, Wang TW, Cornelius M, et al. “Tobacco Product Use and Associated Factors Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021,” Centers for Disease Control and Prevention, March 2022.
https://www.cdc.gov/mmwr/volumes/71/ss/ss7105a1.htm?s_cid=ss7105a1_w

Future Surveys between 2012 and 2020, “Continuing declines in adolescent menthol prevalence indicate that both menthol prevalence and also black/non-black disparities in its use are steadily decreasing.” Overall, relative menthol levels for African Americans were lower versus all adolescents in all study years, according to the authors.⁸

Given that youth menthol use is already at de minimis levels, the lack of evidence on facilitating youth initiation, and the relative unpopularity of the product compared to non-menthol cigarettes FDA should revise its assumptions on future public health benefits of a menthol ban.

DEPENDENCE

FDA’s most recent scientific evaluation finds the weight of the evidence supports the conclusion that menthol is associated with greater dependence in youth. But as previously mentioned, smoking has been largely eliminated amongst youth, with current menthol smoking for middle and high school students standing at 0.5% in 2021. The prohibition of menthol cigarettes, based in large part on issues of youth initiation and dependence, is an extreme policy response to a situation where 99.5% of youth are not using the product in question.

Among the significantly larger adult smoking population, menthol accounts for 43% of smokers, according to the 2020 National Survey on Drug Use and Health. But when the FDA examined menthol’s association with dependence among adult menthol smokers over four decades, no association could be found: “Based on the weight of evidence spanning 1980-2021, the evidence is not sufficient to support conclusions of an association of menthol in cigarettes with dependence among adults. A relationship between menthol and dependence among adults cannot be determined due to the inconsistency of findings across the body of evidence.” Given the weight the FDA places on a menthol ban’s ability to reduce dependency in the smoking population, the agency should further consider the wide difference in dependence between adult and youth smoking populations while also accounting for the low and falling levels of youth use.

DISEASE RISK

Menthol and non-menthol cigarettes are both addictive and can cause smoking-related diseases, but non-menthol cigarettes are not safer than their menthol counterparts. The FDA’s 2011 review stated: “No studies found an increased risk of cancer or noncancer diseases in menthol smokers compared to nonmenthol smokers. From the available studies, the weight of

⁸ Miech RA, Leventhal AM, Johnson LD. “Recent, national trends in US adolescent use of menthol and non-menthol cigarettes.” Tobacco Control. December 2021.
<https://pubmed.ncbi.nlm.nih.gov/34853161/>

evidence supports the conclusion that menthol in cigarettes is not associated with an increase in disease risk to the user compared to non-menthol cigarette smokers.” However, this is not entirely accurate when accounting for the consumption patterns of menthol and non-menthol smokers.

Research published in the *Journal of the National Cancer Institute* found menthol smokers were somewhat less likely to develop lung cancer than non-menthol smokers.⁹ “Black men are known to have a higher incidence of lung cancer and are more likely to smoke mentholated cigarettes compared with white men,” said the study’s lead author, Vanderbilt-Ingram Cancer Center’s William Blot, Ph.D. “It has been hypothesized that menthol in cigarettes influences smoking behavior, perhaps increasing dependency or adversely affecting the biology of the lung. However, our large study found no evidence to support those theories.”

According to the study, menthol smokers using 20 or more cigarettes per day were around 12 times more likely to develop lung cancer than never-smokers. But non-menthol smokers using 20 or more cigarettes per day were 21 times more likely to develop lung cancer than never-smokers. The differences in lung cancer prevalence were reflected in lung cancer death rates. The researchers also found that both white and African American menthol smokers reported smoking fewer cigarettes per day than non-menthol smokers. Further research specifically examining cardiovascular disease mortality (CVD) published in *Circulation* finds menthol is not a greater contributor to CVD than non-menthols.¹⁰

While menthol cigarettes present no greater inherent health risk than non-menthol cigarettes, the behavioral differences between these two groups are cause for concern. If non-menthol smokers are at a significantly elevated risk of developing lung cancer, the FDA must consider the possibility that in response to the restriction of menthol, a large portion of those who switch to a non-menthol product will change their smoking behavior and position themselves to be at greater risk of long-term health damage. The FDA should conduct a prospective analysis on consumer perceptions of the relative safety of non-menthol versus menthol cigarettes were menthol to be banned to investigate whether smokers and the general public will perceive non-menthols to be safer than menthol cigarettes.

