EXHIBIT B

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U.S. FOOD AND DRUG ADMINISTRATION

DOCKET NO. FDA-2021-N-1349

("TOBACCO PRODUCT STANDARD FOR MENTHOL IN CIGARETTES")

30 JUNE 2022

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1. INTRODUCTION

On April 28, 2022, the U.S. Food and Drug Administration ("**FDA**") issued a proposed rule to establish a tobacco product standard that would prohibit menthol as a characterizing flavor in cigarettes[1] (the "**Proposed Rule**").

The FDA states that it is proposing the ban "[a]fter careful consideration of the scientific evidence"[2] and that it has determined that the ban would be appropriate for the protection of the public health because it will decrease cigarette consumption by reducing initiation rates of cigarette smoking and increase the likelihood of cessation among current smokers. Further, the FDA claims that it expects the public health benefit of the ban will be particularly pronounced among vulnerable populations, including youth and young adults, as well as Black smokers.[3]

However, there is no credible evidence that banning menthol cigarettes will lead to any appreciable reduction of smoking in general or among any particular group of people, which is the central basis of the FDA's claim that the proposed standard is appropriate for the protection of the public health. Public health policy must be based on reliable empirical scientific evidence that is relevant to the regulation at hand. Extrapolating the effects of altogether different regulations is invalid and predicting the effects of a menthol ban on that basis amounts to mere speculation. Likewise, estimates based on smokers' stated intentions about what they hypothetically would do in the face of a ban are unreliable since smokers' actions very rarely match their professed intentions.

To the extent that the FDA offers actual empirical evidence of the impact of a menthol ban on smoking behaviors, it relies on methodologically questionable studies from a single jurisdiction (Canada) while ignoring more rigorous studies examining the issue of how menthol bans affect smoking. The FDA also largely ignores the experience of the European Union ("**EU**") with its menthol ban which went into effect in May 2020. The FDA proposes an extreme policy based on a very thin empirical basis and a selective review of the scientific literature.

Furthermore, the FDA's entire basis for its estimated benefit of the proposed ban is derived from an FDA-funded survey of the predictions of the impact of a menthol ban by a group of anti-tobacco proponents who have previously expressed strong views in favor of menthol bans. Rather than being objectively science based, this is tantamount to letting menthol ban advocates fill in whatever numbers they want in order to justify the FDA's proposed menthol ban. Expert speculation is still speculation.[4]

To fill in the evidentiary record, in this report I examine the European experience with a menthol ban using data from a large-scale longitudinal survey of four EU markets[5] where adult smokers were repeatedly surveyed about their actual smoking behavior pre and post the EU menthol cigarette ban. Data were also collected from U.S. respondents to provide a counterfactual comparison group. I rigorously examine how smoking changed before and after the European ban using modern panel data methods. The data represent the most comprehensive individual-level longitudinal data available to examine the effects of the most recent major menthol ban on adult smoking behavior. The countries examined in this longitudinal

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1 Food and Drug Administration Proposed Rule, Tobacco Product Standard for Menthol in Cigarettes, Docket No. FDA-2021-N-1349, 87 Fed. Reg. No. 86 at 26,454.

2 Proposed Rule, Federal Register / Vol. 87, No. 86 at 26458.

3 Ibid.

4 There is mounting evidence, in fact, that predictions by experts who have committed themselves to particular positions through public proclamations of the efficacy of a policy or who have specialized their work in a particular area might be particularly unreliable. For an overview of this work, see Philip E. Tetlock (2017), Expert Political Judgment: How Good Is It? How Can We Know?

5 The U.K. is included as one of the EU countries in the survey as it was a member of the EU when the ban on menthol cigarettes came into effect and it has continued to apply the ban following its exit from the EU.

survey are amongst the highest menthol share markets in the EU, and they have strong historical correlations with the U.S. in terms of both smoking prevalence and overall cigarette consumption. This ensures that they can usefully be compared to the U.S. The longitudinal data also allow me to focus on how smoking behavior changes for a particular person over time.[6]

Smokers in the U.S. were surveyed so as to provide a counterfactual comparator for the EU markets subject to the menthol ban. The use of a counterfactual jurisdiction when evaluating the effect of the menthol ban is crucial as it allows us to better account for confounding factors and trends that may also be affecting smoking behaviors (e.g., seasonality effects). Accordingly, this specifically designed, unique survey[7] enables a comprehensive assessment of the impact of the menthol bans in countries that are comparable to the U.S. This provides far more reliable guidance regarding the likely effect of a menthol cigarette ban in the U.S. than the FDA's selective presentation of the Canadian experience. Analyses of these data also provide more reliable estimates of the effect of a menthol cigarette ban than studies relied on by the FDA that use survey data of behavioral intentions and hypothetical choice experiments.

The large sample size and longitudinal nature of my research generate more reliable estimates than those studies used by the FDA that are based on smaller and/or non-longitudinal datasets. The European estimates discussed in this report represent the best available evidence regarding the real-world effects of menthol cigarette bans on smoking behavior in contrast to the hypothetical effects the FDA assumes based upon the predictions of experts drawing only on their own intuition.

This research provides key findings regarding the efficacy of menthol bans:

- The decline in smoking likelihood for all EU respondents after the EU menthol cigarette ban is statistically identical to the decline observed among all U.S. smokers in the same time period, suggesting that the EU menthol ban failed to reduce the likelihood that an individual smokes.
- The likelihood of being a daily smoker among EU respondents increased right after the EU menthol cigarette ban, whereas U.S. respondents were less likely to report being a daily smoker in the same time period, suggesting that menthol bans have led to unintended consequences that do not improve public health.
- The EU menthol cigarette ban was not associated with a systematic difference in reported cigarettes smoked per day among EU respondents relative to U.S. respondents, suggesting that the EU menthol ban had no effect on the consumption of cigarettes.

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[6] While longitudinal data allow a researcher to follow a particular person over time, examining how that specific person's behavior changes as a law changes, repeated cross-sectional surveys (i.e., surveys of different people at different times) can only examine aggregate behavior, making it impossible to determine whether a particular individual's response at a given time represents a behavioral change that is related to variation in the law. All other things being equal, this difference allows one to draw more reliable causal inferences from the analysis of longitudinal datasets than is possible with cross-sectional datasets. For example, in a cross-sectional sample, an individual who quit smoking before a policy change and an individual who quit smoking after the policy change are observationally equivalent if each is included in a post policy change sample wave even though, arguably, only the second individual's behavior was potentially affected by the policy change.

[7] While survey data require an analyst to rely on the assumption that respondents are not making systematic misstatements (purposely or mistakenly), the survey discussed in this report guards against any bias arising from misstatements in two ways: 1) the longitudinal nature of the data and the associated analysis allow me to adjust for any constant degree of misstatement for an individual respondent through the individual fixed effects; and 2) the use of the U.S. respondents to provide a counterfactual group accounts for any changes in misstatements (likelihood or degree), as long as those changes are also present in the counterfactual group as well. Regarding the second point, if changes in general societal opinions about smoking lead respondents to falsify their responses, the use of the U.S. as a comparator allows one to adjust for this effect if it is generally present in both the treatment and comparison groups through the wave fixed effects, guarding against any statistical bias arising from inaccuracies in the survey responses.

- All of these findings are unchanged if the analysis is restricted to those individuals who reported that they smoked menthol cigarettes in the period before the EU menthol cigarette ban went into place. This includes a finding of a statistically significant increase of about 7 percent in the likelihood of an EU country menthol smoker being a daily smoker after the EU menthol ban, again highlighting that the menthol ban was counterproductive.
- Despite many EU menthol smokers claiming they would quit smoking when the ban went into effect, very few actually quit. In fact, during the period of the EU menthol cigarette ban, quit rates among U.S. menthol smokers equaled or exceeded the quit rates observed among menthol smokers in the EU. These results indicate that stated intentions about quitting in response to a proposed menthol ban do not provide reliable evidence of the actual impact of a ban. This finding stands in stark contrast to the assumption used by Levy et al (2011)[8] to simulate the long-term effects of a menthol ban on smoking rates. In their simulation, they assume bans will lead 10-30 percent of menthol smokers to quit. Levy et al's (2021)[9] subsequent simulation also uses quit assumptions (15 to 18 percent depending on the age group) that are wildly optimistic compared with my findings of actual quit rates based on the European experience with a menthol ban. Levy et al's (2021) quit assumptions were not based on any study of an actual menthol ban but rather came from an elicitation of what 11 anti-tobacco researchers decided the effect of a ban would be.[10] The FDA's heavy reliance on Levy et al's (2021) overly optimistic simulations in its support for a menthol ban is unscientific and contrary to real world evidence.

Overall, these results provide comprehensive evidence that the EU menthol cigarette ban has not achieved its goal of reducing smoking generally or specifically among menthol smokers, and there is evidence of a counterproductive effect of the EU menthol ban, leading to an increase in daily smoking among smokers in the EU countries.

To calibrate my survey results, I examine Nielsen retail sales data from the same countries (with the exception of Finland for which the sales data are unavailable). The analysis of the sales data confirms the survey results. None of the models analyzing the Nielsen retail sales data generates a statistically significant estimate of the effect of the EU menthol ban. In each case, the point estimate is positive suggesting an increase in cigarette sales, although the increase is not statistically significant. Accordingly, there is no evidence that the EU menthol ban has reduced smoking. This complementary analysis eliminates the potential concerns that arise with survey data, namely that respondents' stated answers do not accurately represent their actual behavior and that survey response bias (either at the sampling stage or via attrition at follow-up waves) is present. My retail sales results are also consistent with recent work by Liber et al (2022)[11], discussed below, which also found no significant change in the sale of cigarettes in Poland attributable to the EU menthol ban, based on analysis of Nielsen retail sales data.

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8 David T. Levy, Jennifer L. Pearson, Andrea C. Villanti, Kenneth Blackman, Donna M. Vallone, Raymond S. Niaura, and David B. Abrams (2011), "Modeling the Future Effects of a Menthol Ban on Smoking Prevalence and Smoking-Attributable Deaths in the United States," *American Journal of Public Health*, 101(7): 1236-1239.

9 David T Levy, Rafael Meza, Zhe Yuan, Yameng Li, Christopher Cadham, Luz Maria Sanchez-Romero, Nargiz Travis, Marie Knoll, Alex C Liber, Ritesh Mistry, Jana L Hirschtick, Nancy L Fleischer, Sarah Skolnick, Andrew F Brouwer, Cliff Douglas, Jihyoun Jeon, Steven Cook, and Kenneth E Warner (2021), "Public health impact of a U.S. ban on menthol in cigarettes and cigars: a simulation study," *Tobacco Control*, Published Online First: 02 September 2021. Doi: 10.1136/tobaccocontrol-2021-056604.

10 See David T. Levy, Christopher J. Cadham, Luz Maria Sanchez Romero, Marie Knoll, Nargiz Travis, Zhe Yuan, Yameng Li, Ritesh Mistry, Clifford E Douglas, Jamie Tam, Aylin Sertkaya, Kenneth E. Warner, Rafael Meza (2021), "An Expert Elicitation on the Effects of a Ban on Menthol Cigarettes and Cigars in the United States," *Nicotine and Tobacco Research*, 23(11): 1911–1920.

11 Alex C. Liber, Michal Stoklosa, David T. Levy, Luz Marıa Sa´nchez-Romero, Christopher J. Cadham, Michael F. Pesko (2022), "An analysis of cigarette sales during Poland's menthol cigarette sales ban: small effects with large policy implications," European Journal of Public Health, https://doi.org/10.1093/eurpub/ckac063.

As noted above, the European longitudinal survey results discussed in this report provide the single most comprehensive assessment of a recent menthol ban on adult smoking behavior (smoking status and consumption) on which to predict the impact of an anticipated menthol ban in the U.S. The results stand in contrast to the FDA's depiction of the Canadian experience with menthol bans and the conclusions drawn by the FDA from the other studies it relies on, leading me to independently examine the research on the Canadian menthol ban and the other literature which the FDA relies on to support a U.S. ban. A more complete accounting of the literature on the Canadian ban shows that it is problematic for the FDA to cite Canada as a basis to believe that a U.S. menthol ban will improve public health. Many of the Canadian studies the FDA relies on are little more than data mining exercises where the authors contrive finer and finer sub-group analyses until they finally discover a statistically significant effect as described later in this report. Perhaps most egregious is the FDA's decision to largely disregard the high-quality study by Carpenter and Nguyen (2021),[12] which provides the best available evidence of the effect of the menthol ban in Canada. Consistent with my analysis of the European experience, Carpenter and Nguyen (2021) clearly demonstrate that the Canadian ban did not reduce smoking in Canada.

The studies that the FDA relies on regarding the impact of the federal non-menthol flavor ban in the U.S. and flavor bans in some U.S. States and localities, and studies that examine intentions and reactions to hypothetical scenarios also do not provide a reliable basis to believe that a U.S. menthol ban will improve public health. It is clear from many studies that such stated intentions and hypothetical reactions rarely materialize in actual behavioral responses.

The FDA's reliance on simulation studies to support the ban and as the basis for estimating the anticipated benefits of the ban is also flawed and unscientific. As indicated above, Levy et al (2011 and 2021) rely on unsupported assumptions about the effects a menthol ban will have on quit rates and initiation rates. These simulations are based on mere guesses and speculation by experts many of whom have stated their personal preferences that menthol bans be enacted in the U.S. These studies amount to little more than question begging.

Taken together with the results presented in this report, the scientific evidence does not support the claim that a menthol ban in the U.S. would reduce smoking initiation and increase smoking cessation. Put simply, the evidence base does not indicate that a U.S. menthol ban is appropriate for the protection of the public health.

The organization of the remainder of this report is as follows. Section 2 provides the details of my experience and expertise, section 3 describes the longitudinal study of smokers in the EU and the U.S., and section 4 presents the results of my analyses of the effect of the EU menthol ban on overall smoking and on menthol smokers specifically. Section 5 provides the analysis of Nielsen retail sales data. Section 6 provides a review of the menthol ban studies examining Canada and the other studies relied on by the FDA to claim that the ban would reduce smoking initiation and increase smoking cessation. Section 7 concludes. In the appendices, I provide robustness checks of the main findings, such as examining specific sub-populations of smokers, different weighting approaches, and explicitly examining if sample attrition might be affecting my results.

2. EXPERIENCE AND EXPERTISE

I am the Charles A. Heimbold Jr. Professor of Law at the University of Pennsylvania where I have been a tenured full professor since 2008, and I am the Erasmus Chair of Empirical Legal Studies at Erasmus

[12] Christopher Carpenter and Hai V. Nguyen (2020), "Intended and Unintended Effects of Banning Menthol Cigarettes," *The Journal of Law and Economics,* 64:3 629-650, also available as NBER working paper 26811 (2020).

University Rotterdam since 2009. I held the Maurice A. Greenberg Visiting Professorship at the Yale Law School in 2013 and was the Jeffrey A. Stoops Professor of Law and Economics at Florida State University from 2005-2008. I was also the inaugural Dean's Distinguished Fellow at the Villanova University School of Law from 2017-2020. Additionally, I have held visiting professorships at the following law schools: Columbia University, Northwestern University, the University of Southern California, Waseda University (Japan), Bar Ilan University (Israel), and the University of Hamburg (Germany). I was also a visiting professor in the following economics departments: University of Ljubljana (Slovenia), the University of Canterbury (New Zealand), and Goethe-Universität Frankfurt (Germany). I have been a lecturer at the Swiss National Bank's Study Center Gerzensee, as well as at Germany's Max Planck Institute. I was a senior economist at the Rand Corporation from 2007-2009.

I earned a Ph.D. in economics from George Mason University in 2002 and a J.D. from the George Mason University Law School in 2003. I have published extensively in peer-reviewed journals including the Journal of the Royal Statistical Society, the Journal of Economic Perspectives, the Journal of Law and Economics, the Journal of Legal Studies, the Journal of Law, Economics, and Organization, the American Law and Economics Review, the Journal of Quantitative Criminology, Perspectives in Biology and Medicine, and Health Economics, among others. I also regularly publish in law reviews, including the Stanford Law Review, the Columbia Law Review, and the University of Chicago Law Review.

I frequently teach courses in scientific evidence, causal inference, statistical methods, and policy evaluation in law schools and economics departments. I also regularly teach statistical methods, benefit cost analysis, and regulatory analysis to state, federal, and international judges and regulators through programs at the University of Pennsylvania and the George Mason University.

My academic work on the causal effects of health regulations on behavior has been published in the Journal of the Royal Statistical Society, the Journal of Law and Economics, the Journal of Legal Studies, the Journal of Law, Economics, and Organization, the American Law and Economics Review, and Health Economics. I have presented my research at Harvard University, including the Harvard Medical School, Yale University, Columbia University, Stanford University, the University of California Berkeley, UCLA, the University of Chicago, and many other top universities throughout the world.

My curriculum vitae is attached to this report as Appendix 1.

3. OVERVIEW OF EU LONGITUDINAL STUDY

VisionOne Research Limited,[13] an online market research company, was retained to implement an online survey of adult smokers (18 years and above) in selected EU countries. Funding for the survey and this report was provided by RAI Services Company. I designed the survey and carried out the subsequent analysis, and the views expressed in this report are my own.

In selecting the EU countries to survey, I considered those countries that are most comparable to the U.S. Focusing on the five EU markets with the highest pre-EU ban menthol consumption rates (Finland 13%, Hungary 14%, Poland 20%, Sweden 8%, and the United Kingdom 8%)[14]. Figure 1 below indicates that all

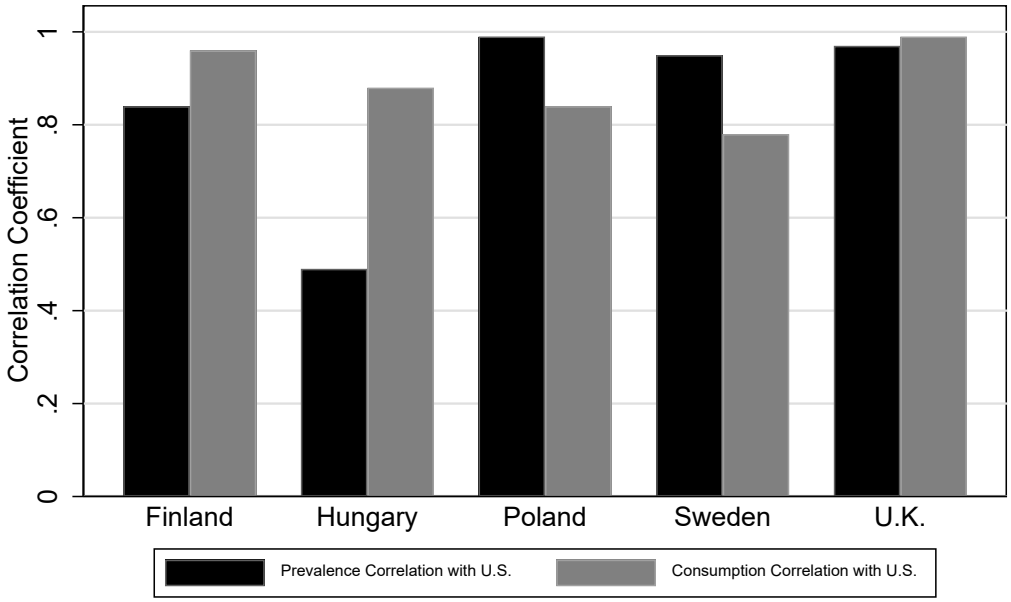
[13] VisionOne Research Limited has over 20 years' experience in providing both qualitative and quantitative market research. It is a Company Partner of the Market Research Society (MRS), the UK governing organization, and a member of ESOMAR, the global research and insight organization. It has also attained the ISO20252 accreditation specifically for the research industry. VisionOne was selected because of its experience in the field of survey research combined with its ability to implement the survey in all of the required markets. I worked closely with VisionOne to monitor the implementation of the survey in each of the markets, including directing VisionOne on attrition issues in subsequent waves.

[14] https://www.smokefreeworld.org/eu-menthol-cigarette-ban-survey/.

of these countries have high correlation coefficients with the U.S.[15] with respect to the prevalence of cigarette smoking and overall consumption, except for smoking prevalence for Hungary (which is barely above 0.5, whereas for each of the other EU countries, the correlation with U.S. prevalence exceeds 0.89). On this basis, the above markets, with the exception of Hungary, were selected to be included in the survey. I note also that the correlation coefficients for these countries are in line with the correlations between the U.S. and Canada (prevalence 0.99; consumption 0.90).[16]

Smokers in the U.S. were also surveyed so as to provide a counterfactual comparator for EU markets subject to the menthol ban.

Figure 1: Correlations with U.S.
Prevalence and Consumption



JAMA (2014) data cover period 1980-2012

Respondents were surveyed before and after the EU menthol cigarette ban. Table 1 below provides the dates during which the waves of the survey took place, as well as the number of surveys completed. Two survey waves were conducted prior to the implementation of the EU-wide menthol ban on May 20, 2020 and three waves were conducted after the ban.

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15 Correlation coefficients provide a sense of whether (and to what extent) two variables move together. Correlation coefficients range from 1 (implying that the two variables move completely together relative to their average levels and adjusting for scale differences) to -1 (implying that the variables move as mirror images of each other relative to their average levels and adjusting for scale differences). A correlation coefficient of 0 implies that the two variables are statistically independent of each other. While there are no absolute cut-offs for what constitutes a strong correlation, all other things equal, a higher correlation coefficient in the smoking metrics of two countries suggests a higher degree of similarity.

16 Data are available at http://ghdx.healthdata.org/record/ihme-data/global-smoking-prevalence-and-cigarette-consumption-1980-2012. The methods used to regularize the definitions across countries and years in generating these data are presented in Marie Ng, Michael K. Freeman, Thomas D. Fleming, et al. (2014), "Smoking Prevalence and Cigarette Consumption in 187 Countries, 1980-2012,", *JAMA.* 311(2): 183–192. doi:10.1001/jama.2013.284692 https://jamanetwork.com/journals/jama/fullarticle/1812960. Similar findings are yielded if other more current data are used for comparison as well.

Table 1: Survey Dates and Number of Observations		
	Date Range	Number of Surveys Completed
Wave 1	June 21, 2019 – July 12, 2019	11,526
Wave 2	November 29, 2019 – January 15, 2020	5,409
Wave 3	June 1, 2020 – July 7, 2020	4,261
Wave 4	November 23, 2020 – December 21, 2020	3,214
Wave 5	May 24, 2021-July 6, 2021	2,670

The surveys inquired about cigarette product consumption, awareness of the menthol ban, and intentions and actual responses to the ban. The English language version of the survey questions for all the jurisdictions are available in Appendix 7 to this report.

The survey over-sampled menthol smokers (Finland: 33%; Poland: 49%; Sweden: 31%; U.K.: 30%; U.S.: 52%) at wave 1 to ensure it was possible to focus[17] on the behavior of those smokers most targeted by the regulation (although as discussed below, there is fluidity between menthol and non-menthol cigarettes for some smokers). In Appendix 4 to this report, I demonstrate that the empirical conclusions do not change if the data are re-weighted to bring the survey in line with the actual relative menthol and non-menthol smoking populations in each country.

As is standard in the online survey market, there was attrition in the follow-up waves as shown in Table 2. By wave 5, 37 percent of the respondents in Finland were still in the sample, 25 percent of Poland's respondents remained, 21 percent of Swedish respondents were left, 29 percent of British respondents, and 15 percent of U.S. respondents completed all five waves. In Appendix 5 to this report, I demonstrate that my results are not driven by sample attrition.

Table 2: Survey Responses by Country and Wave					
(Percent of Wave 1 Respondents Remaining in Parentheses)					
	Wave 1	Wave 2	Wave 3	Wave 4	Wave 5
Finland	1,242	760 (61%)	650 (52%)	523 (42%)	459 (37%)
Poland	2,725	1,224 (45%)	972 (36%)	772 (28%)	675 (25%)
Sweden	1,172	466 (40%)	372 (32%)	280 (24%)	241 (21%)
United Kingdom	2,373	1,286 (54%)	1,076 (45%)	825 (35%)	699 (29%)
United States	4,014	1,673 (42%)	1,191 (30%)	814 (20%)	596 (15%)
Total	11,526	5,409 (47%)	4,261 (37%)	3,214 (28%)	2,670 (23%)

The basic method employed in analyzing these data is a difference-in-difference research design. While more detail is provided below, the basic intuition of such a design is to allow each group of observations (in this case, up to five observations for a given individual) to have its own intercept or baseline in the regression model. This so-called "fixed effect" absorbs any constant heterogeneity (even unobservable heterogeneity) in the person's outcome variable. This is equivalent to de-meaning the data. Essentially, this fixed effects method allows me to focus on changes over time within a specific person. In non-longitudinal data (i.e., data where there are different people in each period), one must assume that different behavior by different people over time represents a change in behavior when it could simply capture individuals who behave differently than the earlier people observed without actually changing their behavior themselves. The validity of such an assumption is impossible to test. Using longitudinal data avoids having to make such an assumption since the same individuals are followed over time.

[17] For a non-technical discussion of the motivation for oversampling, see https://www.pewresearch.org/fact-tank/2016/10/25/oversampling-is-used-to-study-small-groups-not-bias-poll-results/.

The other important element of the difference-in-difference model is the inclusion of separate period (in this case, wave) baselines. These fixed effects account for any period-specific changes that are common to all of the observations. In effect, these period effects adjust for any background trends (even trends that could be non-linear or even non-monotonic).

These two sets of fixed effects account for any unobservable heterogeneity that is either constant within a person over time,[18] or, if there is changing heterogeneity within people, if that heterogeneity is common across people, it is also accounted for in these models. Accounting for this unobserved heterogeneity allows one to isolate the causal effect of the menthol ban, as long as: 1) individual unobserved heterogeneity is constant (and so is accounted for by the individual fixed effects); or 2) any non-constant individual-level unobserved heterogeneity is common across individuals (and so is accounted for by the period fixed effects); or 3) any non-constant, non-common individual unobservable heterogeneity is not correlated with the passage of the European menthol ban.

4. RESULTS

In this section I provide the main results of my analyses. For my primary analyses, I use a difference-in-difference model,[19] which compares the change in smoking outcomes in the EU countries from the pre-ban waves to outcomes in the post-ban waves, while netting out the contemporaneous change observed in the U.S. where no menthol ban was implemented.[20] This treatment/control type comparison is largely absent from the literature relied on by the FDA, making it impossible to draw any causal inferences from those studies.

4.1 Effect on Overall Smoking

As an initial analysis, I do not separate out menthol and non-menthol smokers and, instead, examine the effect of the EU menthol ban on smoking in general. As observed in other studies,[21] a number of smokers in the current survey switched back and forth between menthol and non-menthol products. For example, by wave 2, 11 percent of those who indicated they smoked menthol cigarettes in wave 1 had switched to non-menthol cigarettes, and 7 percent of wave 1 non-menthol cigarette smokers had switched to menthol cigarettes by wave 2. This switching behavior was observed both among EU country and U.S. smokers. Given this menthol fluidity, I first examine the effect of the menthol ban on smoking in general which is also central to whether the proposed menthol rule is appropriate for the protection of public health.

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18 The regression models the within individual variation.

19 A difference-in-difference model mimics the treatment/control set-up from randomized trials where the researcher identified the causal effect as the average change in outcome for the treatment group net of the contemporaneous change in outcome for the control group. By focusing on the changes from a pre-period baseline, the researcher avoids conflating pre-existing differences in the treatment and control groups with a causal treatment effect. By netting out the contemporaneous change in the control group, the researcher avoids conflating any coincidental background trends (common to both the treatment and control groups) with the treatment effect. For a discussion of difference-in-difference designs in a public health context, see Coady Wing, Kosali Simon, Ricardo A. Bello-Gomez (2018), "Designing Difference in Difference Studies: Best Practices for Public Health Policy Research," *Annual Review of Public Health*,. 1(39): 453-469.

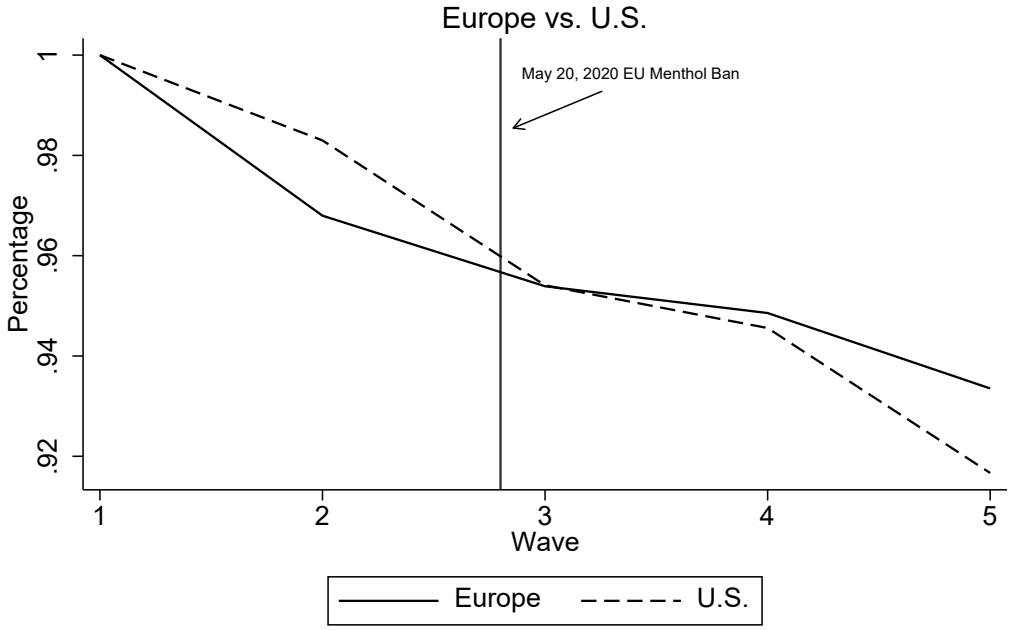
20 Similar results are obtained if, instead of using the U.S. to account for counterfactual background trends, I drop the U.S. altogether and assume a background linear trend, as well as other varieties of parametric trends in Europe.

21 See, for example, Mateusz Zatoński et al (2020), "Cessation behaviors among smokers of menthol and flavoured cigarettes following the implementation of the EU Tobacco Products Directive: findings from the EUREST-PLUS ITC Europe Surveys", *European Journal of Public Health*, Volume 30, Issue Supplement_3, iii34–iii37, https://doi.org/10.1093/eurpub/ckaa05 https://academic.oup.com/eurpub/article/30/Supplement_3/iii34/5904938, which found substantial switching of menthol smokers in the EU toward non-menthol products well before the menthol ban. There was also some switching of non-menthol smokers toward menthol products in the same time period.

4.1.1 **Smoking Status**

As shown in Figure 2, the downward trend in smoking behavior actually lessens in the EU countries after the menthol ban. Further, the ultimate smoking likelihood in the EU countries after the ban among survey respondents is slightly higher than that observed in the U.S., highlighting that the ban failed to reduce the likelihood an individual smokes.

Figure 2: Smoking Likelihood



Based on respondents who completed all waves

To examine this more thoroughly, Table 3 presents the results of a linear probability model regressing the 0-1 dichotomous outcome regarding smoking in a model that includes both individual fixed effects and wave specific fixed effects (i.e., a difference-in-difference model). This model compares the smoking likelihood for a given person (i.e., examines within individual variation) adjusting for generalized time period effects (e.g., seasonality effects common to all respondents) as laid out in the following equation:

$$\text{smoker}_{iw} = \alpha + \beta ban_{iw} + \sum_{i=1}^{I} \lambda_i + \sum_{w=1}^{4} \omega_w$$

Where *i* represents the individual respondent and *w* represents the wave. The set of λ coefficients represent the individual fixed effects which account for the pre-period baselines, while the set of ω coefficients represent the period fixed effects, accounting for any background trends common to both the treatment and control groups.

I provide two sets of results: the estimated ban effect where all respondents are used and the estimated ban effect where only those individuals answering the survey questions in all five survey waves are included in the sample. In the full sample, the effect of the ban on the probability of an EU country respondent reporting that he/she is a smoker relative to U.S. respondents is statistically indistinguishable from zero, and the estimated magnitude of the effect is trivially small with the effect being an increase of less than 0.07 percentage points. When the sample is restricted to only those completing all five waves,[22] the

[22] Complete case estimates have been shown to have reasonably good properties under a wide range of assumptions about the attrition process and, at a minimum, provide some sense of the sensitivity of the estimates

estimated effect is statistically significant (at the 10 percent level) and indicates that the ban is associated with an increase of more than one percentage point in the likelihood an EU respondent indicates that he/she smokes.

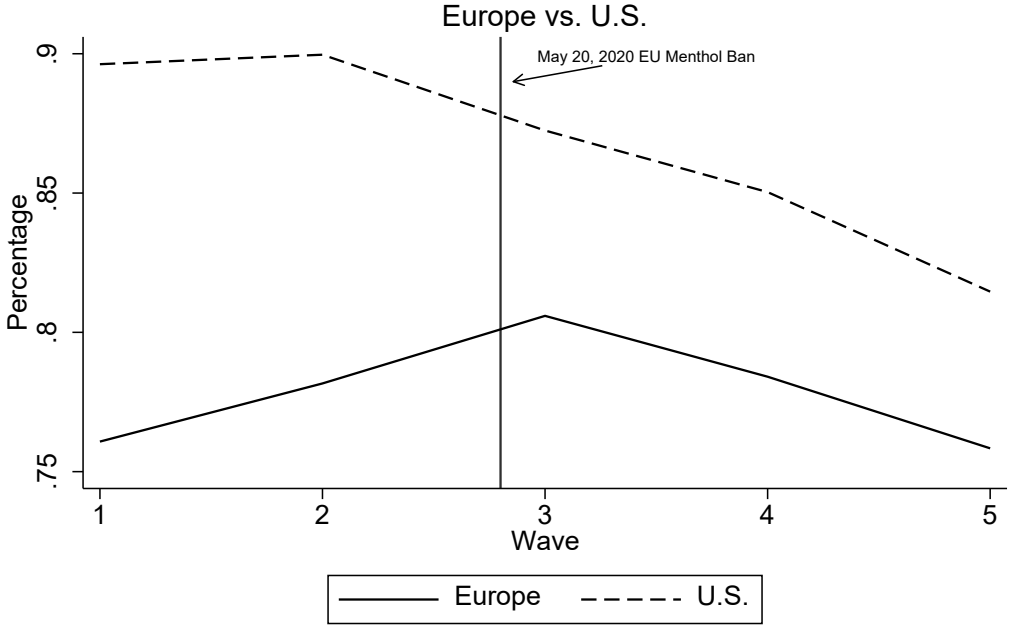
Table 3: Linear Probability Model (OLS) of Smoking Status		
All Wave 1 Smokers		
(Standard Errors Clustered at the Individual Level in Parentheses)		
	All Data	Respondents Completing 5 Waves
Ban Effect	0.0007 (0.0061)	0.0141* (0.0084)
All models include individual and wave fixed effects. *p < 0.10		

4.1.2 **Daily smoking**

Figure 3 provides the comparison of daily smoking rates across the survey waves and between the U.S. and EU country respondents. For the EU countries, the daily smoking likelihood actually increases right after the ban goes into effect and then starts to decline by waves 4 and 5. Interestingly, although the wave 1 to wave 2 slope in the U.S. is comparable to that observed in the EU countries, the U.S. slope begins to decline after wave 2 (as compared to the increasing slope in the EU countries), even though there is no menthol ban in the U.S. and the wave 3 to wave 5 slopes are comparable across the jurisdictions. This indicates that the EU menthol ban did not lessen daily smoking rates.

to attrition (see, for example, Fong Wang-Clow, Mary Lange, Nan Laird, and James Ware (1995), "A Simulation Study of Estimators for Rates of Change in Longitudinal Studies with Attrition," *Statistics in Medicine*, 14: 283-297) and is the most common way of handling attrition in clinical research (see, for example, Michael J. Mason (1999), "A Review of Procedural and Statistical Methods for Handling Attrition and Missing Data in Clinical Research," *Measurement and Evaluation in Counseling and Development*, 32(2): 111-118).

