Bott 6-12-19

IMPACT OF MENTHOL CIGARETTES ON YOUTH SMOKING INITIATION AND HEALTH DISPARITIES

Cigarettes with specific characterizing flavors were prohibited in the U.S. on September 22, 2009, as part of the Family Smoking Prevention and Tobacco Control Act (TCA) that gave the U.S. Food and Drug Administration (FDA) authority over tobacco products.[1] This provision excluded menthol cigarettes, which make up more than a quarter of the cigarette market in the United States, and pose tremendous public health harms.[2] The FDA has determined that menthol cigarettes lead to increased smoking initiation among youth and young adults, greater addiction and decreased success in quitting smoking.[3] Further, FDA's Tobacco Products Scientific Advisory Committee's (TPSAC)* concluded, "**Removal of menthol cigarettes from the marketplace would benefit public health in the United States**."[4]

Menthol Makes it Easier for Youth to Initiate Tobacco Use

The tobacco companies know that almost all new tobacco users begin their addiction as kids, but they also know that to novice smokers, tobacco can be harsh and unappealing. Internal tobacco industry documents show that tobacco companies have a long history of using flavors to reduce the harshness of their products to make them more appealing to new users, almost all of whom are under age 18.[5] By masking the harshness and soothing the irritation caused by tobacco smoke, flavors make it easier for beginners – primarily kids – to experiment with the product and ultimately become addicted.
Menthol has particularly appealing qualities for novice smokers. Menthol is a chemical compound that cools and numbs the throat, reducing the harshness of cigarette smoke, thereby making menthol cigarettes more appealing to youth who are initiating tobacco use.[6] As TPSAC noted, "Menthol cannot be considered merely a flavoring additive to tobacco. Its pharmacological actions reduce the harshness of smoke and the irritation from nicotine."[7] According to TPSAC's conclusions:[8]

- Menthol cigarettes increase the number of children who experiment with cigarettes and the number of children who become regular smokers, increasing overall youth smoking.
- Young people who initiate using menthol cigarettes are more likely to become addicted and become long-term daily smokers.

As the only flavored cigarette left on the market, it is no surprise that menthol cigarettes remain popular among youth. In fact, a study analyzing the impact of the 2009 ban on characterizing flavors in cigarettes on youth tobacco use found that use of menthol cigarettes among high schoolers significantly increased after the ban.[9] National data clearly demonstrates the popularity of menthol cigarettes among youth:

- Youth smokers are more likely to use menthol cigarettes than any other age group. Over half (54 percent) of youth smokers ages 12-17 use menthol cigarettes, compared to less than one-third of smokers ages 35 and older.[10]
- Prevalence of menthol use is even higher among African American youth: seven out of ten African-American youth smokers smoke menthol cigarettes.[11]

* TPSAC is a group of scientific experts charged with advising the Commissioner of Food and Drugs on safety, dependence, and health issues relating to tobacco. See https://www.fda.gov/advisoryCommittees/CommitteesMeetingMaterials/tobaccoproductsScientificAdvisoryCommittee/default.htm for more details.

- The popularity of menthol flavored cigarettes is also evidenced by brand preference among youth. According to data from the 2014 National Survey on Drug Use and Health, one in five smokers ages 12-17 prefers Newport cigarettes, a heavily marketed menthol cigarette brand. Preference for Newport is even higher among African-American youth smokers (64.3%) because of targeted marketing by the tobacco industry.[12]

Menthol Increases Addiction and Makes it Harder for Smokers to Quit

While the tobacco industry initially marketed menthol cigarettes as safer and healthier cigarettes, because of their cooling properties and reduced throat irritability, this could not be further from the truth.[13] In fact, because menthol cigarettes are less harsh, they are associated with increased initiation and greater addiction, and FDA found that it is "**likely that menthol cigarettes pose a public health risk above that seen with nonmenthol cigarettes**."[14]

Both TPSAC's and FDA's own scientific analyses conclude that menthol cigarettes are associated with increased nicotine dependence and reduced success in smoking cessation.[15] In fact, menthol smoking has hindered overall declines in cigarette smoking. While smoking rates have declined overall in recent years, use of menthol cigarettes has increased significantly. Overall, nearly 40 percent (38.8%) of smokers use menthol cigarettes. Menthol smoking rates have increased among young adults and remained constant among youth and adults, while non-menthol smoking has decreased in all three age groups.[16] In recent years, use of menthol cigarettes has increased among White, Asian, and Hispanic smokers. Use of menthol cigarettes has remained constant among African-American smokers, who continue to use menthol cigarettes more than any other racial/ethnic group.[17]

TPSAC projected that by 2020, about 17,000 premature deaths will be attributable to menthol cigarettes and about 2.3 million people will have started smoking because of menthol cigarettes.[18]

Use of Menthol Cigarettes Leads to Health Disparities for African Americans

Prevalence of menthol use is highest among African Americans - 85 percent of all African-American smokers smoke menthol cigarettes, compared to 29 percent of Whites.[19] The tobacco industry's "investment" in the African-American community has had a destructive impact. TPSAC's report and FDA's analysis conclude that African Americans are disproportionately burdened by the health harms of menthol cigarettes. Specifically, TPSAC concluded that the marketing and availability of menthol cigarettes increases the overall prevalence of smoking and reduces cessation among African Americans.[20]

- African Americans generally have higher levels of nicotine dependence as a consequence of their preference for mentholated cigarettes.[21] While research shows that African American smokers are highly motivated to quit smoking and are more likely than White smokers to have made a quit attempt and used counseling services in the previous year, they are less likely than White smokers to successfully quit smoking.[22]

- TPSAC estimated that by 2020, 4,700 excess deaths in the African-American community will be attributable to menthol cigarettes, and over 460,000 African Americans will have started smoking because of menthol cigarettes.[23]

- African Americans suffer the greatest burden of tobacco-related mortality of any racial or ethnic group in the United States. Each year, approximately 45,000 African Americans die from a smoking-caused illness. Unless action is taken, an estimated 1.6 million African Americans alive today, who are now under the age of 18, will become regular smokers; and about 500,000 of these will die prematurely from a tobacco-related disease.[24]

- Lung cancer is the second most common cancer in both African-American men and women, but it kills more African Americans than any other type of cancer.[25] Decreased cessation success due to the popularity of menthol cigarettes among African Americans likely contributes to this mortality disparity.[26]

The Tobacco Industry Targets Minorities and Youth with Menthol Cigarette Marketing

The greater popularity of menthol cigarettes among African Americans, youth, and other minorities is a direct result of a decades-long marketing campaign by the tobacco industry. In fact, TPSAC concluded that menthol cigarettes are marketed disproportionately to younger smokers and African Americans.[27] Dating back to the 1950s, the tobacco industry has targeted these communities with marketing for menthol cigarettes through sponsorship of community and music events, targeted magazine advertising, youthful imagery, and marketing in the retail environment.

Music and Community Event Sponsorship. Beginning in the 1970s, the major tobacco companies competed for the African American market share by sponsoring music and community events like Brown & Williamson's "Kool Jazz Festival," R.J. Reynolds' "Salem Summer Street Scenes," and Phillip Morris's "Club Benson & Hedges" promotional bar nights.[28] Kool also sponsored Latin music festivals, including the branded "Kool Latino Festival," in the 1970s and 1980s.[29]

Magazine Advertising. Expenditures for magazine advertising of mentholated cigarettes increased from 13 percent of total ad expenditures in 1998 to 76 percent in 2006.[30] During the two years after the Master Settlement Agreement (MSA) in November 1998, the average annual expenditures for Newport in magazines with high youth readership increased 13.2 percent (from $5.3 to $6.0 million).[31] Between 1998–2002, *Ebony,* a magazine tailored to African-American culture, was 9.8 times more likely than *People* to contain ads for menthols.[32] One study comparing the English and Spanish language versions of *Cosmopolitan* and *Glamour* from 1998-2002 found that 51 percent of the cigarette ads in the Spanish language versions were for menthol brands, compared to only 28 percent in the English language versions.[33]

Youthful Imagery. The tobacco companies commonly use youthful imagery in its advertising to appeal to young consumers. As a R.J. Reynolds document from 1981 noted, "The benefit of smoking which has most frequently and most successfully been exploited by brand families appears to be Social Interaction. For example, some brands, such as Newport, have focused on the younger adult 'peer group' aspect of social interaction."[34] Newport's "Alive with Pleasure" campaign, which continues today, portrays smokers in fun, social environments in its advertisements.[35] In 2004, Brown & Williamson started an ad campaign for their Kool brand cigarettes clearly aimed at youth—and African-American youth, in particular. The Kool Mixx campaign featured images of young rappers, disc jockeys and dancers on cigarette packs and in advertising. The campaign also included radio giveaways with cigarette purchases and a Hip-Hop disc jockey competition in major cities around the country. The themes, images, radio giveaways and music involved in the campaign all clearly have tremendous appeal to youth, especially African-American youth. Attorneys General from several states promptly filed motions against Brown & Williamson for violating the Master Settlement Agreement.[36]

Retail Promotions. For decades, tobacco companies have specifically targeted minority communities, particularly African Americans, with intense advertising and promotional efforts. Beginning in the 1970s, the major tobacco companies used mobile van programs, like the Newport Pleasure Van, to expand their reach in urban areas through product sampling and coupon distribution.[37] The tobacco companies also developed specific strategies and specially designed product displays to adapt their point-of-sale marketing to smaller retailers that were more common in urban areas. Phillip Morris implemented promotion programs and paid retailers to exhibit product displays and grow their inventory. Brown &