CESSATION

⁹ Dagny Stuart. “Study Snuffs out Menthol Myths.” Vanderbilt-Ingram Cancer Center. March 2011. <https://news.vicc.org/2011/03/cancer-center-study-snuffs-out-menthol-myths/>

¹⁰ Munro HM, Tarone RE, Wang TJ, Blot WJ. “Menthol and Nonmenthol Cigarette Smoking: All-Cause Deaths, Cardiovascular Disease Deaths, and Other Causes of Death Among Blacks and Whites.” *Circulation*. May 2016. <https://pubmed.ncbi.nlm.nih.gov/27022064/>

The FDA claims the weight of the evidence suggests that menthol is likely associated with reduced cessation success in the general population and particularly among African American smokers. The most recent evidence contradicts the assertion that menthol is associated with reduced cessation in the general population. A meta-analysis published in 2020 identified 22 reports from 19 studies on the association between menthol use and cessation.¹¹ The model found no overall association between menthol use and cessation. However, African Americans were shown to be somewhat less likely to successfully quit smoking than other groups.

Considering menthol smokers of all groups are using the same product, the lower quit rate for African Americans must be explained. It would be extraordinary and not in line with the scientific evidence for the FDA to claim there is some biological difference as to why African American menthol smokers quit at lower rates than their peers. Instead, the FDA should examine what other factors may explain this difference. The African American smoking population has less access to education and financial resources than their white counterparts, both of which are strongly associated with quitting success. There is also evidence to suggest that smoking cessation services are not provided to the levels or as easily accessible to African Americans as they are to smokers of other groups.¹²

But even these somewhat lower rates of cessation amongst African American menthol smokers may themselves be out of date. The most recent evidence published in the *Journal of the National Cancer Institute* shows quit rates among menthol and non-menthol smokers are indistinguishable.¹³ The study also found no significant difference in quit rates between African American and white smokers. These findings reflect earlier research published in 2011 showing no significant difference between menthol and non-menthol smokers in terms of cessation.

REASON ANALYSIS OF YOUTH AND ADULT MENTHOL USE

In order to measure the relationship between menthol cigarette access and youth use, Reason Foundation employed National Survey on Drug Use and Health (NSDUH) data from the

¹¹ Smith PH, Assefa B, Kainth S, Salas-Ramirez KY, McKee SA, Giovino GA. "Use of Mentholated Cigarettes and Likelihood of Smoking Cessation in the United States: A Meta-Analysis." *Nicotine & Tobacco Research*. March 2020.

<https://academic.oup.com/ntr/article/22/3/307/5514242>

¹² Bandi P, Minihan AK, Siegel RL, Islami F, Nargis N, Jemal A, Fedewa SA. "Updated Review of Major Cancer Risk Factors and Screening Test Use in the United States in 2018 and 2019, with a Focus on Smoking Cessation." *Cancer Epidemiology, Biomarkers and Prevention*. July 2021.

<https://pubmed.ncbi.nlm.nih.gov/34011554/>

¹³ Munro HM, Shrubsole MJ, Zheng W, Wen W, Blot WJ. "Smoking Quit Rates Among Menthol vs Nonmenthol Smokers: Implications Regarding a US Ban on the Sale of Menthol Cigarettes." *Journal of the National Cancer Institute*. July 2022.

<https://academic.oup.com/jnci/advance-article-abstract/doi/10.1093/jnci/djac070/6571153?redirectedFrom=PDF#no-access-message>

Substance Abuse and Mental Health Services Administration (SAMHSA) and fiscal-year industry cigarette distribution figures for the months October to September. Our panel model dataset was completed for all 50 states and Washington, D.C. for the years 2008 through 2020, and evaluated:

- (1) The number of packs of menthol and nonmenthol cigarettes distributed per capita
- (2) The percentage of cigarettes distributed that are menthol, and
- (3) The smoking rates for ages 12-17, 18 and older, and 12 and older

With these data, we used standard descriptive statistics and metric techniques to analyze the relationship between the distribution of various types of cigarettes and their use among different age groups in the population. Correlation coefficients among the variables are published in Table 1. The correlation coefficient between cigarettes distributed per capita ages 12 and above and cigarette past month use ages 12 and above is 0.722 (*), signaling a proxy-level relationship. This suggests that the surveys measuring use reflect market patterns and likely lack an exact 1-to-1 relationship due to the variance in how many cigarettes are consumed on average during any given amount of time among cigarette smokers nationwide. Another correlation of interest is between cigarette past month use 12 to 17 and the percentage of packs that are menthol among all distributed cigarettes, which at -0.358 (**) communicates a weak negative relationship.