Figure 3: Daily Smoking Likelihood



Based on respondents who completed all waves

Table 4 presents the results of the difference-in-difference model that compares the daily smoking likelihood for a given respondent. As above, I examine this relationship more rigorously using a linear probability model with individual and wave specific fixed effects as laid out in the formula below (where *i* represents the individual respondent and *w* represents the wave):[23]

$$\text{daily smoker}_{iw} = \alpha + \beta ban_{iw} + \sum_{i=1}^{I} \lambda_i + \sum_{w=1}^{4} \omega_w$$

In both the full sample and the sample using only those respondents who completed all five survey waves, the menthol ban is associated with an increase in daily smoking rates in the EU countries of about 5 to 6 percentage points relative to U.S. respondents, and the estimated effects are statistically significant at the 1 percent type 1 error level.[24] This highlights the unintended effect of the menthol ban, leading to an increase in daily smoking among menthol smokers in the EU countries relative to U.S. menthol smokers.[25]

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23 As before, the set of λ coefficients represent the individual fixed effects which account for the pre-period baselines, while the set of ω coefficients represent the period fixed effects, accounting for any background trends common to both the treatment and control groups.

24 Effectively, this means that if there was no actual effect of the menthol ban, one would expect to find estimates as large (in magnitude) as this estimate in less than 1 percent of all possible samples.

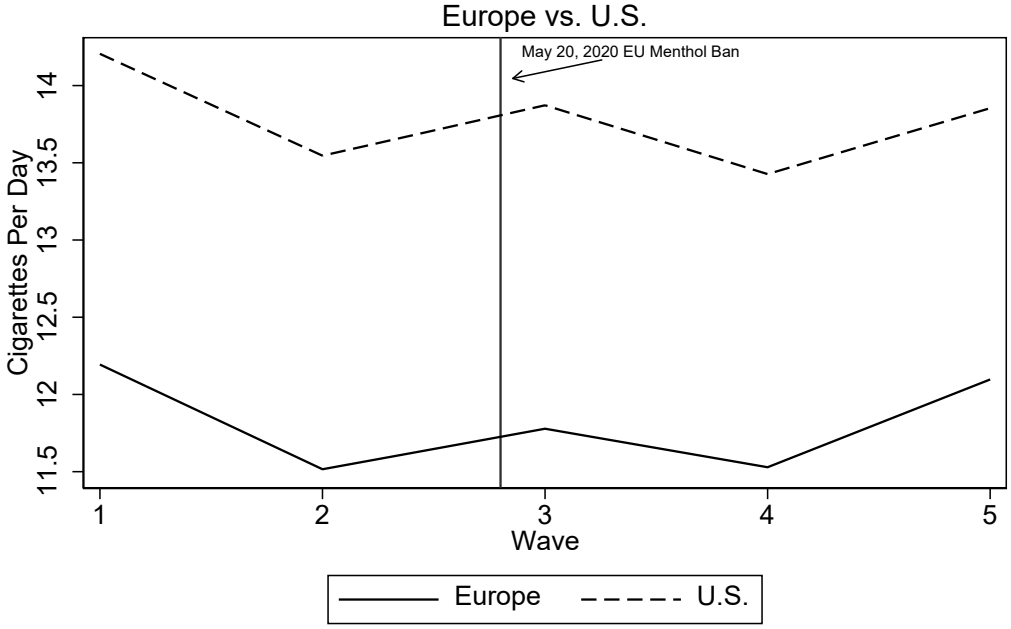
25 As for the causal mechanism for this increase in daily smoking, one possibility is that after a ban, consumers believe those products left on the market are relatively safer than the products that have been removed. Research suggests that risk perceptions can influence smoking behaviors, with lower perceptions of risk being associated with increased odds of smoking and reduced quitting. (see e.g. Anna V. Song, Holly E. Morrell, Jodi L. Cornell, et al. (2009), "Perceptions of smoking-related risks and benefits as predictors of adolescent smoking initiation," *American Journal of Public Health*, 99(3): 487-492; Mary Jean Costello, Christine Logel, Geoffrey T Fong, Mark P. Zanna, Paul W. McDonald (2012), "Perceived risk and quitting behaviors: results from the ITC 4-country survey," *American Journal of Health Behavior*, 36(5): 681-92. doi: 10.5993/AJHB.36.5.10. PMID: 22584095; PMCID: PMC4009356; Renee E. Magnan (2017) "Comparisons of health-related and appearance-related

Table 4: Linear Probability Model (OLS) of Daily Smoking Status		
All Wave 1 Smokers		
(Standard Errors Clustered at the Individual Level in Parentheses)		
	All Data	Respondents Completing 5 Waves
Ban Effect	0.0489*** (0.0091)	0.0637*** (0.0120)
All models include individual and wave fixed effects. ***p < 0.01		

4.1.3 **Cigarettes smoked per day**

Figure 4 compares the reported average number of cigarettes smoked per day (including non-smokers as smoking 0 cigarettes per day) on those days smoked, and the trends throughout all four waves are strikingly similar between the EU countries and the U.S. This indicates that smoking consumption evolved similarly in the EU countries compared to the U.S. despite the menthol ban only existing in the EU. The EU menthol ban did not systematically affect the number of cigarettes consumed by smokers per day.

Figure 4: Cigarettes Per Day



Based on respondents who completed all waves

smoking risk perceptions and worry on motivation to quit," *Health Psychology Open*, 4(2): 2055102917729541. doi: 10.1177/2055102917729541. PMID: 29379619; PMCID: PMC5779929).

The regression results in Table 5 examine the cigarettes per day outcome in an ordinary least squares (OLS) regression[26] with individual and wave fixed effects as modeled in the function below (where *i* represents the individual respondent and *w* represents the wave):[27]

$$cpd_{iw} = \alpha + \beta ban_{iw} + \sum_{i=1}^{I} \lambda_i + \sum_{w=1}^{4} \omega_w$$

Table 5: OLS Regression of Cigarettes Per Day		
All Wave 1 Smokers		
(Standard Errors Clustered at the Individual Level in Parentheses)		
	All Data	Respondents Completing 5 Waves
Ban Effect	-0.1122 (0.1558)	0.1190 (0.1978)
All models include individual and wave fixed effects.		

In neither sample is the estimated EU menthol ban effect statistically distinguishable from zero even at the 10 percent type 1 error level. In any event, the estimated coefficients are very small, representing declines of less than 1 percent (on a pre-ban EU cigarettes per day baseline of about 12 cigarettes) relative to U.S. consumption in the complete sample with similar proportionate effects (though in the opposite direction) in the sample of those who completed every wave. Again, this indicates that the EU menthol ban did not systematically affect the number of cigarettes consumed by smokers per day.

4.2 Effect on Menthol Smokers Specifically

As indicated above, identifying exclusive menthol smokers is complicated by the fact that there is some fluidity between these groups. For that reason, the foregoing analysis focused on smokers in general. However, I also provide an analysis below focusing on people who appear to primarily smoke menthol cigarettes. In this analysis, I treat anyone who indicated that they smoked menthol cigarettes in either wave 1 or wave 2 (the pre-EU menthol ban waves) as a 'menthol smoker'. [28]

4.2.1 Smoking status

As shown in Figure 5 below, the post-ban downward trend in smoking probability among this group of EU menthol smokers is not as steep as the one observed among U.S. menthol smokers in the period when the EU menthol ban was in place. This is inconsistent with a claim that the EU menthol ban led menthol smokers to quit smoking.

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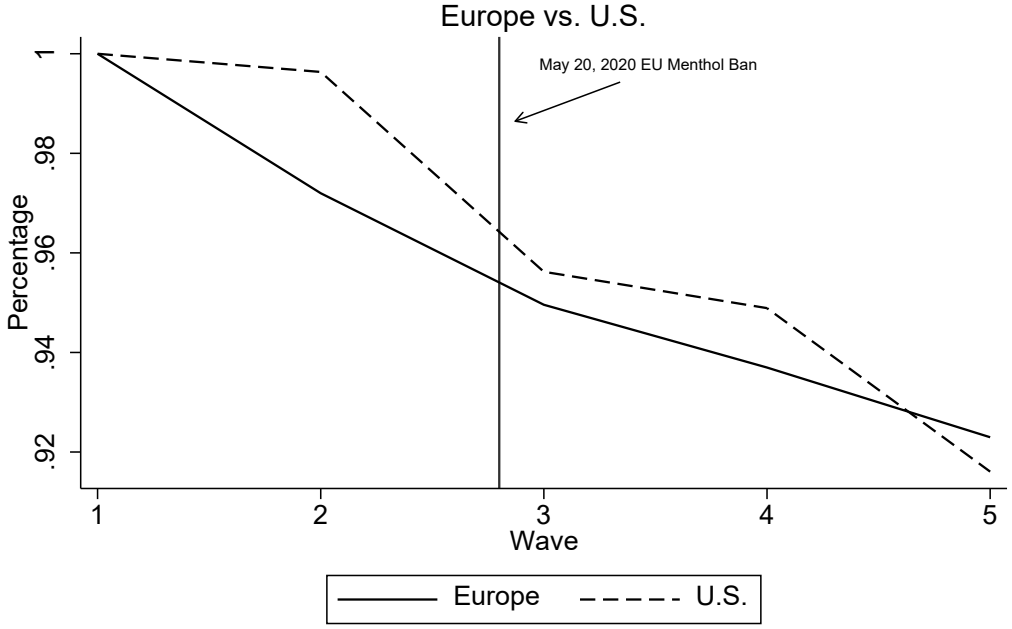
[26] The results do not significantly change if count data models (e.g., Poisson or negative binomial), that account for the fact that the data are restricted to integer, outcomes are used.

[27] As before, the set of λ coefficients represent the individual fixed effects which account for the pre-period baselines, while the set of ω coefficients represent the period fixed effects, accounting for any background trends common to both the treatment and control groups.

[28] Quantitatively similar results are estimated if, instead, I examine only those respondents who indicated they were menthol smokers in wave 1. That is, the estimated menthol ban effects are not statistically significant in the regressions examining whether an individual is a smoker. For the daily smoker regressions focusing on those indicating they smoked menthols in wave 1, in both the full sample and the sample using only those who completed surveys in all five survey waves, the estimated ban effect suggests a statistically significant increase in daily smoking in the EU countries relative to the U.S. For the cigarette per day regressions using only those indicating a menthol preference in wave 1, neither sample yields a statistically significant menthol ban effect. These results are provided in Appendix 2.

Figure 5: Smoking Likelihood Among Menthol Smokers



Based on respondents who completed all waves

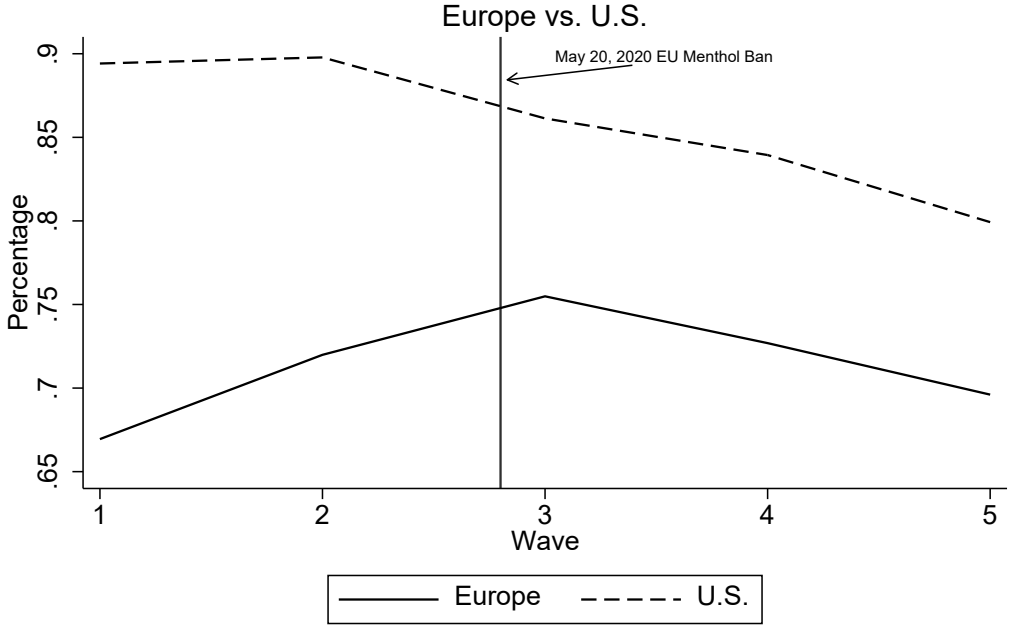
The regression results, again estimating a linear probability model with individual and wave fixed effects, indicate that there is no statistically significant effect of the EU menthol ban on the probability that an EU respondent indicates he/she smokes relative to his/her U.S. counterpart.

Table 6: Linear Probability Model (OLS) of Smoking Status		
Menthol Smokers in Either Wave 1 or Wave 2		
(Standard Errors Clustered at the Individual Level in Parentheses)		
	All Data	Respondents Completing 5 Waves
Ban Effect	-0.0086 (0.0098)	0.0083 (0.0138)
All models include individual and wave fixed effects.		

4.2.2 **Daily smoking**

Figure 6 provides the comparison of daily smoking rates across the survey waves and between the U.S. and EU country respondents among menthol smokers. As shown, U.S. menthol smokers reduced their likelihood of being a daily smoker more than did the EU country menthol smokers following the EU menthol ban.

Figure 6: Daily Smoking Among Menthol Smokers



Based on respondents who completed all waves

The difference-in-difference regression results shown in Table 7 are consistent with the picture above. That is, the estimated effect of the menthol ban was to increase the likelihood of an EU country menthol smoker reporting being a daily smoker relative to menthol smokers in the U.S. by about seven percentage points. This estimated effect is statistically significant at the 1 percent type 1 error level,[29] and this is true whether all respondents are used in the sample or if the sample is restricted to just those respondents participating in every survey wave. This highlights an unintended effect of the menthol ban having led to an increase in daily smoking among menthol smokers in the EU countries relative to U.S. menthol smokers.

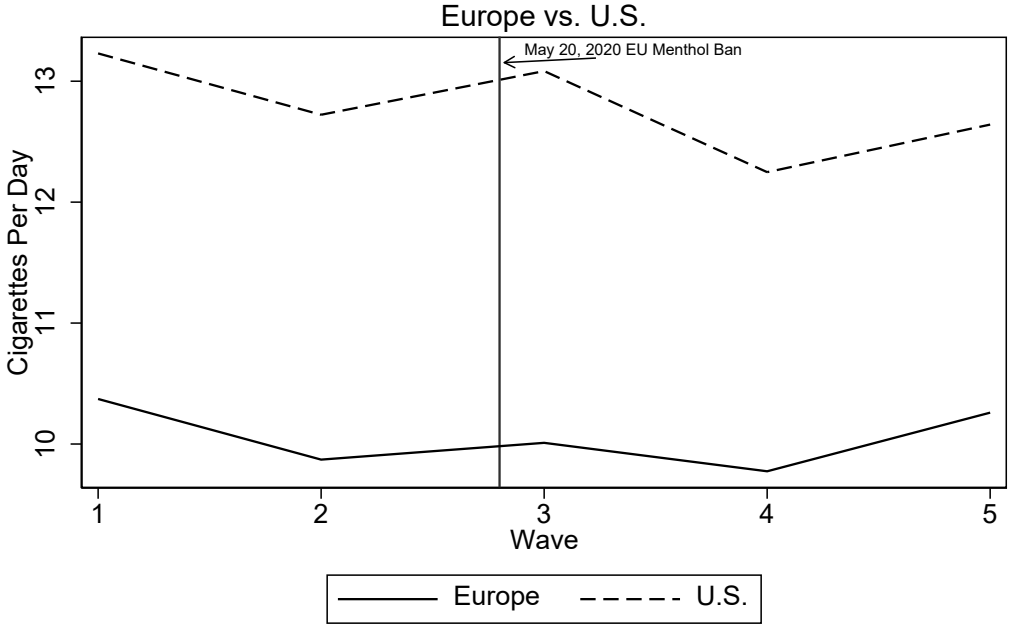
Table 7: Linear Probability Model (OLS) of Daily Smoking Status		
Menthol Smokers in Either Wave 1 or Wave 2		
(Standard Errors Clustered at the Individual Level in Parentheses)		
	All Data	Respondents Completing 5 Waves
Ban Effect	0.0700*** (0.0142)	0.0939*** (0.0184)
All models include individual and wave fixed effects. ***p < 0.01		

4.2.3 **Cigarettes smoked per day**

Figure 7 compares the reported average cigarettes smoked per day for this group of menthol smokers across the survey waves and between the U.S. and EU country respondents (including non-smokers as smoking 0 cigarettes per day) on those days smoked. As shown, the trends throughout all five survey waves are strikingly similar between EU countries and the U.S., indicating that the ban had no systematic effect on the number of cigarettes smoked per day by this group.

[29] Five percent is the conventional standard for statistical significance. An effect that is statistically significant at the 1 percent level provides more confidence that the estimated effect cannot be explained by random variation.

Figure 7: Cigarettes Per Day Among Menthol Smokers



Based on respondents who completed all waves

Table 8 presents the results of the difference-in-difference model that compares the cigarettes smoked per day among this group of menthol smokers. The estimated effect of the menthol ban on cigarettes smoked per day for EU menthol smokers is not statistically distinguishable from zero in both the full sample and the sample using only those respondents who completed all five survey waves relative to U.S. menthol smokers.

Table 8: OLS Regression of Cigarettes Per Day		
Menthol Smokers in Either Wave 1 or Wave 2		
(Standard Errors Clustered at the Individual Level in Parentheses)		
	All Data	Respondents Completing 5 Waves
Ban Effect	-0.0214 (0.2417)	0.2166 (0.2991)
All models include individual and wave fixed effects.		

4.3 Menthol vs. Non-Menthol (DDD Model)

In this section I present the results of an alternative regression model that exploits two layers of treatment/control comparisons by examining the effect of the EU menthol cigarette ban on smoking outcomes for EU country menthol smokers[30] relative to EU country non-menthol smokers and also nets out this menthol vs. non-menthol comparison in the U.S. to account for any background trends affecting menthol and non-menthol smokers differently (e.g., if, perhaps, menthol smokers are less likely to smoke in months with colder temperatures).

[30] In the results that follow, I continue to define a respondent as a menthol smoker if they indicated a preference for menthols in wave 1 or wave 2.

This approach is sometimes referred to as a triple differences ("**DDD**") model.[31] Effectively, the DDD model allows for a within EU comparison group (the pre-ban non-menthol smokers) to constitute a counterfactual to account for potentially changing background smoking trends in the EU countries. It augments the difference-in-differences model with another difference for the new control group (the pre-ban non-menthol smokers), hence the name 'triple differences'. Netting out the contemporaneous change in the difference between U.S. menthol and non-menthol smokers also accounts for any potential background change in how these two different groups of smokers mirror each other.

Another way to think about the DDD design is to consider that there are two simultaneous difference-in-difference designs. The first design estimates how menthol smokers in Europe change their behavior when the European menthol ban comes into force as compared to how U.S. menthol smoking behavior changes at the same time period. Then, the second difference-in-difference analysis isolates how behavior among European non-menthol smokers changes at the time of the menthol ban (presumably for reasons independent of the menthol ban) relative to the contemporaneous change in behavior among U.S. non-menthol smokers. This second European non-menthol smoking change reflects any generic European-specific overall smoking trend change that should be netted out of the first estimated change in European menthol smoking behavior associated with the menthol ban, so as not to conflate it with the treatment effect of the menthol ban itself (i.e., since any changes show up among European non-menthol smokers, it presumably should not be attributed to the menthol ban).

The model is estimated via ordinary least squares with the following specification (where *i* represents the individual respondent and *w* represents the wave):[32]

$$\text{smoking outcome}_{iw} = \alpha + \beta\left(Menthol_i * Europe_i * ban_w\right) + \phi\left(Menthol_i * Europe_i\right) + \varphi\left(Menthol_i * US_i\right) +$$

$$\gamma\left(Non-Menthol_i * Europe_i\right) + \eta\left(Non-Menthol_i * US_i\right) + Europe_i \sum_{w=1}^{4} \tau_w + US_i \sum_{w=1}^{4} \upsilon_w +$$

$$Menthol_i \sum_{w=1}^{4} \pi_w + Non-Menthol_i \sum_{w=1}^{4} \psi_w$$

Essentially, this model allows for different group intercepts or baselines for EU country menthol smokers, EU country non-menthol smokers, U.S. menthol smokers, and U.S. non-menthol smokers.[33] That is, the model allows each of these groups to have different average outcomes that pre-date any effects of the EU

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31 For a famous early example of this triple differences model, see Jonathan Gruber (1994), "The Incidence of Mandated Maternity Benefits," *The American Economic Review*, 84(3): 622-641. For a discussion of the triple differences model and its use in public health research designs, see the discussion in Coady Wing, Kosali Simon, Ricardo A. Bello-Gomez (2018), "Designing Difference in Difference Studies: Best Practices for Public Health Policy Research," *Annual Review of Public Health*, 1(39): 453-469.

32 The τ coefficients represent the (potentially non-monotonic) background European trend in smoking; the υ coefficients represent the (potentially non-monotonic) background U.S. trend in smoking; the π coefficients represent the (potentially non-monotonic) background trend among menthol smokers in general; and the ψ coefficients represent the (potentially non-monotonic) background trend among non-menthol smokers in general. The φ coefficient represents the pre-existing European menthol smoker baseline behavior before the period of the ban; the φ coefficient represents the pre-existing U.S. menthol smoker baseline behavior before the period of the ban; the γ coefficient represents the pre-existing European non-menthol smoker baseline behavior before the period of the ban; and η represents the pre-existing U.S. non-menthol smoker behavior before the ban. After accounting for all of these differential baselines and background trends, β represents the estimated treatment effect of the ban on the treatment group (European menthol smokers).

33 In practice, these effects are estimated through individual fixed effects with the average of these individual effects in each group constituting the group intercepts.[34] See, for example, James F. Burke, Jeremy B. Sussman, David M. Kent, Rodney A. Hayward (2015), "Three simple rules to ensure reasonably credible subgroup analyses," *British Medical Journal*, 351 :h5651 doi:10.1136/bmj.h5651, https://www.bmj.com/content/351/bmj.h5651.

menthol ban. The model also allows for separate intercepts for each wave in the EU and separate intercepts for each wave in the U.S. (allowing for differential potentially non-linear trends by jurisdiction). Lastly, the model allows for separate wave intercepts for menthol smokers and separate wave intercepts for non-menthol smokers (allowing for differential potentially non-linear trends by smoker group). The estimated ban effect then is the effect for EU country individuals who report smoking menthols in wave 1 or wave 2 relative to what is going on among EU country non-menthol smokers and relative to any contemporaneous change in the relationship between U.S. menthol and non-menthol smokers.

4.3.1 **Smoking Status**

Table 9 presents the results of the DDD model estimating the effect of the EU menthol ban on the probability an individual respondent is a smoker. These indicate that there is no statistically significant effect of the menthol ban on the probability of an EU country menthol smoker indicating that he/she smokes. This is true whether I use the entire sample or only those respondents who completed all five survey waves.

Table 9: Linear Probability Model (OLS) of Smoking Status		
Triple Differences Model: Menthol vs Non-Menthol		
(Standard Errors Clustered at the Individual Level in Parentheses)		
	All Data	Respondents Completing 5 Waves
Ban Interacted with Menthol Status	-0.0140 (0.0126)	-0.0071 (0.0174)
Individual Fixed Effects	Yes	Yes
Europe-Specific Wave Fixed Effects	Yes	Yes
U.S.-Specific Wave Fixed Effects	Yes	Yes
Menthol-Specific Wave Fixed Effects	Yes	Yes
Non-Menthol-Specific Wave Fixed Effects	Yes	Yes

4.3.2 **Daily Smoking Status**

Table 10 presents the results of the DDD model estimating the effect of the EU menthol ban on the probability an individual respondent is a daily smoker. These indicate that the menthol ban increased the probability that an EU country menthol smoker (at wave 1 or wave 2) would be a daily smoker following the ban. For the full sample, the estimate implies a 3 percentage point increase in the likelihood of daily smoking following the ban, and the effect is statistically significant at the 10 percent type 1 error level. For the sample where only those respondents who completed all five waves of the survey are included, the estimate indicates an increase in the likelihood of daily smoking for EU country menthol smokers of almost 5 percentage points following the ban, and the effect is statistically significant at the 5 percent type 1 error level.

Table 10: Linear Probability Model (OLS) of Daily Smoking Status		
Triple Differences Model: Menthol vs Non-Menthol		
(Standard Errors Clustered at the Individual Level)		
	All Data	Respondents Completing 5 Waves
Ban Interacted with Menthol Status	0.0343* (0.0187)	0.0498** (0.0246)
Individual Fixed Effects	Yes	Yes
Europe-Specific Wave Fixed Effects	Yes	Yes
U.S.-Specific Wave Fixed Effects	Yes	Yes
Menthol-Specific Wave Fixed Effects	Yes	Yes
Non-Menthol-Specific Wave Fixed Effects	Yes	Yes
**p < 0.05 *p < 0.10		

4.3.3 **Cigarettes smoked per day**

Table 11 presents the results of the DDD model estimating the effect of the EU menthol ban on the number of cigarettes smoked per day by EU country menthol smokers. The estimated effect of the menthol ban on cigarettes smoked per day for menthol smokers is not statistically distinguishable from zero in both the full sample and the sample using only those respondents who completed all five survey waves.

Table 11: OLS Regression of Cigarettes Per Day		
Triple Differences Model: Menthol vs Non-Menthol		
(Standard Errors Clustered at the Individual Level in Parentheses)		
	All Data	Respondents Completing 5 Waves
Ban Interacted with Menthol Status	0.1888 (0.3139)	0.2020 (0.4004)
Individual Fixed Effects	Yes	Yes
Europe-Specific Wave Fixed Effects	Yes	Yes
U.S.-Specific Wave Fixed Effects	Yes	Yes
Menthol-Specific Wave Fixed Effects	Yes	Yes
Non-Menthol-Specific Wave Fixed Effects	Yes	Yes

Taken together, there is no evidence of the EU menthol ban leading to a systematic reduction in smoking rates, or cigarette consumption levels regardless of whether overall smoking is examined or whether the model focuses on the behavior of individuals with stated menthol preferences. Moreover, there is evidence of a counterproductive effect with the ban leading to an increase in the rates of daily smoking among EU smokers following the ban. This evidence underscores that the proposed ban on the sale of menthol cigarettes is not appropriate for the protection of the public health.

4.4 Effects on Specific Groups

While the foregoing analysis underscores the lack of efficacy of a menthol ban, I also consider if there is evidence of an effect of the EU menthol ban in specific subgroups. While such subgroup analyses are

always potentially problematic to the extent they devolve into data-mining exercises,[34] I re-run the prior analyses on daily smokers at wave 1 of the survey and smokers who planned to quit in either wave 1 or wave 2. The results are reported in Appendix 2. As can be observed in Appendix 2, in all these cases, the results of these sub-group analyses are in line with the main results reported above for smokers in general and menthol smokers specifically. Taken together, there is no evidence of the EU menthol ban leading to any systematic improvements in smoking rates for daily smokers or those smokers indicating that they planned to quit in wave 1 or wave 2. Moreover, there is evidence of a counterproductive effect with some analyses indicating that the ban led to statistically significant increases in the rates of daily smoking and cigarettes smoked per day for those EU smokers indicating that they planned to quit in wave 1 or wave 2. Again, this evidence underscores that the proposed ban on the sale of menthol cigarettes is not appropriate for the protection of the public health.

4.5 Impact of COVID-19

The COVID-19 pandemic struck between waves 2 and 3 of the survey, which raises a potential concern that the impact of the pandemic may be influencing the results of the survey. Given this, I re-run the prior analyses with an adjustment for the potential effect of COVID-19 in analyses reported in Appendix 3. Briefly, if I control for how respondents said the pandemic affected their smoking, my results are qualitatively similar to the results presented here. As an additional check on whether COVID-19 may be influencing the results of the survey, I also examined European retail sales data from Nielsen and find no statistically significant change in cigarette sales in Europe or in the U.S. starting in January 2020 (the advent of COVID-19 cases) relative to existing background trends.

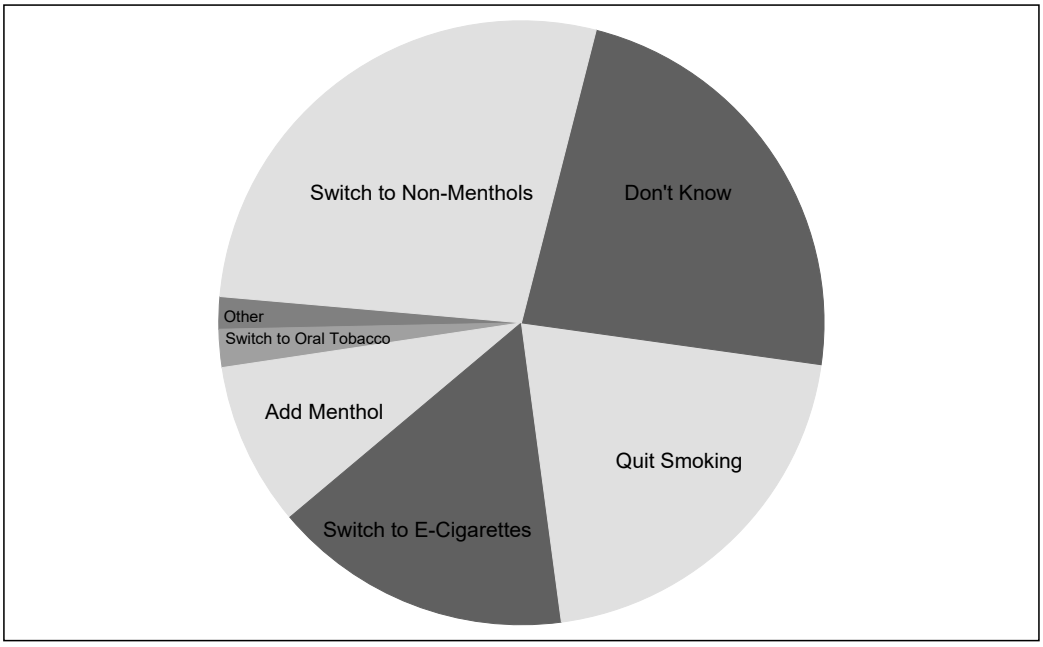
Collectively, the results of these analyses indicate that there is no COVID-19 effect biasing my estimates. There is no evidence that COVID-19 somehow obscured improvements generated by the EU menthol ban. There were no such improvements.

4.6 Comparison of menthol smokers' intentions and actual responses to the EU menthol ban

If menthol smokers did not stop smoking or even smoke less after the EU menthol ban, it is reasonable to investigate how they adapted their smoking once their preferred cigarettes were no longer available. In the pre-ban survey waves, EU respondents who indicated they primarily smoked menthol cigarettes were asked what they plan to do when menthols are banned. The responses as aggregated over waves 1 and 2 are shown in Figure 8.

[34] See, for example, James F. Burke, Jeremy B. Sussman, David M. Kent, Rodney A. Hayward (2015), "Three simple rules to ensure reasonably credible subgroup analyses," *British Medical Journal*, 351 :h5651 doi:10.1136/bmj.h5651, https://www.bmj.com/content/351/bmj.h5651.

Figure 8:
Plans For After Menthol Ban



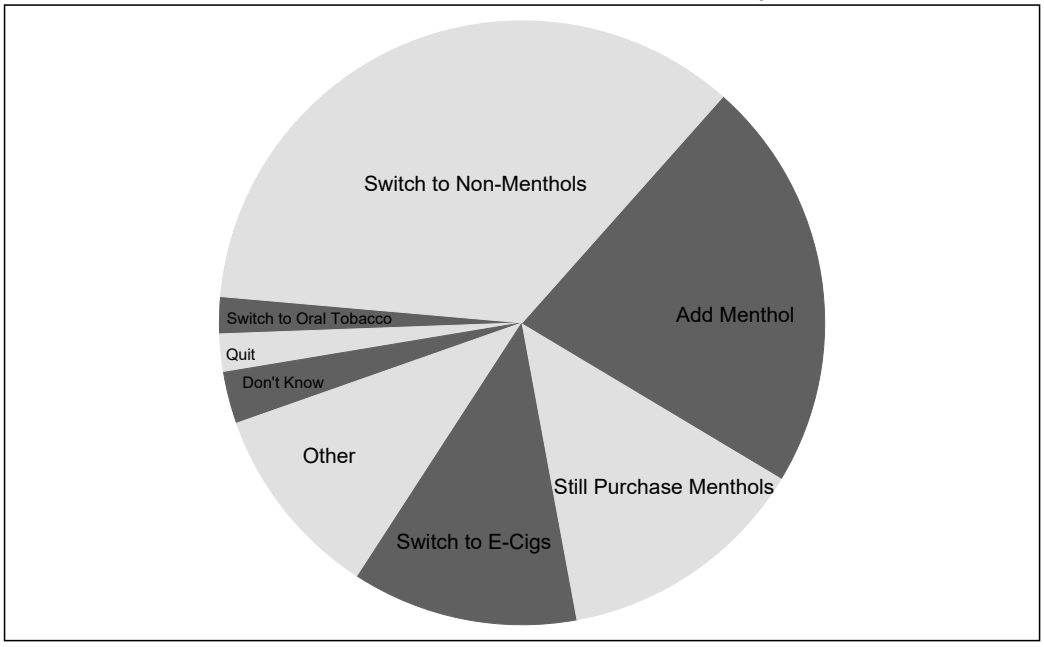
Responses of European Menthol Smokers During Waves 1 & 2

Table 12 shows that in both pre-ban waves, the modal menthol smoker indicated he/she planned to switch to non-menthol cigarettes. The next biggest group in each wave said that they do not know what they will do. In both waves, sizeable numbers said they would quit smoking after the menthol ban goes into effect.

Table 12: What EU Menthol Smokers Plan to Do After Menthol Ban		
	Wave 1	Wave 2
Switch to Non-Menthols	27%	30%
Don't Know	22%	25%
Quit Smoking	22%	17%
Switch to E-Cigarettes	16%	15%
Add Menthol to Cigarettes	8%	11%
Other	2%	0%
Switch to Oral Tobacco	2%	2%
Note: Columns may not sum to 100% due to rounding.		

Figure 9, which aggregates responses over waves 3, 4, and 5, shows that while most people did switch to non-menthol cigarettes as they said they would, very few of the menthol smokers quit smoking after the ban went into place.

Figure 9:
What European Menthol Smokers Actually Did



Responses of European Menthol Smokers in Waves 3-5

For comparison purposes, Table 13 shows that among individuals who report smoking menthols in wave 1 or wave 2 and who participated in all five survey waves, the quit rates between the waves are quite comparable between the U.S. (where there was no menthol cigarette ban) and the EU (which banned menthol cigarettes after wave 2), except for the wave 4 to wave 5 period where U.S. quit rates were higher.

Table 13: Percentage of Menthol Smokers Quitting Between Waves		
	EU	U.S.
Wave 2 to Wave 3	4%	4%
Wave 3 to Wave 4	3%	3%
Wave 4 to Wave 5	3%	5%
Individuals who smoked menthol cigarettes in wave 1 or wave 2 who identified as smoking in the previous wave but had quit by the next wave, examining individuals who responded to all five waves.		