Williamson launched its Kool Inner City Point of Purchase Program, later the Kool Inner City Family Program, with the explicit goal, "to reach the core of Kool's franchise (young, black, relatively low income and education),"[38] with both retailer and consumer promotions.[39] Today, menthol cigarettes continue to be heavily advertised, widely available, and priced cheaper in certain African-American communities, making them more appealing, particularly to price-sensitive youth. A wealth of research indicates that African-American neighborhoods have a disproportionate number of tobacco retailers, pervasive tobacco marketing, and in particular, more marketing of menthol products.[40]

- Like many minority and low-income neighborhoods, African-American neighborhoods tend to have more tobacco retailers. Nationwide, census tracts with a greater proportion of African American residents have higher tobacco retailer density.[41]

- A 2011 study of cigarette prices in retail stores across the U.S. found that Newport cigarettes are significantly less expensive in neighborhoods with higher proportions of African Americans.[42]

- The 2011 California Tobacco Advertising Survey reports that there were significantly more menthol advertisements at stores in neighborhoods with a higher proportion of African-American residents and in low-income neighborhoods.[43]

- Another 2011 California study found that as the proportion of African-American high school students in a neighborhood rose, the proportion of menthol advertising increased, the odds of a Newport promotion were higher, and the cost of Newport cigarettes was lower.[44]

- A 2013 study of tobacco retail outlets in St. Louis found more tobacco advertising, including more menthol advertising, in areas with a greater proportion of African-American residents.[45] Another 2013 study found similar patterns in Ramsey County, Minnesota.[46]

State and Local Action to Restrict the Sale of Menthol Tobacco Products

States and localities can implement additional sales restrictions on menthol cigarettes and flavored non-cigarette tobacco products. Despite inevitable challenges from tobacco companies, states and localities have clear authority to restrict the sale of flavored tobacco products (or any tobacco product) to reduce tobacco use and its harms to its citizens. Recently, the National Association for the Advancement of Colored People (NAACP) adopted a resolution to support state and local restrictions on flavored tobacco products, including menthol. Several localities have included restrictions on menthol tobacco products as part of a broader restriction on flavored tobacco products, but more and more communities around the country are considering such policies.[47] For example:

- Minneapolis and St. Paul, MN originally passed restrictions that restricted the sale of all flavored tobacco products, excluding menthol, in all stores except adult-only tobacco retailers (effective 1/1/2016 and 4/15/2016, respectively). However, in 2017, both cities voted to expand these laws to also restrict the sale of menthol flavored tobacco products in all stores except adult-only tobacco retailers and liquor stores (effective 8/1/2018 and 11/1/2018, respectively).[48]

- Oakland, CA's ordinance, slated to go into effect on July 1, 2018, will restrict the sale of all flavored tobacco products, including menthol cigarettes and e-cigarettes, except in adult-only tobacco retailers.[49] Several other smaller California municipalities have passed or are considering similar ordinances.

- In 2017, the San Francisco Board of Supervisors unanimously passed an ordinance to prohibit the sale of all flavored tobacco products, including menthol cigarettes and e-cigarettes.[50] This law, originally slated to go into effect on April 1, 2018, would be the strongest flavor restriction in the US. However, R.J. Reynolds, manufacturer of the top-selling menthol brand, quickly responded by

gathering signatures for a referendum petition, allowing voters to decide on the June 2018 ballot whether the restriction should be repealed.[51]

- Chicago, IL's ordinance restricts the sale of all flavored tobacco products, including menthol products and electronic cigarettes, in retail stores within 500 feet of any school, with the exception of stores that sell primarily tobacco products (at least 80% of revenue). Originally slated to go into effect in 2014, litigation and subsequent revisions to the regulations delayed enforcement of the ordinance until July 20, 2016. Chicago's ordinance was subsequently amended to only apply to stores near high schools as of February 4, 2017.[52]

- Berkeley, CA's ordinance restricts the sale of all flavored tobacco products, including menthol products and electronic cigarettes, in all retailers within 600 feet of schools. Berkeley's ordinance went into effect on January 1, 2017.

Campaign for Tobacco-Free Kids, January 18, 2018 / Laura Bach

More information on Tobacco and African Americans is available at https://www.tobaccofreekids.org/fact-sheets/tobaccos-toll-health-harms-and-cost/toll-of-tobacco-on-specific-populations-african-americans

More information on Flavored Tobacco Products is available at tfk.org/flavortrap and http://www.tobaccofreekids.org/research/factsheets/pdf/0383.pdf.

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[1] See U.S. Food and Drug Administration's (FDA) Flavored Tobacco webpage at http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/FlavoredTobacco/default.htm.

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It's All About Flavors in Schools - MINT & MENTHOL, too

Dr. Lester Hartman, MD, MPH

Senior Partner

Westwood-Mansfield Pediatric Associates

List of Communities Restricting MINT & MENTHOL to 21+ Smoke/Vape Shop

- Somerville
- Needham
- Ashland
- Framingham
- Swampscott
- Sherborn
- Walpole
- Brookline (even further to ban flavors)
- Barnstable

According to CDC data,
Massachusetts is the 9th worst
State for teen vaping rates.

Centers of Disease Control and Prevention

Teens and elementary school youth are now vaping at a rate 6 times the rate of adults.

Centers of Disease Control and Prevention

MINT and MENTHOL

In 2009, the FDA took a bold step and banned all flavored cigarettes; however, Big Tobacco exempted MINT and MENTHOL.

When all other flavors were removed kids default to the remaining MINT and MENTHOL flavored tobacco.

On average, MENTHOL tobacco smokers delay quitting 20% longer than non-mentholated cigarette users.

Bold Leadership – We are here to protect health!

- **We are here for the kid's and adults' health <u>NOT</u> the economic health of retailers.**

- **THEY CAN MORPH**

Businesses Can Morph

- Physicians in the early part of the 20th century discouraged breastfeeding; patients had to come to the office to learn how to mix formulas.

- In hindsight, this was found to be a big mistake and unhealthy for children.

- I suspect this would have initially hurt physicians businesses.

- But as with any business, they had to morph.

- Similarly, convenience stores know they're selling a deadly product. They have become too reliant on it. They must think of ways to diversify your offerings. Ideas could be to add a deli area or incorporate a Subway shop or a Dunkin Donuts to the store.

While last years YRBSS study showed 42% of Massachusetts kids had tried vaping, I believe this figure is a gross underestimation.

Talking to teens daily, it feels closer to 80%!

The nicotine in JUUL has a patented formulation linked with Benzoic Acid which is suspected to cause a bigger head rush than cigarettes making it more addictive.

I suspect MINT and MENTHOL augment this furthering the addiction even more!

JUUL and other vaping devices are adolescent nicotine initiation addiction devices

The largest tobacco company, just bought 1/3 of JUUL's stock

MENTHOL creates a cooling effect, it reduces the harshness of cigarette smoke and suppresses coughing.

These effects make MENTHOL cigarettes and vaping flavors more appealing to young, inexperienced smoker/vaper

What harm does MINT and MENTHOL cause?

1. Easier to start, it anesthetizes the back of the throat to reduce coughing
2. The nicotine does the rest
3. The Menthol users take 20% longer to try to quit
4. African American kids are especially vulnerable through target advertising and 90% of 12-18 year old's start with mentholated cigarettes

Boston and the State are moving towards bans on the sale of all flavored nicotine products including MINT, MENTHOL, and WINTERGREEN to 21+ smoke/vape shops and may enact even further restrictions.

But this won't happen until a majority of community's restrict or ban all flavors including MINT and MENTHOL.

MENTHOL cigarettes are slowing the reductions in overall cigarette smoking rates.

From 2004 to 2014, the decline in cigarette consumption was greater for non-MENTHOL cigarettes than MENTHOL cigarettes.

Youth smokers remain the age group most likely to use MENTHOL cigarettes.

Flavored E-Nicotine Juice with Menthol

Does banning menthol have any effect?

Yes

"I think these papers are highly relevant to the banning of mint and menthol in cities and town. Basically a doubling of adult quit rate after menthol bans—29.1% quit rate."

Dr. Jonathan Winickoff, MD, MPH

Dr. Cynthia Grondin

Mother and Toxicogenetcist

MINT and MENTHOL e-cigarette products, specifically, have been shown to contain the following chemicals: 3-hexen-1-ol, Acetone, acrolein, Alpha-terpineol, Benzaldehyde, Benzoic acid, benzyl acetate, benzyl alcohol, cyclotene, decanaldehyde, et formaldehyde, glycerol, isoamyl acetate, Menthol, Menthone, Methyl acetate, Methyl salicylate, Propylene glycol, and vanillin.

These chemicals interact with over 4,700 unique genes in multiple ways, including changing gene expression, protein activity, and mutating genetic material. This set of chemicals, when used as an input data set in CTD's Set Analyzer tool, yields 840 diseases that are statistically enriched among the genes that interact with these chemicals.

- From CTDBase.org

In my practice of 14,000 kids, notably, when MINT and MENTHOL are exempt and left to be sold in convenience stores, mint-based flavors are among the top two most popular flavors for teens.

Nothing will happen until a majority of communities take action and restrict or ban all flavors including MINT and MENTHOL.

Keep an eye on:

Senate Bill 1279 – Banning All Flavored Tobacco
An Act Regulating Flavored Tobacco Products
Sponsored by: John F. Keenan

Bold Leadership – Internet Regulation

"I think it's important that we update our law to address and try to curb this (vaping) epidemic. I'd like to start by treating these products as we treat other tobacco products. Ban flavors and tax them,"

Attorney General Maura Healey, April 11, 2019

Attorney General Maura Healey was the first state AG to sue JUUL for it's marketing strategy.

Reminder:

- Exposure in convenience store matters!

- Kids visit convenience stores once or twice a week – prospectively the more frequently kids go to convenience stores the more likely they are to use smoke and vaping products.