Table 2 reports the average number of packs of cigarettes consumed per year for smokers age 12 and older. By dividing the total number of cigarette packs sold for each flavor by the number of associated smokers for each year, measured by multiplying NSDUH smoking percentage estimates for individuals reporting they have smoked at least once a month by the included Census Bureau population estimates for that age group, we estimate the number of cigarette packs regular, menthol, and all smokers consumed each year. According to these methods, the most recent year of data from 2020 suggests menthol smokers consumed 24.3% fewer cigarettes than regular smokers. Given that the NSDUH asks, “Were the cigarettes you smoked during the past 30 days menthol?” without asking whether menthol cigarettes are the primary type of cigarette smoked, the denominator for the number of menthol smokers is likely underestimated. However, smokers who smoke primarily non-flavored cigarettes sometimes smoke menthol cigarettes, meaning that the numerator for the number of packs smoked by menthol smokers is also overestimated. From 2008 to 2014, cigarette consumption per smoker gradually decreased, but in 2015 jumped to 8.6%, which was then followed by another gradual decrease until 2020. The COVID-19 pandemic was accompanied by a 12.2% increase in total cigarette sales and was the highest rate of consumption since 2008.

TABLE 1: VARIABLE CORRELATION COEFFICIENTS

	Percentage packs menthol	Total packs	Total menthol packs	Packs per capita 12 and older	Menthol packs per capita 12 and older	Cigarette use past month 12 and older	Cigarette use past month 12 to 17	Cigarette use past month 18 and older
Percent packs menthol	1							
Total packs	0.150	1						
Total menthol packs	0.359	0.940	1					
Packs per capita 12 and older	-0.211	0.095	0.050	1				
Menthol packs per capita 12 and older	0.503	0.247	0.372	0.679	1			
Cigarette use past month 12 and older	-0.199	0.105	0.047	*0.722	0.454	1		
Cigarette use past month 12 to 17	** -0.358	0.057	-0.036	0.590	0.224	0.794	1	
Cigarette use past month 18 and older	-0.196	0.115	0.058	0.721	0.462	0.999	0.773	1

TABLE 2: AVERAGE NUMBER OF CIGARETTE PACKS SMOKED PER YEAR BY FLAVOR

Year	Packs per Year:		
	All Smokers	Menthol Smokers	Nonflavored Smokers
2008	274.07	234.18	294.58
2009	251.42	228.70	262.61
2010	244.00	211.74	261.78
2011	249.56	213.23	271.02
2012	235.39	201.80	255.81
2013	232.03	199.83	252.15
2014	224.00	194.48	242.68
2015	243.28	219.04	258.06
2016	236.90	215.82	249.82
2017	240.01	217.90	254.06
2018	233.94	210.45	249.27
2019	225.59	201.78	241.60
2020	253.22	214.13	282.85

The regression section employs an elementary robustness analysis, utilizing two different specifications: ordinary least squares (OLS) with no controls and an OLS “panel” analysis with fixed effects (γ_i), time effects (λ_t), and state linear time trends ($\delta_i T$). The panel model dummy variables account for unobserved factors that vary over time, constantly between states, and change uniquely in each state. If the variables pass the robustness tests, signaled by overly consistent results in both models, the panel model coefficients equal the predictive effects. The panel model clusters standard errors by state and all observations are weighted by the state population. Variables in the panel model are in their natural log form and their coefficients are elasticities. The below equations represent the relationship between smoking (s_{it}) and cigarette distribution (d_{it}):

$$\text{OLS: } s_{it} = \beta_0 + \beta_d d_{it} + \epsilon_{it}$$

$$\text{Panel: } s_{it} = \beta_0 + \beta_d d_{it} + \lambda_t + \gamma_i + \delta_i T + \epsilon_{it}$$

Table 3 reports the coefficients (β_d) from the OLS model. Relationships of interests include adult and child past month cigarette use as a function of the percentage of cigarettes distributed that are menthol, and separately, packs of menthol and all cigarettes distributed per capita (population age 12 and older). We also evaluated the relationship between child (age 12 to 17) and adult smoking rates.¹⁴

TABLE 3: OLS REGRESSION ANALYSIS RESULTS

Independent Variable	Dependent Variable	Estimate	Standard Error	t-statistic	p-value	95% CI:	
						(High	Low)
Youth Smoking Rate	Proportion Menthol	-0.498	0.081	-6.177	0.000	-0.657	-0.340
Adult Smoking Rate	Proportion Menthol	-0.026	0.028	-0.916	0.360	-0.082	0.030
Youth Smoking Rate	Cigarette packs per capita	0.821	0.039	21.081	0.000	0.745	0.898
Adult Smoking Rate	Cigarette packs per capita	0.364	0.010	36.589	0.000	0.345	0.384
Youth Smoking Rate	Menthol cigarette packs per capita	0.464	0.039	11.891	0.000	0.387	0.540
Adult Smoking Rate	Menthol cigarette packs per capita	0.258	0.011	23.805	0.000	0.237	0.279

¹⁴ Angrist, Joshua & Pischke, Jörn-Steffn. “Mostly Harmless Econometrics: An Empiricist’s Companion.” Princeton University Press. 2008.