These results are also consistent with an analysis of individuals who specifically claim they are going to quit in the near future. As shown in the Appendix 2 analysis of individuals intending to quit, the menthol ban had no systematic effect on the likelihood that they continue to smoke.

Looking more closely at the evolution of what these smokers did, as shown in Table 14, the immediate response was to switch to non-menthol cigarettes, but by waves 4 and 5, almost as many of the menthol smokers had adapted by adding menthol to their cigarettes (self-mentholation), and a smaller, though still sizable group still found ways to purchase menthol cigarettes after the ban. In each wave, these three options accounted for more than 2/3 of the respondents.

Table 14: What EU Menthol Smokers Actually Did After the Menthol Ban			
	Wave 3	Wave 4	Wave 5
Switch to Non-Menthols	42%	29%	29%
Add Menthol to Cigarettes	14%	30%	29%
Still Purchase Menthols	12%	15%	14%
Switch to E-Cigarettes	11%	12%	13%
Other	11%	9%	10%
Don't Know	4%	2%	2%
Quit Smoking	3%	2%	1%
Switch to Oral Tobacco	2%	1%	3%
Note: Columns may not sum to 100% due to rounding.			

In the post ban waves, only 2 percent actually reported quitting smoking following the ban.[35] These results indicate that smokers' stated intentions with regards to quitting in response to a proposed menthol ban do not provide reliable evidence of the actual impact of a ban. The results also highlight how wildly optimistic Levy et al's (2011, 2021) assumptions are in their simulated effects of a menthol ban. In those analyses, the cessations estimates are higher by a factor of seven or more compared with my findings of actual quit rates based on the European experience with a menthol ban.

The results suggesting that a sizable share of menthol smokers self-mentholate mirrors results from Chaiton et al (2021)[36] which found that 15 percent of daily menthol smokers had used flavor additives after the 2017 Canadian menthol ban which is quite close to the share of menthol smokers indicating they "add menthol to cigarettes" in wave 3 in this European survey.

Chaiton et al (2021) speculate that the availability of flavor cards "may limit the effectiveness of the upcoming menthol restrictions in the Europe." The European survey suggests this concern is unfounded. There is no evidence that those who self-mentholate appreciably affect smoking rates in Europe. Specifically, if those who self-mentholate are dropped from the sample, none of the preceding analyses of the effect of the menthol ban on smoking outcomes changes significantly.[37]

Another way to examine whether self-mentholation inhibits quitting is to compare those who added menthol in wave 3 in terms of whether they still smoke in wave 4 with the probability of continued smoking (into wave 4) for individuals who continued to smoke in wave 3 without adding menthol. The difference in wave 4 smoking rates for these two groups is quite small and statistically indistinguishable (mentholators: 0.980; non-mentholators: 0.972; p value of equal proportions > 0.99). The same is true if daily smoking is compared (mentholators: 0.906; non-mentholators: 0.932; p value of equal proportions > 0.97).

These results suggest that even if menthol flavor cards (or other sources of aftermarket menthol) were completely eliminated, it would have no systematic effect on my estimates of the effects of the EU menthol ban. The general implication of this analysis is that the FDA's proposals to also ban menthol as a characterizing flavor in cigarette components and parts would not meaningfully affect the impact of the ban on smoking rates, based on the analysis of the effects of the EU menthol ban.

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35 Interestingly, from wave to wave, the average increase in the quit rate among EU menthol smokers is about 2 percent, even between waves 1 and 2 when the menthol ban was not in effect.

36 Michael O. Chaiton, Robert Schwartz, Joanna E. Cohen, Eric Soule, Bo Zhang, Thomas Eissenberg (2021), "The use of flavour cards and other additives after a menthol ban in Canada," *Tobacco Control*, 30(5): 601-602.

37 For the probability of smoking outcome, the full sample coefficient for the European menthol ban is 0.001 and is not statistically significant. If those adding menthol are dropped, the coefficient is -0.002 and is still not statistically significant. For daily smoking, the full sample coefficient is 0.049 and is statistically significant at the 0.01 level. If those adding menthol are dropped, the coefficient is 0.046 and is still statistically significant at the 0.01 level. Similar results are obtained if attention is restricted to those completing all five waves.

5. EFFECT OF EU MENTHOL BAN ON RETAIL SALES OF CIGARETTES

While survey data are necessary to examine individual-level smoking outcomes, survey data pose two potential concerns. First, respondents' self-reports of their behaviors may not always be accurate. Second, surveys could suffer from sample selection bias issues.[38] While the foregoing survey analysis is robust to both of these concerns,[39] it is useful to calibrate the survey results with retail sales data to ameliorate any residual concerns.[40]

5.1 Analysis of retail sales data for cigarettes in the U.S., Poland, Sweden, and the U.K.

Retail sales data for cigarettes in the U.S., Poland, Sweden, and the U.K. for the period beginning January 2017 and ending December 2021 were purchased from the Nielsen company, a well-known data provider whose data are often used in academic studies. Finnish data were not available for purchase from Nielsen. The collection frequency for the U.S., Poland, and Sweden is comparable, with data available at the monthly level. U.K. data are only available in four-week frequencies.

Figures 10-13 provide a locally-weighted lowess regression of the ln(Sticks Sold) data for each country. Put simply, a locally weighted lowess regression runs a regression that allows for non-linear relationships by weighting the data points in a given bandwidth around a particular data point more heavily and doing this throughout the sample. This creates a smooth line through a timeplot of the data to help identify the relationship between variables (in this case, the amount of cigarette sticks sold over time) and to observe trends in the data.

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38 While it is possible to address non-representative samples through weighting procedures as I do in Appendix 4, it is only possible to weight (or to otherwise assess) a sample based on observable characteristics. If, however, people differ in their unobservable characteristics and those differences affect an individual's willingness to complete a survey, sample results could differ systematically from effects in the population. The retail data, however, do not present these issues.

39 As for the concern that people answer inaccurately, the panel data nature of the analysis mitigates this concern. First, to the extent that an individual misstates his true behavior, if the individual is consistent in his error across waves, it will be accounted for through the individual fixed effects. If the errors are not consistent at the individual level but are, instead, random, this will not bias my estimates either since random errors will not be correlated with the adoption of the EU menthol ban. The only way misstatements can affect my estimates is if the misstatements change systematically when the ban goes into effect and, even then, if the systematic changes are mirrored in the U.S. comparison group, no bias will arise. As for sample selection issues, results in Appendix 5 suggest that attrition bias (i.e., selection issues in who continues to respond to the survey) is not affecting my results and the results are robust to a variety of weighting schemes.

40 The FDA notes in its Proposed Rule that "studies have shown that sales and consumption tend to be highly correlated (Refs. 206–208). Additionally, sales data provide information on purchases of tobacco products in a defined area (which could include neighboring jurisdictions) (Refs. 200 and 209) and can serve as a proxy for consumption of tobacco products after policy implementation." See Proposed Rule, Federal Register / Vol. 87, No. 86 at 26472.

Figure 10:

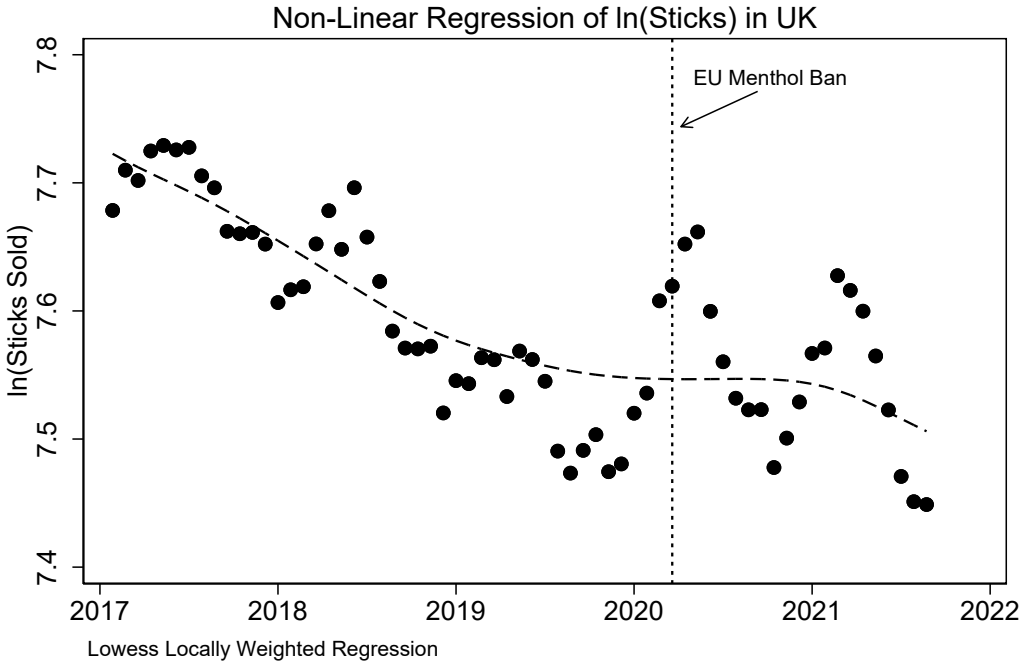


Figure 11:

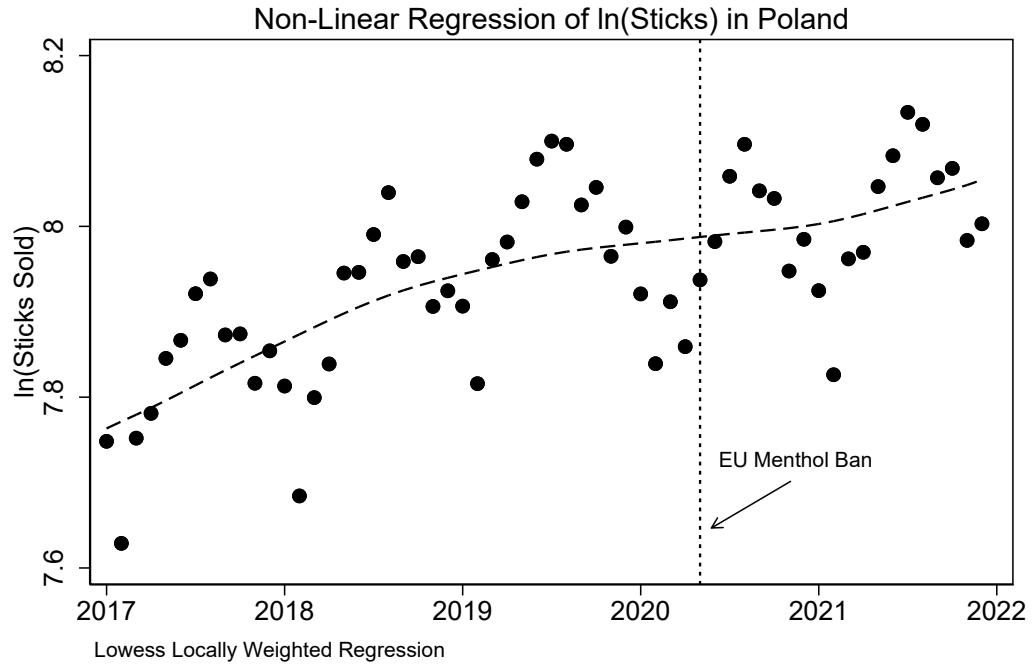


Figure 12:

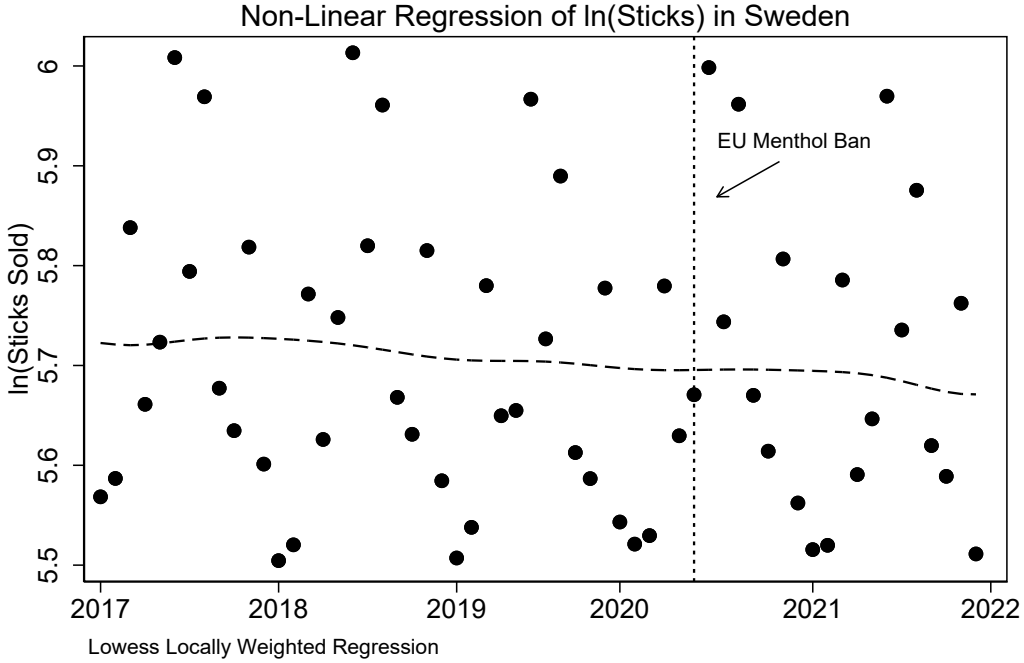
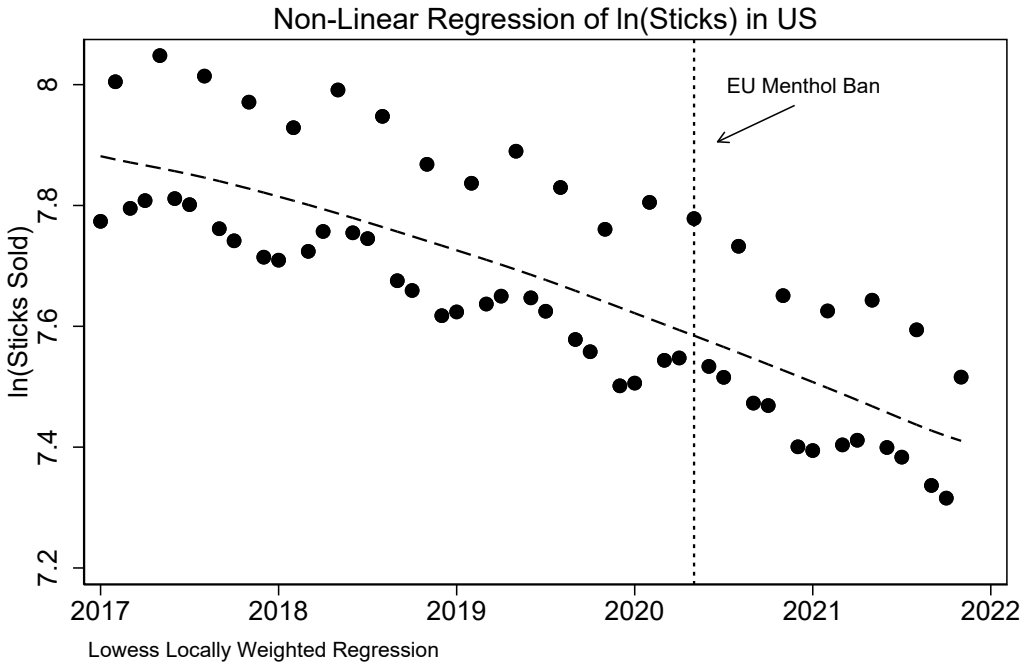


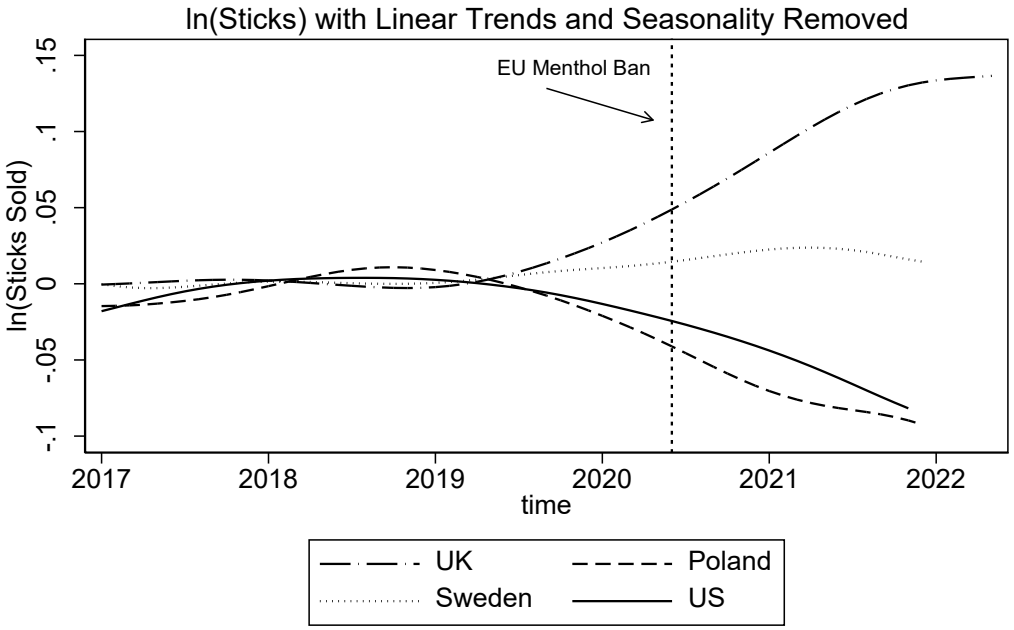
Figure 13:



In each of the four countries, there is evidence of seasonality (repeated cyclical patterns) and trends prior to May 2020. In the case of the U.K. and Poland, the trends are quadratic (i.e., the slope changes), whereas for Sweden and the U.S. the trends are linear (i.e., the slope does not change). In no case does there appear to be a trend change in May 2020 (designated in the figures by the vertical dashed line).

To further isolate any effect of the May 2020 EU menthol ban, Figure 14 provides the sales data by country after adjusting for the pre-existing linear trend exhibited before the EU menthol ban and country-specific seasonality at the monthly frequency.[41]

Figure 14:



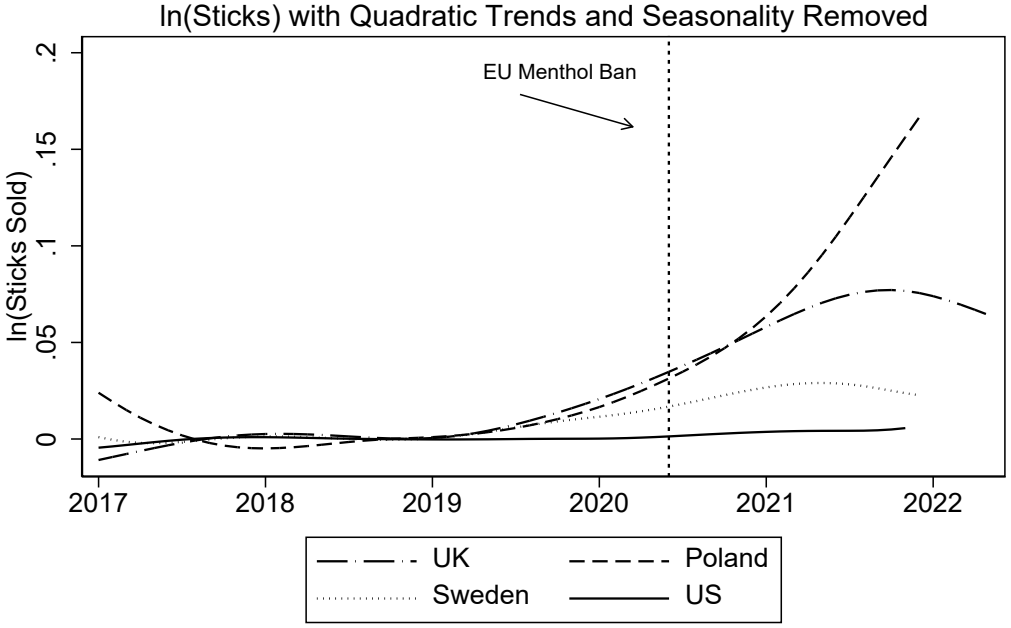
Note: UK on Different Time Scale -- Ban 4 Periods Later

As seen in the figure, two of the countries exhibit declines in cigarette sales after May 2020 – Poland and the U.S. The other two countries, the U.K. and Sweden, exhibit increases in sales. It is clear, however, that each of these trends pre-dates the EU menthol ban and, obviously, the U.S. sales cannot be affected by that ban. Taken together, this indicates that the EU ban did not reduce cigarette sales.

Figure 15 allows for more generality by including quadratic pre-ban trends for each country while still adjusting for country-specific seasonality. These more general trends are appropriate for the U.K. and Poland as indicated in the country-specific figures above since the slopes clearly are not constant for those countries. Allowing for quadratic trends in the case of Sweden and the U.S. is not harmful in that quadratic trends can accommodate linearity as well (i.e., the quadratic portion of the trend estimate would simply yield a zero coefficient).

[41] Formally, I first regress the sales data by country on a linear time indicator (i.e., January 2017 equals 1, February 2017 equals 2, and so on) and month-specific dummy variables for the period January 2017 through April 2020, and generate the residuals between the actual sales and the sales predicted by that regression. I then plot those residuals using a locally weighted regression (lowess regression in Stata) to allow for non-linear relationships.

Figure 15:



Note: UK on Different Time Scale -- Ban 4 Periods Later

Again, there is no indication that the EU menthol ban reduced cigarette sales. If anything, sales went up after the ban went into place (after accounting for pre-existing trends and seasonality) in the three European countries, while sales were flat in the U.S.

To examine the retail sales data more closely, I estimated difference-in-difference models as I did with the survey data. In the models presented in Table 15 below, I allow for country-specific linear and quadratic trends, and I provide models that both do and do not allow for country-specific seasonality. Because of the mismatch created by the different collection frequency available in the U.K., I drop that country from the sample.

Table 15: Difference-in-Difference Model of ln(Total Sticks Sold)				
Poland, Sweden, United States				
(standard errors clustered at country level)				
Ban	0.07 (0.07)	0.11 (0.06)	0.02 (0.06)	0.00 (0.04)
Country FE	Yes	Yes	Yes	Yes
Period FE	Yes	Yes	Yes	Yes
Country-Specific Trends	Linear	Quadratic	Linear	Quadratic
Country-Specific Seasonality	No	No	Yes	Yes

None of the models generate a statistically significant estimate of the effect of the EU menthol ban. In each case, the point estimate is positive, suggesting an increase in cigarette sales, although it is not statistically significant. Accordingly, there is no evidence the ban reduced the retail sales of cigarettes. This is consistent with the survey results.

The Nielsen data also allow me to control for price effects, which I do in Table 16.

Table 16: Difference-in-Difference Model of ln(Total Sticks)				
Poland, Sweden, United States				
(standard errors clustered at country level)				
Ban	0.05 (0.05)	0.13** (0.03)	0.00 (0.04)	0.02 (0.02)
Ln(price)	-1.74* (0.44)	-2.17*** (0.19)	-1.40 (0.50)	-1.34* (0.45)
Country FE	Yes	Yes	Yes	Yes
Period FE	Yes	Yes	Yes	Yes
Country-Specific Trends	Linear	Quadratic	Linear	Quadratic
Country-Specific Seasonality	No	No	Yes	Yes
*** p < 0.01 ** p < 0.05 * p < 0.10				

Again, all of the estimates of the effect of the EU ban are positive, even when adjusting for changing prices. In one instance, the effect is statistically significant. Again, these results do not suggest the EU menthol ban reduced cigarette sales. This is consistent with the survey results.

In Table 17, I allow the price elasticity to differ by country.

Table 17: Difference-in-Difference Model of ln(Total Sticks)				
Poland, Sweden, United States				
(standard errors clustered at country level)				
Ban	0.08 (0.05)	0.14* (0.04)	0.03 (0.02)	0.02 (0.02)
Country-Specific ln(price) effect	Yes	Yes	Yes	Yes
Country FE	Yes	Yes	Yes	Yes
Period FE	Yes	Yes	Yes	Yes
Country-Specific Trends	Linear	Quadratic	Linear	Quadratic
Country-Specific Seasonality	No	No	Yes	Yes
* p < 0.10				

Adding a more general price control does not change the results. In each specification, the EU ban is associated with an increase in retail cigarette sales, though the estimates are not generally statistically significant.

In Table 18, I provide difference-in-difference analyses separately for Poland and the U.S. as well as Sweden and the U.S.

Table 18: Two Country Difference-in-Difference Models		
(robust standard errors in parentheses)		
	Countries Compared	
	Poland & United States	Sweden & United States
Ban	0.01 (0.02)	0.04*** (0.01)
Country-Specific ln(price) effect	Yes	Yes
Country FE	Yes	Yes
Period FE	Yes	Yes
Country-Specific Trends	Quadratic	Quadratic
Country-Specific Seasonality	Yes	Yes
*** p < 0.01		

Once again, I find no evidence that the European menthol ban reduced cigarette sales. This is consistent with the survey results above. The positive coefficients, a statistically significant increase of 4% in Sweden's case, but not significant for Poland, in fact corroborate my findings in the survey data that the ban was associated with more people smoking on a daily basis.

This analysis of retail sales data is complementary to the survey analysis in that it provides reassurance that the survey results were not driven by measurement error (caused by respondents mischaracterizing their behavior in a way that systematically changes in May 2020) or by sample selection issues. The retail sales data are not affected by either of these issues and yet, they tell a similar story to the survey data. In all of the analyses that I have conducted on the Nielsen data, the EU ban is associated with an increase in retail cigarette sales, though the estimates are not generally statistically significant. My analysis of the sales data provides consistent evidence across a number of different models that the EU menthol ban did not reduce smoking, and, indeed, there is some evidence that the ban led to the unintended consequence of people actually smoking more as menthol smokers became more likely to smoke on a daily basis once the ban went into effect.

5.2 Analysis of retail sales data for Poland by Liber et al (2022).

My retail sales results are consistent with recent work by Liber et al (2022)[42] which examines Nielsen data for Poland.

Liber and coauthors examine what they describe as a bite-style regression model in which they compare Nielsen retail sales data in Poland before and after the EU menthol ban came into effect, covering the period May 2018 through April 2021. Since all of Poland was subject to the ban, they compare areas of Poland where pre-ban menthol smoking rates were relatively low as the effective control group against the treatment group composed of areas where pre-ban menthol consumption was relatively high. The authors note that Poland represents an especially important case study given that it is the only country with a substantial menthol market (28 percent according to the authors) share to have banned menthol cigarettes.

Practically speaking, given that the range of menthol use among the Polish regions lies in a fairly small range (25 percent to 28 percent) except for Warsaw which had a pre-ban menthol share of almost 37

[42] Alex C. Liber, Michal Stoklosa, David T. Levy, Luz Marıa Sa´nchez-Romero, Christopher J. Cadham, Michael F. Pesko (2022), "An analysis of cigarette sales during Poland's menthol cigarette sales ban: small effects with large policy implications," European Journal of Public Health, https://doi.org/10.1093/eurpub/ckac063

percent, the treatment-control element of their study boils down to comparing the change in Warsaw against the change in the other regions. Looking at the aggregate before and after change across all of Poland, the authors conclude, "We found no significant change in the sale of cigarettes in Poland attributable to the menthol ban." When leveraging the treatment-control design, the "mean menthol ban effect size" (presented in Table 3) generates a combined effect of the ban that is not statistically significant at any conventional type 1 error level.

Despite this lack of any statistically significant total effect, the authors describe their results as mixed in that they do find "the post-ban decline in cigarettes, and RYO sales were steeper in regions with higher pre-ban shares of menthol cigarette sales." They go on to state, "We find that regions with more menthol share before the ban, like Warsaw, saw a significant reduction in total cigarette sales. Regions with sub-average baseline menthol cigarette share did not see significant declines. These limited effects resulted in a non-statistically significant reduction in cigarette sales overall." As they note, however, and as is seen clearly in their Figure 1, even these declines in Warsaw were short-lived with the authors concluding "Most of the initial reduction in cigarette sales because of the menthol ban was lost within three months."

Even the apparent Warsaw reduction might be a mirage. Warsaw, like many cities worldwide, experienced residents leaving the city at the advent of the COVID-19 pandemic as residents sought out larger accommodations and more abundant outdoor space.[43] Such movement would mechanically lower estimated per capita cigarette sales in Warsaw and increase them elsewhere. While the authors include a control based on Apple maps data which is meant to account for differential mobility that might affect sales changes, their control variable is highly problematic. First, as the authors note "we have an incomplete understanding of movement trends before COVID. The Apple mobility data were only provided after February 2020, so we cannot fully understand the role of movement in the pre-COVID period." This limitation means the authors are not able to sort out seasonal differences from mobility differences from differences generated by the ban itself. Second, Apple data will not provide a representative proxy for mobility in Poland, as Apple's market share in Poland is very low (i.e., less than 10 percent)[44] and highly unlikely to be representative of the Polish population. Given this, this paper's aggregate results for the country as a whole are more reliable than its separate analyses by region within Poland.

The Liber et al (2022) results provide an independent verification of my retail sales results. Both analyses indicate that the EU menthol ban has had no effect on overall smoking.

6. REVIEW OF MENTHOL AND FLAVOR BAN STUDIES RELIED ON BY THE FDA

In this section I review the menthol and flavor ban studies that are relied on by the FDA to reach its determination the proposed standard is "appropriate for the protection of the public health." The FDA's depiction of these studies is set in section V of the Proposed Rule and also the FDA's review of studies, titled "Review of Studies Assessing the Potential Impact of Prohibiting Menthol as a Characterizing Flavor in Cigarettes".[45]

I start by reviewing the studies evaluating the Canadian menthol ban experience which is the most relevant set of research considered by the FDA in making its claim that the proposed ban would lead to increased smoking cessation. I then review the studies of behavioral intentions and hypothetical choice experiments regarding menthol bans which the FDA also relies on to support its claim that the proposed ban will increase

[43] See, for example, https://notesfrompoland.com/2022/02/18/warsaws-population-continues-to-decline-as-residents-leave-central-districts/

[44] See, for example, https://www.statista.com/statistics/1042592/poland-mobile-vendor-market-share/

[45] See Proposed Rule, Federal Register / Vol. 87, No. 86 at 26494, Ref. 77.

smoking cessation. These studies do not involve examining any actual behavior and so are largely irrelevant to predicting the real-world effects of a menthol ban. After this I review the evaluations of national and local non-flavor bans that are relied on by the FDA to claim that the proposed ban will reduce smoking initiation and increase cessation. Lastly, I review the simulation modelling papers that are relied on by the FDA and which the FDA utilizes to estimate the anticipated benefits of its proposed menthol product standard.

6.1 Evaluation of the Canadian menthol ban experience

The FDA relies on studies evaluating the impact of Canada's menthol bans as real-world evidence to support its assessment of the likelihood of the proposed menthol ban increasing smoking cessation in the U.S. The FDA claims that "studies evaluating the impact of these [menthol ban laws in Canada] have found increased reports of quit attempts and quitting smoking following policy implementation" and "[T]hese findings are consistent with the Agency's expectation that, following implementation, the proposed menthol product standard would increase the number of menthol cigarette smokers who quit cigarette use."[46]

While the FDA also refers to two studies evaluating San Francisco's ban on flavored tobacco products (including menthol) to support its position regarding anticipated increases in quitting following the ban, the FDA concedes that these studies only provide limited evidence of the impact of menthol cigarette sales restrictions on cessation in the U.S. and both studies rely on convenience samples and do not include a control group limiting their generalizability to people other than study participants. Given this, the FDA states that it relies more on the evidence from Canada.[47] I note however that these U.S. specific studies (which I review in Appendix 8) do not provide any consistent evidence of a meaningful effect of flavor bans on reducing smoking and, in fact, one of the studies found that following the ban there was a significant increase in cigarette smoking overall in the 18–24 age group.[48] The other study also found no evidence that the ban was associated with decreased number of cigarettes per day or increased readiness to quit among current smokers in residential substance use disorder treatment programs.[49]

Below, I provide a review of the studies analyzing the Canadian menthol ban which are cited by the FDA, as well as another more recent Canadian study.[50] In general, the more rigorous studies find no effect of the Canadian menthol ban on smoking. This includes the work by Carpenter and Nguyen (2021),[51] which the FDA only briefly considers in its assessment of the impacts of a menthol ban on smoking consumption and cessation.[52] However, this study provides a far more thorough and methodologically sophisticated analysis of the Canadian experience than other studies of the Canadian experience that are relied on by the FDA. As discussed below, Carpenter and Nguyen (2021) finds that the provincial menthol bans in Canada had no systematic effect on smoking rates, quit rates, or initiation rates among youth or adults.

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46 Proposed Rule, Federal Register / Vol. 87, No. 86 at 26475.

47 Proposed Rule, Federal Register / Vol. 87, No. 86 at 26476.

48 Yong Yang, Eric N. Lindblom, Ramzi G. Salloum and Kenneth D. Ward (2020), "The impact of a comprehensive tobacco product flavor ban in San Francisco among young adults," *Addictive Behaviors* Reports, 11: 100273.

49 Joseph R. Guydish, Elana R. Straus, Thao Le, Noah Gubner, Kevin L. Delucchi (2021) "Menthol cigarette use in substance use disorder treatment before and after implementation of a county-wide flavoured tobacco ban," *Tobacco Control*, 30(6): 616-622. doi: 10.1136/tobaccocontrol-2020-056000. Epub 2020 Nov 11. PMID: 33177211; PMCID: PMC8110613.

50 See Geoffrey T. Fong, Janet Chung-Hall, Gang Meng, Lorraine V. Craig, Mary E. Thompson, Anne C. K. Quah, K. Michael Cummings, Andrew Hyland, Richard J. O'Connor, David T. Levy, Cristine D. Delnevo, Ollie Ganz, Thomas Eissenberg, Eric K. Soule, Robert Schwartz, Joanna E, Cohen, Michael O. Chaiton (2022), "Impact of Canada's menthol cigarette ban on quitting among menthol smokers: pooled analysis of pre-post evaluation from the ITC Project and the Ontario Menthol Ban Study and projections of impact in the U.S.," *Tobacco Control*, tobaccocontrol-2021-057227. doi: 10.1136/tobaccocontrol-2021-057227. Epub ahead of print. PMID: 35483720.

51 Christopher Carpenter and Hai V. Nguyen (2021), "Intended and Unintended Effects of Banning Menthol Cigarettes," *The Journal of Law and Economics,* 64(3): 629-650, also available as NBER working paper 26811 (2020).

52 As discussed below, the study is also briefly noted, but dismissed, in the FDA's assessment of the impacts of a menthol ban on smoking initiation (see Proposed Rule, Federal Register / Vol. 87, No. 86 at 26471).

Instead, they find that youth were more likely to smoke non-menthol cigarettes after the ban, and that adults evaded the menthol bans by shifting purchases to other sources of menthol products (in particular, First Nations Reserves which are exempt from compliance with the Canadian menthol bans). As for the studies purporting to find that the Canadian bans reduced smoking, many of the results are the artifact of questionable methodological choices. Overall, therefore, the studies assessing the Canadian experience do not provide a credible scientific basis to support the FDA's proposed menthol cigarette ban.