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Brief report

Evaluating a Real World Ban on Menthol Cigarettes: An Interrupted Time-Series Analysis of Sales

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Abstract

Background: Menthol in cigarettes has been shown to increase regular cigarette smoking and nicotine dependence, and decrease success in smoking cessation. Owing to these reasons, in May 2015, the province of Ontario introduced a menthol ban on tobacco products that came into effect in January 2017 prior to a Federal Canadian Ban in October 2017. The objective of this article was to assess the effect of a provincial menthol ban on cigarette wholesale sales in Ontario.

Methods: Wholesale data submitted by tobacco manufacturers to Health Canada pursuant to the federal *Tobacco Reporting Regulations* from October 2012 to September 2017 were analyzed using interrupted time-series analysis. Changes in sales of cigarettes with and without menthol were estimated, using the province of British Columbia as a comparison. Analyses were seasonally adjusted.

Results: Sales of menthol and nonmenthol cigarettes increased from 2013 until the implementation of the 2017 provincial ban. Subsequently, a sharp decline of 55 million menthol cigarettes and 128 million total cigarettes was observed in Ontario. As a comparison, no significant changes were observed in British Columbia.

Conclusion: This study supports the conclusion that implementation of a menthol ban in Ontario was associated with significant reduction of menthol cigarette sales and total cigarettes sales, compared to British Columbia where there was no provincial menthol ban. This suggests that menthol regulations in jurisdictions with a larger percentage of menthol smokers are likely to be highly effective.

Implications: The 2017 menthol ban was associated with significant reduction of menthol cigarette sales and total cigarette sales suggesting that menthol regulations will have important effects on cigarette consumption.

Background

Menthol in cigarettes has been shown to increase regular cigarette smoking and nicotine dependence, and decrease success in smoking cessation.[1,2] On January 1, 2017, the province of Ontario implemented a ban on all use of menthol in tobacco products.[3] A Canada-wide federal menthol ban was then implemented in October 2017, banning the use of menthol in cigarettes, blunt wraps, and most cigars sold in Canada,.[4] Menthol sales comprised approximately 5% of cigarette sales in Canada in 2015,[5–7] in comparison,

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Table. Expected, Short-term Actual, and Long-term Planned Reactions to the Ban on Menthol in Tobacco, Ontario, Canada

Reaction	No. (%; 95% CI) (n = 206)		
	Expected Reaction Before Ban	Actual Short-term Reaction[a]	Long-term Planned Reaction
Use of nonmenthol cigarettes only[b]	123 (59.7; 52.8-66.2)	51 (28.2; 22.0-35.2)	102 (49.5; 42.7-56.4)
Quit	30 (14.5; 10.3-20.1)	60 (29.1; 23.3-35.8)[c]	35 (17.0; 12.4-22.3)
Use of alternative flavored products (e-cigarettes, cigars, and other flavored tobacco products)	12 (5.8; 3.3-10.2)	60 (29.1; 23.3-35.8)	6 (2.9; 1.3-6.4)
Use of contraband menthol	23 (11.2; 7.5-16.3)	29 (14.1; 10.0-19.6)[d]	34 (16.5; 12.0-22.3)
Adding menthol or other reaction	4 (1.9; 0.7-5.1)	29 (14.1; 10.0-19.6)	NR
Don't know	14 (6.8; 4.1-11.2)	6 (2.9; 1.3-6.4)	29 (14.1; 10.0-19.6)

Abbreviation: NR, not reported.

[a] Column does not total 100% because actual behaviors were not mutually exclusive.

[b] Continued or new users of nonmenthol cigarettes who did not try to quit, use any menthol product, use any other flavored product, or add flavor to nonmenthol cigarettes.

[c] Quit or made serious quit attempt. The number (percentage) not currently smoking by follow-up was 25 (12.1%; 95% CI, 8.3%-17.4%).

[d] Purchasing menthol cigarettes from a First Nations reserve, other province, other country, or online. Does not include stockpiled cigarettes, cigarettes bought from existing stocks that enforcement allowed stores to sell out, or those provided by friends. A total of 72 individuals (35.1%; 95% CI, 28.9%-42.0%) used menthol from all sources in the past month.

smokers in Canada, where menthol cigarettes comprise 5% of cigarette sales[4,5] compared with 30% in the United States[6] and use is not concentrated among black Canadians.[5] The initial results suggest that removing menthol tobacco from the market is a feasible strategy that may influence cessation behavior, although differences between menthol users in Ontario, Canada, and other jurisdictions may affect the potential influence of a ban.

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Concept and design: All authors.
Acquisition, analysis, or interpretation of data: Chaiton, Schwartz, Cohen, Eissenberg.
Drafting of the manuscript: Chaiton.
Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: Chaiton.
Obtained funding: Chaiton, Schwartz, Eissenberg.
Administrative, technical, or material support: Schwartz, Cohen.
Supervision: Chaiton.

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Invited Commentary

Local Movement to Ban Menthol Tobacco Products as a Result of Federal Inaction

The article by Chaiton et al[1] in this issue of *JAMA Internal Medicine* is the first empirical confirmation that banning the sale of menthol tobacco products is good for public health. The investigators surveyed individuals in Ontario, Canada, who smoked menthol cigarettes before and 1 month after the province implemented a full menthol cigarette ban on January 1, 2017. They found that 40% of menthol smokers attempted to quit smoking and 12% succeeded, substantial increases over historical levels and higher than the percentage who predicted that they would try to quit before experienc-

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Medicine, Chicago, Illinois (Levine); Rush University Medical Center, Chicago, Illinois (O'Mahony, Fitchett).

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Author Contributions: Drs Lee and Fitchett had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Lee, McGinness, Fitchett.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Lee, Fitchett.
Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: Lee, Fitchett.
Administrative, technical, or material support: Lee, McGinness, O'Mahony, Levine.
Study supervision: Lee, Fitchett.

Conflict of Interest Disclosures: None reported.

Additional Contributions: This project was conducted while Board-Certified Chaplain Aoife Lee was a fellow in the Coleman Palliative Medicine Training Program, Chicago, Illinois–Cohort 2, 2015 to 2017. Chaplain Lee is grateful for the support of the coauthors.

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HEALTH CARE POLICY AND LAW

Association of Ontario's Ban on Menthol Cigarettes With Smoking Behavior 1 Month After Implementation

The province of Ontario, Canada, implemented a full menthol cigarette ban on January 1, 2017. To date, there has been no population-wide, systematic evaluation of the association of the implementation of a menthol ban with smoker behavior. Assessments of perceived behavioral responses to hypothetical menthol flavor bans are useful[1]; however, there is no guarantee that individuals will follow through with their planned behaviors. This study compares respondents' planned behavior before the ban with actual behavior 1 month after the ban.

Methods | Eligible participants were residents of Ontario 16 years or older who had smoked at least 1 menthol cigarette in the past year and were past-month smokers. A total of 325 participants were recruited using random-digit dialing of residential telephone numbers from September 12 through December 31, 2016. Participation rate for the random-digit dialing was 44.1%, with a 6.7% refusal rate among known eligible participants, consistent with an established provincial health monitoring survey. Participants were contacted for follow-up beginning 1 month (February 1, 2017) after the implementation of the ban (January 1, 2017) through an online survey (206 recontacted [63.4%]). Those who were unavailable for follow-up did not differ by level of menthol smoking, age, sex, income, educational level, or smoking characteristics. Planned reaction to the ban, actual behavior at 1 month after the ban, and planned future reaction beyond 1 month after the ban were compared. Oral consent was obtained from all participants, and the analytic data set was deidentified. This study was approved by the research ethics board of the University of Toronto, Toronto, Ontario, Canada.

Results | A total of 325 participants participated in the study (181 [55.7%] male; 143 [44.0%] female; mean [SD] age, 47.1 [0.9] years). Before the ban, most menthol smokers (123 [59.7%]) said that they would switch to or only use nonmenthol cigarettes, but only 51 (28.2%) had done so at follow-up (**Table**). In contrast, a larger proportion (60 [29.1%]) attempted to quit compared with only 30 (14.5%) who said they would do so. Similarly, a larger proportion (60 [29.1%]) reported using other flavored tobacco or e-cigarette products (menthol was not banned in e-cigarette products) compared with their preban plans (12 [5.8%]). After the ban, participants were less likely to anticipate using other flavored products. Of those who made a quit attempt, 16 (80.0%; 95% CI, 56.3%-92.5%) of those who primarily smoked menthol cigarettes at baseline suggested that the ban affected their decision to quit at least a little compared with 10 (25.6%; (95% CI, 14.1%-41.0%) of those who smoked menthol cigarettes only occasionally. Before the ban, 1 individual (0.3%) suggested trying to switch to marijuana and 4 (1.2%) suggested adding menthol to cigarettes separately using flavor cards, oils, or papers as substitutes for the lack of menthol, but none reported planning to use these substitutes in the future.

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Discussion | This study is, to our knowledge, the first evaluation of the immediate association of a menthol cigarette ban with behavior change. Actual behaviors contrast sharply with planned behaviors. Although a substantial decrease in menthol cigarette use was observed, there was a considerable increase in use of flavored e-cigarettes and cigars. Furthermore, 29.1% of menthol smokers attempted to quit smoking shortly after ban implementation. Because previous studies[2,3] have found an expected rate of 0.5 quit attempts and a 7.7% abstinence rate during a 6-month period in this population, this finding suggests that the ban substantially increased quit attempts. Few smokers used aftermarket additive flavorings, and there was no increase in the use of contraband tobacco. Limitations of this study include the unique demographics of menthol cigarette

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Hypoglycemia in Hospice Patients With Type 2 Diabetes in a National Sample of Nursing Homes

Approximately one-quarter of the US population die in nursing homes,[1] where end-of-life care is of variable quality.[2] In particular, it is unknown whether patients with chronic illness, such as diabetes, continue to receive burdensome testing and treatment after transitioning to hospice care in nursing homes. Experts and the American Diabetes Association recommend relaxing glycemic control target levels for patients with diabetes and advanced disease and eventual discontinuation of medications as patients near death to avoid hypoglycemia.[3,4] Hypoglycemia causes symptoms of weakness, diaphoresis, confusion, shakiness, and dizziness,[5] and is a potentially preventable cause of suffering among hospice patients. Whether nursing home patients with type 2 diabetes on hospice are assessed for dysglycemia, receive insulin or oral hypoglycemic medications, or experience hypoglycemia and hyperglycemia has not previously been described.