Youth Smoking Rate	Adult monthly smoking rate	2.425	0.062	38.814	0.000	2.302	2.548
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In general, OLS reports average relationships that describe typical states, without confirming causal relationships. States that increase their menthol distribution relative to all cigarettes reduce their rates of child past month cigarette use, with a 1% increase in the proportion of menthol cigarettes leading to a 0.49% reduction (95% CI: -0.657, -0.340) in youth use. Additionally, states with higher distribution per capita of either type of cigarette have higher rates of use among both children and adults. States that experience a 1% increase in adult smoking on average increase their child smoking rates by 2.4%. This last observation is consistent with the literature that finds 25% of children with parents who smoke cigarettes eventually initiate smoking themselves, as opposed to 8% of children from stable nonsmoking parents.¹⁵

TABLE 4: PANEL REGRESSION ANALYSIS RESULTS

Independent Variable	Dependent Variable	Estimate	Standard Error	t-statistic	p-value	95% CI:	
						High	Low
Youth Smoking Rate	Proportion Menthol	0.513	0.199	2.580	0.010	0.122	0.904
Adult Smoking Rate	Proportion Menthol	-0.004	0.076	-0.059	0.953	-0.154	0.145
Youth Smoking Rate	Cigarette packs per capita	0.281	0.091	3.085	0.002	0.102	0.460
Adult Smoking Rate	Cigarette packs per capita	-0.063	0.035	-1.802	0.072	-0.131	0.006
Youth Smoking Rate	Menthol cigarette packs per capita	0.252	0.073	3.443	0.001	0.108	0.395
Adult Smoking Rate	Menthol cigarette packs per capita	-0.041	0.028	-1.470	0.142	-0.096	0.014
Youth Smoking Rate	Adult monthly smoking rate	0.492	0.110	4.467	0.000	0.276	0.708

Table 3 presents the results from the panel regressions. Although some estimates remain statistically significant, their signs often switch directions relative to the OLS model, meaning that the relationships are overly sensitive to which control variables are chosen and do not communicate a predictive effect. The only associations that are robust enough to claim a causal relationship are increases in adult smoking rates causing an increase in youth smoking and

¹⁵ Vuolo, Mike and Jeremy Staff. "Parent and Child Cigarette Use: A Longitudinal, Multigenerational Study." *Pediatrics*. 2013 Sep; 132(3): e568–e577. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3876755/>

increases in cigarette sales increasing youth smoking. After controlling for unobserved factors, a 1% decrease in adult smoking causes a 0.49% decrease (inverse of Est. = 0.49; 95% CI: 0.276, 0.708) in child smoking. We do not expect reverse causality to explain this relationship since it is not likely that children will influence their parents to initiate smoking. The relationship is significant above the 99.9% confidence level, which is reasonable given the near-perfect correlation coefficient of 0.773 from Table 1. This finding indicates that one of the best ways to reduce child smoking rates is to help their parents quit.

Finally, to further illustrate the lack of a relationship between menthol cigarette distribution and youth use, we ranked states in ascending order by their youth cigarette use and in descending order by the proportion of cigarettes sold that are menthol in Table 5. Although there is not a one-to-one relationship, states loosely follow having higher menthol cigarette market shares and lower rates of youth smoking. Such an observation seems to indicate that menthol cigarettes do not pose a unique threat to youth cigarette uptake relative to non-flavored cigarettes.

TABLE 5: STATES RANKED BY YOUTH CIGARETTE USE AND MENTHOL MARKETSHARE

State	Cigarette use past month 12 to 17	State	Percentage packs menthol
California	0.114	Hawaii	0.675
Utah	0.114	District of Columbia	0.597
New Jersey	0.132	Maryland	0.554
Connecticut	0.139	Delaware	0.501
Hawaii	0.141	Mississippi	0.484
Massachusetts	0.145	Pennsylvania	0.481
New York	0.145	North Carolina	0.479
New Hampshire	0.146	South Carolina	0.473
Maryland	0.148	Georgia	0.458
Florida	0.155	Virginia	0.442
Idaho	0.156	Rhode Island	0.439
Arizona	0.156	New Jersey	0.435
Oregon	0.159	Louisiana	0.430
Illinois	0.163	Alabama	0.415
District of Columbia	0.163	Connecticut	0.411
Minnesota	0.163	Wisconsin	0.410
Rhode Island	0.163	Michigan	0.406
Colorado	0.163	Florida	0.391
Georgia	0.164	New York	0.389
Virginia	0.165	Illinois	0.383