It is striking that the FDA focuses on these Canadian studies while ignoring the European menthol ban experience.[53] Canada's low level of menthol usage prior to the ban (4 percent of the Canadian market) is substantially below the U.S. menthol share (26 percent of the market) according to the FDA.[54] Europe's menthol use in general (8 percent)[55] stands closer to the U.S. numbers and, as noted above, there are a number of individual EU countries which had, up until the EU-wide menthol ban came into effect in May 2020, menthol smoking rates closer to those found in the U.S. than did Canada. Moreover, the smoking prevalence and tobacco consumption rates of many of these European countries correlate very strongly with prevalence and consumption rates in the U.S. Despite the opportunity that the EU menthol ban provides to evaluate the efficacy of menthol cigarette bans, there is no indication that the FDA has undertaken any assessment of the experience in the EU. Such reliance on a single jurisdiction's experience is not prudent, as any single jurisdiction could prove to be an anomaly. Further, as noted above, the best evidence assessing the Canadian experience clearly concludes that the menthol ban in Canada did not reduce cigarette smoking.

As described in this report, the results of my analysis of EU data provides comprehensive evidence that the EU menthol cigarette ban has not achieved its goal of reducing smoking generally or specifically amongst menthol smokers, and there is evidence of a counterproductive effect of the EU menthol ban, leading to an increase in daily smoking among smokers in the EU countries. Taken together, these results along with the complementary high-quality study by Carpenter and Nguyen (2021), which provides the best available evidence of the effect of the menthol ban in Canada,[56] clearly demonstrate that there is no credible scientific foundation to support the claim that a menthol ban in the U.S. will advance public health.

Canadian Menthol ban Studies

Chaiton et al (2018)[57]

Chaiton et al. (2018) conducted a survey assessing menthol smokers' behavioral response to Ontario's menthol cigarette sales restriction (effective January 1, 2017) one month following policy implementation. The FDA cites this survey for the proposition that 14 percent of Canadian respondents reported continuing using menthol cigarettes after the ban (similar to both my European results and Carpenter and Nguyen's (2021) Canadian results); the survey also indicates that respondents were more likely to have added menthol to cigarettes and to have switched to other flavored products than the respondents themselves had anticipated. As the FDA notes in its supporting materials, this small (analyzed sample of 206) survey

53 A keyword search for "Europe" or "European" results in zero hits in the 167-page Proposed Rule. See Proposed Rule, Federal Register / Vol. 87, No. 86.

54 Proposed Rule, Federal Register / Vol. 87, No. 86 at 26475.

55 European Commission. Special Eurobarometer 458: Attitudes of Europeans towards tobacco and electronic cigarettes. 2017. doi:10.2875/245123.

56 As noted above, survey data allow us to examine smoking status but rely on self-reported measures. Sales data, as used in Christopher Carpenter and Hai V. Nguyen (2020), "Intended and Unintended Effects of Banning Menthol Cigarettes," The Journal of Law and Economics 2021, 64:3, 629-650), provide independently observed data on aggregate consumption. Taken together, sales data mitigate any concerns arising from the self-report aspects of survey data, and survey data provide insights about individual smoking status.

57 Michael Chaiton, Robert Schwartz, Joanna E. Cohen, et al. (2018), "Association of Ontario's Ban on Menthol Cigarettes with Smoking Behavior 1 Month After Implementation," *JAMA Internal Medicine*, 178(5): 710-711.

does not provide a comparison group, nor does it account for background trends in any way.[58] As such, this study provides no credible evidence of the impact of the menthol ban on smoking initiation or cessation.

Chaiton, Nicolau, Schwartz, Cohen, Soule, Zhang, and Eissenberg (2020) [59]

Chaiton, Nicolau, Schwartz, et al (2020) provide a study of the provincial menthol ban in Ontario. The researchers purport to find that daily menthol users were statistically significantly more likely to make a quit attempt and to quit successfully (relative to non-menthol smokers in general) after the Ontario ban.

This analysis does nothing to account for the statistical issues that arise with longitudinal data (e.g. accounting for the serial dependence[60] that arises when one has repeated observations for a given individual).[61] This is especially concerning in this paper given how borderline many of the findings are in terms of statistical significance. With very limited adjustments for dependence issues (such as clustering on the individual level), all of the results could very easily end up not being statistically significant. When covariate adjustments were made, Ontario's menthol ban was associated with statistically significant increases in quit attempts and quitting at 1 year after the ban only for daily menthol smokers compared to non-menthol smokers, while occasional menthol smokers were statistically indistinguishable from non-menthol smokers. This need to dig deeper into subsamples in the data to find statistically significant results is concerning and raises questions about the reliability of the research. This concern is exacerbated when it is noted that the authors compare occasional and daily smokers separately to non-menthol smokers in total (i.e., both daily and occasional combined). Comparisons of comparable groups of menthol and non-menthol smokers (i.e., daily menthol compared to daily non-menthol; occasional menthol to occasional non-menthol) could easily yield insignificant differences in quit attempts and quit behavior between menthol and non-menthol smokers. Alternatively, comparing menthol and non-menthol users in the aggregate could also generate very different conclusions.[62]

Putting aside the possibility that these differences are only due to inapt comparisons (daily menthol smokers compared to the aggregate of daily and occasional non-menthol smokers), it is worth considering why the ban seems to have effects on more dedicated users than it has on more marginal users. If we generally think that daily users are more committed smokers, with occasional users less so, it is somewhat counter-intuitive that the ban's effects would play out this way. Given the issues with the study (as well as the study by Chung-Hall, et al (2021) discussed below), this surprising result should generate skepticism. If this odd result is not due to the inapt comparison problem raised above, it might expose another problem with the paper. Included in the occasional menthol smoker group are those "who used menthol occasionally or rarely in the past year (p. 342)." Essentially, the occasional menthol group might have a number of individuals who smoke non-menthol cigarettes frequently while rarely (but sometimes) smoking menthol cigarettes. This again suggests that the researchers engaged in potentially non-sensical comparisons since many individuals in the "treatment" group are actually people who primarily smoke non-menthol cigarettes.

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58 FDA, Review of Studies Assessing the Potential Impact of Prohibiting Menthol as a Characterizing Flavor in Cigarettes, p. 85.

59 Michael O. Chaiton, Ioana Nicolau, Robert Schwartz, Joanna E. Cohen, Eric Soule, Bo Zhang and Thomas Eissenberg (2020), "Ban on menthol-flavoured tobacco products predicts cigarette cessation at 1 year: a population cohort study," *Tobacco Control*, 29: 341–347.

60 As noted below at fn 72, in longitudinal data, an individual's behavior in period t is not statistically independent from his/her behavior in period t+1. Failure to account for this fact will often lead to standard errors of an estimate that suggest too much precision than is actually justified leading to potentially faulty claims of statistical significance. I account for this issue in my analyses by using a standard method of clustering the standard errors by individual.

61 Clustering standard errors at the subject level would be one way to account for this dependence.

62 There is something odd about the results as presented. In the adjusted comparisons, it is indicated that the researchers control for daily and non-daily smoking (see Tables 2, 3, and 4) but then continue to compare daily and non-daily menthol users separately. If the daily vs. non-daily adjustment has already been made, it is not clear what comparison is actually being made.

Also, when the authors examine subgroups, they find that the increase in quitting of daily menthol smokers compared to non-menthol smokers after the ban was observed in older but not younger adults. Ignoring the sub-sampling problem raised above, which given the already relatively small overall sample size leads to significant questions of reliability when making inferences based on even smaller sub-samples, this too seems odd given how much menthol ban supporters have suggested the ban will be particularly helpful in reducing smoking among the young. The authors acknowledge this (p. 346) and attribute it to a lack of brand preference among younger smokers, who, they conjecture, may more readily switch to other nicotine products. The authors then suggest that this means a menthol ban will have "an even greater impact in at-risk subpopulations such as the youth and young adults," even though it is at least as plausible that the results suggest young people will more readily choose non-menthol cigarettes in the face of a menthol ban.

Chaiton, Papadhima, Schwartz, Cohen, Soule, Zhang, and Eissenberg (2020)[63]

Chaiton, Papadhima, Schwartz, et al (2020) examined product substitution following Ontario's sales restriction (effective January 1, 2017) on menthol tobacco products except cigars over 6g and electronic cigarettes (which are not classified as tobacco products in Canada). The authors find various substitution patterns and suggest that a menthol ban that also restricts the availability of other flavored products would be more effective in terms of getting people to quit smoking. However, this study provides no reliable evidence in support of a menthol ban, including because it uses a convenience sample which draws into question the representativeness of its findings, and there is no attempt to compare those affected by the ban with a plausible counterfactual control group (beyond the pre-period baseline) or provide any other approach to accounting for background trends.

Chaiton, Schwartz, Shuldiner, Tremblay, and Nugent (2020)[64]

Chaiton, Schwartz, Shuldiner et al. (2020) examine the time series of wholesale cigarette sales in Ontario, which banned menthol cigarettes beginning January 2017, relative to British Columbia, which only banned menthol cigarettes in October 2017 when the Canadian federal ban came into effect. Although they find an immediate decline in overall cigarette sales (which the authors appear to acknowledge could have been influenced by retailers and smokers stockpiling menthol cigarettes in advance of the ban),[65] overall the sales differentials from baseline in Ontario caught back up to British Columbia's sales differentials from baseline within four months. Further, the re-aligning of sales with British Columbia occurred because Ontario's sales shot up, not because British Columbia's declined. This could suggest that at least some of the initial sales decline involved a running down of the pre-ban stockpiling. The study by Carpenter and Nguyen (2021), discussed below, also improves on the analysis of the sales data for Canada in several key ways, including using more comprehensive sales data for all provinces over a longer time period.

Chaiton, Schwartz, Cohen, Soule, Zhang, and Eissenberg (2021a) [66]

Chaiton, Schwartz, Cohen, et al (2021a) examined changes in the use of menthol additives after Ontario's menthol sales restriction (effective January 1, 2017). The primary relevance of this research involves the

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63 Michael Chaiton, ,Ismina Papadhima, , Robert Schwartz, , Joanna E. Cohen, , Eric K. Soule, Bo Zhang, and Thomas Eissenberg, (2020), "Product Substitution After A Real-World Menthol Ban: A Cohort Study", *Tobacco Regulatory Science*, 6(3), 205–212. https://doi.org/10.18001/trs.6.3.5 .

64 Michael Chaiton, Robert Schwartz, Jennifer Shuldiner, Gabrielle Tremblay, and Robert Nugent, (2020) "Evaluating a Real World Ban on Menthol Cigarettes: An Interrupted Time-Series Analysis of Sales," *Nicotine and Tobacco Research*, 2020: 576–579.

65 Evidence of stockpiling has also been observed in other data, see e.g. Carpenter and Nguyen (2021), infra at fn 35.

66 Michael Chaiton, Ismina Papadhima, Robert Schwartz, Joanna E. Cohen, Eric K. Soule, Bo Zhang and Thomas Eissenberg (2021a) "The use of flavour cards and other additives after a menthol ban in Canada" *Tobacco Control*, tobaccocontrol-2020-055698. Advance online publication. https://doi.org/10.1136/tobaccocontrol-2020-055698 .

authors' claims that their findings that a large number of menthol users responded to Ontario's menthol ban by adding flavor cards to their cigarettes indicates that such behavior undermines the effect of menthol bans. However, as shown above in my European analysis, these behaviors have little effect on whether an individual continues to smoke.

Chaiton, Schwartz, Cohen, Soule, Zhang, and Eissenberg (2021b)[67]

Chaiton, Schwartz, Cohen et al (2021b) examines survey data to see if menthol preference (prior to the Ontario menthol ban) was associated with quitting and quit attempts at a two-year follow-up survey. Finding that individuals in the group of those who previously smoked menthol cigarettes daily (or almost daily) and those who previously smoked menthols occasionally were more likely to have quit and exhibited more quit attempts. However, these results exhibit substantial heterogeneity in the likelihood the quit outcomes are available for each group. That is, most non-menthol smokers (52 percent) did not report their quit status, while the fraction with missing data was only about half as large in the two menthol groups (28 percent for occasional menthol; 27 percent for daily menthol) and this difference is statistically significant. This leaves open the possibility that this differential likelihood of missing data drives the article's results. Although the authors purport to use multiple imputation analysis to examine the degree to which the missing data could be influencing their results, they provide no details regarding this analysis. Essentially, while multiple imputation can give some sense of changes in estimate certainty on the assumption that observations are "missing at random," the large heterogeneity here suggests such an assumption is highly unlikely.

Chung-Hall, et al (2021)[68]

Chung-Hall, et al (2021) uses the Canadian portion of the 2016 and 2018 ITC Four Country Smoking and Vaping surveys which allow a longitudinal analysis. Longitudinal data, such as that analyzed in this report above, allows researchers to focus on within person variation. That is, how does a menthol ban affect smoking for a given person. However, the Chung-Hall, et al (2021) study examines only 138 menthol smokers (1,098 non-menthol smokers).

The main question, whether menthol smokers were more likely to quit than non-menthol smokers, yields a result that is not statistically significant. To generate any statistically significant findings, the authors need to examine the subgroup of daily menthol smokers who, in the results adjusted for covariates, were more than twice as likely as daily non-menthol smokers to have quit smoking after the Canadian menthol ban.[69] In the raw percentages, the authors report that 21 percent of (pre-ban) daily menthol smokers quit post-ban as compared to 11.6 percent of (pre-ban) daily non-menthol smokers (Table 2). While a doubling seems impressive, the authors do not point out in the paper that these numbers represent very few individuals. First, there are only a total of 138 menthol smokers in the sample, and, of them, 30 quit (menthol smokers overall had a 21.5 percent quit rate). That 30 is made up of 21 percent of daily menthol smokers quitting and 23.3 percent of non-daily menthol smokers quitting. Though not reported in this way, this means that 23 out of 108 daily menthol smokers quit between the two waves of the survey, as compared to about 104 out of 900 daily non-menthol smokers. Moreover, if the 11.6 percent quit rate observed among

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67 Michael Chaiton, Robert Schwartz, Joanna E. Cohen, Eric Soule, Bo Zhang, Thomas Eissenberg, (2021b) "Prior Daily Menthol Smokers More Likely to Quit 2 Years After a Menthol Ban Than Non-menthol Smokers: A Population Cohort Study," *Nicotine & Tobacco Research*, 23(9): 1584-1589.

68 Janet Chung-Hall, Geoffrey T Fong, Gang Meng, K Michael Cummings, Andrew Hyland, Richard J O'Connor, Anne C K Quah, Lorraine V Craig, (2021) "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*, doi:10.1136/tobaccocontrol-2020-056259.

69 The paper is confusing on exactly what is included in this result. While the Table 2 heading "Post-ban quit smoking" implies that this result includes individuals who quit after the ban only, the authors report: "There was no significant difference in short-term quitting after the nationwide menthol ban between daily menthol smokers and daily non-menthol smokers (p. 6)." This implies that this result includes both those who quit before and those who quit after the ban.

daily non-menthol smokers had also been observed amongst daily menthol smokers, 12.5 daily menthol smokers would have reported quitting rather than the 23 who did. Accordingly, the entire result is driven by having about 10 more daily menthol smokers quitting than would have been expected given the quit rates of the daily non-menthol smokers. While this could represent a true difference, it is surely the case that there is more variability among the small daily menthol smoker group than there would be in the much larger daily non-menthol group. Statisticians have repeatedly pointed out that statistically significant results in relatively small samples are likely to be over-estimates.[70]

The second main statistically significant result in the paper is the so-called "post-ban remained quit" finding where Canadian ITC respondents who said they smoked menthols in 2016 but quit before the nationwide 2017 menthol ban were twice as likely to have remained quit after the nationwide ban than non-menthol smokers who stopped smoking before the nationwide ban.[71] There are a number of oddities to this analysis. First, the table where these findings are reported (Table 3) does not provide raw percentages, instead only providing the adjusted odds ratios, so it is impossible to tell how many respondents are driving this result. This information would be helpful to understand or resolve a seeming inconsistency in the paper. Specifically, on page 2 of the paper, in describing the sample used, the authors state that the Canadian ITC arm in 2018 included 1,072 smokers and 164 quitters for the total reported sample size of 1,236 (Table 1). However, the quit rates reported in Table 2 suggest that there were 30 menthol smokers who quit and 154 non-menthol smokers who quit, yielding a total of 184 post quitters in a sample that supposedly only had 164 quitters. Some of this might be explained by the authors' comments on page 2 that individuals who smoked less than monthly were also considered quitters. In any event, it is very likely we are dealing with very few menthol-smoking individuals who quit between the 2016 survey and the nationwide 2017 menthol ban.

The opaqueness of these findings, tied with the very small survey sample, make this research and its conclusions unreliable, to say nothing of other technical issues with the paper. For example, there is no discussion regarding dependence issues involved in calculating standard errors. With longitudinal data, it is known that a failure to correct for period-to-period dependence in repeated observations of a given entity (in this case person) yields invalid standard errors and therefore makes statistical inference problematic.[72] Moreover, the ITC study itself indicates that its data on quitters is highly problematic ("quitters in the 4CV sample should not be considered to be representative of quitters in the population. For example, comparisons between the quitters in the ITC sample and quitters in the cross-sectional Smoking Toolkit Study showed an important discrepancy in distribution of length of time quit"),[73] though the authors of this

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70 See, for example, Shravan Vasishtha, Daniela Mertzena, Lena A. Jägera, and Andrew Gelman (2018), "The statistical significance filter leads to overoptimistic expectations of replicability", *Journal of Memory and Language*, 103: 151-175. They cite a number of other analyses that reach the same conclusion throughout the statistics literature.

71 This work was then used by Fong and Meng to claim that a menthol ban would lead to almost 50,000 California menthol smokers to stop smoking, see Geoffrey Fong and Gang Meng (2021), The Impact of the Canada-Wide Menthol Cigarette Ban on Increasing Quitting: Implications for California, available at https://itcproject.org/findings/fact-sheets/april-5-2021-impact-of-canada-wide-menthol-cigarette-ban-on-increasing-quitting-implications-for-california/.

72 See, for example, A. Colin Cameron and Douglas L. Miller (2015), "A Practitioner's Guide to Cluster-Robust Inference". *Journal of Human Resources*. 50 (2): 317–372 or the related older work Kung-Yee Liang and Scott L. Zeger, (1986) "Longitudinal data analysis using generalized linear models", *Biometrika*, 73 (1): 13–22 . Intuitively, with longitudinal data where, say, you have 2 observations for each of 1,000 people, you do not really have 2,000 independent observations and, so, some adjustment needs to be made for this lack of independence. Often, failure to account for this yields estimates that are seen as much more precise than they actually are (which leads to mistaken claims of statistical significance). A standard way to account for this issue is to cluster the standard errors by individual, which is what I have done in my analyses.

73 ITC Four Country Smoking and Vaping Survey Wave 2 (4CV2) Technical Report, version date 10 January 2020 at p. 103 available at https://itcproject.s3.amazonaws.com/uploads/documents/4CV2_Technical_Report_15Jan202.pdf.

study do not mention this fact. Given the concerns raised with the underlying estimation, this issue clearly makes this research and its conclusions unreliable.

The ITC group itself has also raised another issue regarding the reliability of the data used by Chung-Hall, et al in discussing the menthol smokers who appear to continue smoking menthol cigarettes after the ban (19.5% of the pre-ban menthol smokers). Geoffrey T. Fong indicates that after inspection, it appears as though many of those incorrectly identified the brands they smoked as menthol cigarettes. The ITC group determined this by examining the ITC respondents' responses about which brands they last purchased. "Of the 38 pre-ban menthol smokers who said they still smoked menthol cigarettes at follow-up, 13 reported a menthol cigarette brand as their last purchase (36.1%, 95% CI 22.5 to 52.3), 5 reported a menthol 'replacement' brand (6.9%, 95% CI 2.7 to 16.8) and 20 reported a non-menthol brand or indeterminate brand (57.0%, 95% CI 41.4 to 71.4). Among the 13 post-ban menthol smokers who reported a menthol cigarette brand as their last purchase, 54.7% (95% CI 28.6 to 78.4) reported buying them from a First Nations reserve and 31.0% (95% CI 12.3 to 58.9) from convenience stores. Few smokers purchased menthol cigarettes from all other sources (range: 2.7% in bars/pubs (95% CI 0.2 to 26.5) to 7.5% by internet (95% CI 0.7 to 48.4))".[74] While Fong interprets this as evidence that there were few illicit purchases going on, it could just as easily be the case that the respondents were correct about smoking menthols and made their mistake when it came to remembering the brand they last bought.

More importantly, though, if individuals did make a mistake in remembering whether they smoked menthols after the ban, why would it not be possible that individuals also made comparable mistakes before the ban? Given the small number of "extra" daily menthol smokers who quit after the ban (recall the primary results are driven by about 10 such quitters), even a few mistakes in categorizing oneself as a menthol smoker could easily flip the Chung-Hall results from statistically significant to statistically insignificant. As indicated above, results based on small subsamples are often misleading.

Given the subgroup analysis of daily smokers in Chung-Hall, et al (2021), I specifically examine in Appendix 2 to this report the effect of the EU menthol cigarette ban on those respondents who indicated they were daily smokers at wave 1 of the survey. The results of this analysis indicate that the EU menthol ban was associated with statistically significant increases in the probability a respondent was a smoker as well as the probability he/she was a daily smoker, for those survey respondents who indicated they were a daily smoker at wave 1. There was no statistically significant effect of the EU menthol ban on cigarettes smoked per day for this group. Accordingly, consistent with my main results, there is no evidence of the EU menthol cigarette ban leading to any statistically significant improvements in smoking rates for daily smokers and there is evidence of a counterproductive effect.

Chaiton, Schwartz, Kundu, Houston, and Nugent (2021)[75]

Chaiton, Schwartz, Kundu, Houston, and Nugent (2021) examines the effects of Canadian provincial menthol bans on menthol and overall wholesale cigarette sales. This research letter provides limited details of the analysis undertaken. While the paper reports a decline in menthol sales and a decline in cigarette sales for the same month in the previous year, it finds no statistically significant change in the trend of overall wholesale cigarette figures following the ban. However, these wholesale figures do not account for sales to First Nation sellers. As shown in Carpenter and Nguyen (2021) (discussed below), there is evidence that a large number of adult menthol smokers obtained menthol cigarettes from these sources.

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74 Geoffrey T. Fong (2021), "The Canada-Wide Menthol Cigarette Ban Did NOT Increase Illicit Purchases.", available at https://itcproject.s3.amazonaws.com/uploads/documents/ITC-Menthol_Ban-No_Increase_in_Illicit_Purchases-Apr52021.pdf.

75 Michael Chaiton, Robert Schwartz, Anasua Kundu, Christopher Houston and Robert Nugent, (2021) "Analysis of Wholesale Cigarette Sales in Canada After Menthol Cigarette Bans", *JAMA Network Open*. 2021;4(11):e2133673.

Such purchases would substantially reduce the estimated decline in overall sales identified in this paper. The authors note that a limitation of the study is that it does not include contraband cigarette sales.[76]

Brown et al. (2021)[77]

Brown et al. (2021) evaluated the effect of Ontario, Canada's menthol cigarette sales restriction (effective January 1, 2017) on tobacco product sales using Nielsen data. Although they indicate they found little evidence of product substitution, there are a number of factors which call into question the reliability of the study. First, they provide no indications of the precision of their estimates (and therefore no assessment of statistical significance). Second, although they purport to use a counterfactual comparison through the use of sales data in British Columbia, they provide no indication that Ontario and British Columbia sales are comparable historically. Further, their own data raise concerns about using British Columbia as a comparison given some of the odd swings they find in British Columbia (e.g., finding that the sale of menthol capsule cigarettes increased by 1500 percent and non-menthol capsule cigarette sales increased almost fivefold), the putative "control" group. These concerns suggest that this study does not provide a valid counterfactual comparison. Additionally, as is known from other sources, including Carpenter and Nguyen (2021) (discussed below), First Nation Reserves sales, which will not be captured in the Nielsen data, are a significant form of substitution that occurred after the Canadian menthol bans. Thus, it is not justified to conclude that substitution was limited on the basis of these incomplete data.

Carpenter and Nguyen (2021)[78]

Work by Carpenter and Nguyen (2021) examines both survey data and sales data on smoking, finding resounding evidence that Canada's provincial menthol ban did not significantly reduce smoking prevalence or consumption measures among youth or adults. Compared to the survey studies above, Carpenter and Nguyen (2021) use the much larger[79] Canadian Student Tobacco, Alcohol and Drugs Survey ("**CSTADS**") to examine cigarette use among young people and Canadian Tobacco, Alcohol and Drugs Survey ("**CTADS**")[80] to examine use among adults.

Their Figure 6 using the CSTADS data shows clearly that the menthol ban-induced decline in menthol cigarette use during the past 30 days is completely offset by an increase in non-menthol use, for a net effect of zero in terms of overall cigarette use among youth. Likewise, for adults, there is no statistically significant change in smoking likelihood after the menthol ban, as many adults purchased menthol cigarettes from First Nations Reserves which are exempt from compliance with the Canadian menthol bans (Table 5). Table 6 also shows that the menthol bans did not affect overall smoking initiation, smoking status, or quit attempts among youth. For the sales data analysis in the paper, the authors present results suggesting that menthol sales fell by a statistically significant amount while sales of non-menthols did not change by a statistically significant amount. Although the authors do not present the total sales results, Figure 3 gives us some insight. The +1 year effect after the ban indicates a jump in non-menthol sales, the scale of which is comparable to the decline in menthol sales, especially given the noisiness of the estimate of the menthol effect. The other years examined after the ban generally yield statistically insignificant estimates for both menthol and non-menthol sales. Further, these data do not include the First Nations sales that the survey results indicate as being important. It is very likely that if these results were put together, there would not

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76 Ibid, at p. 3.

77 Elizabeth M Brown, Doris G Gammon, Todd Rogers, Ellen M Coats, Lindsay T Olson, Ashley Ross, Martha Engstrom and James M Nonnemaker (2021),"Changes in retail sales of tobacco products in Ontario after a menthol sales restriction", *Tobacco Control,* advance online publication. https://doi.org/10.1136/tobaccocontrol-2021-056489 .

78 Christopher Carpenter and Hai V. Nguyen, "Intended and Unintended Effects of Banning Menthol Cigarettes," *The Journal of Law and Economics,* 2021 64:3, 629-650, also available as NBER working paper 26811 (2020).

79 This survey interviews about 40,000 students in grades 6-12.

80 This survey interviews about 15,000 adults.

be a statistically significant change in total cigarette sales associated with the Canadian menthol ban. This would be consistent with the survey results provided by Carpenter and Nguyen (2021).

The FDA makes only scant reference to the Carpenter and Nguyen paper in its assessment of the impacts on smoking consumption and cessation and does not discuss the study's main findings. The study is also only briefly noted, but dismissed, in the FDA's assessment of the impacts on smoking initiation. The FDA states that: "[w]hile this study found that provincial menthol sales restrictions were not associated with an overall change in youth and adult past 30-day cigarette use, this finding is inconsistent with the authors' supplemental analysis that found decreases in menthol cigarette sales and no effect on nonmenthol cigarette sales post-implementation. The study also found an increase in adult self-reported purchasing of cigarettes from First Nations reserves, which were exempt from the sales restriction. This purchasing behavior was not assessed among youth. In the United States, however, the proposed menthol product standard would apply nationwide, including on Tribal lands, which likely would increase the effectiveness of a nationwide menthol standard as compared to Canada."[81]

This conclusion is unfounded. Firstly, as regards the claim that the study's results are self-contradictory, as noted above, it is very likely that if the First Nations sales were included in the Canadian sales data, there would not be a statistically significant change in total cigarette sales associated with the Canadian menthol ban, consistent with the survey results provided by Carpenter and Nguyen (2021). Secondly, as regards the FDA's claim that the study's findings are inapplicable to the U.S. because they were driven to some extent by the exemption for First Nations reserves, the FDA implicitly assumes that, in the absence of these exempted sales channels in Canada (as would be the case in the U.S.), individuals would simply not smoke. It is logically possible (and based on the observed European experience, quite likely) that, instead, individuals unable to secure menthol cigarettes through such channels will substitute in other ways (e.g. non-menthol cigarettes, illicit sources, etc.). Just because Canadian smokers found it easy to substitute to First Nations sources for their purchases, it does not follow that had that channel been foreclosed they would have simply given up. What Carpenter and Nguyen show is that many menthol smokers are motivated to find alternative supply sources when faced with a ban. While the European menthol smokers in my data do not have First Nation suppliers to rely on, they overwhelmingly were still able to substitute alternative sources (primarily adding menthol to regular cigarettes) or they switched to non-menthol cigarettes, as opposed to simply quitting.

Carpenter and Nguyen provide evidence against the efficacy of the Canadian menthol ban in terms of improving smoking outcomes of adults and children alike. Their research, even beyond simply being noted as part of a more general literature on the Canadian experience, deserves significant weight given the sophisticated methods employed and the variety of large datasets consulted. Compared to most of the rest of the literature on Canada, this paper is superior to most of the existing literature. This makes it especially troubling that the FDA dismisses it with little discussion while crediting papers that are inferior from a methodological standpoint.

However, as noted above, there are strong reasons to look beyond Canada. At a minimum, attention should have been paid to the EU experience with a menthol ban. As illustrated by my analysis, the EU experience indicates that a menthol cigarette ban in the U.S. is not likely to lead to less smoking and is also unlikely to achieve the stated public health objectives underpinning the ban.

[81] Proposed Rule, Federal Register / Vol. 87, No. 86 at 26471.

Fong et al (2022)[82]

This is a recent publication which is not referred to in the Proposed Rule. However, I provide a review of the study here, given its relevance to the issue being discussed. This study uses the ITC data to estimate a quit rate among Canadian menthol smokers around the time of the Canadian menthol ban and then extrapolates those numbers to arrive at a U.S. figure they purport represents how many Americans in general and African American smokers specifically would quit due to a U.S. ban. In addition to the caveats the authors themselves raise (such as the differences between U.S. and Canada in terms of menthol usage), this paper suffers from many of the same flaws raised above in relation to the Chung-Hall et al (2021) study using ITC data to estimate the effect of the Canadian menthol ban on smoking among menthol users. Specifically, there are very few menthol smokers in the ITC data pre-ban (n = 128) and so any estimate of a differential quit rate between menthol and non-menthol smokers is driven by just a tiny number of people (as discussed above, likely on the order of 10 or so). For the reasons stated above, this analysis is unreliable in terms of determining whether there was even a systematic effect of the Canadian menthol ban, but to then take such a speculative number (whose representativeness even of the Canadian experience is questionable given the small numbers involved) and apply it to the very different U.S. context is highly irresponsible.

6.2 Studies of behavioral intentions and hypothetical choice experiments

In addition to the studies evaluating the impact of Canada's menthol bans laws, the FDA also relies on studies of behavioral intentions and hypothetical choice experiments regarding menthol bans, as supporting its claim that the menthol ban will increase smoking cessation.[83] These studies are also reviewed in Section 2 of the FDA's Review of Studies Assessing the Potential Impact of Prohibiting Menthol as a Characterizing Flavor in Cigarettes. The FDA claims that these studies "are consistent with the Agency's expectation that many menthol smokers would attempt to quit smoking following the implementation of the proposed menthol standard."[84]

However, this literature provides no reliable evidence that banning menthol cigarettes will lead to reductions in smoking. Studies based on surveys of respondents' intentions with regards to a possible future menthol ban lack external validity. Because the link between these intentions and subsequent behavior is never verified, the conclusions do not follow. Such surveys also have the potential to suffer from significant biases as individuals have little incentive to provide correct, well-reasoned responses and, in fact, may be induced to provide socially acceptable responses based on the researchers' desired outcomes. These limitations are recognized in the FDA's evidence review which states: "[s]tudies that examine behavioral intentions in response to hypothetical scenarios have substantial threats to external validity. Participants' reported behavioral intentions may or may not predict actual behavior. People may not accurately comprehend hypothetical menthol cigarette bans or may be unable to accurately predict how they would behave in a hypothetical scenario. Studies that assess behavioral intentions in response to hypothetical menthol cigarette bans may be particularly susceptible to social desirability and availability biases."[85]

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82 Geoffrey T. Fong, Janet Chung-Hall, Gang Meng, Lorraine V. Craig, Mary E. Thompson, Anne C. K. Quah, K. Michael Cummings, Andrew Hyland, Richard J. O'Connor, David T. Levy, Cristine D. Delnevo, Ollie Ganz, Thomas Eissenberg, Eric K. Soule, Robert Schwartz, Joanna E, Cohen, Michael O. Chaiton (2022), "Impact of Canada's menthol cigarette ban on quitting among menthol smokers: pooled analysis of pre-post evaluation from the ITC Project and the Ontario Menthol Ban Study and projections of impact in the U.S.," Tobacco Control, tobaccocontrol-2021-057227. doi: 10.1136/tobaccocontrol-2021-057227. Epub ahead of print. PMID: 35483720..

83 Proposed Rule, Federal Register / Vol. 87, No. 86 at 26474-5.

84 Proposed Rule, Federal Register / Vol. 87, No. 86 at 26474.

85 FDA, Review of Studies Assessing the Potential Impact of Prohibiting Menthol as a Characterizing Flavor in Cigarettes, p. 123.

Of all the hypothetical choice studies that are referred to, only Guillory et al (2020)[86] actually examines potential smoking cessation in response to a menthol cigarette ban and so it is the only such study having any potential relevance to evaluating the likely impact of a U.S. menthol ban on smoking cessation.

Guillory et al (2020) conducted an experimental marketplace study assessing menthol cigarette smokers' purchases in response to hypothetical experimental conditions that affected menthol tobacco product availability. The authors found that participants in the menthol cigarette ban and all menthol product ban conditions were less likely to purchase cigarettes of any type than participants in the no ban condition. However, a fundamental issue with this study, as with hypothetical choice experiments generally, is that there is no reliable evidence that hypothetical choices in a virtual environment bear any relationship to real world purchasing situations. Whether a study participant chooses to purchase any cigarettes or not in the simulated ban condition does not affect whether he actually gets cigarettes. Such a study, where the ultimate outcome is invariant to the hypothetical decision made, is not reflective of actual purchasing situations at all. As seen in my European analysis, despite many EU menthol smokers claiming they would quit smoking when the ban went into effect, very few actually quit. The study also has a number of other limitations that the authors note, which also mean that it does not provide reliable scientific support for the FDA's proposal (e.g., the sample is not representative of the smoking population; the experimental control condition was different than all of the other conditions in that participants were provided a text prompt when they tried to purchase virtual cigarettes in the non-control condition whereas no prompt was provided in the control condition – this leaves open the likely possibility that the prompt affected choices and drove some of the estimated effect). As regards the external validity or relevance of this study, the design did not allow for other real world choices that exist such as purchasing non-menthol cigarettes and self-mentholating or the purchase of contraband menthol cigarettes.

Another study, Denlinger-Apte et al. (2021)[87] conducted an experimental marketplace task to assess the product purchases of adult menthol cigarette smokers' (N = 40) in response to price increases and the availability of some alternative products. This is not directly relevant to a menthol cigarette ban. However, the study found that increasing the price of menthol cigarettes led to product substitution. It is also notable that no participants opted to abstain from using tobacco products during the field trial, even though doing so would have allowed them to receive their account balances at their final visit – a finding which the authors noted: "…may indicate a potential discrepancy between self-reported intentions and actual behavior." Again, as noted above, there is no reliable evidence that these hypothetical choices bear any relationship to actual choices. The study also has a number of other limitations that the authors note, which also mean that it does not provide reliable scientific support for the FDA's proposal (including the use of a small non-representative sample, so the results may not generalize to all menthol cigarette smokers, and the use of experimental conditions that do not reflect the real world).

The other hypothetical choice studies (discrete choice experiments) referred to by the FDA examine preferences between different tobacco products in response to limitations on product availability and flavors. Even putting aside the fact that these studies do not reflect real world decisions, they do not provide any evidence supporting the FDA's claim that the menthol ban will increase smoking cessation.