Methods | We conducted a retrospective cohort study of patients older than 65 years with type 2 diabetes admitted to Veterans Affairs (VA) nursing homes between January 1, 2006, and June 30, 2015, using linked laboratory, pharmacy, and administrative data. We identified patients with type 2 diabetes by *International Classification of Diseases, Ninth Revision* (*ICD-9*) code or glycated hemoglobin values greater than 6.5%. We excluded patients with type 1 diabetes by *ICD-9* code. For patients with multiple admissions during the study period, we chose the last admission. We used descriptive statistics to analyze demographic variables, comorbidities, and diabetes management (laboratory testing and drug administration), and stratified the cohort by whether patients received insulin while on hospice. We analyzed the cumulative incidence of hypoglycemia (glucose <70 mg/dL [to convert to mmol/L, multiply by 0.0555]), severe hypoglycemia (glucose <50 mg/dL), hyperglycemia (glucose ≥400 mg/dL), and the competing risk of death among all hospice patients and among patients treated with insulin vs patients not treated with insulin. This study was reviewed and approved by the University of California, San Francisco Committee on Human Research.

Results | The study cohort included 20 329 hospice patients (**Table**), 98% of whom were men (n = 19 991). Hospice patients had an 83% 100-day mortality rate (n = 16 791 deaths), and a median length of stay of 10 days. Eight percent of patients in the cohort received insulin (n = 1687). Among patients treated with insulin, mean baseline glycated hemoglobin levels were higher than patients not treated with insulin (7.4% vs 6.8%; $P < .001$), and the mortality rate at 100 days was lower (61% vs 85%; $P < .001$). Patients treated with insulin had more frequent glucose tests (mean 1.7 glucose tests/d, vs 0.6 glucose tests/d among patients not treated with insulin; $P < .001$). The cumulative incidence of hypoglycemia (glucose <70 mg/dL) among all patients, accounting for the competing risk of death, was 12% at 180 days, and that of severe hypoglycemia (glucose <50 mg/dL) was 5% (**Figure**). Among patients treated with insulin, 38% experienced hypoglycemia and 18% experienced severe hypoglycemia at 180 days. The highest risk of hypoglycemia occurred in the first 20 days of admission. The cumulative incidence of hyperglycemia (glucose >400 mg/dL) at 180 days was 9% in all patients, higher in the group treated with insulin (35%).

Discussion | Despite guidelines that stress avoiding hypoglycemia in hospice patients with diabetes,[4] we found that 1 in 9 nursing home patients with type 2 diabetes experienced hypoglycemia (glucose <70 mg/dL) while 1 in 20 experienced severe hypoglycemia (glucose <50 mg/dL) while on hospice. The risk of hypoglycemia was highest among patients treated with insulin, one-third of whom experienced hypoglycemia. Patients treated with insulin lived longer and experienced more hyperglycemia than patients not treated with insulin, which suggests that clinicians may be choosing to continue insulin for those hospice patients with a longer life expectancy and more severe diabetes at hospice admission. Nevertheless, hypoglycemia is not consistent with a goal of comfort, and these data demonstrate suboptimal avoidance of dysglycemia

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ing the ban. In addition, they found that a larger proportion (29%) reported using other flavored tobacco or e-cigarette products (menthol was not banned in e-cigarette products) compared with preban self-predictions (6%).

Menthol is a particularly important additive to cigarettes because, in addition to being a flavor, it is a local anesthetic that makes it easier to inhale tobacco smoke and modulates the effects of nicotine in a way that allows tobacco companies to tune nicotine and menthol delivery to maximize nicotine's addictive effect.[2] The 2009 Family Smoking Prevention and Tobacco Control Act, which gave the US Food and Drug Administration (FDA) authority to regulate tobacco products, included a provision that prohibited the use of characterizing flavors, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, but notably not menthol, in cigarettes. It is easy to understand why the tobacco industry fought so hard[3] to successfully exclude menthol from the flavor ban. Menthol cigarettes are a starter product for youths,[4] comprise 30% of cigarette sales,[5] and are the dominant product smoked by African American individuals. Tobacco companies threatened to block the bill if menthol was prohibited.[3]

The US Congress compromised by directing the FDA to have its new Tobacco Products Scientific Advisory Committee complete a report on "the impact of the use of menthol in cigarettes on the public health, including such use among African Americans, Hispanics, and other racial and ethnic minorities"[6] within a year to inform future regulation. The Tobacco Products Scientific Advisory Committee completed the report within a year, concluding in July 2011 that "the removal of menthol products from the marketplace would be beneficial to the public's health."[7]

Despite menthol cigarettes representing 5% of cigarette sales in Canada compared with 30% in the United States, the results of the study by Chaiton et al[1] have 2 important implications for the United States and the rest of the world. First, as predicted, eliminating menthol is good for public health because it leads to an increase in quitting. Second, it is important that flavor bans be comprehensive, including all tobacco products (such as e-cigarettes) and all flavors. There are also likely to be additional public health benefits because elimination of menthol and flavors will make cigarettes and other tobacco products less attractive and less easy to smoke for youths.

In 2016, the FDA tried to limit the use of menthol and other flavors in e-cigarettes and other noncigarette tobacco products but was blocked by the Obama Administration.[8] As of January 12, 2018, the FDA had not regulated menthol in cigarettes or any other tobacco product.

This failure at the federal level has spawned local action to stop the sales of menthol tobacco products. After community outreach by health advocates, town hall meetings, and work with clergy, aldermen, and women to argue that menthol products were being disproportionately marketed to black youths, in December 2013, the Chicago City Council passed the first menthol restrictions, forbidding the sale of menthol and all flavored products within 500 ft of Chicago public schools. In June 2017, the city and county of San Francisco prohibited the sale of all flavored tobacco products, including menthol.[9]

This move was too much for the tobacco industry. Shortly after Mayor Ed Lee signed the new law in San Francisco, with $700 000 from tobacco giant RJ Reynolds, a group of self-proclaimed concerned citizens and local grocers announced that they were going to force a referendum on the new law to oppose government overreach and to protect freedom of choice.[10] Their Let's Be Real San Francisco collected enough signatures to force a popular vote on the ordinance on the June 2018 ballot.

Far from a group of concerned citizens, Let's Be Real is led by a tobacco industry executive and attorneys from a law firm with longstanding ties to the industry. According to official filings, the principal officer of the committee is David Spross, not of San Francisco but of Winston-Salem, North Carolina. Spross is vice president of state government relations at tobacco company RJ Reynolds. Attorneys from the well-connected law film Nielsen Merksamer (which represents RJ Reynolds and Altria) are serving as treasurer and assistant treasurer, respectively, of the campaign.

This situation is a replay of the industry's 1983 referendum campaign to overturn San Francisco's then-new law that limits smoking in the workplace and public places. (Nielsen Merksamer worked on that one, too.) Despite being outspent more than 10 to 1, health advocates successfully defended the ordinance, which subsequently encouraged states and communities around the world to create smoke-free environments.

What about the FDA? They are still thinking about what to do, which means that meaningful action on menthol and flavors is years away, if ever.

In the meantime, as with clean indoor air and tobacco tax policy, the action will occur at the local and state levels. On the basis of the 1983 experience, a win in San Francisco could substantially accelerate the movement to end the sale of menthol and flavored tobacco products, making the FDA increasingly irrelevant.

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truth initiative
INSPIRING TOBACCO-FREE LIVES

MENTHOL

Menthol makes cigarettes easier to smoke and harder to quit.

Current law prohibits the use of flavors in cigarettes, except for menthol.

Percentage of students who smoke and use menthol cigarettes:

54.5% high school

48.4% middle school

Nearly 9 in 10 African-American smokers aged 12 and older use menthol cigarettes.

Nearly 65% of young menthol smokers say they would quit if menthol cigarettes were banned.

If a menthol cigarette ban had been enacted in 2011, it could have saved 320,000 lives by 2050.

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Jonathan P. Winickoff, M.D., M.P.H.

Professor of Pediatrics

To the Town Meeting Members of the Town of Brookline,

RE: Warrant Article 19.

I live at 16 Stetson Street and have three kids in the Brookline schools (two teenagers at BHS and a 5th grader at CCS). I am also a pediatrician at Massachusetts General Hospital for Children in the Pediatric Group Practice and Professor of Pediatrics at Harvard Medical School. I'm honored to care for many Brookline kids in my practice. My expertise and training includes neurobiology, statistics, behavioral theory, and tobacco control. My academic credentials in tobacco are summarized in a footnote at the end of this letter. I write in support of Warrant Article 19 which would have a profound benefit for the health of our children and fellow residents.

All major health groups including the American Heart Association, American Cancer Society, American Lung Association, American Academy of Pediatrics and The Tobacco Free Mass Coalition support banning flavored tobacco including mint and menthol.

Eliminating sales of flavored tobacco is a necessary move at this critical time given the 78% rise of adolescent electronic cigarette use in the past year and the reversal of decades of progress in tobacco control. Every day in my clinical practice, I have patients who I've known for years coming in with nicotine addiction due to JUUL and other flavored e-cigarettes. We were down to single digits of tobacco use in my patients. **Now every teenager I treat is either using JUUL or has friends who currently use**. The number one flavor kids use in Brookline is mint. Although 20% of high school students are current users of e-cigarettes (*YRBSS 2018 survey data*), the rate in higher socio-economic towns tends to be higher because the kids have more money to spend on their pods. **Kids who use electronic cigarettes are over three times more likely to use combusted tobacco. For the first time in recent years, the combusted tobacco use rate is increasing in adolescents.** Those who graduate to combusted tobacco often use mint and menthol products because it acts as an anesthetic, allowing the toxins to be inhaled more deeply so that kids can overcome their natural aversion to tobacco smoke.