Texas	0.167	Massachusetts	0.344
Nevada	0.170	Ohio	0.336
Washington	0.170	Texas	0.330
Maine	0.172	Indiana	0.326
Delaware	0.175	Missouri	0.324
Alaska	0.175	Arkansas	0.318
Vermont	0.175	Tennessee	0.317
Wisconsin	0.179	Nevada	0.309
Nebraska	0.180	California	0.284
Kansas	0.183	Nebraska	0.282
South Dakota	0.186	Kansas	0.281
Michigan	0.190	Minnesota	0.270
Pennsylvania	0.191	Iowa	0.263
New Mexico	0.193	Arizona	0.262
North Dakota	0.195	Utah	0.252
Missouri	0.197	Washington	0.248
North Carolina	0.198	New Mexico	0.241
Wyoming	0.200	Oklahoma	0.239
Iowa	0.206	Alaska	0.237
Tennessee	0.207	South Dakota	0.236
Montana	0.208	West Virginia	0.235
Ohio	0.212	Colorado	0.234
South Carolina	0.213	Kentucky	0.229
Louisiana	0.221	New Hampshire	0.229
Indiana	0.224	North Dakota	0.218
Arkansas	0.226	Wyoming	0.190
Alabama	0.227	Idaho	0.181
Oklahoma	0.237	Oregon	0.179
Mississippi	0.242	Maine	0.176
Kentucky	0.251	Vermont	0.176
West Virginia	0.259	Montana	0.167

EQUITY

Given the disproportionate use of menthol among African American smokers, it has been suggested by the FDA and public health groups that prohibition of menthol will narrow public disparities and advance racial equity. The proposed rule references Executive Order 13995, stating the FDA and federal government “now recognize the advancement of health equity as both a moral imperative and pragmatic policy.” According to the CDC, approximately 45,000 African Americans die annually from tobacco-related diseases.

But attributing racial disparities in health outcomes to a preference for menthol as opposed to non-menthol cigarettes among African Americans ignores the evidence examining menthol's specific contribution to these disparities compared to wider societal factors. For example, an examination of menthol and smoking-related cancers found that differences in four cancers by sex and race over a 35-year period when menthol sales were stable and African American smokers were far more likely to use them compared to white smokers "are not consistent with a large contribution of menthol over and above the effect of smoking *per se*."¹⁶ A systematic review of the epidemiological evidence on lung cancer risks of menthol and non-menthol smokers found similar lung cancer risks for African American and white female smokers. The review did find an elevated lung cancer risk for African American males but concluded the preference for menthol cigarettes "cannot possibly explain their higher lung cancer risk."¹⁷

According to the American Cancer Society, disparities in lung cancer death rates among smokers have already narrowed significantly because there has been a greater reduction in smoking initiation among African Americans than in other groups. This trend began in the 1970s and continued through the 1990s.¹⁸ To this day, the African American youth smoking rate is lower than that of whites and there is no substantial difference in the adult smoking rates. These trends seem dispositive of the FDA's claim that menthol is especially effective at initiating youth smoking given that menthol is the flavor of choice for African American smokers.

In its proposed rule, the FDA states that it accounted for the disproportionate toll menthol cigarettes have taken on certain population subgroups. "We note that the expected health benefits of this proposed standard are expected to be greater in these subgroups than in the population more generally," says the FDA.¹⁹ As previously discussed, menthol cigarettes are not inherently more dangerous than non-menthol cigarettes. But menthol smokers start later in life and smoke fewer cigarettes per day. Given the lack of evidence attributing health disparities in the U.S. to preferences for menthol versus non-menthol, prohibition of menthol is not supported by an equity-focused analysis. However, there are a host of reasons for disparate

¹⁶ Kabat GC, Shivappa N, Hébert JR. "Mentholated cigarettes and smoking-related cancers revisited: an ecologic examination." *Regulatory Toxicology and Pharmacology*. March 10. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3773183/>

¹⁷ Lee PN. "Systematic review of the epidemiological evidence comparing lung cancer risk in smokers of mentholated and unmentholated cigarettes." *BMC Pulmonary Medicine*. April 2011. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3103484/>

¹⁸ Islami, F, Guerra, CE, Minihan, A, Yabroff, KR, Fedewa, SA, Sloan, K, Wiedt, TL, Thomson, B, Siegel, RL, Nargis, N, Winn, RA, Lacasse, L, Makaroff, L, Daniels, EC, Patel, AV, Cance, WG, Jemal, A. "American Cancer Society's report on the status of cancer disparities in the United States, 2021." *CA: A Cancer Journal for Clinicians*. December 2021. <https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21703>

¹⁹ "Tobacco Product Standard for Menthol in Cigarettes," Food and Drug Administration. May 2022. <https://www.regulations.gov/document/FDA-2021-N-1349-0001>

health outcomes other than tobacco use. For example, older black adults are significantly more likely to die as a result of air pollution than their white peers.²⁰ As will be examined later, prohibition of menthol may run severely counter to a framework of advancing equity thanks to the likely behavioral responses most menthol smokers will have to prohibition and the threats of greater law enforcement activity in minority communities.

