

January 22, 2021

ATTORNEY GENERAL RAOUL URGES FDA TO BAN MENTHOL CIGARETTES

Raoul, 22 AGs Argue Menthol Cigarette Use Disproportionately Impacts Youth, Minority Populations

Chicago — Attorney General Kwame Raoul and Idaho Attorney General Lawrence Wasden led a coalition of 23 attorneys general calling on the Food and Drug Administration (FDA) to ban menthol cigarettes. In a letter submitted today, Raoul and the coalition argue that a ban on menthol cigarettes would benefit public health overall, decrease youth smoking, and help mitigate the harm menthol cigarettes do to minority populations.

“I am asking the FDA to ban menthol cigarettes because even though cigarette use has decreased over the years, menthol-flavored cigarettes continue to attract and addict new smokers – particularly youth and minority smokers,” Raoul said. “The FDA’s own data underscores the need to ban menthol cigarettes, which could save thousands of lives and support state efforts to combat youth smoking.”

[The letter submitted by Raoul](#) and the attorneys general urges the FDA to complete rulemaking to prohibit menthol cigarettes. Raoul and the coalition argue that such a prohibition would save thousands of lives and should be implemented immediately. Despite the overall decline in non-menthol smoking, the coalition points out that the prevalence of menthol smoking has remained constant in recent years – and disproportionately impacts youth and minority populations. The attorneys general state that menthol cigarettes remain a major barrier to smoking cessation and the reduction of smoking-related health conditions.

The 1998 Tobacco Master Settlement Agreement (MSA) entered into between 46 states, including Illinois, and the major cigarette manufacturers placed restrictions on the advertising, marketing and promotion of cigarettes and committed the parties to reducing underage tobacco use. Due in part to the MSA, youth cigarette smoking has declined significantly; however, menthol remains the primary reason youths begin, continue and become addicted to smoking. Menthol in cigarettes disguises their harsh flavor, making it attractive for beginners who experiment with cigarettes, and ultimately become addicted.

In the letter, Raoul and the attorneys general highlight the FDA’s own data showing the addictiveness of menthol cigarettes. Research into the health impact of menthol in cigarettes conducted by the FDA and its Tobacco Products Scientific Advisory Committee (TPSAC) concluded that the removal of menthol cigarettes from the marketplace would benefit public health. Reports issued by both entities determined menthol cigarettes were associated with increased smoking initiation by youth and young adults, greater likelihood of progression to regular smoking, reduced success in smoking cessation, and greater addiction and nicotine dependency among smokers.

According to the coalition, data has demonstrated that menthol cigarettes increase the number of youth smokers because they find menthol cigarettes to be easier to smoke and perceive them to be less harmful than non-menthol cigarettes. The attorneys general point to 2019 data that estimated 46.7% of middle and high school-aged smokers use menthol cigarettes. Studies have also shown that the use of menthol cigarettes by youth is even higher among African American youth, as menthol cigarettes are marketed disproportionately to younger people and African Americans. Recent data shows that menthol use is highest among African American smokers, with 89% of all African American smokers smoking menthol cigarettes – compared to 26% of white smokers. More than 93% of African American smokers began cigarette usage by smoking menthol cigarettes.

Raoul and the coalition also argue the sensory effects and flavor of menthol can make cigarettes more addictive. Additionally, menthol smokers are less likely to successfully quit than non-menthol smokers. The attorneys general argue that scientific evidence consistently demonstrates that removing menthol cigarettes from the marketplace will prevent more youth from smoking, improve smoking cessation outcomes and benefit public health overall.

Joining Attorneys General Raoul and Wasden in submitting the letter are the attorneys general of Connecticut, Delaware, the District of Columbia, Hawaii, Iowa, Maine, Maryland, Massachusetts, Minnesota, Nebraska, Nevada, New Mexico, New York, North Carolina, the Northern Mariana Islands, Oregon, Pennsylvania, Puerto Rico, Vermont, Washington and Wisconsin.



Attorneys General of Connecticut, Delaware, District of Columbia, Hawaii, Idaho, Illinois, Iowa, Maine, Maryland, Massachusetts, Minnesota, Nebraska, Nevada, New Mexico, New York, North Carolina, Northern Mariana Islands, Oregon, Pennsylvania, Puerto Rico, Vermont, Washington, Wisconsin

January 22, 2021

Via Federal eRulemaking Portal

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2013-P-0435 – Comments on Tobacco Control Legal Consortium, et. al., Citizen Petition to the Federal Food and Drug Administration Related to Prohibiting Menthol as a Characterizing Flavor in Cigarettes (April 12, 2013)

The undersigned state attorneys general write to urge the Food and Drug Administration (“FDA”) to act in the best interest of the public by addressing the above petition and completing rulemaking to prohibit menthol cigarettes.