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86 Jamie Guillory, Annice E Kim, James M Nonnemaker, Brian Bradfield, Nathaniel Harlan Taylor, Lauren Dutra, Ashley Feld (2020), "Effect of menthol cigarette and other menthol tobacco product bans on tobacco purchases in the RTI iShoppe virtual convenience store," *Tobacco Control*, 29: 452–459.

87 Rachel L. Denlinger-Apte, Rachel N. Cassidy, Kate B. Carey, Christopher W. Kahler, Warren K. Bickel, Richard O'Connor, Shreeya Thussu and Jennifer W Tidey, (2021),"The impact of menthol flavoring in combusted tobacco on alternative product purchasing: A pilot study using the Experimental Tobacco Marketplace," *Drug and Alcohol Dependence*, 218, 108390.

As the FDA acknowledges,[88] there are a number of further limitations of this literature, including potential publication bias (this is particularly acute here given the politically charged nature of tobacco research and the policy preferences of the public health community, which favors the publication of statistically significant results and results supporting the researchers' pre-conceived beliefs.[89]); the use of small sample sizes and convenience samples which limits the generalizability of results; and the potential for social desirability and cognitive biases to influence participants' responses. The FDA claims that despite these limitations, these studies can provide useful insights about the range of behaviors that people may engage in if menthol cigarettes are banned.[90] However, insights of potential behaviors (even if valid) are not evidence of an effect. The limitations of these studies are fundamental and mean that the studies cannot be relied upon to support any conclusions with regards to the impact of a menthol cigarette ban.

6.3 Review of studies evaluating national and local flavor bans that are relied on by the FDA

The FDA relies on studies evaluating national and local flavor bans to claim that the proposed ban will reduce smoking initiation. The FDA states: "FDA's expectation of a significant reduction in youth initiation and progression to regular cigarette smoking is supported by real-world experience of youth tobacco use prevalence decreasing following implementation of policies restricting the sales of flavored tobacco products".[91] In addition the FDA also refers to some studies evaluating national and local flavor bans in its assessment of whether the ban will increase smoking cessation.[92] These studies are also reviewed in Section 1 of the FDA's Review of Studies Assessing the Potential Impact of Prohibiting Menthol as a Characterizing Flavor in Cigarettes.

In Appendix 8, I provide a review of each of the studies evaluating national and local flavor bans that are relied on by the FDA. I note however that very few of these studies concern menthol bans and those that do are limited to local jurisdictions which limits the relevance and generalizability of the findings from these studies to a U.S. national menthol ban. The FDA ban in 2009 on characterizing flavors in cigarettes, other than menthol (e.g., cherry, chocolate), affected very few smokers and is not a reliable comparator for a ban on menthol cigarettes which represent 26 percent of the cigarette market according to the FDA.[93] Extrapolating the effects of altogether different regulations is invalid.

The FDA claims that a nationwide standard that prohibits menthol cigarettes would likely have a greater impact in decreasing youth cigarette use compared to that observed from policies from limited jurisdictions, because a nationwide product standard would eliminate the manufacture of these products as well as the opportunity to easily travel to neighboring jurisdictions within the United States that do not have a menthol sales restriction or use online retailers to purchase menthol cigarettes.[94] This is merely speculative and assumes that individuals unable to secure menthol cigarettes through such channels will not substitute in other ways (e.g. non-menthol cigarettes, illicit sources, etc.). As discussed below in Appendix 8, the studies also suffer from deficiencies in study designs, methods, and reporting which makes them unreliable. A principal concern is that very few of the studies employ a counterfactual comparison, or establish that the counterfactual comparison that is used is valid, which prevents a determination of whether any effects are causal or merely the result of pre-existing trends. Accordingly, these studies cannot be relied on to support any conclusions with regards to the impact of a menthol ban on smoking behaviors.

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88 FDA, Review of Studies Assessing the Potential Impact of Prohibiting Menthol as a Characterizing Flavor in Cigarettes, pp. 122-124.

89 On this general issue, see Kay Dickersin, Yuan-I Min, and Curtis L. Meinert (1992), "Factors Influencing Publication of Research Results: Follow-up of Applications Submitted to Two Institutional Review Boards," *JAMA,* 267: 374-378.

90 FDA, Review of Studies Assessing the Potential Impact of Prohibiting Menthol as a Characterizing Flavor in Cigarettes, p. 124.

91 Proposed Rule, Federal Register / Vol. 87, No. 86 at 26470.

92 Ibid at 26475.

93 Ibid at 26475.

94 Ibid at 26472.

6.4 Review of modelling papers relied on by the FDA

The FDA also relies on results from simulation modelling studies of the estimated effects of menthol bans to justify the ban.[95]These papers are also reviewed in Section 3 of the FDA's Review of Studies Assessing the Potential Impact of Prohibiting Menthol as a Characterizing Flavor in Cigarettes. The FDA concludes that: "population health models simulating menthol ban policies are consistent with a substantial public health benefit."[96] The estimates provided by the most recent modelling paper by Levy et al (2021) are also used by the FDA as the primary inputs to its calculation of the anticipated benefits of the proposed menthol product standard for the purposes of its cost benefit analysis.[97]

Below I provide my review of these modelling papers. However, as a general point, I note that these simulation studies make up starting parameters in terms of assumed effects of a menthol ban on quit rates and initiation and then model what the ultimate effects will be on smoking rates over time. It is not an overstatement to say that the outcomes of these studies are entirely driven by the assumed values of the effects of the ban. These values are not derived from any empirical evidence; they are merely asserted. As such, these studies do not provide any evidence of the impact of a menthol ban on smoking behaviors.

Levy et al (2011)[98]

This early simulation study compares smoking rates over the period 2010 to 2050 between a baseline scenario and a projected scenario where menthol cigarettes are banned, assuming increases in quit rates and decreases in initiation rates due to the ban of 10, 20, and 30 percent. They "show" that if you assume quit rates will be higher and initiation rates will be lower, ultimate smoking prevalence will decline. However, beyond characterizing these changes to quit and initiation rates as "plausible"[99] and a vague reference to "studies cited above" without explicitly noting which of the studies had arrived at these assumptions, Levy et al (2011) provides no justification for these assumptions. Indeed, given that none of the papers referenced in Levy et al (2011) actually estimates quit and initiation rates, these assumptions are entirely made up. Despite referring to the assumptions as conservative, relative to my European analysis or even the questionable estimates FDA relies on from the Canadian experience, these assumptions are likely overstated by at least an order of magnitude.

Le and Mendez (2021)[100]

This paper attempts to use simulations to calculate what smoking rates and deaths would have looked like over the period 1980 to 2018 if menthol cigarettes had not been in the market. Again, given that the paper cites no real-world empirical evidence regarding the effects of menthol's presence or absence on initiation or the likelihood that individuals would simply choose to smoke non-menthol cigarettes, the authors simply assume these parameters to arrive at the conclusion that the smoking prevalence decline over the period was slowed by the presence of menthol, and menthol cigarettes led to 10 million life years lost and almost 400,000 premature deaths due to smoking. The authors could have arrived at even larger numbers if they had assumed that if menthol cigarettes did not exist, people would have exercised more and had healthy

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95 Ibid at 26480-81.

96 Ibid at 26481.

97 See FDA, Preliminary Regulatory Impact Analysis; Initial Regulatory Flexibility Analysis; Unfunded Mandates Reform Act Analysis, Tobacco Product Standard for Menthol in Cigarettes; and Proposed Rule, Federal Register / Vol. 87, No. 86.[98] David T. Levy, Jennifer L. Pearson, Andrea C. Villanti, et al., (2011), "Modeling the future effects of a menthol ban on smoking prevalence and smoking-attributable deaths in the United States," *American Journal of Public Health,* 101(7): 1236-1240.

98 David T. Levy, Jennifer L. Pearson, Andrea C. Villanti, et al., (2011), "Modeling the future effects of a menthol ban on smoking prevalence and smoking-attributable deaths in the United States," *American Journal of Public Health,* 101(7): 1236-1240.

99 Ibid at 1237.

100 Thuy TT Le and David Mendez (2021), "An estimation of the harm of menthol cigarettes in the United States from 1980 to 2018," *Tobacco Control.*

diets. Such an assumption would have no less empirical grounding than the assumptions made by the authors. This kind of research has no scientific basis and amounts to question begging. The fact that FDA relies on studies like this belies its claims to ground its proposal on a strong scientific foundation.

Levy et. al. (2021)[101]

Although this paper purports to find that overall smoking would decline in the U.S. by 15% by 2026 due to menthol smokers quitting or switching to vaping products due to a simulated menthol cigarette ban, the simulation itself is predicated on the mere opinions of 11 "experts" who answered a questionnaire regarding their beliefs about what effect a ban would have on smoking transitions, in a FDA funded exercise.[102] These simulation results are only accurate if the expert consensus itself is accurate.

However, even if this approach had any validity, the way that the expert elicitation was undertaken made a flawed approach even worse. In particular, the experts were identified and ranked based on their prior menthol publications, and in consultation with the FDA.[103] This led to a panel of experts who have expressed strong opinions in favor of various tobacco control measures including banning menthol cigarettes before their involvement with the expert elicitation. These experts regularly opine on legal and policy issues outside the scope of their training and expertise blurring the lines between science and advocacy.[104] As Philip Tetlock has documented repeatedly, expert predictions generally have little predictive value and the experts who have committed themselves to particular policy positions do a particularly poor job refining and revising their beliefs when new information becomes available.[105] The selection of such experts also ignores best practice guidance for conducting formal, structured elicitation, including those set out in the U.S. Department of Health and Human Services White Paper (2021, September 3) addressing Uncertainty in Regulatory Impact Analysis,[106] which specify that the experts should be free of financial or personal conflicts of interest and other characteristics that may make them

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101 David T. Levy, Rafael Meza, Zhe Yuan, et al., (2021), "Public health impact of a US ban on menthol in cigarettes and cigars: a simulation study," *Tobacco Control*, Published Online First: 02 September 2021.

102 This questionnaire study is described in David T. Levy, Christopher J. Cadham, Luz Maria Sanchez Romero, Marie Knoll, Nargiz Travis, Zhe Yuan, Yameng Li, Ritesh Mistry, Clifford E Douglas, Jamie Tam, Aylin Sertkaya, Kenneth E. Warner and Rafael Meza (2021), "An Expert Elicitation on the Effects of a Ban on Menthol Cigarettes and Cigars in the United States," *Nicotine and Tobacco Research*, 23(11): 1911–1920.

103 Ibid at 1913. The experts chosen for the expert elicitation were: David Ashley, Georgia State University, Michael Chaiton, University of Toronto, Christine Delnevo, Rutgers University, Pebbles Fagan, University of Arkansas for Medical Sciences, Ray Niaura, New York University, Kola Okuyemi, University of Utah, Richard O'Connor, University of Buffalo, Jennifer Pearson, University of Nevada, Reno, Kurt Ribisl, University of North Carolina, Chapel Hill, Andrea Villanti, University of Vermont, Valerie Yerger, University of California at San Francisco.

104 For example, David Ashley has advocated that the U.S. FDA has the authority to implement a policy to reduce nicotine in cigarettes to non-addictive levels (see Micah L. Berman, Patricia J. Zettler and David L. Ashley (2018), "Anticipating Industry Arguments: The US Food and Drug Administration's Authority to Reduce Nicotine Levels in Cigarettes," *Public Health Reports* 133(4): 502–506. https://doi.org/10.1177/0033354918776935); Michael Chaiton has advocated for menthol bans as well as additional policies (see Jennifer Brown, Teresa DeAtley, Kevin Welding and Michael Chaiton, (2017), "Tobacco industry response to menthol cigarette bans in Alberta and Nova Scotia, Canada," *Tobacco Control*, 26: e71–e74); Christine Delnevo has advocated for menthol bans including making the strident call that "The US tobacco control community has unfinished business with menthol cigarettes and the FDA should continue to pursue closing this flavored cigarette loophole" (see Olivia A. Wackowski, Kiameesha R. Evans, Melissa B. Harrell, Alexandra Loukas, M Jane Lewis, Cristine D. Delnevo and Cheryl L. Perry (2018), "In Their Own Words: Young Adults' Menthol Cigarette Initiation, Perceptions, Experiences and Regulation Perspectives," *Nicotine & Tobacco Research* 20(9): 1076–1084. https://doi.org/10.1093/ntr/ntx048); Pebbles Fagan is quoted in https://www.arkansasonline.com/news/2021/may/15/leaders-warn-of-menthol-threat/ as indicating that menthol cigarettes should have been banned in 2009 already. Similar indications of advocacy are plentiful throughout these experts' writings.

105 For an overview of the evidence, see Philip Tetlock (2017), Expert Political Judgment. Princeton University Press.

106 Available at: https://aspe.hhs.gov/sites/default/files/documents/21240d1e084da25b0cdb7348bc53203a/uncertainty-analysis-draft-white-paper.pdf.

appear to lack impartiality and that the experts should also represent a balanced range of opinions, particularly when the stakes are high, as they clearly are in this case.

Making matters worse, the questionnaire primes the experts by telling them their responses will be used to estimate the health impact of a U.S. menthol ban.[107] Such a framing invites the experts to answer in ways that support their favored policy outcomes. Further, the experts are not asked to provide any indication of the uncertainty surrounding their beliefs which makes it largely impossible to gauge the uncertainty of the simulation results.

Again, these simulation studies, even if there were no concern about advocacy, are not scientifically valid. They essentially assume the answer by choosing their starting parameters based on little more than intuition and the hopes of the researchers. When these assumptions are calibrated against real-world estimates, such as my European analyses or even the Canadian literature, it is clear that the simulations make wildly optimistic assumptions which then drive the conclusions. The FDA then relies on this speculation, especially Levy (2021), in its proposal and benefit cost estimates.[108] This is not how scientifically informed policy is formulated.

Further, Liber et al (2022)[109] shows that Levy (who is a coauthor on the Liber paper) and his coauthors make wildly unrealistic assumptions regarding the effects of a menthol ban on smoking. Liber et al (2022) demonstrates that a more plausible, scientifically-based estimate of the net effect of a menthol ban on existing smokers is zero, as menthol smokers substitute to non-menthol cigarettes rather than quit smoking in the face of a menthol ban.

7. CONCLUSION

Using a large longitudinal survey specifically designed to study the effects of the EU menthol ban, I find that there is no evidence that the ban reduced smoking in the EU in general or among previous menthol cigarette smokers specifically. Despite many menthol cigarette smokers claiming they would quit smoking altogether after the EU menthol ban was implemented, EU quit rates among previous menthol cigarette smokers were equaled or exceeded by their menthol-smoking U.S. counterparts.

The FDA claims that its support for a menthol cigarette ban is evidence-based. However, the FDA selectively cites from the literature examining Canada's menthol ban, noting methodologically flawed papers, while essentially ignoring a much more comprehensive and methodologically reliable study of the Canadian experience by Carpenter and Nguyen (2021) which finds that Canada's ban did not reduce smoking.

As discussed above, the other studies relied on by the FDA to support the proposed ban also suffer from numerous methodological problems and limitations. In particular, a number of the studies do not actually assess menthol ban scenarios or impacts on smoking initiation or cessation. Very few of the studies employ an appropriate study design, including the use of any, or a validated, control or comparison group which

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[107] "Instructions for Experts: We intend to model the public health impact of a federal ban on menthol tobacco products in the U.S. The analyses will be conducted using simulation models. We will consider the potential effects of the ban on smoking initiation, cessation, and switching to other tobacco and vaping products, and the consequent impacts on smoking prevalence and deaths attributable to smoking. The questionnaire below will provide some of the needed parameters for our models."

[108] See https://www.fda.gov/media/158012/download

[109] Alex C. Liber, Michal Stoklosa, David T. Levy, Luz Maria Sa´nchez-Romero, Christopher J. Cadham, Michael F. Pesko (2022), "An analysis of cigarette sales during Poland's menthol cigarette sales ban: small effects with large policy implications," European Journal of Public Health, https://doi.org/10.1093/eurpub/ckac063

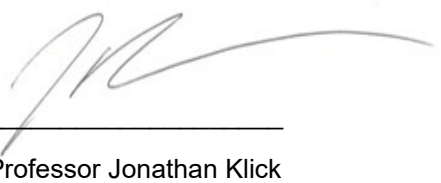
prevents a determination of whether any effects are causal or merely the result of pre-existing trends. Other methodological issues and limitations that prevent the studies from being relied on to support a menthol ban, include the failure to account for other confounding factors that may impact on smoking behaviors, the use of small sample sizes and convenience samples; and reliance on unreliable statements of future intentions and hypothetical choice experiments that do not reflect real world decisions.

The potential for publication bias also undercuts the reliability of the menthol ban literature. Although bias of this sort is ubiquitous in the public health literature,[110] given the politically charged nature of tobacco research and the policy preferences of the public health community, there is a strong presumption that publication bias is particularly acute here, which favors the publication of results supporting the researchers' pre-conceived beliefs. Further concern is generated by the fact that the same authors publish repeatedly in this literature, reinforcing any bias arising from these sources as authors have a tendency to want to support their previous conclusions.[111]

The methodological flaws and limitations of this literature are fundamental and cannot be disregarded. Reliance on multiple flawed studies cannot create a reliable evidence base. The scientifically honest approach to this literature is to infer that there is no sound evidence that a menthol ban will reduce smoking.

The FDA also promotes the modelling studies of the estimated effects of menthol bans as evidence supporting the ban and, in estimating the benefits of the proposed ban, relies exclusively on modelling derived from the opinions of a group of experts that it was involved in selecting and who have publicly stated their policy preferences. Rather than be science based, this amounts essentially to 'rigging the deck'.

A fair reading of the literature combined with my work on the effects of the European menthol ban indicate that a U.S. menthol ban is not appropriate for the protection of public health.



Professor Jonathan Klick
30 June 2022

[110] For a discussion of this concern, see Iain Chalmers (1990), "Underreporting Research Is Scientific Misconduct," *JAMA*, 263: 1405-1408.

[111] For example, Chaiton and colleagues have co-authored 9 out of the 12 Canadian menthol ban studies.

APPENDIX 1: PROFESSOR JONATHAN KLICK CURRICULUM VITAE

JONATHAN KLICK

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EDUCATION

J.D., *George Mason University School of Law*, Arlington Virginia, Awarded May 2003 (*cum laude*)
Robert A. Levy Fellow in Law and Liberty (Tuition Waiver and Stipend); Whitney Writing Prize

Ph.D., Economics, *George Mason University*, Fairfax Virginia, Defended November 2001
Fields: Public Choice, Industrial Organization and Public Policy

M.A., Economics, *University of Maryland at College Park*, Awarded May 1999
Fields: Public Finance, Political Economy of Growth & Income Distribution, Microeconometrics

B.S., Economics, *Villanova University*, Villanova Pennsylvania, Awarded May 1997 (*summa cum laude)*
Villanova University Presidential Scholar and British Marshall Scholarship Finalist (100 nationally)

PROFESSIONAL EXPERIENCE

University of Pennsylvania: Charles A. Heimbold, Jr. Professor of Law (Fall 2021 – Present); Professor of Law (Summer 2008 – Present); Visiting Professor of Law (Fall 2007).

Erasmus University Rotterdam: Erasmus Chair of Empirical Legal Studies (2009 – Present).

Lodestar Law & Economics: Chief Economist (2021 – Present).

Waseda University: Visiting Law Professor (Summer 2016).

Yale Law School: Maurice R. Greenberg Visiting Professor (Fall 2013).

University of Ljubljana Faculty of Economics: Visiting Professor (Summer 2013).

Bar Ilan University Faculty of Law: Visiting Professor (December 2012).

University of Canterbury Department of Economics and Finance: Erskine Visitor (Summer 2010).

Property and Environment Research Center: Julian Simon Fellow (Summer 2009); Lone Wolf Fellow (Summer 2012).

The RAND Corporation, Institute for Civil Justice: Senior Economist (2007 – 2009).

Northwestern University Searle Center: Visiting Scholar (January 2009); Instructor in Judicial Education Program (Spring 2009 – Spring 2010); Senior Economist (Spring 2009 – Spring 2010).

University of Hamburg: Visiting Professor of Law and Economics (Summer 2008, 2010, 2011).

Columbia Law School: Visiting Professor (Spring 2008).

University of Southern California School of Law: Visiting Professor (August/September 2007).

Northwestern University School of Law: Visiting Professor (November 2006).

Florida State University: Visiting Professor (Spring 2022); Assistant Professor of Law (Summer 2004 – Summer 2007); Jeffrey A. Stoops Professor of Law (Summer 2005 – Spring 2008); Associate Professor (August 2007 – Spring 2008); Courtesy Professor of Economics (Summer 2004 – Spring 2008).

TEACHING EXPERIENCE

Antitrust (Penn, Waseda); Corporate Finance (Florida State, Columbia); Corporations/Business Associations (Penn, Florida State, Waseda); Econometrics (Canterbury – Graduate Level); Econometrics (George Mason – Undergraduate Level); Empirical Law and Economics (Penn; Florida State, Erasmus, Hamburg, Bar Ilan, Goethe-Universität Frankfurt, Max Planck Research School, Ljubljana, Study Center Gerzensee, Lucerne Graduate Academy); Evidence Based Crime Prevention (Penn Criminology Department); Expert Evidence (Penn); Law and Economics (Penn, Florida State, Villanova University); Law and Economics of the Firm (Penn – JD/MBA); Micro/Macro (Prince George's County Community College, University of Maryland, George Mason); Police and Crime Policy Seminar (Florida State); Statistics for Lawyers (Penn, Florida State, Max Planck Institute Hamburg);Torts (Penn, Yale

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- Chinese University of Political Science and Law, 70th Anniversary Conference (June 2022).
- Florida State University College of Law Faculty Workshop (March 2022).
- Law and Economics Center Conference on Woke Capitalism (February 2022).
- Latin American Law and Economics Association Annual Meeting (2021).
- Keynote Address, Polish Association of Law and Economics Annual Meeting (September 2021).
- Penn Law Faculty Workshop (July 2021).
- La Pontificia Universidad Católica del Perú, Law and Economics Lecture (May 2021)
- George Mason Law and Economics Workshop (March 2021).
- Texas A&M Crime Workshop (August 2020).
- Penn Law Faculty Workshop (February 2020).
- Rotterdam Institute of Law and Economics Workshop (January 2020).
- Amsterdam Center for Law and Economics Workshop (January 2020).
- Georgetown Law and Economics Workshop (November 2019).
- George Mason Law and Economics Workshop (November 2019).
- Penn Antitrust Symposium (October 2019).
- FTC Hearing, Roundtable with State Attorneys General (June 2019).
- Instituto Tecnológico Autónomo de México Economics Department Seminar (April 2019).
- Instituto Tecnológico Autónomo de México Law School Seminar (April 2019).
- Rotterdam Institute of Law and Economics Seminar (February 2019).
- Tilburg University Economics Department Seminar (January 2019).
- Columbia University Law and Economics Seminar (October 2018).
- Herbert Smith Freehills Connected and Autonomous Vehicles Conference (April 2018).
- Erasmus University Young Scholars' Conference Keynote Speech (April 2018).
- Vanderbilt University Law School Seminar (March 2018).
- University of North Carolina Law School Seminar (March 2018).
- West Virginia University Economics Seminar (February 2018).
- George Mason Law Review Antitrust Symposium (February 2018).
- Washington & Lee Journal of Civil Rights and Social Justice Symposium (November 2017).
- Penn Program on Regulation, The Distribution of Regulatory Impacts in the US (October 2017).
- Bloomberg Government, Health Disparities in Medicare Bundled Payments (October 2017).
- Penn Law Faculty Workshop (September 2017).
- Conference on Empirical Legal Studies Asia, Advanced Empirical Methods (June 2017).
- Journal of Institutional and Theoretical Economics Conference (June 2017).
- Villanova University Law School Workshop (March 2017).
- Erasmus University Rotterdam, Experiments at the Crossroads of Law and Economics (March 2017).
- George Mason University, Philosophy, Politics, and Economics Workshop (February 2017).
- UCLA, Law and Economics Workshop (February 2017).

- Indiana University, Ostrom Workshop, Symposium on Natural Resource Governance (October 2016).
- University of Missouri School of Law, Paternalism Conference (October 2016).
- Notre Dame University, Law and Economics Workshop (September 2016).
- Waseda University, Symposium on the Determinants of Health and Healthcare Costs (July 2016).
- Hitotsubashi University, Institute of Economic Research (June 2016).
- American Law and Economics Association Annual Meeting (May 2016).
- Erasmus University Rotterdam, European Doctorate in Law and Economics Seminar (March 2016).
- University of Chicago, Law and Economics Workshop (February 2016).
- Hebrew University of Jerusalem, Law and Economics Workshop (January 2016).
- University of Virginia, Law and Economics Workshop (October 2015).
- University of Sassari, Institutions, Individual Behavior, and Economic Outcomes Workshop (June 2015).
- Chinese University of Political Science and Law, University Lecture (May 2015).
- Chinese University of Political Science and Law, Rise of the Regulatory State Conference (May 2015).
- Florida State University, Global Justice Seminar (February 2015).
- University of Texas, Law and Economics Workshop (November 2014).
- University of Bologna, Keynote Address, EDLE Meeting (November 2014).
- Rutgers Camden, Healthcare Entitlements Discussion (November 2014).
- University of Leeds, Keynote Address, Behavioral Approach to Law Conference (June 2014).
- Erasmus Experiments at the Crossroads of Law and Economics Workshop (April 2014).
- Cardozo School of Law, Faculty Workshop (March 2014).
- NYU Colloquium on Market Institutions and Economic Processes (February 2014).
- George Washington University Law School Faculty Workshop (February 2014).
- University of Toronto Law and Economics Workshop (February 2014).
- LEC Workshop for Law Professors on Risk, Injury, Liability, & Insurance (February 2014).
- NYU Law and Economics Workshop (January 2014).
- Yale Faculty Seminar (December 2013).
- American Law and Economics Association Annual Meeting (May 2013).
- Villanova University, Department of Economics (February 2013).
- Hospital of University of Pennsylvania, Radiology Department Seminar (January 2013).
- Law and Economics Center, Law and Economics of Contracts (January 2013).
- Florida State University College of Law Workshop (January 2013).
- Bar-Ilan University Faculty of Law Seminar (December 2012).
- University of Haifa Faculty of Law Seminar (December 2012).
- Conference on Empirical Legal Studies, Stanford University (November 2012).
- University of Texas Law School Law and Economics Seminar (October 2012).
- Max Planck Research School Uncertainty Topics Keynote Speech (October 2012).
- University of Ljubljana Faculty of Economics Seminar (October 2012).
- University of Pennsylvania Law School Faculty Seminar (October 2012).
- Georgetown University Law Center Law and Economics Workshop (September 2012).
- Property and Environment Research Center Conference on Environmental Finance (August 2012).

- Property and Environment Research Center Workshop (July 2012).
- Cornell University, Empirical Health Law Conference (April 2012).
- Brooklyn Law School, Federalist Society Workshop (March 2012).
- Washington University in St. Louis Law School, Federalist Society Workshop (March 2012).
- Penn/NYU Law & Finance Conference (February 2012).
- West Virginia University Economics Seminar, (February 2012).
- Rotterdam Institute of Law and Economics Workshop (December 2011).
- Regulatory Breakdown Conference, Penn Program on Regulation (September 2011).
- Journal of Institutional and Theoretical Economics Conference (June 2011).
- Law and Economics Center, Workshop on Empirical Methods for Law Professors (May 2011).
- Queen's University, Faculty of Law, Law and Economics Workshop (April 2011).
- European Masters in Law and Economics Program, Mid-Year Meeting Keynote Lecture (February 2011).
- AALS, Law and Economics Panel (January 2011).
- Law and Economics Center, American Disease Conference (December 2010).
- University of Arizona/Resources for the Future, Wildfire Symposium (November 2010).
- George Mason University, Levy Workshop (November 2010).
- Erasmus University Rotterdam, European Doctorate in Law and Economics Seminar (October 2010).
- Erasmus University School of Law, Inaugural Empirical Legal Studies Chair Lecture (November 2010).
- University of Amsterdam, Center for the Study of EU Contract Law, Workshop (October 2010).
- University of Otago, Economics Department Seminar (September 2010).
- University of Canterbury, Economics and Finance Department Seminar (September 2010).
- University of Hamburg, Hamburg Lectures on Law and Economics (July 2010).
- Penn Law European Society, Academic Program Lecture (June 2010).
- American Law and Economics Association, Annual Conference (May 2010).
- St. Louis Lawyers Chapter of the Federalist Society, Health Care Reform Lecture (April 2010).
- Temple University Beasley School of Law, Human Behavior Colloquium (April 2010).
- University of Virginia Law School, Olin Conference on Crime (March 2010).
- Erasmus University School of Law, Behavioral Approaches to Contract and Tort Group (January 2010).
- European Doctorate in Law and Economics Program, Erasmus University Rotterdam (January 2010).
- University of Illinois Corporate Colloquium (November 2009).
- New York Law School Federalist Society, Health Care Lecture (October 2009).
- Fordham University Federalist Society, Health Care Reform Debate (October 2009).
- University of Pennsylvania, Wharton Research Scholars Seminar (September 2009).
- Property and Environment Research Center (August 2009).
- Harvard Medical School, Race Disparities Panel (April 2009).
- Northwestern University Federalist Society Panel Discussion (November 2009).
- Stanford Law School, Law and Economics Workshop (February 2009).
- University of Virginia School of Law, Law & Economics Workshop (January 2009).

- Southern Economic Association, Annual Meeting (November 2008).
- Northwestern University, Searle Center, Symposium on Civil Liability (October 2008).
- University of Pennsylvania Law School, Faculty Retreat (September 2008).
- Harvard University, Petrie-Flom Center, Our Fragmented Health Care System (June 2008).
- CUNY Graduate Center/NBER, Seminar in Health, Labor, and Demography (May 2008).
- Columbia University, Empirical Methods and the Law Workshop (May 2008).
- The Rand Corporation, Institute for Civil Justice Annual Board Meeting (March 2008).
- George Mason University, Philosophy, Politics, and Economics Workshop (March 2008).
- Columbia University Law School, Faculty Workshop (March 2008).
- Claremont McKenna College/RAND, The Future of Securities Litigation Conference (February 2008).
- University of Michigan Law School, Law and Economics Workshop (February 2008).
- American Economic Association, Annual Meeting (January 2008).
- Harvard Law School, Law and Economics Workshop (November 2007).
- Conference on Empirical Legal Studies (November 2007).
- Emory University School of Law, Faculty Colloquium (November 2007).
- Rice University/University of Houston Economics, Microeconomics Workshop (October 2007).
- University of Pennsylvania Law School, Faculty Workshop (October 2007).
- George Mason University School of Law, Levy Fellows Workshop (October 2007).
- The RAND Corporation, Institute for Civil Justice Workshop (September 2007).
- University of Southern California School of Law, Faculty Workshop (September 2007).
- University of Southern California School of Law, Faculty Workshop (August 2007).
- Yale Law School, Faculty Enrichment Lectures (July 2007).
- Florida State College of Law, Primer on Statistics for Legal Scholars (July 2007).
- Federal Trade Commission, Behavioral Economics and Consumer Policy Workshop (April 2007).
- Yale Law School, Law Economics and Organization Workshop (March 2007).
- Florida State University, Center for Demography and Population Health Workshop (March 2007).
- University of Toronto, Law & Economics Workshop (February 2007).
- Florida State University Department of Economics, Faculty Workshop (March 2007).
- University of Georgia School of Law, Faculty Workshop (February 2007).
- University of Southern California School of Law, Law and Economics Workshop (February 2007).
- Cornell Department of Policy Analysis and Management, Faculty Workshop (November 2006).
- Boston University School of Law, Faculty Workshop (November 2006).
- University of Illinois College of Law, Faculty Workshop (November 2006).
- Northwestern University School of Law, Faculty Workshop (October 2006).
- Conference on Empirical Legal Studies (October 2006).
- American Law and Economics Association, Annual Meeting (May 2006).
- University of Maryland Department of Economics, Labor/Public Workshop (April 2006).
- Columbia University School of Law, Blue Sky Workshop (March 2006).
- American Enterprise Institute, Health Disparities Myth Panel (February 2006).
- William & Mary School of Law, Faculty Workshop (February 2006).
- Georgetown University Law Center, Law and Economics Workshop (February 2006).

- George Mason University School of Law, Levy Workshop (February 2006).
- Northwestern University School of Law, Faculty Workshop (February 2006).
- American Association of Law Schools, Annual Meeting (January 2006).
- International Society for New Institutional Economics, Annual Meeting (September 2005).
- Northwestern University School of Law, Law and Economics Workshop (September 2005).
- University of California Berkeley, Law and Economics Workshop (August 2005).
- Southeastern Association of Law Schools, Annual Meeting (July 2005).
- American Law and Economics Association, Annual Meeting (June 2005).
- West Virginia University Department of Economics, Faculty Workshop (January 2005).
- Southern Economics Association, Annual Meeting (November 2004).
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PROFESSIONAL SERVICE

- Editor, *International Review of Law and Economics* (2012 – Present).
- Dean's Distinguished Fellow, Villanova University Charles Widger School of Law (2017-2020).
- Instructor: Various Law and Economics Center Training Programs (judges, law professors, regulators, etc); Global Antitrust Institute; European Doctorate in Law and Economics; European Masters in Law and Economics.
- External Reviewer for Chair/Tenure/Appointments Candidates: Harvard University Law School; Columbia University Law School; NYU School of Law; Northwestern University School of Law; University of Michigan Law School; Georgetown University Law School; Washington University Law; Cornell Law School; Boston University Law School; Emory University Law; University of Toronto Law School; UC Irvine Law School; Duke University School of Law; George Mason University School of Law; William & Mary Law School; University of Alberta Law School; Mercer University School of Law; Institutum Jurisprudentiae Academia Sinica; Clemson University; Claremont McKenna College; Cornell University; UNC Chapel Hill; West Virginia University; University of Southern California Medical School; University of Southern California School of Pharmacy; University of Wisconsin; ITAM.
- Grant Reviewer: National Science Foundation; Smith Richardson Foundation; Hong Kong Research Grants Council, Israel Science Foundation; French National Research Agency; Research Foundation Flanders; Netherlands Organization for Scientific Research (NWO), Eutopia European University.
- Referee: *Journal of Law & Economics*; *Journal of Legal Studies*; *Journal of Law, Economics, and Organization*; *American Law & Economics Review*; *International Review of Law and Economics*; *Law & Social Inquiry*; *Supreme Court Economic Review*; *Review of Law and Economics*; *Journal of Empirical Legal Studies; Review of Economics and Statistics; American Economic Journal: Applied Economics*, *Journal of Public Economics*; *Review of Industrial Organization; Journal of Health Economics; American Journal of Health Economics; Health Affairs; Journal of Policy Analysis and Management*; *European Journal of Health Economics*; *European Journal of Political Economy; Public Choice*; *Journal of Institutional Economics; Economic Inquiry*; *Southern Economic Journal*; *Health Services Research Journal; Eastern Economic Journal*; *Contemporary Economic Policy*; *Social Science Quarterly*; *Policy Studies*

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C.V. current as of July 1, 2022 (https://www.law.upenn.edu/faculty/jonathan-klick)

APPENDIX 2: EFFECT ON SPECIFIC GROUPS

In this section I report the results of analyses of specific groups of interest, namely, those EU respondents who indicated they were daily smokers at wave 1 of the survey, and those individuals who claimed they plan to quit smoking cigarettes in either wave 1 or wave 2. I also provide results for an alternate definition of menthol smokers. Specifically, in section 4.2 above, I define menthol smokers as those who indicated they smoked menthol cigarettes in either wave 1 or wave 2, but here I provide basic results for those who indicated they smoked menthol cigarettes in wave 1.