DOMESTIC AND INTERNATIONAL CASES OF MENTHOL PROHIBITION

While the prohibition of menthol cigarettes is a relatively new policy both within and without the U.S., there is a reasonable evidence-base from which to draw conclusions about the likely impact such a ban will have. One such study cited by the FDA, Asare et al, examined the ban on flavored tobacco products in Massachusetts. While the study is accurate in showing a substantial decline in cigarette sales within Massachusetts, it is fatally undermined by excluding cigarette sales in neighboring states. A Reason Foundation analysis found that in the year following the ban, the state sold 29.96 million fewer cigarette packs compared to the prior period. However, a total of 33.36 million additional cigarette packs were sold during the same post-ban period in the counties bordering Massachusetts. Given decreasing rates of smoking in all five bordering states between 2019 and 2020, the increase in border-state cigarette sales following the flavor ban should be interpreted as a lower-bound estimate for cigarettes that were ultimately consumed in Massachusetts.²¹

The most optimistic case study of menthol prohibition comes via Chung-Hall et al examining Canada. According to the study, while the vast majority of menthol smokers continued to smoke after the ban was implemented, a significant portion reported quitting.²² The study found that “59.1 percent of pre-ban menthol smokers switched to non-menthol cigarettes; 21.5 percent quit smoking and 19.5 percent still smoked menthols, primarily purchased from First Nations reserves.” These results might seem somewhat underwhelming given the severity of the policy but are still impactful.

²⁰ “Analysis of PM2.5-Related Health Burdens Under Current and Alternative NAAQS,” Industrial Economics. April 2022.

<https://globalcleanair.org/files/2022/05/Analysis-of-PM2.5-Related-Health-Burdens-Under-Current-and-Alternative-NAAQS.pdf>

²¹ Rich, Jacob. “Estimates of Cross-Border Menthol Cigarette Sales Following the Comprehensive Tobacco Flavor Ban in Massachusetts.” medRxiv. April 2022.

<https://www.medrxiv.org/content/10.1101/2022.04.24.22274236v1>

²² Chung-Hall J, Fong GT, Meng G, *et al*. “Evaluating the impact of menthol cigarette bans on cessation and smoking behaviours in Canada: longitudinal findings from the Canadian arm of the 2016–2018 ITC Four Country Smoking and Vaping Surveys.” Tobacco Control. July 2022.

<https://tobaccocontrol.bmj.com/content/31/4/556>

However, when we compare menthol smokers to non-menthol smokers, we see a disappointing result. According to the study's authors, menthol smokers increased their attempts to quit smoking, relative to non-menthol smokers by 9.7%. However, overall, just 7.5% more menthol smokers quit compared to non-menthol. It is also unclear whether menthol smokers from before the ban had more quit attempts than regular smokers. The study notes that between its baseline and follow-up, "[M]enthol smokers did not differ significantly from non-menthol in quit success." Compared to the U.S., menthol was also a small part of the Canadian cigarette market, accounting for 5% of Canadian sales compared to menthol products accounting for more than one-third of cigarette sales south of the border. It should also be noted that during the study period Canadian menthol smokers had access to a wide variety of safer nicotine alternatives like e-cigarettes including menthol e-cigarettes. The FDA has yet to authorize a single menthol e-cigarette and has denied market authorization to 99% of e-cigarette products.

The European Union, with its 27 member states and a population of about 450 million, is the largest region to have banned menthol cigarettes. Menthols were not a substantial part of most E.U. markets. However, Poland had the largest menthol market in the E.U. at 28%, closest to America's market at 36%. A study funded by the Norwegian Cancer Society in partnership with the Polish Health Ministry found no statistically significant change in cigarette sales after the ban.²³ Whilst significant switching to non-menthol cigarettes and increases in illicit menthol sales are to be expected after prohibition further accounting must be made for the proliferation of devices to flavor non-menthol cigarettes.

After the ban in the EU, a study of young Danish smokers found that many were still smoking menthols, 20% after the ban compared to 29% before; it was not measured whether total smoking had declined.²⁴ One reason for the high prevalence of menthol in the wake of prohibition is the rise of flavor accessories that can effectively give a menthol flavor to non-menthol cigarettes. These accessories are and will be widely available for internet purchase and the FDA will not have the resources to prevent their inflow into the U.S. or sale by domestic sources seeking to circumvent FDA's intent. Alex Liber, the author of the previously mentioned Polish study and a continued supporter of a menthol product ban said of the Danish research: "My takeaway is that any government that moves forward with a menthol ban should temper its expectations on immediate consumption declines. Tobacco companies will protect their cigarette cash cow."