Flavored cigarettes were banned by the Federal Government in 2009. **The tobacco industry was able to exempt menthol flavoring and non-cigarette tobacco products through intense lobbying efforts.** Menthol products have directly targeted African-American/black population through advertisements. **Warrant article 19 closes this loophole.** The tobacco industry needs menthol and mint in their products to get the next generation hooked on tobacco. That is why they are fighting so hard against it. **Over half of adolescent smokers 12-17 years of age use menthol cigarettes (references 1-3)**. Menthol is extremely dangerous given its ability to invoke a deep inhalation and increase addiction (4-10). Nearly 95% of tobacco product users start before the age of 21. **Over 85% of user say that flavors are the reason they started using tobacco products. The use of e-cigarettes can cause anxiety, depression, mood disorders, asthma, impacts brain development, may cause cancer, and can alter the reward pathways of the brain to potentiate addiction to combusted tobacco and other drugs. (National Academy of Sciences, Surgeon General Report**

on E-cig, and NEJM)

Based on the Youth Risk Behavior Surveillance System Data, and Brookline's socio-economic profile, I estimate that approximately 100 Brookline kids per year become regular users of tobacco products, the majority initiating with flavored e-cigarette products. Among adolescents who used e-cigarettes daily at some time in the past, 97% will still be using currently. Shut down the flavors and we protect a large proportion of these kids. Nothing works 100% but each measure Brookline Town Meeting takes can be a piece of the solution. As we saw with raising the tobacco sales age to 21, kids are most sensitive to what is advertised and for sale in local retail stores. One town's actions can have a big effect on tobacco use even when other surrounding neighbors take more time to act. When Needham became the first town to raise the age to 21, they saw a 47% reduction in teen tobacco use in their high school. Kids who are not addicted will typically not travel to purchase product—most don't even drive. Studies now show that over 60% of kids get their flavored tobacco products from retail stores or from older friends who get them from retail stores. **The MA DPH has run compliance checks for Brookline over the past 4 years and our compliance rates are worse than the state average. It only takes a single store selling to an adolescent to supply product for an entire high school.**

In Massachusetts the rate of adolescent use of eCigarettes is nine times higher than adults. However, among never smokers, the rates is over 15 times that of adults. (*NYTS and BRFSS 2018*) If it sounds like the kids are the targets for JUUL and other flavored tobacco, its because they are. **Adults who are trying to quit tobacco have many evidence-based options for quitting tobacco use. FDA approved nicotine replacement gum and patch quadruple the chances of cessation.** (*treating tobacco use and dependence guideline 2008*) **A recent NEJM article demonstrated that when adults try to quit smoking using e-cigarettes, 19% quit successfully but 80% of those who quit remain addicted to electronic cigarettes a year later.** In that same study 10% of smokers quit using approved nicotine replacement medicine, but only 10% of them were still using the approved nicotine product one year later. **FDA approved nicotine patch and gum was 2.5 times more effective than e-cigs at helping smokers get off all nicotine and tobacco products.** The electronic cigarette is a dream come true for the tobacco industry because they are so addictive. Partly because of the perpetuation of addiction and partly because of the unsafe nature of the products, the FDA has not approved e-cigarettes as a cessation device. **As part of this Warrant article, adults who may want to try e-cigs as a last resort to get off of traditional cigarettes would still be able to buy tobacco flavored e-cigarettes. There is no evidence that tobacco flavor e-cigarettes wouldn't work for adults trying to get off combusted tobacco cigarettes—after all, smokers are already used to smoking tobacco.** Luckily, kids who have never smoked tobacco find tobacco flavor repulsive. **Warrant article 19 does not ban e-cigarettes, it restricts them and all other tobacco products so that they cannot have the mint, menthol, and other flavors that appeal to kids.**

Historically, the tobacco industry added mint and menthol flavor to help get Black smoking rates higher in the 1960's because they lagged behind the White smoking rate. In a nationally representative study, the majority of Whites want mint and menthol banned from tobacco products. **However, an even larger majority of Blacks want mint and menthol banned than Whites**. (AM J Prev Med)

Warrant article 19 as written has precedent and would have the support of our town counsel and the not-for-profit *Public Health Law Institute* at Northeastern. My interest in Warrant article 19 is strictly as a volunteer with only the interests of public health and children at heart. I hope that this letter will help set the record straight on the benefits to our town of Warrant article 19.

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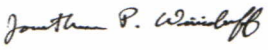
Sincerely,



Jonathan P. Winickoff MD, MPH

Academic Credentials: In addition to over 100 peer-reviewed original research publications in tobacco, I've drafted tobacco control policy and served as a scientific advisor for the CDC Communities Putting Prevention to Work, Massachusetts Tobacco Control Program, Indiana Tobacco Control Program, Head Start, WIC, the Food and Drug Administration, Department of Housing and Urban Development, the National Academy of Medicine, and the U.S. Surgeon General through the Interagency Committee on Smoking and Health. I've received numerous awards including the HHS Secretary's Award for Distinguished Service for "protecting the health of the United States public," and the 2011 Academic Pediatric Association Health Policy Award for cumulative public policy and advocacy efforts that have improved the health and well-being of infants, children, and adolescents. I participated in research that helped support the creation of smokefree public housing in the city Boston, the state of Maine, and facilitated HUD's successful national effort to make all public housing buildings smokefree in 2018. Recently, in four research papers, I studied raising the tobacco sales age to 21 and co-founded a volunteer campaign to help communities raise the age to 21. As of April 2019, over 450 communities as well as NYC, Kansas City, Cleveland, and the states of Hawaii, California, Massachusetts, Oregon, New Jersey, Maine, Virginia, Washington, Illinois, Utah, and Arkansas have raised their age of sale to 21—covering over 40% of the United States population. Currently, I've been researching electronic nicotine delivery systems and volunteering with the Massachusetts Attorney General's Office and others across the country to combat the epidemic of JUULing and eCig use in youth.

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BMC Public Health

RESEARCH ARTICLE Open Access

Menthol cigarettes and the public health standard: a systematic review

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Abstract

Background: Although menthol was not banned under the Tobacco Control Act, the law made it clear that this did not prevent the Food and Drug Administration from issuing a product standard to ban menthol to protect public health. The purpose of this review was to update the evidence synthesis regarding the role of menthol in initiation, dependence and cessation.

Methods: A systematic review of the peer-reviewed literature on menthol cigarettes via a PubMed search through May 9, 2017. The National Cancer Institute's Bibliography of Literature on Menthol and Tobacco and the FDA's 2011 report and 2013 addendum were reviewed for additional publications. Included articles addressing initiation, dependence, and cessation were synthesized based on study design and quality, consistency of evidence across populations and over time, coherence of findings across studies, and plausibility of the findings.

Results: Eighty-two studies on menthol cigarette initiation ($n = 46$), dependence ($n = 14$), and cessation ($n = 34$) were included. Large, representative studies show an association between menthol and youth smoking that is consistent in magnitude and direction. One longitudinal and eight cross-sectional studies demonstrate that menthol smokers report increased nicotine dependence compared to non-menthol smokers. Ten studies support the temporal relationship between menthol and reduced smoking cessation, as they measure cessation success at follow-up.

Conclusions: The strength and consistency of the associations in these studies support that the removal of menthol from cigarettes is likely to reduce youth smoking initiation, improve smoking cessation outcomes in adult smokers, and in turn, benefit public health.

Keywords: Cessation, Dependence, Policy, Youth tobacco use, Public health

Background

Menthol has been added to tobacco products as a characterizing flavor since at least the 1920s, but many of the current menthol brands were introduced in the mid-1950s [1, 2]. In 2013, the most recent year of data from the Federal Trade Commission, menthol cigarettes represented 30% of the cigarette market [3]. Tobacco companies have also noted that the menthol segment of the market continues to grow [4], including Reynolds American and Philip Morris USA who have continued to expand their distribution of menthol cigarettes in the past year [5].

The Tobacco Control Act banned all candy and fruit flavors as characterizing flavors of cigarettes. The law did not include menthol in that ban, nor did it address flavors in non-cigarette tobacco products [6]. However, the Act makes clear that the Food and Drug Administration (FDA) has the authority to issue a product standard to ban menthol in cigarettes, or any other tobacco product, to protect public health. In fact, the Act required the Tobacco Product Scientific Advisory Committee (TPSAC), as its first order of business, to review the state of the science on menthol and make a recommendation to the FDA based on the public health standard [7]. TPSAC undertook a review of the science and issued a comprehensive report concluding that it would be in

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Brief report

Evaluating a Real World Ban on Menthol Cigarettes: An Interrupted Time-Series Analysis of Sales

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Abstract

Background: Menthol in cigarettes has been shown to increase regular cigarette smoking and nicotine dependence, and decrease success in smoking cessation. Owing to these reasons, in May 2015, the province of Ontario introduced a menthol ban on tobacco products that came into effect in January 2017 prior to a Federal Canadian Ban in October 2017. The objective of this article was to assess the effect of a provincial menthol ban on cigarette wholesale sales in Ontario.

Methods: Wholesale data submitted by tobacco manufacturers to Health Canada pursuant to the federal *Tobacco Reporting Regulations* from October 2012 to September 2017 were analyzed using interrupted time-series analysis. Changes in sales of cigarettes with and without menthol were estimated, using the province of British Columbia as a comparison. Analyses were seasonally adjusted.