1. WAVE 1 DAILY SMOKERS

As indicated above, Chung-Hall, et al (2021)[112] relies on a subgroup analysis of daily smokers to generate a statistically significant effect of Canada's menthol ban on smokers quitting. In light of this, I examine the effect of the EU menthol ban on those respondents who indicated they were daily smokers at wave 1 of the survey. As before, I examine smoking probability, daily smoking probability, and cigarettes smoked per day. For brevity, I only present results using those who responded to all five waves of the survey, though the results are not substantially different if I use the entire sample of all survey respondents who indicated they were a daily smoker at wave 1.

Table A2-1 presents the results of the difference-in-difference model examining smoking status, whether the person is a daily smoker, and reported number of cigarettes smoked per day for this sample of daily smokers. These results indicate that the EU menthol ban was associated with statistically significant increases in the probability a respondent was a smoker as well as the probability he/she was a daily smoker, for those survey respondents who indicated they were a daily smoker at wave 1. There was no statistically significant effect on cigarettes smoked per day.

Table A2-1: Effects of EU Menthol Ban on Respondents Indicating Daily Smoking at Wave 1			
Sample Consists of Individuals Participating in All Survey Waves			
(Standard Errors Clustered at the Individual Level in Parentheses)			
	Prob(Smoker)	Prob(Daily Smoker)	Cigarettes Per Day
Ban Effect	0.0199** (0.0084)	0.0255** (0.0110)	0.0392 (0.2043)
All models include individual and wave fixed effects. **p < 0.05			

As shown in Table A2-2, if I perform this analysis on only those individuals who were daily smokers at wave 1 and who expressed a preference for menthol cigarettes in either wave 1 or wave 2 of the survey, none of the estimated effects are statistically significant.

[112] Janet Chung-Hall, Geoffrey T. Fong, Gang Meng, K Michael Cummings, Andrew Hyland, Richard J. O'Connor, Anne C. K. Quah, Lorraine V. Craig (2021), "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*, doi:10.1136/tobaccocontrol-2020-056259.

Table A2-2: Effects of EU Menthol Ban on Respondents Indicating Daily Smoking at Wave 1			
Menthol Smokers in Waves 1 or 2			
Sample Consists of Individuals Participating in All Survey Waves			
(Standard Errors Clustered at the Individual Level in Parentheses)			
	Prob(Smoker)	Prob(Daily Smoker)	Cigarettes Per Day
Ban Effect	0.0177 (0.0133)	0.0171 (0.0177)	-0.1255 (0.3337)
All models include individual and wave fixed effects.			

Finally, as shown in Table A2-3, the results also indicate that the EU menthol ban had no statistically significant effect if I perform the DDD model on only those individuals indicating they were daily smokers in wave 1.

Table A2-3: Effects of EU Menthol Ban on Respondents Indicating Daily Smoking at Wave 1			
DDD Model			
Sample Consists of Individuals Participating in All Survey Waves			
(Standard Errors Clustered at the Individual Level in Parentheses)			
	Prob(Smoker)	Prob(Daily Smoker)	Cigarettes Per Day
Ban Effect	-0.0043 (0.0172)	-0.0113 (0.0228)	-0.2237 (0.4219)
Individual Fixed Effects	Yes	Yes	Yes
Europe-Specific Wave Fixed Effects	Yes	Yes	Yes
U.S.-Specific Wave Fixed Effects	Yes	Yes	Yes
Menthol-Specific Wave Fixed Effects	Yes	Yes	Yes
Non-Menthol-Specific Wave Fixed Effects	Yes	Yes	Yes

Taken together, the above results indicate that the EU menthol ban had no systematic effect on smoking rates, frequency of smoking, or consumption levels of daily smokers specifically.

2. SMOKERS WHO PLAN TO QUIT

Some advocates claim that a menthol ban will especially help those smokers who want to quit smoking. In the survey, individuals were asked whether they plan to quit smoking. To examine the impact of the EU menthol ban on individuals who planned to quit, I re-run the analysis focusing on those individuals who claimed they plan to quit smoking cigarettes in either wave 1 or wave 2. Again, for brevity, I only present results using those who responded to all five waves of the survey, though the results are not substantially different if I use the entire sample of all survey respondents who indicated they plan to quit smoking cigarettes in either wave 1 or wave 2.

Table A2-4 presents the results of the difference-in-difference model examining smoking status, whether the person is a daily smoker, and reported number of cigarettes smoked per day for this sample of smokers who planned to quit in wave 1 or wave 2 of the survey. These results indicate that the EU menthol ban had no statistically significant effect on the probability of an individual being a smoker, or the number of cigarettes smoked per day, for this group. The menthol ban is associated with an increase in the probability of daily smoking for this group of 7 percentage points, which is statistically significant at the 1 percent type 1 error level.

Table A2-4: Effects of EU Menthol Ban on Respondents Indicating They Plan to Quit in Wave 1 or 2			
Sample Consists of Individuals Participating in All Survey Waves			
(Standard Errors Clustered at the Individual Level in Parentheses)			
	Prob(Smoker)	Prob(Daily Smoker)	Cigarettes Per Day
Ban Effect	0.0212 (0.0143)	0.0702*** (0.0193)	0.3111 (0.2685)
All models include individual and wave fixed effects. ***p < 0.01			

Table A2-5 presents the results of the difference-in-difference model examining smoking status, whether the person is a daily smoker, and reported number of cigarettes smoked per day for those individuals saying they planned to quit in wave 1 or wave 2 who were menthol smokers in either wave 1 or 2. These results indicate that among menthol smokers planning to quit, the menthol ban had no statistically significant effect on the likelihood of an individual being a smoker, a statistically significant increase of 8 percentage points in the likelihood of an individual being a daily smoker, and a statistically significant increase in the number of cigarettes smoked per day.

Table A2-5: Effects of EU Menthol Ban on Menthol Smokers Indicating They Plan to Quit in Wave 1 or 2			
Sample Consists of Individuals Participating in All Survey Waves			
(Standard Errors Clustered at the Individual Level)			
	Prob(Smoker)	Prob(Daily Smoker)	Cigarettes Per Day
Ban Effect	0.0255 (0.0251)	0.0834*** (0.0298)	0.8084** (0.3957)
All models include individual and wave fixed effects. ***p < 0.01 **p < 0.05			

As shown in Table A2-6, the DDD model indicates the effect of the EU menthol ban on individuals saying they plan to quit in wave 1 or wave 2, is not statistically significant with respect to the probability of an individual being a smoker or daily smoker. The cigarettes per day model indicates a statistically significant increase ($p < 0.10$) in the average number of cigarettes smoked per day.

Table A2-6: Effects of EU Menthol Ban on Respondents Indicating They Plan to Quit			
DDD Model			
Sample Consists of Individuals Participating in All Survey Waves			
(Standard Errors Clustered at the Individual Level in Parentheses)			
	Prob(Smoker)	Prob(Daily Smoker)	Cigarettes Per Day
Ban Effect	0.0118 (0.0301)	0.0198 (0.0394)	0.8910* (0.5362)
Individual Fixed Effects	Yes	Yes	Yes
Europe-Specific Wave Fixed Effects	Yes	Yes	Yes
U.S.-Specific Wave Fixed Effects	Yes	Yes	Yes
Menthol-Specific Wave Fixed Effects	Yes	Yes	Yes
Non-Menthol-Specific Wave Fixed Effects	Yes	Yes	Yes
*p < 0.10			

Taken together, there is no evidence of the EU menthol ban leading to any systematic improvements in smoking rates for those smokers indicating that they planned to quit in wave 1 or wave 2. Moreover, there is some evidence of a counterproductive effect with some analyses indicating that the menthol cigarette ban led to statistically significant increases in the rates of daily smoking and cigarettes smoked per day for this group.

3. ALTERNATE MENTHOL SMOKER DEFINITION

In section 4.2 above, when focusing on menthol smokers alone, I defined menthol smokers as those indicating they preferred menthol cigarettes in either wave 1 or wave 2 inclusively. To examine the sensitivity of the estimates to this choice, here I provide results examining just those smokers indicating a preference for menthol cigarettes in wave 1. As indicated above, this definition change does not qualitatively affect the estimates.

Table A2-7: Linear Probability Model (OLS) of Smoking Status		
Menthol Smokers in Wave 1		
(Standard Errors Clustered at the Individual Level in Parentheses)		
	All Data	Respondents Completing 5 Waves
Ban Effect	-0.0113 (0.0103)	0.0045 (0.0144)
All models include individual and wave fixed effects.		

Table A2-8: Linear Probability Model (OLS) of Daily Smoking Status		
Menthol Smokers in Wave 1		
(Standard Errors Clustered at the Individual Level in Parentheses)		
	All Data	Respondents Completing 5 Waves
Ban Effect	0.0635*** (0.0144)	0.0876*** (0.0185)
All models include individual and wave fixed effects. *** p < 0.01		

Table A2-9: OLS Regression of Cigarettes Per Day		
Menthol Smokers in Wave 1		
(Standard Errors Clustered at the Individual Level in Parentheses)		
	All Data	Respondents Completing 5 Waves
Ban Effect	-0.0379 (0.2493)	0.1771 (0.3099)
All models include individual and wave fixed effects.		

APPENDIX 3: IMPACT OF COVID-19

In this section I report the results of analyses where I adjust for the potential effect of COVID-19.

After the COVID-19 pandemic struck between waves 2 and 3 of the survey, respondents were asked whether COVID-19 affected their smoking behavior. More than half of respondents said it did not affect their smoking habits. Less than 0.7 percent said they had quit smoking due to the coronavirus. Some individuals did report a COVID-related change with 28 percent of respondents saying they were smoking more and 14 percent saying they were smoking less. These changes, in principle, will not affect the foregoing analysis if the rates are similar between the treatment (EU) and control (U.S.) group, and for the DDD analyses if the changes are similar between menthol and non-menthol smokers.

1. EFFECT ON DIFFERENCE-IN-DIFFERENCE REGRESSIONS

Although in both the EU countries and the U.S., more individuals said they were smoking more due to COVID-19 than said they were smoking less, the gap is a little larger in the U.S. Specifically, while 35 percent of U.S. smokers said they were smoking more, only 25 percent of EU country smokers indicated the same. In the U.S., 11 percent of smokers said they were smoking less due to COVID-19, while 15 percent of EU country smokers did. Since this implies more COVID-19 period smoking in the U.S., if anything, the results above comparing smokers overall should be biased toward finding a reduction in smoking associated with the EU menthol ban. This suggests that if COVID-19 were not a factor, we would be even less likely to find that the EU menthol ban improved public health outcomes.

Tables A3-1 through A3-3 present the results of the difference-in-difference model examining smoking status, whether the person is a daily smoker, and reported number of cigarettes smoked per day for all respondents, with an adjustment[113] for the potential effect of COVID-19. In each case, the original results were downward biased, indicating that the models that did not adjust for COVID-19 were more likely to find that the EU menthol ban improved public health outcomes. Though not reported here, the results are also substantially the same if all of the other models are re-run with the COVID-19 adjustment.

Table A3-1: Linear Probability Model (OLS) of Smoking Status
All Wave 1 Smokers
Adjusting for COVID-19 Effects
(Standard Errors Clustered at the Individual Level in Parentheses)

	All Data	Respondents Completing 5 Waves
Ban Effect	0.0029 (0.0061)	0.0161* (0.0084)
COVID-19	0.0158*** (0.0028)	0.0168*** (0.0035)

All models include individual and wave fixed effects.
***p < 0.01
*p < 0.10

Table A3-2: Linear Probability Model (OLS) of Daily Smoking Status
All Wave 1 Smokers

[113] The adjustment involved including a variable in the regression that took the value of 1 if the individual said COVID-19 led him/her to smoke more, 0 if the individual said COVID-19 had no effect, and -1 if the individual said COVID-19 led him/her to smoke less. Similar results are achieved if two separate variables (one for whether the person claimed COVID-19 led him/her to smoke more and a separate one for whether the person claimed COVID-19 led him/her to smoke less).

Adjusting for COVID-19 Effects		
(Standard Errors Clustered at the Individual Level in Parentheses)		
	All Data	Respondents Completing 5 Waves
Ban Effect	0.0595*** (0.0090)	0.0731*** (0.0118)
COVID-19	0.0736*** (0.0059)	0.0774*** (0.0069)
All models include individual and wave fixed effects.		
***p < 0.01		

Table A3-3: OLS Regression of Cigarettes Per Day		
All Wave 1 Smokers		
Adjusting for COVID-19 Effects		
(Standard Errors Clustered at the Individual Level in Parentheses)		
	All Data	Respondents Completing 5 Waves
Ban Effect	0.1548 (0.1497)	0.3584* (0.1880)
COVID-19	1.8066*** (0.0835)	1.8967*** (0.0955)
All models include individual and wave fixed effects. ***p < 0.01 *p < 0.10		

2. EFFECT OF COVID-19 IN DDD REGRESSION

I include the COVID-19 adjustment used above in the DDD regression presented in Table A3-4 for smoking status. The inclusion of the COVID-19 variable does not alter the estimated menthol ban effect much at all, but the COVID-19 variable itself is positively related to smoking probability and is statistically significant.

Table A3-4: Linear Probability Model (OLS) of Smoking Status		
Triple Differences Model: Menthol vs Non-Menthol		
Adjusting for COVID-19 Effects		
(Standard Errors Clustered at the Individual Level in Parentheses)		
	All Data	Respondents Completing 5 Waves
Ban Interacted with Menthol Status	-0.0138 (0.0125)	-0.0072 (0.0172)
COVID-19	0.0155*** (0.0028)	0.0165*** (0.0034)
Individual Fixed Effects	Yes	Yes
Europe-Specific Wave Fixed Effects	Yes	Yes
U.S.-Specific Wave Fixed Effects	Yes	Yes
Menthol-Specific Wave Fixed Effects	Yes	Yes
Non-Menthol-Specific Wave Fixed Effects	Yes	Yes
***p < 0.01		

Table A3-5 provides the results for the probability that an individual is a daily smoker. Again, the COVID-19 adjustment generates a positive coefficient that is statistically significant, but the effect of the ban on

daily smoking probability remains positive and statistically significant, suggesting that the results presented in the body of this report were not driven by any COVID-19 related effect.

Table A3-5: Linear Probability Model (OLS) of Daily Smoking Status		
Triple Differences Model: Menthol vs Non-Menthol		
Adjusting for COVID-19 Effects		
(Standard Errors Clustered at the Individual Level in Parentheses)		
	All Data	Respondents Completing 5 Waves
Ban Interacted with Menthol Status	0.0352* (0.0183)	0.0491** (0.0240)
COVID-19	0.0738*** (0.0059)	0.0776*** (0.0069)
Individual Fixed Effects	Yes	Yes
Europe-Specific Wave Fixed Effects	Yes	Yes
U.S.-Specific Wave Fixed Effects	Yes	Yes
Menthol-Specific Wave Fixed Effects	Yes	Yes
Non-Menthol-Specific Wave Fixed Effects	Yes	Yes
***p < 0.01 **p < 0.05 *p < 0.10		

Table A3-6 provides the results for number of cigarettes smoked per day. The cigarettes per day results do not change either, remaining positive and statistically indistinguishable from zero. The COVID-19 effect, however, is statistically significant and raises cigarettes per day substantially.

Table A3-6: OLS Regression of Cigarettes Per Day		
Triple Differences Model: Menthol vs Non-Menthol		
Adjusting for COVID-19 Effects		
(Standard Errors Clustered at the Individual Level in Parentheses)		
	All Data	Respondents Completing 5 Waves
Ban Interacted with Menthol Status	0.2201 (0.3020)	0.1982 (0.3811)
COVID-19	1.8078*** (0.0838)	1.8971*** (0.0959)
Individual Fixed Effects	Yes	Yes
Europe-Specific Wave Fixed Effects	Yes	Yes
U.S.-Specific Wave Fixed Effects	Yes	Yes
Menthol-Specific Wave Fixed Effects	Yes	Yes
Non-Menthol-Specific Wave Fixed Effects	Yes	Yes
***p < 0.01		

Collectively, these results illustrate that any COVID-19 confound should have made it more likely to find that the EU menthol ban improved public health outcomes. Thus, there is no evidence that COVID-19 somehow obscured improvements generated by the EU menthol ban. There were no such improvements.

APPENDIX 4: RE-WEIGHTING SAMPLE

As indicated in the description of the survey, menthol smokers were over-sampled. Also, the distribution of the sample by country does not exactly match the sizes of the relative smoking populations. To ensure that these sampling issues do not drive the results presented here, I created sample weights that ensure that the analysis sample properly matches the sizes of the menthol and non-menthol populations in each country. Specifically, based on measures of the smoking populations[114] and the menthol shares in each country,[115] a representative sample would include 0.17 percent Finnish menthol smokers, 1.16 percent Finnish non-menthol smokers, 2.64 percent Polish menthol smokers, 10.55 percent Polish non-menthol smokers, 0.13 percent Swedish menthol smokers, 1.52 percent Swedish non-menthol smokers, 1.25 percent U.K. menthol smokers, 14.41 UK non-menthol smokers, 24.54 percent U.S. menthol smokers, and 43.63 percent U.S. non-menthol smokers. I created the weights using the iterative proportional fitting algorithm known as "raking" using the ipfweight command in Stata.[116]

For brevity, I only provide the results using respondents who completed all five survey waves (though the results do not change substantially if I examine all respondents). I present the same regressions as above, adding in the weights described above.

Table A4-1: Effects of EU Menthol Ban			
Sample Consists of Individuals Participating in All Survey Waves			
Reweighted to Match Relative Populations			
(Standard Errors Clustered at the Individual Level in Parentheses)			
	Prob(Smoker)	Prob(Daily Smoker)	Cigarettes Per Day
Ban Effect	0.0220** (0.0086)	0.0624*** (0.0135)	0.1549 (0.2162)
All models include individual and wave fixed effects. ***p < 0.01 **p < 0.05			

As shown in Table A4-1, the re-weighted estimates do not differ substantially from those presented above. The same is true if I focus only on those respondents expressing a preference for menthol cigarettes in waves 1 or 2, as shown in Table A4-2 below.

[114] Using the most recent numbers from this dataset http://ghdx.healthdata.org/sites/default/files/record-attached-files/IHME_GBD_2019_SMOKING_TOB_1990_2019_NUM_SMOKERS.zip.

[115] See https://www.smokefreeworld.org/eu-menthol-cigarette-ban-survey/.

[116] As discussed in the documentation for this command (found at https://www.researchgate.net/publication/254395132_IPFWEIGHT_Stata_module_to_create_adjustment_weights_for_surveys), "ipfweight performs a stepwise adjustment (known as iterative proportional fitting or raking) of survey sampling weights to achieve known population margins. The iterative process is repeated until the difference between the sample margins and the known population margins is smaller than a specified tolerance value or the specified maximum number of iterations is obtained. Additionally, thresholds for maximum and minimum weighting factors can be specified as well as a simple replacement of missing values."

Table A4-2: Effects of EU Menthol Ban – Menthol Smokers Only			
Sample Consists of Individuals Participating in All Survey Waves			
Reweighted to Match Relative Populations			
(Standard Errors Clustered at the Individual Level in Parentheses)			
	Prob(Smoker)	Prob(Daily Smoker)	Cigarettes Per Day
Ban Effect	0.0226* (0.0136)	0.1202*** (0.0252)	0.3285 (0.3232)
All models include individual and wave fixed effects. ***p < 0.01 *p < 0.10			

Table A4-3 presents the re-weighted DDD models.

Table A4-3: Effects of EU Menthol Ban			
DDD Model			
Sample Consists of Individuals Participating in All Survey Waves			
Reweighted to Match Relative Populations			
(Standard Errors Clustered at the Individual Level in Parentheses)			
	Prob(Smoker)	Prob(Daily Smoker)	Cigarettes Per Day
Ban Effect	0.0027 (0.0173)	0.0729** (0.0303)	0.2608 (0.4252)
Individual Fixed Effects	Yes	Yes	Yes
Europe-Specific Wave Fixed Effects	Yes	Yes	Yes
U.S.-Specific Wave Fixed Effects	Yes	Yes	Yes
Menthol-Specific Wave Fixed Effects	Yes	Yes	Yes
Non-Menthol-Specific Wave Fixed Effects	Yes	Yes	Yes
**p < 0.05			

Likewise, the DDD models are not substantially affected by the re-weighting. These results suggest that the analysis presented above is not being affected in any important way by the sampling choices.

APPENDIX 5: POTENTIAL ATTRITION CONCERNS

Although all surveys experience attrition,[117] it is a concern for two possible reasons. First, fewer observations translate into less statistical power. Second, if attrition is non-random, sample selection issues can affect the resulting estimates.

As regards the first issue, to ensure that the statistical significance (or lack thereof) of my results is not driven by the reduced sample size, I focused on maintaining a sample size that would have resulted had every respondent completed all five waves. To do this, focusing on the four categories EU Menthol, EU Non-Menthol, U.S. Menthol, and U.S. Non-Menthol, I determined what fraction of the original respondents in each of these categories remained through all five waves. I essentially duplicated the observations from the individuals who completed all five waves proportionately such that the final sample size approximates the sample that would have existed had all of the original respondents completed all five waves. I present these re-weighted full sample regressions in Tables A5-1 through A5-3 below.

Table A5-1: Effects of EU Menthol Ban			
Sample Consists of Individuals Participating in All Survey Waves			
Reweighted to Match Original Sample Proportions and Full Sample Size			
(Standard Errors Clustered at the Individual Level in Parentheses)			
	Prob(Smoker)	Prob(Daily Smoker)	Cigarettes Per Day
Ban Effect	0.0136*** (0.0036)	0.0672*** (0.0052)	0.01341 (0.0815)
All models include individual and wave fixed effects. ***p < 0.01			

Table A5-2: Effects of EU Menthol Ban – Menthol Smokers Only			
Sample Consists of Individuals Participating in All Survey Waves			
Reweighted to Match Original Sample Proportions and Full Sample Size			
(Standard Errors Clustered at the Individual Level in Parentheses)			
	Prob(Smoker)	Prob(Daily Smoker)	Cigarettes Per Day
Ban Effect	0.0083 (0.0056)	0.0939*** (0.0076)	0.2168* (0.1161)
All models include individual and wave fixed effects. ***p < 0.01 *p < 0.10			

[117] For example, Michael Chaiton, Robert Schwartz, Joanna E. Cohen, Eric Soule, and Thomas Eissenberg (2018), "Association of Ontario's Ban on Menthol Cigarettes With Smoking Behavior 1 Month After Implementation," JAMA Internal Medicine, 178(5): 710-711 experienced an attrition rate greater than 35 percent from original contact to follow-up, which was a mere 2 months later.

Table A5-3: Effects of EU Menthol Ban			
DDD Model			
Sample Consists of Individuals Participating in All Survey Waves			
Reweighted to Match Original Sample Proportions and Full Sample Size			
(Standard Errors Clustered at the Individual Level in Parentheses)			
	Prob(Smoker)	Prob(Daily Smoker)	Cigarettes Per Day
Ban Effect	-0.0071 (0.0073)	0.0498*** (0.0106)	0.2021 (0.1640)
Individual Fixed Effects	Yes	Yes	Yes
Europe-Specific Wave Fixed Effects	Yes	Yes	Yes
U.S.-Specific Wave Fixed Effects	Yes	Yes	Yes
Menthol-Specific Wave Fixed Effects	Yes	Yes	Yes
Non-Menthol-Specific Wave Fixed Effects	Yes	Yes	Yes
***p < 0.01			

In no instance does the re-weighting substantively change the estimates. This suggests that an attrition-driven lack of statistical power is not driving my conclusions.

The second concern about attrition leading to sample selection issues is harder to assess. By definition, one does not know if those remaining in the sample have similar smoking outcomes to those dropping out of the sample. One check of whether this attrition bias is present in my analyses is to examine whether individuals likely to smoke more who are in the treatment group are more likely to remain in the sample for all of the waves. To examine this, I constructed an indicator variable taking the value of 1 if an individual participates in all five waves and 0 otherwise. I then create an interaction variable of indicators of heavy smoking (daily smoker) in wave 1 with whether the individual is a menthol smoker in wave 1 and whether the individual is European. I regress the indicator variable for completing all five waves on the daily menthol European indicator and all of the lower-level interactions (Daily interacted with Menthol, Daily interacted with European, Menthol interacted with European) and the individual indicators themselves (Daily, Menthol, European). If heavier smokers in the treatment group are more likely to remain in the sample, it could lead to a bias against finding that the menthol bans were effective, whereas if such smokers are less likely to remain in the sample, the bias might go in the other direction.

Table A5-4 shows that the daily menthol Europe interaction has a negative relationship with whether the individual completes all five waves, but the effect is not statistically significant. This provides evidence that differential attrition is not driving my conclusion that the EU menthol ban has not been effective since heavier EU menthol smokers were not more likely to stay in the sample than heavy EU non-menthol smokers or heavy U.S. smokers.

Table A5-4: Linear Probability (OLS) Model of Likelihood Wave 1 Respondent Participates in All Waves (Robust Standard Errors in Parentheses)	
Daily Smoker*Menthol*Europe	-0.0281 (0.0359)
Daily Smoker*Menthol	0.0066 (0.0275)
Daily Smoker*Europe	0.0271 (0.0275)
Menthol*Europe	0.0154 (0.0311)
Daily Smoker	0.0478** (0.0229)
Menthol	-0.0441* (0.0255)
Europe	0.1115*** (0.0246)
***p < 0.01 **p < 0.05 *p < 0.10	

APPENDIX 6: COUNTRY-SPECIFIC ANALYSES

The foregoing analyses largely compares the average change in smoking outcomes in Europe with the average change in smoking outcomes in the U.S. when the European menthol ban goes into effect. In this section, I present the basic models from above focusing on the comparison of each European country individually with the U.S. portion of the sample.

Table A6-1: Linear Probability Model (OLS) – Smoking and Daily Smoking
Finland and U.S.
(Standard Errors Clustered at the Individual Level in Parentheses)

	All Data		Respondents Completing 5 Waves	
	Smoking	Daily	Smoking	Daily
Ban Effect	-0.0044 (0.0095)	0.0417*** (0.0128)	0.0058 (0.0120)	0.0463*** (0.0156)

All models include individual and wave fixed effects.
***p < 0.01

Table A6-2: Linear Probability Model (OLS) – Smoking and Daily Smoking
Poland and U.S.
(Standard Errors Clustered at the Individual Level in Parentheses)

	All Data		Respondents Completing 5 Waves	
	Smoking	Daily	Smoking	Daily
Ban Effect	0.0144** (0.0072)	0.0679*** (0.0120)	0.0294*** (0.0094)	0.0853*** (0.0147)

All models include individual and wave fixed effects.
***p < 0.01
**p < 0.05

Table A6-3: Linear Probability Model (OLS) – Smoking and Daily Smoking
Sweden and U.S.
(Standard Errors Clustered at the Individual Level in Parentheses)

	All Data		Respondents Completing 5 Waves	
	Smoking	Daily	Smoking	Daily
Ban Effect	-0.0123 (0.0117)	0.0420** (0.0180)	0.0071 (0.0133)	0.0632*** (0.0222)

All models include individual and wave fixed effects.
***p < 0.01
**p < 0.05

Table A6-4: Linear Probability Model (OLS) – Smoking and Daily Smoking
U.K. and U.S.
(Standard Errors Clustered at the Individual Level in Parentheses)

	All Data		Respondents Completing 5 Waves	
	Smoking	Daily	Smoking	Daily
Ban Effect	-0.0035 (0.0080)	0.0391*** (0.0116)	0.0070 (0.0104)	0.0543*** (0.0150)

All models include individual and wave fixed effects.
***p < 0.01

As the tables show, the general conclusions hold in these country-specific comparisons. Specifically, there is no systematic effect of the European menthol ban on the probability of smoking, and there is a statistically

significant increase in the probability of being a daily smoker when the European menthol ban goes into effect. The one major exception is the Poland comparison in which there is a statistically significant increase in the probability of being a smoker and the probability of being a daily smoker when the European menthol ban is enacted. This is perhaps especially informative in terms of projecting the effects of a U.S. menthol ban given that Poland is the market that comes closest to the U.S. in terms of the prevalence of smoking menthol cigarettes. The time series correlation between the U.S. and Poland is also quite high in terms of both cigarette consumption and smoking prevalence.

APPENDIX 7: SURVEY QUESTIONS

SMOKERS STUDY TRACKER WAVE 1

❑ **qcountry**

//hidden

❍ UK
❍ US
❍ Poland
❍ Finland
❍ Sweden

❑ **wave**

//hidden

❍ wave 1

❑ **i177**

Thank you for agreeing to take part in this 5-minute survey.

The sponsor of the survey, Vision One is a member of the Market Research Society (MRS) and all our research is conducted in accordance with the Market Research Society's Code of Conduct.
Survey responses are collected for research purposes only - you will not be contacted for sales or marketing purposes as a result of taking part in this research. All information collected is kept confidential unless explicit consent is provided to share your information. Where anonymity is guaranteed, survey data is amalgamated for analysis and reporting so no one can be personally identified.
Please begin by answering the following questions.

❑ **Q1**

ASK ALL

What is your age?

Select ONE option only.

❍ Under 18 years old [**Close**]
❍ 18-20 years old
❍ 21-29 years old
❍ 30-39 years old
❍ 40-49 years old
❍ 50-59 years old
❍ Over 60 years old

❑ **Q2**

ASK ALL

Have you smoked more than 100 cigarettes in your lifetime?

Select ONE option only.

❍ Yes
❍ No [**Close**]

❑ **Q3**

ASK ALL

Currently, how often do you smoke cigarettes?

Select ONE option only

❍ Everyday
❍ Occasionally (less than everyday)
❍ Not at all [**Close**]

❑ **Q4**

ASK ALL

What type of cigarettes do you usually prefer to smoke? Are they ...

Select ONE option only

❍ Menthol
❍ Non-Menthol

❑ **Q5**

ASK ALL

This is an important behavioural study we are undertaking over the next two years. After this survey we will contact you in December 2019 and then every 6 months until June 2021. Including this questionnaire, that will be a total of 5 times.

In return for your commitment, from the next survey (in December 2019), you will earn enhanced incremental incentives every time you participate. The final incentive will be a minimum of (40£/40€/200zł/400kr/$50) and the chance to enter a prize draw.

If you miss a survey then you will be removed from the study.

Are you happy to continue with this survey and be part of this very important behavioural study?

Select ONE option only

❍ Yes
❍ No [**Close**]

❑ **Q6**

ASK EVERYDAY SMOKERS

Thank you for agreeing to be part of this study.

On average how many cigarettes do you smoke per day? Enter a numerical whole number below.

Enter number _____

❑ **Q7**

ASK OCCASIONAL SMOKERS

Thank you for agreeing to be part of this study.
On the days that you smoke, about how many cigarettes do you smoke per day? Enter a numerical whole number below

Enter number _____

❑ **Q8**

ASK MENTHOL SMOKERS

Thinking about the menthol cigarettes you usually smoke, does the cigarette have a capsule in the filter that you crush to release the menthol flavour?

Select ONE option only

❍ Yes
❍ No

❑ **Q9**

ASK ALL

What is the name of the brand of cigarette that you usually smoke? Please write in the name of ONE brand only below?

Type in brand name

❑ **Q10A**

ASK ALL

In addition to your usual brand, are there any other brands that you regularly smoke?

Select ONE option only

❍ Yes
❍ No

❑ **Q10B**

ASK IF SELECTED YES FOR Q10A

Please use the space below to list the other brands of cigarettes you usually smoke?

Please only list one brand per line. You do not need to complete all the lines. If you smoke more than 5 other brands then please only list the 5 main brands you usually smoke.

_____
_____
_____
_____
_____

❑ **Q11**

ASK ALL

Are you thinking about quitting smoking cigarettes?

Select ONE option only

❍ Yes
❍ No
❍ Don't know/Not sure

❑ **Q12**

ASK IF SELECTED YES FOR Q11

How soon are you likely to quit smoking? Would you say...

Select ONE option only

❍ Within the next 30 days
❍ Within the next 6 months
❍ Within a year
❍ Longer than a year
❍ Don't know/Not sure

❑ **Q13A**

ASK ONLY FOR UK, SWEDEN, POLAND, FINLAND

ASK MENTHOL SMOKERS

Are you aware that menthol cigarettes will be banned for sale in ^f('qcountry')^ from May 2020?

Select ONE option only

❍ Yes
❍ No

❑ **Q13B**

ASK ONLY FOR UK, SWEDEN, POLAND, FINLAND

ASK MENTHOL SMOKERS

When menthol cigarettes are no longer available for sale here, what will you do?

Select ONE option only

❍ Switch to non-menthol cigarettes
❍ Switch to oral tobacco
❍ Find a way to add menthol flavour to cigarettes on your own
❍ Switch to an e-cigarette
❍ Quit smoking
❍ Other/something else
❍ Don't know/Not sure

❑ **Q14**

ASK ALL

And finally, some questions about you for classification.
Please indicate your gender.

Select ONE option only

❍ Male
❍ Female
❍ Other
❍ Prefer not to answer

❑ **Q15**

ASK ALL

What is your current marital status?

Select ONE option only

❍ Married
❍ Separated
❍ Divorced
❍ Widowed
❍ Never married
❍ Prefer not to answer

❑ **Q16**

ASK ALL

What is the highest qualification you have achieved?

Select ONE option only

❍ Less than a high school/upper secondary school qualification
❍ High school/upper secondary school qualification
❍ Trade/Technical/vocational training
❍ Bachelor's degree
❍ Master's degree
❍ Doctorate degree
❍ Prefer not to answer

❑ **Q17**

ASK UK, SWEDEN, POLAND, FINLAND

What is your ethnic background?

Select ONE option only

- ❍ White
- ❍ Asian
- ❍ Black, African, Caribbean
- ❍ Mixed White and Asian
- ❍ Mixed White and Black Caribbean or Black African
- ❍ Other mixed or multiple ethnic groups
- ❍ Other ethnicity
- ❍ Not sure
- ❍ Prefer not to answer

❑ **Q18**

ASK US ONLY

What is your ethnic background?

Select ONE option only

- ❍ White
- ❍ Hispanic or Latino
- ❍ Native American, American Indian or Alaskan Native
- ❍ Native Hawaiian or other Pacific Islander
- ❍ Asian
- ❍ Black, African, Caribbean
- ❍ Mixed White and Asian
- ❍ Mixed White and Black Caribbean or Black African
- ❍ Other mixed or multiple ethnic groups
- ❍ Other ethnicity
- ❍ Not sure
- ❍ Prefer not to answer

❑ **Q19**

ASK ALL

What is your current working status? Are you ...

Select ONE option only

- ❍ Working full-time (35+ hours a week)
- ❍ Working part-time (less than 35 hours a week)
- ❍ Unemployed, looking for work
- ❍ Not working, not looking for work/unable to work
- ❍ Student and working
- ❍ Student, not working
- ❍ Retired
- ❍ Other
- ❍ Prefer not to answer

❑ **Q20A**

ASK UK ONLY

What is your annual household income, before tax deductions?

Select ONE option only

- ❍ Under £10,000
- ❍ £10,000 - £19,999
- ❍ £20,000 - £29,999
- ❍ £30,000 - £39,999
- ❍ £40,000 - £49,999
- ❍ £50,000 - £74,999
- ❍ £75,000 - £99,999
- ❍ £100,000+
- ❍ Don't know/Prefer not to answer

❑ **Q21A**

ASK UK ONLY

In which region do you live?