²³ Liber AC, Stoklosa M, Levy DT, Sánchez-Romero LM, Cadham CJ, Pesko MF. "An analysis of cigarette sales during Poland's menthol cigarette sales ban: small effects with large policy implications." *European Journal of Public Health*. June 2022.
<https://pubmed.ncbi.nlm.nih.gov/35679583/>

²⁴ Brink AL, Glahn AS, Kjaer NT. "Tobacco companies' exploitation of loopholes in the EU ban on menthol cigarettes: a case study from Denmark." *Tobacco Control*. March 2022.
<https://tobaccocontrol.bmj.com/content/early/2022/03/20/tobaccocontrol-2021-057213#ref-2>

To look at an even more extreme example of product restrictions gone awry, the Kingdom of Bhutan banned all tobacco products in 2004. A study in the *International Journal of Drug Policy* found that claims the ban would “induce tobacco consumption to cease or nearly cease has not occurred.”²⁵ The ban sparked an enormous black market, and Bhutan abandoned its prohibition in 2020.²⁶ The available evidence suggests the most common responses among menthol smokers to product restrictions is switching to equally harmful non-menthol cigarettes, continuing to purchase menthols on the illicit market, and seeking out mechanisms to flavor cigarettes to their preferred choice. In each case, when menthol bans have been introduced they have severely underperformed the expectations of their advocates.

ENFORCEMENT AND THE ILLICIT MARKET

The FDA says it will only enforce menthol prohibition against “manufacturers, distributors, wholesalers, importers, and retailers.” However, any implication that a ban would only affect tobacco companies and established retail stores is misconceived. There are already laws on the books that would impose severe penalties on individuals who sell menthols post-prohibition. Anyone selling, importing, or distributing menthol cigarettes would be committing a crime and could land themselves in prison. Thanks to the Federal Cigarette Contraband Trafficking Act (CCTA), smuggling menthol cigarettes across state lines could result in five years in prison. Every state also has laws on the books that criminalize the unlicensed sale and distribution of tobacco products. Additionally, the possession of untaxed cigarettes is already illegal in 36 states and the District of Columbia. States and localities could enact other laws to clamp down on any increase in the illicit tobacco trade. The FDA’s product standard functionally acts as an unfunded mandate for state and local law enforcement to prevent the sale of menthol cigarettes. Given the disproportionate use of menthol among African American smokers it is reasonable to assume a larger portion of the illicit menthol trade will be concentrated in these communities.

This potential for disparate impacts through law enforcement interactions was highlighted by the mother of Eric Garner, who was killed at the hands of the New York Police Department via an interaction sparked by the sale of loose cigarettes. “When you ban a product sold mostly in Black communities, you must consider the reality of what will happen to that very same over-

²⁵ Givel MS. “History of Bhutan's prohibition of cigarettes: implications for neo-prohibitionists and their critics.” *International Journal of Drug Policy*. July 2011.

<https://pubmed.ncbi.nlm.nih.gov/21703843/>

²⁶ “Bhutan lifts tobacco ban amid coronavirus measures,” *Aljazeera.com*, Al Jazeera. 29 August 2020. <https://www.aljazeera.com/news/2020/8/29/bhutan-lifts-tobacco-ban-amid-coronavirus-measures>

represented community in the criminal justice system,” said Gwendolyn Carr.²⁷ The U.S. already suffers from a substantial illicit tobacco market, with estimates ranging from 8.5 to 21% of the total market.²⁸ Given the success of criminal networks in smuggling illicit contraband across U.S. borders, it is reasonable to assume the prohibition of menthol represents a huge profit opportunity for organized crime. With 18 million potential customers and billions of dollars spent per year on menthol cigarettes, thinking this would result in any other outcome would be naive. This is particularly likely to be the case considering that, according to a State Department report on the illicit tobacco trade, tobacco smuggling is a “low-risk, high-reward criminal activity; traffickers can make millions, with little risk of detection or harsh punishments.”²⁹

Given these factors, it is not surprising that groups ranging from law enforcement to civil rights organizations are pleading with the FDA not to move forward with menthol prohibition.³⁰

HARM REDUCTION ALTERNATIVES

While smoking rates have gradually declined over the last few decades, 12.5% of American adults continue to smoke despite the widely known dangers and many smoking cessation resources available. One reason why so many Americans keep smoking traditional cigarettes is that public health officials have mostly failed to let them know that nicotine alternatives like e-cigarettes are substantially safer than combustible cigarettes.

According to the 2020 Health Information National Trends Survey, just 1.6% of adults correctly believe e-cigarettes are much less harmful than traditional cigarettes.³¹

Since there is no burning tobacco in e-cigarette products, they are substantially safer than traditional cigarettes. Research also shows e-cigarettes are far more effective than nicotine

²⁷ Roz Edward. “Mothers of Trayvon Martin, Eric Garner join fight against menthol cigarettes,” Chicago Defender, Real Times Media. October 18, 2019.