Results: Sales of menthol and nonmenthol cigarettes increased from 2013 until the implementation of the 2017 provincial ban. Subsequently, a sharp decline of 55 million menthol cigarettes and 128 million total cigarettes was observed in Ontario. As a comparison, no significant changes were observed in British Columbia.

Conclusion: This study supports the conclusion that implementation of a menthol ban in Ontario was associated with significant reduction of menthol cigarette sales and total cigarettes sales, compared to British Columbia where there was no provincial menthol ban. This suggests that menthol regulations in jurisdictions with a larger percentage of menthol smokers are likely to be highly effective.

Implications: The 2017 menthol ban was associated with significant reduction of menthol cigarette sales and total cigarette sales suggesting that menthol regulations will have important effects on cigarette consumption.

Background

Menthol in cigarettes has been shown to increase regular cigarette smoking and nicotine dependence, and decrease success in smoking cessation.[1,2] On January 1, 2017, the province of Ontario implemented a ban on all use of menthol in tobacco products.[3] A Canada-wide federal menthol ban was then implemented in October 2017, banning the use of menthol in cigarettes, blunt wraps, and most cigars sold in Canada,.[4] Menthol sales comprised approximately 5% of cigarette sales in Canada in 2015,[5–7] in comparison,

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menthol sales are estimated to be about 25% of tobacco products[8] and 30% of the cigarette market in the United States.[1,9]

In the United States, the US Food and Drug Administration is currently assessing the potential benefits of regulating menthol in cigarettes, and their advisory committee concluded that the "removal of menthol cigarettes from the marketplace would benefit public health."[1,9] Other countries, including Brazil, Ethiopia, Turkey, and the European Union, have introduced menthol cigarette bans and restrictions along with partial bans in the city of Chicago, San Francisco, and potentially New Jersey among other juridictions.[10–12]

There are very little data looking at the effectiveness of menthol bans.[13] Therefore, to investigate the impact of the 2017 menthol ban in Ontario, this study uses wholesale sales data to examine trends in menthol sales in Ontario and uses the province of British Columbia, which did not implement menthol legislation, as a comparator during the period of October 2012 to September 2017. British Columbia (2016 population of 4.6 million) is the province with the lowest smoking prevalence in Canada (10.2% in 2015 compared to 11.3% in Canada for ages ≥15 years) but shares some similar demographic characteristics with Ontario (2016 population of 14.0 million) such as high immigrant population and a robust economy and have a similar age distribution in the 16–65 years age range.[14]

Methods

Data Source

The data used for this study are from wholesale sales data that are reported to Health Canada. Manufacturers are required to report by province, each brand of tobacco product, the number of units sold, package sizes, as well as the value of the units sold pursuant to the *Tobacco Reporting Regulations* (SOR/2000–273). Cigarette sales are reported on a monthly basis and returns to companies from wholesalers and retailers are reported as negative values. All data are subject to future review as a result of resubmissions by companies and audits by Health Canada.

Statistical Analysis

Sales data were merged into a master database using Stata, version 14. For each month, net unit sales by product type (menthol, nonmenthol, and all cigarettes) in Ontario and British Columbia were calculated for the period October 1, 2012, to September 30, 2017—a total of 80 monthly periods. To provide comparability between the provinces, the wholesale sales were centered at baseline in October 2012 and divided by 1 000 000. Starting values in October 2012 were 300 million nonmenthol and 17 million menthol cigarettes sold per month in British Columbia, and 1 billion nonmenthol cigarettes and 44 million menthol cigarettes sold per month in Ontario.

This study uses an interrupted time-series design to assess the 2017 regulations using aggregate monthly sales using the program ITSA.[15,16]

The basic model was

$$Y_t = \beta_0 + \beta_1 T_t + \beta_2 X_t + \beta_3 X_t T_t + \beta_4 Z + \beta_5 Z T_t + \beta_6 Z X_t + \beta_7 Z X_t T_t + \varepsilon_t$$

where t is the time since October 2012, X_t is an indicator variable representing the intervention, β_0 represents the starting level of cigarette sales in British Columbia, $\beta_1 T_t$ is the slope or trajectory of sales until the introduction of regulations in British Columbia, $\beta_2 X_t$ represents the change in the level of sales that occurs in the month immediately following the regulations (compared to the counterfactual without regulations) in British Columbia, and $\beta_3 X_t T_t$ represents the difference between the pre- and post-intervention slopes or trajectories in British Columbia. Z is an indicator for Ontario, so that $\beta_4 Z$ and $\beta_5 Z T_t$ represent the difference in level and trend between Ontario and British Columbia at baseline, and $\beta_6 Z X_t$ and $\beta_7 Z X_t T_t$ represent the differences in Ontario post-intervention. The magnitude and confidence intervals of β_6 estimate the immediate association of the regulation in Ontario, and β_7 for the treatment effect over time. Dummy variables representing each month were added to control for seasonality. Newey–West robust standard errors were used to control for autocorrelation.

Results

Figure 1 displays trends in unit sales of menthol, nonmenthol, and all cigarettes in Ontario, and in British Columbia for comparison. Data are displayed as raw unit sales for each month from 2012 to 2017. Sales of menthol cigarettes increased from 2013 until the implementation of the 2017 provincial ban with sharp increases in sales over the period of 2016. Sales of menthol cigarettes (decline of 15%; $\beta = -17.9$; 95% CI = −35.2 to 71.0); nonmenthol cigarettes (increase of 1%; $\beta = 7.5$; 95% CI = −49.8 to 64.7); and overall sales (1% decline; $\beta = -17.9$; 95% CI = −35.2 to 71.0) are consistent with the absence of an intervention in the control province British Columbia.

In contrast, a sudden decline was observed in menthol sales in Ontario with the model attributing a decline of 55.0 million cigarettes (95% CI: = −78.5 to −31.5) (see Table 1) as sales of menthol cigarettes fell to approximately 0 after the ban. The model-based estimate suggests a nonsignificant decline of 4% of nonmenthol sales associated with the implementation of the ban in Ontario ($\beta = -72.8$; 95% CI = −155.6 to 10.0); Figure 1 and Table 1). Overall, sales of all cigarettes fell by 127.8 million cigarettes (95% CI = −208.2 to −47.4) or 11% of all sales. However, there was a significant increase in the sales of all cigarette and nonmenthol cigarettes in Ontario after the ban, suggesting a slight rebound effect.

Discussion

This study supports the conclusion that implementation of a ban restricting the sale of menthol cigarettes in Ontario was associated with significant reduction of menthol cigarette sales and total cigarettes sales, using British Columbia as a comparator. As expected, the ban was successful at eliminating legal sales of menthol cigarettes; furthermore, the ban was associated with an overall change on sales of cigarettes in Ontario. This change was consistent with the levels of sales of menthol cigarettes prior to the ban but may have also affected smokers who did not use menthol or used menthol rarely.

The increase in sales of menthol prior to the ban may have been due to the introduction of cigarettes brands that contained a novel menthol breakable "capsule."[17] These products were advertised in at least one instance to be used to help smokers transition from menthol to regular cigarettes. These results are consistent with Chaiton et al.[13] which show that 29% of menthol smokers made quit attempts in Ontario after the ban. The observed decrease in menthol cigarette sales after the ban and the evidence of some rebound effect is consistent with high levels of quitting behavior followed by some level of relapse.

Other aspects of the model support the hypothesis that the menthol cigarette ban affected cigarette sales. The lack of a significant

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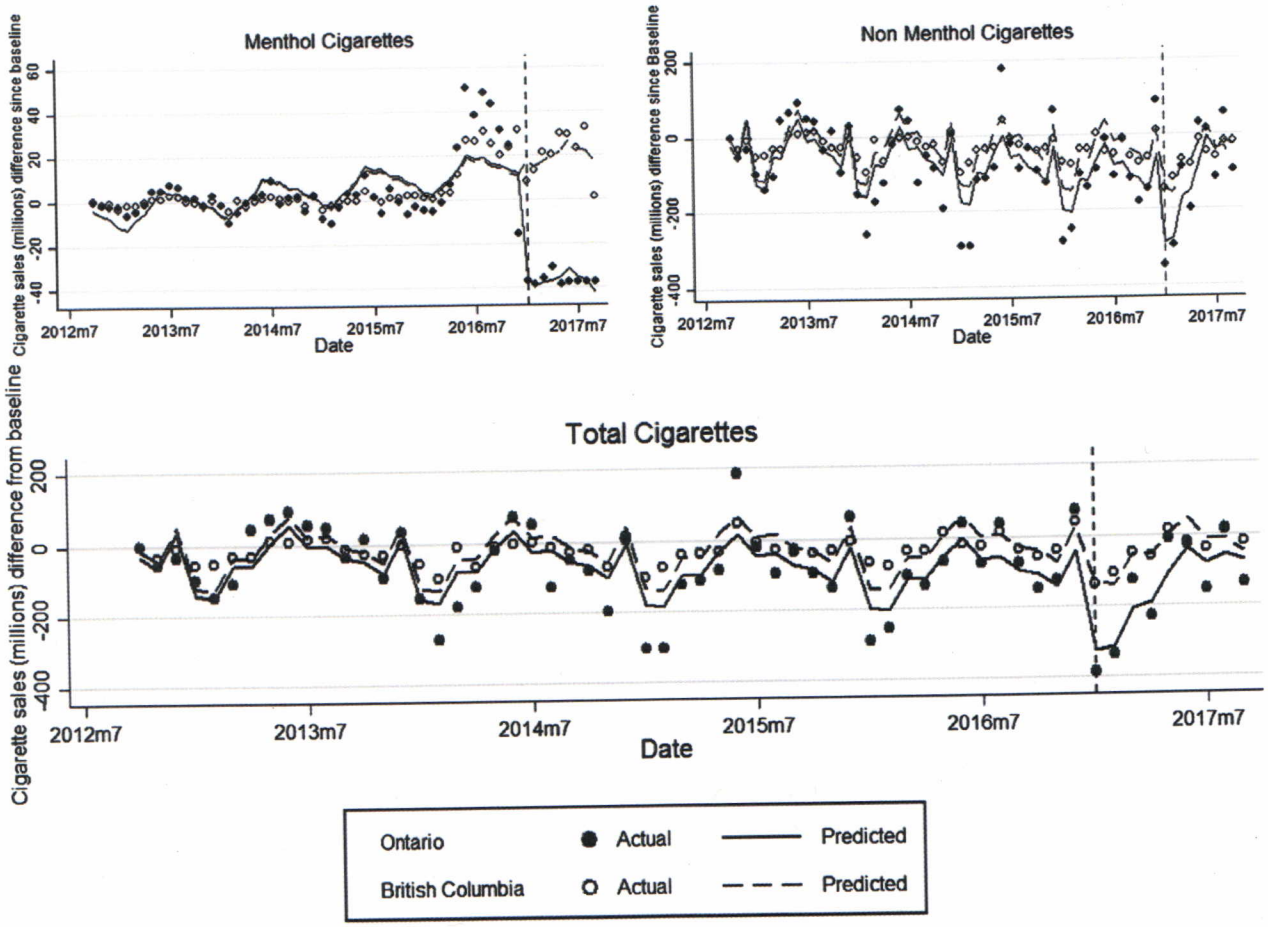