Please click on the map below. *drawTheMap({ qid: "^CurrentForm()^", })*

- ❍ North East England
- ❍ North West England
- ❍ Yorkshire and the Humber
- ❍ East Midlands
- ❍ West Midlands
- ❍ East of England
- ❍ Greater London (Greater London & Central London)
- ❍ South East England
- ❍ South West England
- ❍ Wales
- ❍ Scotland
- ❍ Northern Ireland

❑ **Q20B**

ASK SWEDEN ONLY

What is your annual household income, before tax deductions?

Select ONE option only

- ❍ Under kr100,000
- ❍ kr100,000 – kr249,999
- ❍ kr250,000 – kr359,999
- ❍ kr360,000 – kr479,999
- ❍ kr480,000 – kr599,999
- ❍ Kr600,000 – kr899,999
- ❍ Kr900,000 – kr1,199,999
- ❍ kr1,200,000+
- ❍ Don't know/Prefer not to answer

❑

❑ **Q21B**

ASK SWEDEN ONLY

In which region do you live?

Please click on the map below. drawTheMap({ qid: "^CurrentForm()^", })

❍ East Sweden
❍ North Sweden
❍ South Sweden

❑ **Q20C**

ASK POLAND ONLY

What is your annual household income, before tax deductions?

Select ONE option only

❍ Under zł50,000
❍ zł50,000 – zł94,999
❍ zł95,000 – zł144,999
❍ zł145,000 – zł189,999
❍ zł190,000 – zł249,999
❍ zł250,000 – zł359,999
❍ zł360,000 – zł479,999
❍ zł480,000+
❍ Don't know/Prefer not to answer

❑ **Q21C**

ASK POLAND ONLY

In which region do you live?

Please click on the map below. drawTheMap({ qid: "^CurrentForm()^", })

❍ Central Region
❍ South Region
❍ East Region
❍ Northwest Region
❍ Southwest Region
❍ North Region

❑ **Q20D**

ASK FINLAND ONLY

What is your annual household income, before tax deductions?

Select ONE option only

❍ Under €10,000
❍ €10,000 - €19,999
❍ €20,000 - €29,999
❍ €30,000 - €39,999
❍ €40,000 - €49,999
❍ €50,000 - €74,999
❍ €75,000 - €99,999
❍ €100,000+
❍ Don't know/Prefer not to answer

❑ **Q21D**

ASK FINLAND ONLY

In which region do you live?

Please click on the map below. *drawTheMap({ qid: "^CurrentForm()^", })*

❍ Southern Finland / Etelä-Suomen lääni
❍ Southwestern/Western and Inland Finland
❍ Eastern Finland
❍ Northern Finland
❍ Lapland
❍ Åland

❑ **Q20E**

ASK US ONLY

What is your annual household income, before tax deductions?

Select ONE option only

❍ Under $10,000
❍ $10,000 - $19,999
❍ $20,000 - $29,999
❍ $30,000 - $39,999
❍ $40,000 - $49,999
❍ $50,000 - $74,999
❍ $75,000 - $99,999
❍ $100,000+
❍ Don't know/Prefer not to answer

❑ **Q21E**

ASK US ONLY

In which region do you live?

Please click on the map below. *drawTheMap({ qid: "^CurrentForm()^", })*

❍ East
❍ Midwest
❍ South
❍ West

❑ **Thank you**

Thank you for your participation. Please press the "^Request('__fwd')^" button to send your survey.

SMOKERS STUDY TRACKER WAVE 2

qcountry

//hidden

❍ UK
❍ US
❍ Poland
❍ Finland
❍ Sweden

wave

//hidden

❍ wave 2

InfoNote

Hello and welcome back to the Smokers study!

You have completed the first part of this longitudinal study back in Summer 2019 and now it's time for the second part.

Just to remind you – this is a trackable study, running over a period of 2 years. We will contact you every 6 months until June 2021, each time increasing the incentives we are offering. If you complete all 5 studies, you will win a significant incentive!

Thanks for your continuous support of this piece of research!

i177

Thank you for agreeing to take part in this 5-minute survey.

The sponsor of the survey, Vision One is a member of the Market Research Society (MRS) and all our research is conducted in accordance with the Market Research Society's Code of Conduct.
Survey responses are collected for research purposes only - you will not be contacted for sales or marketing purposes as a result of taking part in this research. All information collected is kept confidential unless explicit consent is provided to share your information. Where anonymity is guaranteed, survey data is amalgamated for analysis and reporting so no one can be personally identified.
Please begin by answering the following questions.

Q1

ASK ALL

What is your age?

Select ONE option only.

❍ Under 18 years old [**Close**]
❍ 18-20 years old
❍ 21-29 years old
❍ 30-39 years old
❍ 40-49 years old
❍ 50-59 years old
❍ Over 60 years old

QTOL1

ASK ALL

How often do you do any of the following?

Select ONE option per row.

	Daily	Weekly	Only socially	Never
Smoke cigarettes	❍	❍	❍	❍
Smoke e-cigarettes (vaping)	❍	❍	❍	❍
Smoke cigars	❍	❍	❍	❍
Use smokeless tobacco products (Glo, IQOS)	❍	❍	❍	❍

QNEW2

This is the continuation of an important behavioural study we are undertaking over two years. After this survey we will contact you again in June 2020 and then every 6 months until June 2021. Including this questionnaire, and the prior one you participated in, that will be a total of 5 times.

In return for your commitment, for this and every additional survey in connection with this study, you will earn enhanced incremental incentives every time you participate.

The increments will have been outlined in the covering email.

The final incentive will be a minimum of (40£/40€/200zł/400kr/$40) and the chance to enter a prize draw.
If you miss a survey then you will be removed from the study.

QNEW1

ASK IF SELECTED NEVER FOR ROW 1 (SMOKE CIGARETTES) AT QTOL1

When did you stop smoking cigarettes?

Select ONE option only.

❍ Within the last 4 weeks [GOTO Q14]
❍ 1 to 2 months ago [GOTO Q14]
❍ 3-4 months ago [GOTO Q14]
❍ 5-6 months ago [GOTO Q14]

❍ Never smoked cigarettes [**Close**]

Q2

ASK ALL

Have you smoked more than 100 cigarettes in your lifetime?

Select ONE option only.

❍ Yes
❍ No [**Close**]

Q3

ASK ALL

Currently, how often do you smoke cigarettes?

Select ONE option only

❍ Everyday
❍ Occasionally (less than everyday)

Q4

ASK ALL

What type of cigarettes do you usually prefer to smoke? Are they ...

Select ONE option only

❍ Menthol
❍ Non-Menthol

Q5

[Substituted with QNEW2 above].

Q6

ASK EVERYDAY SMOKERS

On average how many cigarettes do you smoke per day? Enter a numerical whole number below.

Enter number _____

Q7

ASK OCCASIONAL SMOKERS

On the days that you smoke, about how many cigarettes do you smoke per day? Enter a numerical whole number below

Enter number _____

Q8

ASK MENTHOL SMOKERS

Thinking about the menthol cigarettes you usually smoke, does the cigarette have a capsule in the filter that you crush to release the menthol flavour?

Select ONE option only

❍ Yes
❍ No

Q9

ASK ALL

What is the name of the brand of cigarette that you usually smoke? Please write in the name of ONE brand only below?

Type in brand name

Q10A

ASK ALL

In addition to your usual brand, are there any other brands that you regularly smoke?

Select ONE option only

❍ Yes
❍ No

Q10B

ASK IF SELECTED YES FOR Q10A

Please use the space below to list the other brands of cigarettes you usually smoke?

Please only list one brand per line. You do not need to complete all the lines. If you smoke more than 5 other brands then please only list the 5 main brands you usually smoke.

_____
_____
_____
_____
_____

Q11

ASK ALL

Are you thinking about quitting smoking cigarettes?

Select ONE option only

❍ Yes
❍ No
❍ Don't know/Not sure

Q12

ASK IF SELECTED YES FOR Q11

How soon are you likely to quit smoking? Would you say...

Select ONE option only

❍ Within the next 30 days
❍ Within the next 6 months
❍ Within a year
❍ Longer than a year
❍ Don’t know/Not sure

Q13A

ASK ONLY FOR UK, SWEDEN, POLAND, FINLAND

ASK MENTHOL SMOKERS

Are you aware that menthol cigarettes will be banned for sale in ^f('qcountry')^ from May 2020?

Select ONE option only

❍ Yes
❍ No

Q13B

ASK ONLY FOR UK, SWEDEN, POLAND, FINLAND

ASK MENTHOL SMOKERS

When menthol cigarettes are no longer available for sale here, what will you do?

Select ONE option only

❍ Switch to non-menthol cigarettes
❍ Switch to oral tobacco
❍ Find a way to add menthol flavour to cigarettes on your own
❍ Switch to an e-cigarette
❍ Quit smoking
❍ Other/something else
❍ Other/something else
❍ Don’t know/Not sure

Q14

ASK ALL

And finally, some questions about you for classification.
Please indicate your gender.

Select ONE option only

❍ Male

❍ Female
❍ Other
❍ Prefer not to answer

Q15

ASK ALL

What is your current marital status?

Select ONE option only

❍ Married
❍ Separated
❍ Divorced
❍ Widowed
❍ Never married
❍ Prefer not to answer

Q16

ASK ALL

What is the highest qualification you have achieved?

Select ONE option only

❍ Less than a high school/upper secondary school qualification
❍ High school/upper secondary school qualification
❍ Trade/Technical/vocational training
❍ Bachelor's degree
❍ Master's degree
❍ Doctorate degree
❍ Prefer not to answer

Q17

ASK UK, SWEDEN, POLAND, FINLAND

What is your ethnic background?

Select ONE option only

❍ White
❍ Asian
❍ Black, African, Caribbean
❍ Mixed White and Asian
❍ Mixed White and Black Caribbean or Black African
❍ Other mixed or multiple ethnic groups
❍ Other ethnicity
❍ Not sure
❍ Prefer not to answer

Q18

ASK US ONLY

What is your ethnic background?

Select ONE option only

- ❍ White
- ❍ Hispanic or Latino
- ❍ Native American, American Indian or Alaskan Native
- ❍ Native Hawaiian or other Pacific Islander
- ❍ Asian
- ❍ Black, African, Caribbean
- ❍ Mixed White and Asian
- ❍ Mixed White and Black Caribbean or Black African
- ❍ Other mixed or multiple ethnic groups
- ❍ Other ethnicity
- ❍ Not sure
- ❍ Prefer not to answer

Q19

ASK ALL

What is your current working status? Are you ...

Select ONE option only

- ❍ Working full-time (35+ hours a week)
- ❍ Working part-time (less than 35 hours a week)
- ❍ Unemployed, looking for work
- ❍ Not working, not looking for work/unable to work
- ❍ Student and working
- ❍ Student, not working
- ❍ Retired
- ❍ Other
- ❍ Prefer not to answer

Q20A

ASK UK ONLY

What is your annual household income, before tax deductions?

Select ONE option only

- ❍ Under £10,000
- ❍ £10,000 - £19,999
- ❍ £20,000 - £29,999
- ❍ £30,000 - £39,999
- ❍ £40,000 - £49,999
- ❍ £50,000 - £74,999
- ❍ £75,000 - £99,999
- ❍ £100,000+
- ❍ Don’t know/Prefer not to answer

Q21A

ASK UK ONLY

In which region do you live?

Please click on the map below. *drawTheMap({ qid: "^CurrentForm()^", })*

- ❍ North East England
- ❍ North West England
- ❍ Yorkshire and the Humber
- ❍ East Midlands
- ❍ West Midlands
- ❍ East of England
- ❍ Greater London (Greater London & Central London)
- ❍ South East England
- ❍ South West England
- ❍ Wales
- ❍ Scotland
- ❍ Northern Ireland

Q20B

ASK SWEDEN ONLY

What is your annual household income, before tax deductions?

Select ONE option only

- ❍ Under kr100,000
- ❍ kr100,000 – kr249,999
- ❍ kr250,000 – kr359,999
- ❍ kr360,000 – kr479,999
- ❍ kr480,000 – kr599,999
- ❍ Kr600,000 – kr899,999
- ❍ Kr900,000 – kr1,199,999
- ❍ kr1,200,000+
- ❍ Don’t know/Prefer not to answer

Q21B

ASK SWEDEN ONLY

In which region do you live?

Please click on the map below. *drawTheMap({ qid: "^CurrentForm()^", })*

- ❍ East Sweden
- ❍ North Sweden
- ❍ South Sweden

Q20C

ASK POLAND ONLY

What is your annual household income, before tax deductions?

Select ONE option only

- ❍ Under zł50,000
- ❍ zł50,000 – zł94,999
- ❍ zł95,000 – zł144,999
- ❍ zł145,000 – zł189,999
- ❍ zł190,000 – zł249,999

❍ zł250,000 – zł359,999
❍ zł360,000 – zł479,999
❍ zł480,000+
❍ Don’t know/Prefer not to answer

Q21C

ASK POLAND ONLY

In which region do you live?

Please click on the map below. drawTheMap({ qid: "^CurrentForm()^", })

❍ Central Region
❍ South Region
❍ East Region
❍ Northwest Region
❍ Southwest Region
❍ North Region

Q20D

ASK FINLAND ONLY

What is your annual household income, before tax deductions?

Select ONE option only

❍ Under €10,000
❍ €10,000 - €19,999
❍ €20,000 - €29,999
❍ €30,000 - €39,999
❍ €40,000 - €49,999
❍ €50,000 - €74,999
❍ €75,000 - €99,999
❍ €100,000+
❍ Don’t know/Prefer not to answer

Q21D

ASK FINLAND ONLY

In which region do you live?

Please click on the map below. drawTheMap({ qid: "^CurrentForm()^", })

❍ Southern Finland / Etelä-Suomen lääni
❍ Southwestern/Western and Inland Finland
❍ Eastern Finland
❍ Northern Finland
❍ Lapland
❍ Åland

Q20E

ASK US ONLY

What is your annual household income, before tax deductions?

Select ONE option only

- ❍ Under $10,000
- ❍ $10,000 - $19,999
- ❍ $20,000 - $29,999
- ❍ $30,000 - $39,999
- ❍ $40,000 - $49,999
- ❍ $50,000 - $74,999
- ❍ $75,000 - $99,999
- ❍ $100,000+
- ❍ Don’t know/Prefer not to answer

Q21E

ASK US ONLY

In which region do you live?

Please click on the map below. drawTheMap({ qid: "^CurrentForm()^", })

- ❍ East
- ❍ Midwest
- ❍ South
- ❍ West

Thank you

Thank you for your participation. Please press the "^Request('__fwd')^" button to send your survey.

SMOKERS STUDY TRACKER WAVE 3

qcountry

//hidden

❍ UK
❍ US
❍ Poland
❍ Finland
❍ Sweden

wave

//hidden

❍ wave 3

InfoNote

Hello and welcome back to the Smokers study!

You have completed the first part of this longitudinal study back in Summer 2019 and now it's time for the third part.

Just to remind you – this is a trackable study, running over a period of 2 years. We will contact you every 6 months until June 2021, each time increasing the incentives we are offering. If you complete all 5 studies, you will win a significant incentive!

Thanks for your continuous support of this piece of research!

i177

Thank you for agreeing to take part in this 5-minute survey.

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Please begin by answering the following questions.

Q1

ASK ALL

What is your age?

Select ONE option only.

❍ Under 18 years old [**Close**]
❍ 18-20 years old
❍ 21-29 years old
❍ 30-39 years old
❍ 40-49 years old
❍ 50-59 years old
❍ Over 60 years old

QTOL1

ASK ALL

How often do you do any of the following?

Select ONE option per row.

	Daily	Weekly	Only socially	Never
Smoke cigarettes	❍	❍	❍	❍
Smoke e-cigarettes (vaping)	❍	❍	❍	❍
Smoke cigars	❍	❍	❍	❍
Use smokeless tobacco products (Glo, IQOS)	❍	❍	❍	❍

QNEW2

This is the continuation of an important behavioural study we are undertaking over two years. After this survey we will contact you again in December 2020 and then 6 months later in June 2021. Including this questionnaire, and the prior two you participated in, that will be a total of 5 times.

In return for your commitment, for this and every additional survey in connection with this study, you will earn enhanced incremental incentives every time you participate.

If you fill in this survey, you will receive an extra (£15/15€/76zł/178kr/$18) worth of points into your account!

The final incentive will be a minimum of (40£/40€/200zł/400kr/$40) and the chance to enter a prize draw.
If you miss a survey then you will be removed from the study.

QNEW1

ASK IF SELECTED NEVER FOR ROW 1 (SMOKE CIGARETTES) AT QTOL1

When did you stop smoking cigarettes?

Select ONE option only.

❍ Within the last 4 weeks [GOTO Q14]
❍ 1 to 2 months ago [GOTO Q14]
❍ 3-4 months ago [GOTO Q14]

❍ 5-6 months ago [GOTO Q14]
❍ 6-12 months ago [GOTO Q14]
❍ Never smoked cigarettes [**Close**]

Q2

ASK ALL

Have you smoked more than 100 cigarettes in your lifetime?

Select ONE option only.

❍ Yes
❍ No [**Close**]

Q3

ASK ALL

Currently, how often do you smoke cigarettes?

Select ONE option only

❍ Everyday
❍ Occasionally (less than everyday)

Q3B

ASK ALL

How has the coronavirus pandemic affected how often you smoke cigarettes?

Select ONE option only

❍ It has had no effect
❍ I have been smoking more
❍ I have been smoking less
❍ I have quit smoking due to the coronavirus pandemic
❍ I have quit smoking, but it is not related to the coronavirus pandemic

Q4

ASK ALL

What type of cigarettes do you usually prefer to smoke? Are they ...

Select ONE option only

❍ Menthol
❍ Non-Menthol

Q5

[Substituted with QNEW2 above].

Q6

ASK EVERYDAY SMOKERS

On average how many cigarettes do you smoke per day? Enter a numerical whole number below.

Enter number _____

Q7

ASK OCCASIONAL SMOKERS

On the days that you smoke, about how many cigarettes do you smoke per day? Enter a numerical whole number below

Enter number _____

Q8

ASK MENTHOL SMOKERS

Thinking about the menthol cigarettes you usually smoke, does the cigarette have a capsule in the filter that you crush to release the menthol flavour?

Select ONE option only

❍ Yes
❍ No

Q9

ASK ALL

What is the name of the brand of cigarette that you usually smoke? Please write in the name of ONE brand only below?

Type in brand name

Q10A

ASK ALL

In addition to your usual brand, are there any other brands that you regularly smoke?

Select ONE option only

❍ Yes
❍ No

Q10B

ASK IF SELECTED YES FOR Q10A

Please use the space below to list the other brands of cigarettes you usually smoke?

Please only list one brand per line. You do not need to complete all the lines. If you smoke more than 5 other brands then please only list the 5 main brands you usually smoke.

_____
_____
_____
_____
_____

Q11

ASK ALL

Are you thinking about quitting smoking cigarettes?

Select ONE option only

❍ Yes
❍ No
❍ Don't know/Not sure

Q12

ASK IF SELECTED YES FOR Q11

How soon are you likely to quit smoking? Would you say...

Select ONE option only

❍ Within the next 30 days
❍ Within the next 6 months
❍ Within a year
❍ Longer than a year
❍ Don’t know/Not sure

Q13A

ASK ONLY FOR UK, SWEDEN, POLAND, FINLAND

ASK MENTHOL SMOKERS

Are you aware that menthol cigarettes have been banned from sale in ^f('qcountry')^ since May 2020?

Select ONE option only

❍ Yes
❍ No

Q13B

ASK ONLY FOR UK, SWEDEN, POLAND, FINLAND

ASK MENTHOL SMOKERS

As menthol cigarettes are no longer available for sale here, what have you been doing?

Select ONE option only

- ❍ Switched to non-menthol cigarettes
- ❍ Switched to oral tobacco
- ❍ Found a way to add menthol flavour to cigarettes on your own
- ❍ Switched to an e-cigarette
- ❍ Quit smoking
- ❍ I can still purchase menthol cigarettes from stores near me
- ❍ Other/something else
- ❍ Don't know/Not sure

Q14

ASK ALL

And finally, some questions about you for classification.
Please indicate your gender.

Select ONE option only

- ❍ Male
- ❍ Female
- ❍ Other
- ❍ Prefer not to answer

Q15

ASK ALL

What is your current marital status?

Select ONE option only

- ❍ Married
- ❍ Separated
- ❍ Divorced
- ❍ Widowed
- ❍ Never married
- ❍ Prefer not to answer

Q16

ASK ALL

What is the highest qualification you have achieved?

Select ONE option only

- ❍ Less than a high school/upper secondary school qualification
- ❍ High school/upper secondary school qualification
- ❍ Trade/Technical/vocational training
- ❍ Bachelor's degree
- ❍ Master's degree
- ❍ Doctorate degree
- ❍ Prefer not to answer

Q17

ASK UK, SWEDEN, POLAND, FINLAND

What is your ethnic background?

Select ONE option only

- ❍ White
- ❍ Asian
- ❍ Black, African, Caribbean
- ❍ Mixed White and Asian
- ❍ Mixed White and Black Caribbean or Black African
- ❍ Other mixed or multiple ethnic groups
- ❍ Other ethnicity
- ❍ Not sure
- ❍ Prefer not to answer

Q18

ASK US ONLY

What is your ethnic background?

Select ONE option only

- ❍ White
- ❍ Hispanic or Latino
- ❍ Native American, American Indian or Alaskan Native
- ❍ Native Hawaiian or other Pacific Islander
- ❍ Asian
- ❍ Black, African, Caribbean
- ❍ Mixed White and Asian
- ❍ Mixed White and Black Caribbean or Black African
- ❍ Other mixed or multiple ethnic groups
- ❍ Other ethnicity
- ❍ Not sure
- ❍ Prefer not to answer

Q19

ASK ALL

What is your current working status? Are you ...

Select ONE option only

- ❍ Working full-time (35+ hours a week)
- ❍ Working part-time (less than 35 hours a week)
- ❍ Unemployed, looking for work
- ❍ Not working, not looking for work/unable to work
- ❍ Student and working
- ❍ Student, not working
- ❍ Retired
- ❍ Other
- ❍ Prefer not to answer

Q19B

ASK ALL

How has the coronavirus pandemic effected your employment and how you work?

Select ONE option only

❍ No effect, still go to work outside of home
❍ No effect, always worked from home
❍ Changed to home working: previously worked outside of home but now work primarily from home due to coronavirus pandemic
❍ Working reduced hours
❍ Furlough/Stay-at-home not working
❍ Unemployed due to coronavirus pandemic
❍ Changed job due to the coronavirus pandemic
❍ Unemployed before coronavirus pandemic but have since started a new job
❍ Unemployed before coronavirus pandemic and still unemployed
❍ None of the above

Q19C

ASK ALL

How has the coronavirus pandemic effected how much time you spend at home? (If you are now working from home exclude the time you are working, and just consider if in your free time you feel you are spending more, less or about the same time at home as you were before the pandemic)

Select ONE option only

❍ Has had no effect
❍ Spend more time at home but still go out for non-essential activities
❍ Spend more time at home and only go out for essential activities
❍ Spend less time at home

Q20A

ASK UK ONLY

What is your annual household income, before tax deductions?

Select ONE option only

❍ Under £10,000
❍ £10,000 - £19,999
❍ £20,000 - £29,999
❍ £30,000 - £39,999
❍ £40,000 - £49,999
❍ £50,000 - £74,999
❍ £75,000 - £99,999
❍ £100,000+
❍ Don’t know/Prefer not to answer

Q21A

ASK UK ONLY

In which region do you live?

Please click on the map below. *drawTheMap({ qid: "^CurrentForm()^", })*

- ❍ North East England
- ❍ North West England
- ❍ Yorkshire and the Humber
- ❍ East Midlands
- ❍ West Midlands
- ❍ East of England
- ❍ Greater London (Greater London & Central London)
- ❍ South East England
- ❍ South West England
- ❍ Wales
- ❍ Scotland
- ❍ Northern Ireland

Q20B

ASK SWEDEN ONLY

What is your annual household income, before tax deductions?

Select ONE option only

- ❍ Under kr100,000
- ❍ kr100,000 – kr249,999
- ❍ kr250,000 – kr359,999
- ❍ kr360,000 – kr479,999
- ❍ kr480,000 – kr599,999
- ❍ Kr600,000 – kr899,999
- ❍ Kr900,000 – kr1,199,999
- ❍ kr1,200,000+
- ❍ Don't know/Prefer not to answer

Q21B

ASK SWEDEN ONLY

In which region do you live?

Please click on the map below. *drawTheMap({ qid: "^CurrentForm()^", })*

- ❍ East Sweden
- ❍ North Sweden
- ❍ South Sweden

Q20C

ASK POLAND ONLY

What is your annual household income, before tax deductions?

Select ONE option only

- ❍ Under zł50,000
- ❍ zł50,000 – zł94,999
- ❍ zł95,000 – zł144,999
- ❍ zł145,000 – zł189,999
- ❍ zł190,000 – zł249,999

❍ zł250,000 – zł359,999
❍ zł360,000 – zł479,999
❍ zł480,000+
❍ Don’t know/Prefer not to answer

Q21C

ASK POLAND ONLY

In which region do you live?

Please click on the map below. drawTheMap({ qid: "^CurrentForm()^", })

❍ Central Region
❍ South Region
❍ East Region
❍ Northwest Region
❍ Southwest Region
❍ North Region

Q20D

ASK FINLAND ONLY

What is your annual household income, before tax deductions?

Select ONE option only

❍ Under €10,000
❍ €10,000 - €19,999
❍ €20,000 - €29,999
❍ €30,000 - €39,999
❍ €40,000 - €49,999
❍ €50,000 - €74,999
❍ €75,000 - €99,999
❍ €100,000+
❍ Don’t know/Prefer not to answer

Q21D

ASK FINLAND ONLY

In which region do you live?

Please click on the map below. drawTheMap({ qid: "^CurrentForm()^", })

❍ Southern Finland / Etelä-Suomen lääni
❍ Southwestern/Western and Inland Finland
❍ Eastern Finland
❍ Northern Finland
❍ Lapland
❍ Åland

Q20E

ASK US ONLY

What is your annual household income, before tax deductions?

Select ONE option only

- ❍ Under $10,000
- ❍ $10,000 - $19,999
- ❍ $20,000 - $29,999
- ❍ $30,000 - $39,999
- ❍ $40,000 - $49,999
- ❍ $50,000 - $74,999
- ❍ $75,000 - $99,999
- ❍ $100,000+
- ❍ Don’t know/Prefer not to answer

Q21E

ASK US ONLY

In which region do you live?

Please click on the map below. drawTheMap({ qid: "^CurrentForm()^", })

- ❍ East
- ❍ Midwest
- ❍ South
- ❍ West

Thank you

Thank you for your participation. Please press the "^Request('__fwd')^" button to send your survey.

SMOKERS STUDY TRACKER WAVE 4

qcountry

//hidden

❍ UK
❍ US
❍ Poland
❍ Finland
❍ Sweden

wave

//hidden

❍ wave 4

InfoNote

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analysis and reporting so no one can be personally identified.
Please begin by answering the following questions.

Q1

ASK ALL

What is your age?

Select ONE option only.

❍ Under 18 years old [**Close**]
❍ 18-20 years old
❍ 21-29 years old
❍ 30-39 years old
❍ 40-49 years old
❍ 50-59 years old
❍ Over 60 years old

QTOL1

ASK ALL

How often do you do any of the following?

Select ONE option per row.

	Daily	Weekly	Only socially	Never
Smoke cigarettes	❍	❍	❍	❍
Smoke e-cigarettes (vaping)	❍	❍	❍	❍
Smoke cigars	❍	❍	❍	❍
Use smokeless tobacco products (Glo, IQOS)	❍	❍	❍	❍

QNEW2

This is the continuation of an important behavioural study we are undertaking over two years. After this survey we will contact you again for a final time in June 2021. Including this questionnaire, and the previous three you participated in, that will be a total of 5 times.

In return for your commitment, for this and every additional survey in connection with this study, you will earn enhanced incremental incentives every time you participate.
If you fill in this survey, you will receive an extra (£25/28€/125zł/285kr/$33) worth of points into your account!

The final incentive will be a minimum of (£40€/200zł/400kr/$40) and the chance to enter a prize draw.
If you miss a survey then you will be removed from the study.

QNEW1

ASK IF SELECTED NEVER FOR ROW 1 (SMOKE CIGARETTES) AT QTOL1

When did you stop smoking cigarettes?

Select ONE option only.

❍ Within the last 4 weeks [GOTO Q14]

❍ 1 to 2 months ago [GOTO Q14]
❍ 3-4 months ago [GOTO Q14]
❍ 5-6 months ago [GOTO Q14]
❍ 6-12 months ago [GOTO Q14]
❍ 12-18 months ago [GOTO Q14]
❍ Never smoked cigarettes [**Close**]

Q2

ASK ALL

Have you smoked more than 100 cigarettes in your lifetime?

Select ONE option only.

❍ Yes
❍ No [**Close**]

Q3

ASK ALL

Currently, how often do you smoke cigarettes?

Select ONE option only

❍ Everyday
❍ Occasionally (less than everyday)

Q3B

ASK ALL

How has the coronavirus pandemic affected how often you smoke cigarettes?

Select ONE option only

❍ It has had no effect
❍ I have been smoking more
❍ I have been smoking less
❍ I have quit smoking due to the coronavirus pandemic
❍ I have quit smoking, but it is not related to the coronavirus pandemic

Q4

ASK ALL

What type of cigarettes do you usually prefer to smoke? Are they ...

Select ONE option only

❍ Menthol
❍ Non-Menthol

Q5

[Substituted with QNEW2 above].

Q6

ASK EVERYDAY SMOKERS

On average how many cigarettes do you smoke per day? Enter a numerical whole number below.

Enter number _____

Q7

ASK OCCASIONAL SMOKERS

On the days that you smoke, about how many cigarettes do you smoke per day? Enter a numerical whole number below

Enter number _____

Q8

ASK MENTHOL SMOKERS

Thinking about the menthol cigarettes you usually smoke, does the cigarette have a capsule in the filter that you crush to release the menthol flavour?

Select ONE option only

❍ Yes
❍ No

Q9

ASK ALL

What is the name of the brand of cigarette that you usually smoke? Please write in the name of ONE brand only below?

Type in brand name

Q10A

ASK ALL

In addition to your usual brand, are there any other brands that you regularly smoke?

Select ONE option only

❍ Yes
❍ No

Q10B

ASK IF SELECTED YES FOR Q10A

Please use the space below to list the other brands of cigarettes you usually smoke?

Please only list one brand per line. You do not need to complete all the lines. If you smoke more than 5 other brands then please only list the 5 main brands you usually smoke.

_____
_____
_____
_____
_____

Q11

ASK ALL

Are you thinking about quitting smoking cigarettes?

Select ONE option only

❍ Yes
❍ No
❍ Don't know/Not sure

Q12

ASK IF SELECTED YES FOR Q11

How soon are you likely to quit smoking? Would you say...

Select ONE option only

❍ Within the next 30 days
❍ Within the next 6 months
❍ Within a year
❍ Longer than a year
❍ Don’t know/Not sure

Q13A

ASK ONLY FOR UK, SWEDEN, POLAND, FINLAND

ASK MENTHOL SMOKERS

Are you aware that menthol cigarettes have been banned from sale in ^f('qcountry')^ since May 2020?

Select ONE option only

❍ Yes
❍ No

Q13B

ASK ONLY FOR UK, SWEDEN, POLAND, FINLAND

ASK MENTHOL SMOKERS

As menthol cigarettes are no longer available for sale here, what have you been doing?

Select ONE option only

- ❍ Switched to non-menthol cigarettes
- ❍ Switched to oral tobacco
- ❍ Found a way to add menthol flavour to cigarettes on your own
- ❍ Switched to an e-cigarette
- ❍ Quit smoking
- ❍ I can still purchase menthol cigarettes from stores near me
- ❍ Other/something else
- ❍ Don't know/Not sure

Q14

ASK ALL

And finally, some questions about you for classification.
Please indicate your gender.

Select ONE option only

- ❍ Male
- ❍ Female
- ❍ Other
- ❍ Prefer not to answer

Q15

ASK ALL

What is your current marital status?

Select ONE option only

- ❍ Married
- ❍ Separated
- ❍ Divorced
- ❍ Widowed
- ❍ Never married
- ❍ Prefer not to answer

Q16

ASK ALL

What is the highest qualification you have achieved?

Select ONE option only

- ❍ Less than a high school/upper secondary school qualification
- ❍ High school/upper secondary school qualification
- ❍ Trade/Technical/vocational training
- ❍ Bachelor's degree
- ❍ Master's degree
- ❍ Doctorate degree
- ❍ Prefer not to answer

Q17

ASK UK, SWEDEN, POLAND, FINLAND

What is your ethnic background?

Select ONE option only

- ❍ White
- ❍ Asian
- ❍ Black, African, Caribbean
- ❍ Mixed White and Asian
- ❍ Mixed White and Black Caribbean or Black African
- ❍ Other mixed or multiple ethnic groups
- ❍ Other ethnicity
- ❍ Not sure
- ❍ Prefer not to answer

Q18

ASK US ONLY

What is your ethnic background?

Select ONE option only

- ❍ White
- ❍ Hispanic or Latino
- ❍ Native American, American Indian or Alaskan Native
- ❍ Native Hawaiian or other Pacific Islander
- ❍ Asian
- ❍ Black, African, Caribbean
- ❍ Mixed White and Asian
- ❍ Mixed White and Black Caribbean or Black African
- ❍ Other mixed or multiple ethnic groups
- ❍ Other ethnicity
- ❍ Not sure
- ❍ Prefer not to answer

Q19

ASK ALL

What is your current working status? Are you ...

Select ONE option only

- ❍ Working full-time (35+ hours a week)
- ❍ Working part-time (less than 35 hours a week)
- ❍ Unemployed, looking for work
- ❍ Not working, not looking for work/unable to work
- ❍ Student and working
- ❍ Student, not working
- ❍ Retired
- ❍ Other
- ❍ Prefer not to answer

Q19B

ASK ALL

How has the coronavirus pandemic effected your employment and how you work?

Select ONE option only

❍ No effect, still go to work outside of home
❍ No effect, always worked from home
❍ Changed to home working: previously worked outside of home but now work primarily from home due to coronavirus pandemic
❍ Working reduced hours
❍ Furlough/Stay-at-home not working
❍ Unemployed due to coronavirus pandemic
❍ Changed job due to the coronavirus pandemic
❍ Unemployed before coronavirus pandemic but have since started a new job
❍ Unemployed before coronavirus pandemic and still unemployed
❍ None of the above

Q19C

ASK ALL

How has the coronavirus pandemic effected how much time you spend at home? (If you are now working from home exclude the time you are working, and just consider if in your free time you feel you are spending more, less or about the same time at home as you were before the pandemic)

Select ONE option only

❍ Has had no effect
❍ Spend more time at home but still go out for non-essential activities
❍ Spend more time at home and only go out for essential activities
❍ Spend less time at home

Q20A

ASK UK ONLY

What is your annual household income, before tax deductions?

Select ONE option only

❍ Under £10,000
❍ £10,000 - £19,999
❍ £20,000 - £29,999
❍ £30,000 - £39,999
❍ £40,000 - £49,999
❍ £50,000 - £74,999
❍ £75,000 - £99,999
❍ £100,000+
❍ Don’t know/Prefer not to answer

Q21A

ASK UK ONLY

In which region do you live?

Please click on the map below. *drawTheMap({ qid: "^CurrentForm()^", })*

- ❍ North East England
- ❍ North West England
- ❍ Yorkshire and the Humber
- ❍ East Midlands
- ❍ West Midlands
- ❍ East of England
- ❍ Greater London (Greater London & Central London)
- ❍ South East England
- ❍ South West England
- ❍ Wales
- ❍ Scotland
- ❍ Northern Ireland

Q20B

ASK SWEDEN ONLY

What is your annual household income, before tax deductions?