²⁸ “Understanding the U.S. Illicit Tobacco Market: Characteristics, Policy Context, and Lessons from International Experiences,” National Academies of Sciences Engineering and Medicine. February 2015. <https://nap.nationalacademies.org/catalog/19016/understanding-the-us-illicit-tobacco-market-characteristics-policy-context-and>

²⁹ “The Global Illicit Trade in Tobacco: A Threat to National Security,” United States Department of State. 2017. <https://2009-2017.state.gov/documents/organization/250513.pdf>

³⁰ “ACLU Statement on FDA Menthol Cigarette Ban,” American Civil Liberties Union. April 28 2021. <https://www.aclu.org/press-releases/aclu-statement-fda-menthol-cigarette-ban>

³¹ “Health Information National Trends Survey 2020,” National Institutes of Health, U.S. Department of Health and Human Services. 2020. https://hints.cancer.gov/view-questions-topics/question-details.aspx?red=1&qid=1282&PK_Cycle=8

replacement therapies at helping smokers quit.³² The very analysis that the FDA relies on in its proposed rule to claim that menthol prohibition will result in a substantial number of life-years saved acknowledges this very fact, claiming a large number of menthol smokers will switch to safer nicotine products.³³ This analysis, however, assumes a robust market for these safer nicotine alternatives including menthol e-cigarettes. Yet the FDA has denied market authorization to 99% of e-cigarette products and has yet to authorize a single menthol e-cigarette. The lack of a diverse, appealing, and cost-competitive market for safer nicotine alternatives fundamentally undermines the optimistic assumptions that the FDA relies upon to produce large public health gains from menthol prohibition. A further complication to the FDA's assumptions of how menthol prohibition will work in practice is that there are significant differences among racial groups in the uptake of e-cigarettes. Analysis of the Population Assessment of Tobacco and Health (PATH) shows that non-Hispanic Blacks, Hispanics, and low-income smokers are less likely to use e-cigarettes in the context of quitting smoking. All three of these groups over-index on menthol use.³⁴ Unless the FDA changes risk perceptions around e-cigarettes and authorizes products that will be appealing to menthol smokers harm reduction will remain largely unrealized among the groups of smokers who disproportionately prefer menthol.

Rather than resorting to the failed prohibitionist policies of the past, the FDA and Biden administration should apply the harm reduction model to tobacco policy. The federal government could focus on educating the public about safer nicotine delivery products, and the latest smoking cessation products available as part of a pragmatic approach to improving public health as people choose better options than conventional cigarettes. The harm reduction model has been successfully used by governments to reduce sexually transmitted diseases, reduce overdose deaths and treat drug addiction. In the case of smoking and menthols, a harm reduction strategy would be far more effective in reducing smoking than banning menthols.

According to modeling conducted by Georgetown University Medical Center, if every smoker switched to an e-cigarette over a 10-year period, there could be 6.6 million fewer premature

³² Hajek P, Phillips-Waller A, Przulj D, Pesola F, Myers Smith K, Bisal N, Li J, Parrott S, Sasieni P, Dawkins L, Ross L, Goniewicz M, Wu Q, McRobbie HJ. "A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy." *New England Journal of Medicine*. February 2019. <https://www.nejm.org/doi/full/10.1056/nejmoa1808779>

³³ Levy DT, Meza R, Yuan Z, Li Y, Cadham C, Sanchez-Romero LM, Travis N, Knoll M, Liber AC, Mistry R, Hirschtick JL, Fleischer NL, Skolnick S, Brouwer AF, Douglas C, Jeon J, Cook S, Warner KE. "Public health impact of a US ban on menthol in cigarettes and cigars: a simulation study." *Tobacco Control*. September 2021. <https://tobaccocontrol.bmj.com/content/early/2022/04/13/tobaccocontrol-2021-056604>

³⁴ Harlow AF, Stokes A, Brooks DR. "Socioeconomic and Racial/Ethnic Differences in E-Cigarette Uptake Among Cigarette Smokers: Longitudinal Analysis of the Population Assessment of Tobacco and Health (PATH) Study." *Nicotine & Tobacco Research*. September 2019. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6751515/>

deaths.³⁵ These gains dwarf any potential benefits of menthol prohibition, apply to all smokers, and do not entail the significant costs posed by prohibition in terms of police enforcement or iniquitous treatment of minority populations.

Sincerely,

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³⁵ Levy, David & Borland, Ron & Lindblom, Eric & Goniewicz, Maciej & Meza, Rafael & Holford, Theodore & Yuan, Zhe & Luo, Yuying & O'Connor, Richard & Niaura, Raymond & Abrams, David. "Potential deaths averted in USA by replacing cigarettes with e-cigarettes." Tobacco Control. October 2017. <https://tobaccocontrol.bmj.com/content/27/1/18>