Figure 1. Menthol, nonmenthol, and cigarette sales in net wholesale per quarter Ontario and British Columbia, October 2012 to October 2017 with model predicted sales. Intervention date is January 1, 2017. All analyses control for seasonality by month. Sales are wholesales sales difference from wholesale sales in October 2012. Sales levels centered on October 2012 baseline.

Table 1. Interrupted Time-Series Regression Results for the 2017 Menthol Ban in Canada. Outcome Wholesale Sales of Cigarettes (Millions of Units) per Month, Total and by Brands With or Without Menthol Descriptors. Sales Levels Centered on October 2012 Baseline. $N = 160$

	All cigarettes β (95% CI)	Nonmenthol cigarettes β (95% CI)	Menthol cigarettes β (95% CI)
BC initial level (2012 October) β_0	−32 (−65.7 to 1.8)	−24.6 (−57.3 to 8.0)	−7.9 (−15.9 to 0.1)
BC pre Intervention trend $\beta_1 T_t$	−0.5 (−1.3 to 0.3)	−0.9* (−1.7 to −0.1)	0.4* (0.1 to 0.7)
ON difference in baseline level vs. BC	−15.9 (−63.8 to 31.9)	−14.6 (−58.8 to 29.6)	−0.1 (−11.2 to 10.9)
ON difference in baseline trend vs. BC	−1.0 (−2.5 to 0.4)	−1.1 (−2.5 to 0.3)	0 (−0.5 to 0.6)
BC post-intervention level change $\beta_2 X_t$	17.9 (−35.2 to 71.0)	7.5 (−49.8 to 64.7)	10.5 (−4.4 to 25.3)
BC post-intervention change in trend $\beta_3 X_t T_t$	−4.3 (−14.0 to 5.3)	−2.8 (−13.1 to 7.5)	−1.6 (−4.0 to 0.8)
ON difference in post-intervention level vs. BC	−127.8** (−208.2 to −47.4)	−72.8 (−155.6 to 10.0)	−55.0*** (−78.5 to −31.5)
ON difference in post-intervention change in trend vs. BC	23.0*** (10.3 to 35.6)	23.8*** (10.2 to 37.4)	−0.8 (−2.9 to 1.3)

BC = British Columbia, ON = Ontario. Implementation date of regulation: January 1, 2017. All analyses control for seasonality by month.
$^*p < .05$, $^{**}p < .01$, $^{***}p < 0.001$.

effect, among nonmenthol cigarettes post-intervention suggests that the impact was menthol specific. There was also no effect on level or trend post-intervention in British Columbia suggesting that the effect was Ontario-specific. Similarity in baseline trends between Ontario and British Columbia suggests comparability between the two provinces.

Contraband sales are not included in these figures. Estimates suggest that approximately 11.5% of Canadians had purchased tax-evaded cigarettes.[14] Smoking behavior studies suggest that the smokers who were purchasing menthol cigarettes from contraband sources after the implementation of the ban had been previously purchasing from these sources.[13] A tax increase in Ontario

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effective April 28, 2017, may have influenced tobacco use during the period of the study. Furthermore, a temporary decline may be due to retailers and smokers stockpiling menthol cigarettes in advance of the ban. In addition, a limitation of this study is that the menthol smoking population in Canada differs from that in the United States as menthol smoking is much less prevalent than in the United States, most menthol smokers in Canada are white, and that most smokers who use menthol do so only occasionally rather than using menthol as their primary brand.[7] Because of the greater percentage of menthol cigarette use in the United States, it is expected that a ban would have a greater effect.

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Declarations of Interests

RN and GT are employed by Health Canada who is responsible for the administration of the menthol cigarette regulations.

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Study concept and design: Lee, McGinness, Fitchett.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Lee, Fitchett.
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Statistical analysis: Lee, Fitchett.
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HEALTH CARE POLICY AND LAW

Association of Ontario's Ban on Menthol Cigarettes With Smoking Behavior 1 Month After Implementation

The province of Ontario, Canada, implemented a full menthol cigarette ban on January 1, 2017. To date, there has been no population-wide, systematic evaluation of the association of the implementation of a menthol ban with smoker behavior. Assessments of perceived behavioral responses to hypothetical menthol flavor bans are useful[1]; however, there is no guarantee that individuals will follow through with their planned behaviors. This study compares respondents' planned behavior before the ban with actual behavior 1 month after the ban.

Methods | Eligible participants were residents of Ontario 16 years or older who had smoked at least 1 menthol cigarette in the past year and were past-month smokers. A total of 325 participants were recruited using random-digit dialing of residential telephone numbers from September 12 through December 31, 2016. Participation rate for the random-digit dialing was 44.1%, with a 6.7% refusal rate among known eligible participants, consistent with an established provincial health monitoring survey. Participants were contacted for follow-up beginning 1 month (February 1, 2017) after the implementation of the ban (January 1, 2017) through an online survey (206 recontacted [63.4%]). Those who were unavailable for follow-up did not differ by level of menthol smoking, age, sex, income, educational level, or smoking characteristics. Planned reaction to the ban, actual behavior at 1 month after the ban, and planned future reaction beyond 1 month after the ban were compared. Oral consent was obtained from all participants, and the analytic data set was deidentified. This study was approved by the research ethics board of the University of Toronto, Toronto, Ontario, Canada.

Results | A total of 325 participants participated in the study (181 [55.7%] male; 143 [44.0%] female; mean [SD] age, 47.1 [0.9] years). Before the ban, most menthol smokers (123 [59.7%]) said that they would switch to or only use nonmenthol cigarettes, but only 51 (28.2%) had done so at follow-up (**Table**). In contrast, a larger proportion (60 [29.1%]) attempted to quit compared with only 30 (14.5%) who said they would do so. Similarly, a larger proportion (60 [29.1%]) reported using other flavored tobacco or e-cigarette products (menthol was not banned in e-cigarette products) compared with their preban plans (12 [5.8%]). After the ban, participants were less likely to anticipate using other flavored products. Of those who made a quit attempt, 16 (80.0%; 95% CI, 56.3%-92.5%) of those who primarily smoked menthol cigarettes at baseline suggested that the ban affected their decision to quit at least a little compared with 10 (25.6%; (95% CI, 14.1%-41.0%) of those who smoked menthol cigarettes only occasionally. Before the ban, 1 individual (0.3%) suggested trying to switch to marijuana and 4 (1.2%) suggested adding menthol to cigarettes separately using flavor cards, oils, or papers as substitutes for the lack of menthol, but none reported planning to use these substitutes in the future.

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Discussion | This study is, to our knowledge, the first evaluation of the immediate association of a menthol cigarette ban with behavior change. Actual behaviors contrast sharply with planned behaviors. Although a substantial decrease in menthol cigarette use was observed, there was a considerable increase in use of flavored e-cigarettes and cigars. Furthermore, 29.1% of menthol smokers attempted to quit smoking shortly after ban implementation. Because previous studies[2,3] have found an expected rate of 0.5 quit attempts and a 7.7% abstinence rate during a 6-month period in this population, this finding suggests that the ban substantially increased quit attempts. Few smokers used aftermarket additive flavorings, and there was no increase in the use of contraband tobacco. Limitations of this study include the unique demographics of menthol cigarette

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Table. Expected, Short-term Actual, and Long-term Planned Reactions to the Ban on Menthol in Tobacco, Ontario, Canada

Reaction	No. (%; 95% CI) (n = 206)		
	Expected Reaction Before Ban	Actual Short-term Reaction[a]	Long-term Planned Reaction
Use of nonmenthol cigarettes only[b]	123 (59.7; 52.8-66.2)	51 (28.2; 22.0-35.2)	102 (49.5; 42.7-56.4)
Quit	30 (14.5; 10.3-20.1)	60 (29.1; 23.3-35.8)[c]	35 (17.0; 12.4-22.3)
Use of alternative flavored products (e-cigarettes, cigars, and other flavored tobacco products)	12 (5.8; 3.3-10.2)	60 (29.1; 23.3-35.8)	6 (2.9; 1.3-6.4)
Use of contraband menthol	23 (11.2; 7.5-16.3)	29 (14.1; 10.0-19.6)[d]	34 (16.5; 12.0-22.3)
Adding menthol or other reaction	4 (1.9; 0.7-5.1)	29 (14.1; 10.0-19.6)	NR
Don't know	14 (6.8; 4.1-11.2)	6 (2.9; 1.3-6.4)	29 (14.1; 10.0-19.6)

Abbreviation: NR, not reported.