Select ONE option only

- ❍ Under kr100,000
- ❍ kr100,000 – kr249,999
- ❍ kr250,000 – kr359,999
- ❍ kr360,000 – kr479,999
- ❍ kr480,000 – kr599,999
- ❍ Kr600,000 – kr899,999
- ❍ Kr900,000 – kr1,199,999
- ❍ kr1,200,000+
- ❍ Don't know/Prefer not to answer

Q21B

ASK SWEDEN ONLY

In which region do you live?

Please click on the map below. *drawTheMap({ qid: "^CurrentForm()^", })*

- ❍ East Sweden
- ❍ North Sweden
- ❍ South Sweden

Q20C

ASK POLAND ONLY

What is your annual household income, before tax deductions?

Select ONE option only

- ❍ Under zł50,000
- ❍ zł50,000 – zł94,999
- ❍ zł95,000 – zł144,999
- ❍ zł145,000 – zł189,999
- ❍ zł190,000 – zł249,999

❍ zł250,000 – zł359,999
❍ zł360,000 – zł479,999
❍ zł480,000+
❍ Don’t know/Prefer not to answer

Q21C

ASK POLAND ONLY

In which region do you live?

Please click on the map below. drawTheMap({ qid: "^CurrentForm()^", })

❍ Central Region
❍ South Region
❍ East Region
❍ Northwest Region
❍ Southwest Region
❍ North Region

Q20D

ASK FINLAND ONLY

What is your annual household income, before tax deductions?

Select ONE option only

❍ Under €10,000
❍ €10,000 - €19,999
❍ €20,000 - €29,999
❍ €30,000 - €39,999
❍ €40,000 - €49,999
❍ €50,000 - €74,999
❍ €75,000 - €99,999
❍ €100,000+
❍ Don’t know/Prefer not to answer

Q21D

ASK FINLAND ONLY

In which region do you live?

Please click on the map below. drawTheMap({ qid: "^CurrentForm()^", })

❍ Southern Finland / Etelä-Suomen lääni
❍ Southwestern/Western and Inland Finland
❍ Eastern Finland
❍ Northern Finland
❍ Lapland
❍ Åland

Q20E

ASK US ONLY

What is your annual household income, before tax deductions?

Select ONE option only

- ❍ Under $10,000
- ❍ $10,000 - $19,999
- ❍ $20,000 - $29,999
- ❍ $30,000 - $39,999
- ❍ $40,000 - $49,999
- ❍ $50,000 - $74,999
- ❍ $75,000 - $99,999
- ❍ $100,000+
- ❍ Don’t know/Prefer not to answer

Q21E

ASK US ONLY

In which region do you live?

Please click on the map below. drawTheMap({ qid: "^CurrentForm()^", })

- ❍ East
- ❍ Midwest
- ❍ South
- ❍ West

Thank you

Thank you for your participation. Please press the "^Request('__fwd')^" button to send your survey.

SMOKERS STUDY TRACKER WAVE 5

qcountry

//hidden

❍ UK
❍ US
❍ Poland
❍ Finland
❍ Sweden

wave

//hidden

❍ wave 5

InfoNote

Hello and welcome back to the Smokers study!

You have completed the first part of this longitudinal study back in Summer 2019 and now it's time for the final part.

Thanks for your continuous support of this piece of research!

i177

Thank you for agreeing to take part in this 5-minute survey.

The sponsor of the survey, Vision One is a member of the Market Research Society (MRS) and all our research is conducted in accordance with the Market Research Society's Code of Conduct.
Survey responses are collected for research purposes only - you will not be contacted for sales or marketing purposes as a result of taking part in this research. All information collected is kept confidential unless explicit consent is provided to share your information. Where anonymity is guaranteed, survey data is amalgamated for analysis and reporting so no one can be personally identified.
Please begin by answering the following questions.

Q1

ASK ALL

What is your age?

Select ONE option only.

- ❍ Under 18 years old [**Close**]
- ❍ 18-20 years old
- ❍ 21-29 years old
- ❍ 30-39 years old
- ❍ 40-49 years old
- ❍ 50-59 years old
- ❍ Over 60 years old

QTOL1

ASK ALL

How often do you do any of the following?

Select ONE option per row.

	Daily	Weekly	Only socially	Never
Smoke cigarettes	❍	❍	❍	❍
Smoke e-cigarettes (vaping)	❍	❍	❍	❍
Smoke cigars	❍	❍	❍	❍
Use smokeless tobacco products (Glo, IQOS)	❍	❍	❍	❍

QNEW2

This is the continuation of an important behavioural study we are undertaking over two years.

This is the 5th and final last time you will have to take part in this survey.

As a thank you for your commitment and continued participation, at the end of the survey you will be rewarded a total of (£40/46€/210zł/471kr/$56) points into your account!

QNEW1

ASK IF SELECTED NEVER FOR ROW 1 (SMOKE CIGARETTES) AT QTOL1

When did you stop smoking cigarettes?

Select ONE option only.

- ❍ Within the last 4 weeks [GOTO Q14]
- ❍ 1 to 2 months ago[GOTO Q14]
- ❍ 3-4 months ago [GOTO Q14]
- ❍ 5-6 months ago [GOTO Q14]
- ❍ 6-12 months ago [GOTO Q14]
- ❍ 12-18 months ago [GOTO Q14]
- ❍ 18-24 months ago [GOTO Q14]

❍ Never smoked cigarettes [**Close**]

Q2

ASK ALL

Have you smoked more than 100 cigarettes in your lifetime?

Select ONE option only.

❍ Yes
❍ No [**Close**]

Q3

ASK ALL

Currently, how often do you smoke cigarettes?

Select ONE option only

❍ Everyday
❍ Occasionally (less than everyday)

Q3B

ASK ALL

How has the coronavirus pandemic affected how often you smoke cigarettes?

Select ONE option only

❍ It has had no effect
❍ I have been smoking more
❍ I have been smoking less
❍ I have quit smoking due to the coronavirus pandemic
❍ I have quit smoking, but it is not related to the coronavirus pandemic

Q4

ASK ALL

What type of cigarettes do you usually prefer to smoke? Are they ...

Select ONE option only

❍ Menthol
❍ Non-Menthol

Q5

[Substituted with QNEW2 above].

Q6

ASK EVERYDAY SMOKERS

On average how many cigarettes do you smoke per day? Enter a numerical whole number below.

Enter number _____

Q7

ASK OCCASIONAL SMOKERS

On the days that you smoke, about how many cigarettes do you smoke per day? Enter a numerical whole number below

Enter number _____

Q8

ASK MENTHOL SMOKERS

Thinking about the menthol cigarettes you usually smoke, does the cigarette have a capsule in the filter that you crush to release the menthol flavour?

Select ONE option only

❍ Yes
❍ No

Q9

ASK ALL

What is the name of the brand of cigarette that you usually smoke? Please write in the name of ONE brand only below?

Type in brand name

Q10A

ASK ALL

In addition to your usual brand, are there any other brands that you regularly smoke?

Select ONE option only

❍ Yes
❍ No

Q10B

ASK IF SELECTED YES FOR Q10A

Please use the space below to list the other brands of cigarettes you usually smoke?

Please only list one brand per line. You do not need to complete all the lines. If you smoke more than 5 other brands then please only list the 5 main brands you usually smoke.

_____
_____
_____
_____
_____

Q11

ASK ALL

Are you thinking about quitting smoking cigarettes?

Select ONE option only

❍ Yes
❍ No
❍ Don't know/Not sure

Q12

ASK IF SELECTED YES FOR Q11

How soon are you likely to quit smoking? Would you say...

Select ONE option only

❍ Within the next 30 days
❍ Within the next 6 months
❍ Within a year
❍ Longer than a year
❍ Don’t know/Not sure

Q13A

ASK ONLY FOR UK, SWEDEN, POLAND, FINLAND

ASK MENTHOL SMOKERS

Are you aware that menthol cigarettes have been banned from sale in ^f('qcountry')^ since May 2020?

Select ONE option only

❍ Yes
❍ No

Q13B

ASK ONLY FOR UK, SWEDEN, POLAND, FINLAND

ASK MENTHOL SMOKERS

As menthol cigarettes are no longer available for sale here, what have you been doing?

Select ONE option only

❍ Switched to non-menthol cigarettes
❍ Switched to oral tobacco

❍ Found a way to add menthol flavour to cigarettes on your own
❍ Switched to an e-cigarette
❍ Quit smoking
❍ I can still purchase menthol cigarettes from stores near me
❍ Other/something else
❍ Don't know/Not sure

Q14

ASK ALL

And finally, some questions about you for classification.
Please indicate your gender.

Select ONE option only

❍ Male
❍ Female
❍ Other
❍ Prefer not to answer

Q15

ASK ALL

What is your current marital status?

Select ONE option only

❍ Married
❍ Separated
❍ Divorced
❍ Widowed
❍ Never married
❍ Prefer not to answer

Q16

ASK ALL

What is the highest qualification you have achieved?

Select ONE option only

❍ Less than a high school/upper secondary school qualification
❍ High school/upper secondary school qualification
❍ Trade/Technical/vocational training
❍ Bachelor's degree
❍ Master's degree
❍ Doctorate degree
❍ Prefer not to answer

Q17

ASK UK, SWEDEN, POLAND, FINLAND

What is your ethnic background?

Select ONE option only

- ❍ White
- ❍ Asian
- ❍ Black, African, Caribbean
- ❍ Mixed White and Asian
- ❍ Mixed White and Black Caribbean or Black African
- ❍ Other mixed or multiple ethnic groups
- ❍ Other ethnicity
- ❍ Not sure
- ❍ Prefer not to answer

Q18

ASK US ONLY

What is your ethnic background?

Select ONE option only

- ❍ White
- ❍ Hispanic or Latino
- ❍ Native American, American Indian or Alaskan Native
- ❍ Native Hawaiian or other Pacific Islander
- ❍ Asian
- ❍ Black, African, Caribbean
- ❍ Mixed White and Asian
- ❍ Mixed White and Black Caribbean or Black African
- ❍ Other mixed or multiple ethnic groups
- ❍ Other ethnicity
- ❍ Not sure
- ❍ Prefer not to answer

Q19

ASK ALL

What is your current working status? Are you ...

Select ONE option only

- ❍ Working full-time (35+ hours a week)
- ❍ Working part-time (less than 35 hours a week)
- ❍ Unemployed, looking for work
- ❍ Not working, not looking for work/unable to work
- ❍ Student and working
- ❍ Student, not working
- ❍ Retired
- ❍ Other
- ❍ Prefer not to answer

Q19B

ASK ALL

How has the coronavirus pandemic effected your employment and how you work?

Select ONE option only

- ❍ No effect, still go to work outside of home
- ❍ No effect, always worked from home
- ❍ Changed to home working: previously worked outside of home but now work primarily from home due to coronavirus pandemic
- ❍ Working reduced hours
- ❍ Furlough/Stay-at-home not working
- ❍ Unemployed due to coronavirus pandemic
- ❍ Changed job due to the coronavirus pandemic
- ❍ Unemployed before coronavirus pandemic but have since started a new job
- ❍ Unemployed before coronavirus pandemic and still unemployed
- ❍ None of the above

Q19C

ASK ALL

How has the coronavirus pandemic effected how much time you spend at home? (If you are now working from home exclude the time you are working, and just consider if in your free time you feel you are spending more, less or about the same time at home as you were before the pandemic)

Select ONE option only

- ❍ Has had no effect
- ❍ Spend more time at home but still go out for non-essential activities
- ❍ Spend more time at home and only go out for essential activities
- ❍ Spend less time at home

Q20A

ASK UK ONLY

What is your annual household income, before tax deductions?

Select ONE option only

- ❍ Under £10,000
- ❍ £10,000 - £19,999
- ❍ £20,000 - £29,999
- ❍ £30,000 - £39,999
- ❍ £40,000 - £49,999
- ❍ £50,000 - £74,999
- ❍ £75,000 - £99,999
- ❍ £100,000+
- ❍ Don’t know/Prefer not to answer

Q21A

ASK UK ONLY

In which region do you live?

Please click on the map below. drawTheMap({ qid: "^CurrentForm()^", })

- ❍ North East England
- ❍ North West England
- ❍ Yorkshire and the Humber
- ❍ East Midlands

- ❍ West Midlands
- ❍ East of England
- ❍ Greater London (Greater London & Central London)
- ❍ South East England
- ❍ South West England
- ❍ Wales
- ❍ Scotland
- ❍ Northern Ireland

Q20B

ASK SWEDEN ONLY

What is your annual household income, before tax deductions?

Select ONE option only

- ❍ Under kr100,000
- ❍ kr100,000 – kr249,999
- ❍ kr250,000 – kr359,999
- ❍ kr360,000 – kr479,999
- ❍ kr480,000 – kr599,999
- ❍ Kr600,000 – kr899,999
- ❍ Kr900,000 – kr1,199,999
- ❍ kr1,200,000+
- ❍ Don’t know/Prefer not to answer

Q21B

ASK SWEDEN ONLY

In which region do you live?

Please click on the map below. drawTheMap({ qid: "^CurrentForm()^", })

- ❍ East Sweden
- ❍ North Sweden
- ❍ South Sweden

Q20C

ASK POLAND ONLY

What is your annual household income, before tax deductions?

Select ONE option only

- ❍ Under zł50,000
- ❍ zł50,000 – zł94,999
- ❍ zł95,000 – zł144,999
- ❍ zł145,000 – zł189,999
- ❍ zł190,000 – zł249,999
- ❍ zł250,000 – zł359,999
- ❍ zł360,000 – zł479,999
- ❍ zł480,000+
- ❍ Don’t know/Prefer not to answer

Q21C

ASK POLAND ONLY

In which region do you live?

Please click on the map below. drawTheMap({ qid: "^CurrentForm()^", })

- ❍ Central Region
- ❍ South Region
- ❍ East Region
- ❍ Northwest Region
- ❍ Southwest Region
- ❍ North Region

Q20D

ASK FINLAND ONLY

What is your annual household income, before tax deductions?

Select ONE option only

- ❍ Under €10,000
- ❍ €10,000 - €19,999
- ❍ €20,000 - €29,999
- ❍ €30,000 - €39,999
- ❍ €40,000 - €49,999
- ❍ €50,000 - €74,999
- ❍ €75,000 - €99,999
- ❍ €100,000+
- ❍ Don’t know/Prefer not to answer

Q21D

ASK FINLAND ONLY

In which region do you live?

Please click on the map below. drawTheMap({ qid: "^CurrentForm()^", })

- ❍ Southern Finland / Etelä-Suomen lääni
- ❍ Southwestern/Western and Inland Finland
- ❍ Eastern Finland
- ❍ Northern Finland
- ❍ Lapland
- ❍ Åland

Q20E

ASK US ONLY

What is your annual household income, before tax deductions?

Select ONE option only

- ❍ Under $10,000
- ❍ $10,000 - $19,999
- ❍ $20,000 - $29,999
- ❍ $30,000 - $39,999

❍ $40,000 - $49,999
❍ $50,000 - $74,999
❍ $75,000 - $99,999
❍ $100,000+
❍ Don’t know/Prefer not to answer

Q21E

ASK US ONLY

In which region do you live?

Please click on the map below. drawTheMap({ qid: "^CurrentForm()^", })

❍ East
❍ Midwest
❍ South
❍ West

Thank you

Thank you for your participation. Please press the "^Request('__fwd')^" button to send your survey.

APPENDIX 8: REVIEW OF STUDIES EVALUATING NATIONAL AND LOCAL FLAVOR BANS THAT ARE RELIED ON BY THE FDA

Courtemanche et al. (2017)[118]

Courtemanche et al. (2017) evaluated the impact of the U.S. 2009 federal flavored cigarette ban (effective September 22, 2009), excluding menthol, in the U.S. on adolescent (aged 11-19) use of tobacco products. The authors used a cross-sectional pre/post design using data from the 1999, 2000, 2002, 2004, 2006, 2009, 2011, 2012, and 2013 NYTS, a school-based, nationally representative survey (N=197,834) of middle and high school students (pre-policy: 1999 to 2009; post-policy: 2011 to 2013). The authors find that the flavor ban was associated with a large degree of substitution across tobacco products. While they do report a reduction in overall tobacco use, their failure to use a counterfactual control group prevents a determination of whether this effect is causal or merely the result of pre-existing trends. The federal nature of the regulation would require comparison with data from other jurisdictions which is not available in the dataset the authors use. While the authors control for a quadratic trends, their own graphs show that the background trends exhibit more slope changes than would be implied by a simple quadratic trend. There is no confidence in a causal interpretation of these results.

Farley and Johns (2017)[119]

Farley and Johns (2017) conducted an evaluation of New York City's tobacco sales restriction of flavored other tobacco products ("**OTP**") – i.e., flavored cigars, cigarillos, little cigars, chew, snuff, snus, tobacco, pipe tobacco, RYO tobacco, and dissolvables (excluding menthol, mint, or wintergreen flavor) (effective July 2010). This paper has no counterfactual comparison and so it is not a reliable research design in drawing counterfactual comparisons. Interestingly, however, though the authors interpret their results as suggesting that the New York City flavor ban was successful, their own results show that the odds of smoking increased by 30 percent. Although the effect is not statistically significant at the 5 percent level, it looks as though it would be at the 10 percent level. In any event, the flavor ban did not reduce the likelihood an individual currently smoked.

Rogers et al. (2017)[120]

Rogers et al. (2017) examined the impact of New York City's policy restricting the sale of non-tobacco flavored tobacco products (effective July 2010) on tobacco product sales. Although this paper does attempt to provide comparisons with areas close to New York City and with the U.S. in general, they do not provide enough of a pre-policy period to adequately judge whether these comparators provide decent counterfactuals for New York City. Further, although they examine some forms of possible substitution (cigars to smokeless tobacco or roll your own tobacco), they do not examine any substitution into cigarettes, leaving it unclear whether this analysis indicates any actual improvement in public health.

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118 Charles J. Courtemanche, Makayla K. Palmer and Michael F. Pesko (2017), "Influence of the flavored cigarette ban on adolescent tobacco use," *American Journal of Preventive Medicine*, 52(5): e139–e146. https://doi.org/10.1016/j.amepre.2016.11.019.

119 Shannon M. Farley and Michael Johns (2017), "New York City flavoured tobacco product sales ban evaluation," *Tobacco Control*, 26(1): 78–84. https://doi.org/10.1136/tobaccocontrol-2015-052418.

120 Todd Rogers, Elizabeth M. Brown, Tarsha M. McCrae, Doris G. Gammon, Matthew E. Eggers, Kimberly Watson, Martha C. Engstrom, Cindy Tworek, Enver Holder-Hayes and James Nonnemaker (2017),"Compliance with a sales policy on flavored non-cigarette tobacco products," *Tobacco Regulatory Science*, 3(2 Suppl 1): S84–S93. https://doi.org/10.18001/TRS.3.2(Suppl1).9 .

Kingsley et al. (2019)[121]

Kingsley et al. (2019) assessed the short-term impact of a flavored tobacco restriction in Lowell, Massachusetts (effective October 1, 2016), on flavored tobacco availability and youth perceptions/behaviors related to flavored tobacco use. Although this study attempted to create a treatment/control design, it is unclear whether Malden serves as an adequate comparison for Lowell, as indicated in the presented descriptive statistics (e.g., Lowell is a much larger community). Perhaps what is worse, since the data are not longitudinal, different people were surveyed before and after and as can be seen in Table 3, the populations surveyed in the two periods differed substantially and, most fatally, the differences often move in opposite directions between the two places (e.g., the age indicators). This leaves open the strong probability that the authors' results could be driven by compositional changes in their sample.

Pearlman et al. (2019)[122]

Pearlman et al. (2019) evaluated the impact of Providence, Rhode Island's sales restriction on flavored (excluding menthol) tobacco products (and price promotions for all tobacco products) on youth tobacco use (effective January 2013). This study does nothing to account for background trends either by using a control comparator or through trend inclusion in the analyses, leaving it impossible to attribute causality to any of the conclusions.

Guydish et al. (2020)[123]

Guydish et al. (2020) evaluated the impact of a 2019 San Francisco sales restriction on flavored (including menthol) tobacco products on cigarette use in clients of two residential substance use treatment facilities. This paper found no evidence that the ban was associated with decreased number of cigarettes per day or increased readiness to quit among current smokers. However, because it does not account for background trends either through a comparator jurisdiction or through statistical means, these results cannot be interpreted causally.

Rogers et al. (2020)[124]

Rogers et al. (2020) examined the effects of Providence, Rhode Island's restriction on the sale of all flavored non-cigarette tobacco products (cigars, smokeless tobacco, loose tobacco, and e-cigarettes with nicotine) (effective January 3, 2013). Menthol, mint, and wintergreen flavors were exempt from this policy. As with Rogers et al. (2017), although there is an attempt to compare the treatment area (Providence) with a control area (here they use the rest of Rhode Island), they do not provide evidence that the rest of the state is a suitable counterfactual for Providence. Further, they do not examine the possibility that

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121 Melody Kingsley, Claude M. Setodji, Joseph D. Pane, William G. Shadel, Glory Song, Jennifer Robertson, Lindsay Kephart, Patricia Henley and W W Sanouri Ursprung (2019), "Short-term impact of a flavored tobacco restriction: Changes in youth tobacco use in a Massachusetts community," *American Journal of Preventive Medicine*, 57(6): 741–748. https://doi.org/10.1016/j.amepre.2019.07.024 .

122 Deborah N. Pearlman, Jasmine A. Arnold, Geri A. Guardino and Erin Boles Welsh (2019), "Advancing tobacco control through point of sale policies," *Preventing Chronic Disease*, 16: E129. https://doi.org/10.5888/pcd16.180614.

123 Joseph R. Guydish, Elana R. Straus, Thao Le, Noah Gubner and Kevin L. Delucchi (2020), "Menthol cigarette use in substance use disorder treatment before and after implementation of a county-wide flavoured tobacco ban," *Tobacco Control*, tobaccocontrol-2020-056000. Advance online publication. https://doi.org/10.1136/tobaccocontrol-2020-056000.

124 Todd Rogers, Ashley Feld, Doris G. Gammon, Ellen M. Coats, , Elizabeth M. Brown, Lindsay T. Olson, James M. Nonnemaker, Martha Engstrom, Tarsha McCrae, Enver Holder-Hayes, Ashley Ross, Erin Boles Boles Welsh, Geri Guardino and Deborah N. Pearlman (2020), "Changes in cigar sales following implementation of a local policy restricting sales of flavoured non-cigarette tobacco products," *Tobacco Control*, 29(4): 412–419. https://doi.org/10.1136/tobaccocontrol-2019-055004 .

Providence cigar smokers substituted toward cigarettes or even the possibility that Providence cigar smokers simply went elsewhere for their flavored cigars.

Rossheim et al. (2020)[125]

Rossheim et al. (2020) purports to evaluate the impact of the 2009 federal ban on flavored cigarettes, excluding menthol, in the U.S. (effective September 22, 2009) on cigarette and menthol cigarette use by youth (aged 12-17), young adults (aged 18-25), adults (aged 26-49) and older adults (aged 50+). The authors do not employ a comparison group, instead focusing their analyses on different effects by age group, even though all age groups were exposed to the ban. They simply assume that the oldest group would be unaffected by the ban since few people in this group smoked flavored cigarettes. However, as is clear from Klein (2008), a very small number of people smoked flavored cigarettes at the time anyway and there is no evidence of that small number showing a strong negative correlation with age.[126] Further, the authors fail to account for numerous factors that could impact on smoking rates to say nothing of the pre-existing downward trend that existed in smoking metrics at the time. For example, the authors note that cigarette prices increased dramatically after the ban went into effect and they are unable to include controls for the prices faced by the individuals examined in the study (they can only include a generalized national price measure). Instead, the authors assume (without empirical evidence) that all such factors that could influence smoking prevalence – except the flavor ban – would equally impact smokers of all ages. However, because young people are more sensitive to price increases,[127] these price effects would not be adequately accounted for by looking at the trends observed in older age groups. This renders the study's conclusions unreliable.

Yang et al. (2020)[128]

Yang et al. (2020) evaluated the impact of San Francisco's flavored tobacco sales restriction (enforcement January 2019; formal enforcement April 2019) on a convenience sample of young adults' tobacco use behaviors (aged 18-34). The restriction covered all flavored e-cigarettes (other than tobacco flavor), menthol cigarettes, and other non-tobacco flavored tobacco products. The authors found a significant reduction in any tobacco use (including e-cigarettes) following San Francisco's flavor ban. However, among the 18–24 age group, there was also a significant increase in cigarette smoking overall. This paper does not attempt to account for background trends either through a counterfactual comparison jurisdiction or through statistical means, so it is impossible to draw any causal interpretation of the paper's results.

Zatoński et al. (2020)[129]

Zatoński et al. (2020) used longitudinal data from the EUREST-PLUS ITC Europe Surveys (n=19,691 from eight EU member states) to assess changes in: 1) the prevalence of cigarette use by flavor; and 2) smoking

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125 Matthew E. Rossheim, Melvin D. Livingston, Jenna R. Krall, Tracey E. Barnett, Dennis L. Thombs, Kayla K. McDonald and Gilbert W. Gimm (2020), "Cigarette use before and after the 2009 flavored cigarette ban," *The Journal of Adolescent Health: Official Publication of the Society for Adolescent Medicine*, 67(3): 432–437. https://doi.org/10.1016/j.jadohealth.2020.06.022 .

126 Sarah M. Klein et al. (2008), "Use of flavored cigarettes among older adolescent and adult smokers: United States, 2004-2005," *Nicotine & Tobacco*. Res. 10(7): 1209–1214.

127 Alexander Ding (2003), "Youth are more sensitive to price changes in cigarettes than adults," *The Yale Journal of Biology and Medicine* 76(3): 115-24.

128 Yong Yang, Eric N. Lindblom, Ramzi G. Salloum and Kenneth D. Ward (2020), "The impact of a comprehensive tobacco product flavor ban in San Francisco among young adults," *Addictive Behaviors Reports*, 11: 100273. https://doi.org/10.1016/j.abrep.2020.100273.

129 Mateusz Zatoński, Aleksandra Herbec, Witold A. Zatoński, Kinga Janik-Koncewicz, Pete Driezen, Tibor Demjén, Esteve Fernández, Geoffrey T. Fong, Anne C. K. Quah, Christina N. Kyriakos, Ann McNeill, Marc Willemsen, Ute Mons, Yannis Tountas, Antigona C. Trofor, Constantine I. Vardavas, Krzysztof Przewoźniak (2020), "Cessation behaviours among smokers of menthol and flavoured cigarettes following the implementation of the EU Tobacco

status, cessation behaviors and cigarette flavor preferences following the Tobacco Products Directive (TPD) 2016 ban on cigarettes and RYO with characterizing flavors, but before the 2020 ban on menthol cigarettes. Because the flavor ban applied to all of the individuals in the sample, the primary comparison is made between smokers of flavored tobacco and smokers of non-flavored tobacco. The authors find that flavored tobacco smokers primarily switched to smoking unflavored tobacco and any quitting observed after the ban was mirrored among those who had been smoking unflavored products prior to the ban. This suggests that flavor bans do not improve public health but merely induce substitution among products.

Friedman (2021)[130]

Friedman (2021) estimated the association between San Francisco's sales restriction on flavored tobacco product sales and smoking among high school students younger than 18 years using data from the 2011-2019 YRBS biennial school district surveys. This short paper takes seriously the need to provide a counterfactual control and uses the Youth Risk Behavior Surveillance System data to create samples of San Francisco young people and comparable young people from other cities. As shown in Figure 1, the comparison cities provide a good match for the smoking patterns of people under 18 in San Francisco. The paper shows convincingly that when flavors were banned in e-cigarettes, San Francisco young people became much more likely (there was a doubling of the likelihood) to smoke cigarettes than their counterparts in other cities. This result was robust to a number of modelling choices. This high-quality analysis, that takes causal inference seriously, provides compelling evidence that individuals tend to substitute to other products when flavors are banned, as opposed to quitting the use of tobacco altogether. Liu et al (2022)[131] claim that the San Francisco youth data were collected before the restriction went into place, suggesting that Friedman (2021) was not actually examining the effect of the sales restriction. There are a number of issues with this criticism. First, the large smoking change observed by Friedman would be unexpected just by random chance; Liu et al (2022) offer no alternative explanation for the change in smoking behavior. It is possible that the youth were changing their choices in anticipation to the restriction. Also, Liu et al appear to be overclaiming about the timing of the enforcement of the ban. Specifically, relying on Vyas et al (2021)[132], Liu et al (2022) write, "Through personal communication (CDC OSH, 15 June 2021), we found that the timing of the survey period of 2019 YRBSS survey in specific school districts varied from one another. San Francisco's assessment period was Fall 2018 (defined as September to December). Thus, the San Francisco survey preceded the enforcement of its flavoured tobacco sales restriction (January 2019), making the 2019 YRBSS an inappropriate data source for evaluating the effects of the city's flavoured tobacco sales restriction. Research on compliance with San Francisco's flavoured tobacco sales restriction found that compliance was fairly low at only 17% in December 2018 and increased through 2019 to up to 80%." However, the Vyas et al (2021) numbers represent the share of retailers, not the share of retail sales. It could easily be the case that bigger retailers complied first, implying that the ban would have already had an effect on purchasing by the time the YRBS data were collected. Given the large change in youth behavior, such a possibility perhaps even seems likely absent some other explanation. Further, the Vyas paper itself indicates that compliance (in terms of stores increased from 17 percent to 77% between December 2018 and January 2019. Combined with the vague "personal communication" that indicates that at least some of the San Francisco data were collected in December 2018, effective compliance (at the store level) could have been quite a bit higher than Liu's implied 17 percent.

Products Directive: Findings from the EUREST-PLUS ITC Europe Surveys," *European Journal of Public Health*, 30(Suppl 3): iii34-iii37. doi: 10.1093/eurpub/ckaa050.

130 Abigail S. Friedman (2021), "A difference-in-differences analysis of youth smoking and a ban on sales of flavored tobacco products in San Francisco, California," *JAMA Pediatrics*, 175(8): 863–865. https://doi.org/10.1001/jamapediatrics.2021.0922.

131 Liu , J., A.S.L. Tan, J.P. Winickoff, et al. "Youth Tobacco Use Before and After Flavoured Tobacco Sales Restrictions in Oakland, California and San Francisco, California." Tobacco Control, Published Online First, 17 March 2022. http://dx.doi.org/10.1136/tobaccocontrol-2021-057135.

132 Vyas, P., P. Ling, B. Gordon, et al. "Compliance with San Francisco's Flavoured Tobacco Sales Prohibition." Tob. Control, 30:227-230, 2021. https://doi.org/10.1136/tobaccocontrol-2019-055549.

Gammon et al. (2021)[133]

Gammon et al. (2021) examined the impact of San Francisco's flavored tobacco product sales restriction on tobacco sales. The authors used an interrupted time series analysis to assess changes in unit sales of tobacco products in San Francisco and in two Californian cities without flavored tobacco sales restrictions (San Jose and San Diego). While this paper attempts to use counterfactual comparisons, the provided detail does little to demonstrate that the jurisdictions are comparable. The provided graphs are too condensed to determine whether sales in the cities mirror each other, and the paper does not provide any descriptive analyses on this point either. However, if one accesses the supplementary material, it is clear in supplemental table 2, the chosen comparison jurisdictions are terrible comparisons in that their pre-period slopes are negative for virtually all tobacco sales, while San Francisco's are positive. That is, the treatment and control jurisdictions were heading in opposite directions before the flavor policy goes into effect in San Francisco. This renders the entire analysis unreliable.

Hawkins et al. (2021)[134]

Hawkins et al. (2021) examined the associations between county-level flavored tobacco product restrictions, tobacco 21 policies, and smoke-free laws prohibiting e-cigarettes with adolescent cigarette and e-cigarette use in Massachusetts using data from the 2011–2017 biennial Massachusetts YHS, a representative cross section of Massachusetts high school students. Although the paper attempts to compare behavior in counties with flavor restrictions to counties that did not, the authors do not provide any way to assess whether the counties are in fact comparable in the pre-period. This significantly limits confidence in the causal interpretation of these results. Further, while the author's cluster at the school level, they should be clustering at the county level (where the policies are chosen) which likely would limit the precision of these already incredibly noisy estimates even further. Given these problems, it is perhaps not surprising that the paper yields mixed results with the flavor restrictions not statistically significantly affecting the likelihood of smoking while significantly affecting the level of cigarette use.

Kingsley et al. (2021)[135]

Kingsley et al. (2021) assessed the impact of flavored tobacco restrictions in Attleboro, Massachusetts (effective January 2016) and Salem, Massachusetts (effective March 2017) on access to, awareness, and use of tobacco among high school students, compared to the control community of Gloucester (with no policy). Although Gloucester is presented as a counterfactual comparator, no evidence is presented to allow one to assess its quality as a comparator. Even the scant descriptive statistics presented in Table 1 are suggestive that the demographics of the communities evolved differently between the pre and post periods of the study. This leaves open the possibility that any estimated treatment effects are actually compositional effects. In any event, the paper has an odd outcome wherein of the two treatment counties, the county with the flavor restrictions in place for a shorter period saw a bigger reduction in tobacco use. While the authors attempt to come up with ad hoc reasons to explain away this result that is suggestive that

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133 Doris G. Gammon, Todd Rogers, Jennifer Gaber, James M. Nonnemaker, Ashley L. Feld, Lisa Henriksen, Trent O. Johnson, Terence Kelley and Elizabeth Andersen-Rodgers (2021), "Implementation of a comprehensive flavoured tobacco product sales restriction and retail tobacco sales," *Tobacco Control*, tobaccocontrol-2021-056494. Advance online publication. https://doi.org/10.1136/tobaccocontrol-2021-056494.

134 Summer Sherburne Hawkins, Claudia Kruzik, Michael O'Brien and Rebekah Levine Coley (2021), "Flavoured tobacco product restrictions in Massachusetts associated with reductions in adolescent cigarette and e-cigarette use," *Tobacco Control*, tobaccocontrol-2020-056159. Advance online publication. https://doi.org/10.1136/tobaccocontrol-2020-056159.

135 Melody Kingsley, Claude M. Setodji, Joseph D. Pane, William G. Shadel, Glory Song, Jennifer Robertson, Lindsay Kephart, Samantha Zepeda, Patricia Henley and W. W. Sanouri Ursprung (2021),"Longer-term impact of the flavored tobacco restriction in two Massachusetts communities: A mixed-methods study," *Nicotine & Tobacco Research: Official Journal of the Society for Research on Nicotine and Tobacco*, tab115. Advance online publication. https://doi.org/10.1093/ntr/ntab115 .

perhaps other things were changing beyond just the flavor restrictions, such incongruous results limit confidence in the causal interpretation of the research.

Kock et al. (2021)[136]

Kock et al. (2021) examined the prevalence of menthol cigarette smoking after the EU ban was implemented in England in May 2020 by sociodemographic and smoking characteristics. Data used for the analysis were from repeated monthly cross-sectional surveys of a representative sample of current smokers (18 years and older) in England (unweighted n=2,681 and weighted n=2,908) between July 2020 and June 2021. Given that this paper only examines behavior after the EU ban was implemented, it is not possible to determine anything related to the causal effect of the ban.

[136] Loren Kock, Lion Shahab, Ilze Bogdanovica and Jamie Brown (2021), "The profile of menthol cigarette smokers in the months following the removal of these products from the market: A cross-sectional population survey in England," *Tobacco Control*; in press. Published on-line November 17, 2021. http://dx.doi.org/10.1136/tobaccocontrol-2021-057005 .