[a] Column does not total 100% because actual behaviors were not mutually exclusive.

[b] Continued or new users of nonmenthol cigarettes who did not try to quit, use any menthol product, use any other flavored product, or add flavor to nonmenthol cigarettes.

[c] Quit or made serious quit attempt. The number (percentage) not currently smoking by follow-up was 25 (12.1%; 95% CI, 8.3%-17.4%).

[d] Purchasing menthol cigarettes from a First Nations reserve, other province, other country, or online. Does not include stockpiled cigarettes, cigarettes bought from existing stocks that enforcement allowed stores to sell out, or those provided by friends. A total of 72 individuals (35.1%; 95% CI, 28.9%-42.0%) used menthol from all sources in the past month.

smokers in Canada, where menthol cigarettes comprise 5% of cigarette sales[4,5] compared with 30% in the United States[6] and use is not concentrated among black Canadians.[5] The initial results suggest that removing menthol tobacco from the market is a feasible strategy that may influence cessation behavior, although differences between menthol users in Ontario, Canada, and other jurisdictions may affect the potential influence of a ban.

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Invited Commentary

Local Movement to Ban Menthol Tobacco Products as a Result of Federal Inaction

The article by Chaiton et al[1] in this issue of *JAMA Internal Medicine* is the first empirical confirmation that banning the sale of menthol tobacco products is good for public health. The investigators surveyed individuals in Ontario, Canada, who smoked menthol cigarettes before and 1 month after the province implemented a full menthol cigarette ban on January 1, 2017. They found that 40% of menthol smokers attempted to quit smoking and 12% succeeded, substantial increases over historical levels and higher than the percentage who predicted that they would try to quit before experienc-

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ing the ban. In addition, they found that a larger proportion (29%) reported using other flavored tobacco or e-cigarette products (menthol was not banned in e-cigarette products) compared with preban self-predictions (6%).

Menthol is a particularly important additive to cigarettes because, in addition to being a flavor, it is a local anesthetic that makes it easier to inhale tobacco smoke and modulates the effects of nicotine in a way that allows tobacco companies to tune nicotine and menthol delivery to maximize nicotine's addictive effect.[2] The 2009 Family Smoking Prevention and Tobacco Control Act, which gave the US Food and Drug Administration (FDA) authority to regulate tobacco products, included a provision that prohibited the use of characterizing flavors, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, but notably not menthol, in cigarettes. It is easy to understand why the tobacco industry fought so hard[3] to successfully exclude menthol from the flavor ban. Menthol cigarettes are a starter product for youths,[4] comprise 30% of cigarette sales,[5] and are the dominant product smoked by African American individuals. Tobacco companies threatened to block the bill if menthol was prohibited.[3]

The US Congress compromised by directing the FDA to have its new Tobacco Products Scientific Advisory Committee complete a report on "the impact of the use of menthol in cigarettes on the public health, including such use among African Americans, Hispanics, and other racial and ethnic minorities"[6] within a year to inform future regulation. The Tobacco Products Scientific Advisory Committee completed the report within a year, concluding in July 2011 that "the removal of menthol products from the marketplace would be beneficial to the public's health."[7]

Despite menthol cigarettes representing 5% of cigarette sales in Canada compared with 30% in the United States, the results of the study by Chaiton et al[1] have 2 important implications for the United States and the rest of the world. First, as predicted, eliminating menthol is good for public health because it leads to an increase in quitting. Second, it is important that flavor bans be comprehensive, including all tobacco products (such as e-cigarettes) and all flavors. There are also likely to be additional public health benefits because elimination of menthol and flavors will make cigarettes and other tobacco products less attractive and less easy to smoke for youths.

In 2016, the FDA tried to limit the use of menthol and other flavors in e-cigarettes and other noncigarette tobacco products but was blocked by the Obama Administration.[8] As of January 12, 2018, the FDA had not regulated menthol in cigarettes or any other tobacco product.

This failure at the federal level has spawned local action to stop the sales of menthol tobacco products. After community outreach by health advocates, town hall meetings, and work with clergy, aldermen, and women to argue that menthol products were being disproportionately marketed to black youths, in December 2013, the Chicago City Council passed the first menthol restrictions, forbidding the sale of menthol and all flavored products within 500 ft of Chicago public schools. In June 2017, the city and county of San Francisco prohibited the sale of all flavored tobacco products, including menthol.[9]

This move was too much for the tobacco industry. Shortly after Mayor Ed Lee signed the new law in San Francisco, with $700 000 from tobacco giant RJ Reynolds, a group of self-proclaimed concerned citizens and local grocers announced that they were going to force a referendum on the new law to oppose government overreach and to protect freedom of choice.[10] Their Let's Be Real San Francisco collected enough signatures to force a popular vote on the ordinance on the June 2018 ballot.

Far from a group of concerned citizens, Let's Be Real is led by a tobacco industry executive and attorneys from a law firm with longstanding ties to the industry. According to official filings, the principal officer of the committee is David Spross, not of San Francisco but of Winston-Salem, North Carolina. Spross is vice president of state government relations at tobacco company RJ Reynolds. Attorneys from the well-connected law film Nielsen Merksamer (which represents RJ Reynolds and Altria) are serving as treasurer and assistant treasurer, respectively, of the campaign.

This situation is a replay of the industry's 1983 referendum campaign to overturn San Francisco's then-new law that limits smoking in the workplace and public places. (Nielsen Merksamer worked on that one, too.) Despite being outspent more than 10 to 1, health advocates successfully defended the ordinance, which subsequently encouraged states and communities around the world to create smoke-free environments.

What about the FDA? They are still thinking about what to do, which means that meaningful action on menthol and flavors is years away, if ever.

In the meantime, as with clean indoor air and tobacco tax policy, the action will occur at the local and state levels. On the basis of the 1983 experience, a win in San Francisco could substantially accelerate the movement to end the sale of menthol and flavored tobacco products, making the FDA increasingly irrelevant.

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Hypoglycemia in Hospice Patients With Type 2 Diabetes in a National Sample of Nursing Homes

Approximately one-quarter of the US population die in nursing homes,[1] where end-of-life care is of variable quality.[2] In particular, it is unknown whether patients with chronic illness, such as diabetes, continue to receive burdensome testing and treatment after transitioning to hospice care in nursing homes. Experts and the American Diabetes Association recommend relaxing glycemic control target levels for patients with diabetes and advanced disease and eventual discontinuation of medications as patients near death to avoid hypoglycemia.[3,4] Hypoglycemia causes symptoms of weakness, diaphoresis, confusion, shakiness, and dizziness,[5] and is a potentially preventable cause of suffering among hospice patients. Whether nursing home patients with type 2 diabetes on hospice are assessed for dysglycemia, receive insulin or oral hypoglycemic medications, or experience hypoglycemia and hyperglycemia has not previously been described.

Methods | We conducted a retrospective cohort study of patients older than 65 years with type 2 diabetes admitted to Veterans Affairs (VA) nursing homes between January 1, 2006, and June 30, 2015, using linked laboratory, pharmacy, and administrative data. We identified patients with type 2 diabetes by *International Classification of Diseases, Ninth Revision* (*ICD-9*) code or glycated hemoglobin values greater than 6.5%. We excluded patients with type 1 diabetes by *ICD-9* code. For patients with multiple admissions during the study period, we chose the last admission. We used descriptive statistics to analyze demographic variables, comorbidities, and diabetes management (laboratory testing and drug administration), and stratified the cohort by whether patients received insulin while on hospice. We analyzed the cumulative incidence of hypoglycemia (glucose <70 mg/dL [to convert to mmol/L, multiply by 0.0555]), severe hypoglycemia (glucose <50 mg/dL), hyperglycemia (glucose ≥400 mg/dL), and the competing risk of death among all hospice patients and among patients treated with insulin vs patients not treated with insulin. This study was reviewed and approved by the University of California, San Francisco Committee on Human Research.

Results | The study cohort included 20 329 hospice patients (**Table**), 98% of whom were men (n = 19 991). Hospice patients had an 83% 100-day mortality rate (n = 16 791 deaths), and a median length of stay of 10 days. Eight percent of patients in the cohort received insulin (n = 1687). Among patients treated with insulin, mean baseline glycated hemoglobin levels were higher than patients not treated with insulin (7.4% vs 6.8%; $P < .001$), and the mortality rate at 100 days was lower (61% vs 85%; $P < .001$). Patients treated with insulin had more frequent glucose tests (mean 1.7 glucose tests/d, vs 0.6 glucose tests/d among patients not treated with insulin; $P < .001$). The cumulative incidence of hypoglycemia (glucose <70 mg/dL) among all patients, accounting for the competing risk of death, was 12% at 180 days, and that of severe hypoglycemia (glucose <50 mg/dL) was 5% (**Figure**). Among patients treated with insulin, 38% experienced hypoglycemia and 18% experienced severe hypoglycemia at 180 days. The highest risk of hypoglycemia occurred in the first 20 days of admission. The cumulative incidence of hyperglycemia (glucose >400 mg/dL) at 180 days was 9% in all patients, higher in the group treated with insulin (35%).

Discussion | Despite guidelines that stress avoiding hypoglycemia in hospice patients with diabetes,[4] we found that 1 in 9 nursing home patients with type 2 diabetes experienced hypoglycemia (glucose <70 mg/dL) while 1 in 20 experienced severe hypoglycemia (glucose <50 mg/dL) while on hospice. The risk of hypoglycemia was highest among patients treated with insulin, one-third of whom experienced hypoglycemia. Patients treated with insulin lived longer and experienced more hyperglycemia than patients not treated with insulin, which suggests that clinicians may be choosing to continue insulin for those hospice patients with a longer life expectancy and more severe diabetes at hospice admission. Nevertheless, hypoglycemia is not consistent with a goal of comfort, and these data demonstrate suboptimal avoidance of dysglycemia

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