I. OVERVIEW

Overwhelming scientific evidence not only supports the prohibition of menthol cigarettes to protect public health and save thousands of lives, but also indicates that a prohibition should be implemented urgently. The prevalence of menthol smoking has remained constant in recent years, despite declines in non-menthol smoking. Menthol flavor in cigarettes increases youth initiation and addiction. Menthol cigarettes disproportionately affect minorities and other vulnerable populations, in particular African-American smokers. Menthol cigarettes remain a major barrier to smoking cessation and reduction of smoking-related diseases. Although the tobacco industry argues that a ban will increase illicit trade, these

warnings are overblown and self-serving. Robust measures for monitoring and enforcement are already in place. A ban on menthol cigarettes will benefit public health and there are no compelling reasons why these products should remain on the market.

II. ATTORNEYS GENERAL HAVE A SUBSTANTIAL INTEREST IN PROTECTING THE HEALTH OF THEIR CITIZENS

State attorneys general have long fought to protect their citizens, particularly youth, from the dangers of tobacco products. For example, state attorneys general sued the major tobacco companies for the harm their products caused and reached settlement agreements, including the 1998 Tobacco Master Settlement Agreement (“MSA”) that placed restrictions on the advertising, marketing, and promotion of cigarettes. The MSA, entered into between 46 states and six other jurisdictions and the major cigarette manufacturers and numerous smaller manufacturers, committed the parties to “reducing underage tobacco use by discouraging such use and by preventing Youth access to Tobacco Products.” MSA § I. The MSA also prohibited signatory tobacco product manufacturers from taking any action to target youth or initiate youth smoking. MSA § III(a).

Thanks in part to the MSA, cigarette smoking by youth has declined significantly. Despite this progress, menthol remains a primary reason for youth cigarette smoking initiation, smokers’ addiction, and continued smoking. Menthol flavor in cigarettes disguises their harsh taste, making it attractive for beginners to experiment with cigarettes and ultimately become addicted. The availability of menthol cigarettes frustrates smoking cessation and contributes to tobacco-related health disparities. Even though cigarette sales overall have declined over the years since the MSA, sales of menthol cigarettes continue to climb in the United States. As of 2018, menthol cigarettes account for 36% of all cigarette sales—the highest proportion since major tobacco companies were required to report domestic market share of menthol and non-menthol cigarettes.¹

¹ U.S. Federal Trade Commission (FTC), Cigarette Report for 2018. Washington: Federal Trade Commission, 2019, *available at* <https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-cigarette-report-2018-smokeless-tobacco-report-2018/p114508cigaretterreport2018.pdf>.

State attorneys general have on numerous occasions commented on tobacco-related topics to the FDA, reported violations to the FDA, and recommended that the FDA take steps to protect their citizens from the dangers of tobacco use and exposure to tobacco products. State attorneys general have also urged the FDA to ban flavored tobacco products. For instance, on November 8, 2013, 27 state attorneys general submitted comments to the FDA in response to the agency's advance notice of proposed rulemaking to support a ban on menthol cigarettes. The 2013 letter emphasized, *inter alia*, the FDA's scientific evaluation in which the agency found that menthol cigarettes are associated with increased smoking initiation by youth and young adults, greater nicotine addiction, higher nicotine dependence, and reduced cessation success.

This letter is a further attempt to urge the FDA to act in the interest of public health by promptly banning menthol cigarettes because the evidence shows these products cause harm to our citizens.

III. PROHIBITION ON MENTHOL CIGARETTES WOULD BENEFIT THE PUBLIC HEALTH

In the 2009 Tobacco Control Act, Congress prohibited all flavors in cigarettes except menthol, gave the FDA authority to ban menthol cigarettes, recognized that "menthol cigarettes may pose unique health risks to those who smoke them," and urged the FDA "to address these issues as quickly as practicable."² Following passage of the Act, the FDA formed the Tobacco Products Scientific Advisory Committee ("TPSAC"), which conducted extensive research and review of the scientific evidence concerning the public health impacts of menthol in cigarettes. On March 23, 2011, TPSAC submitted a report, *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations* (2011) ("TPSAC Report"), concluding that the "[r]emoval of menthol cigarettes from the marketplace would benefit public health in the United States."³

The TPSAC Report found that "the availability of menthol cigarettes has an adverse impact on public health by increasing the numbers of smokers with resulting

²21 U.S.C. § 387g(a)(1), § 387g(e)(3), § 387g(a)(3)(A); H.R. REP. 111-58(I) (2009) available at <https://www.congress.gov/111/crpt/hrpt58/CRPT-111hrpt58-pt1.pdf>.

³ Available at <https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf>.

premature death and avoidable morbidity.” TPSAC Report at 225. It concluded that menthol cigarettes increase the number of youth who begin smoking cigarettes and who become addicted. It concluded that use of menthol cigarettes by youth was even higher among minority youth, in particular African-Americans. *See id.* at 48. The TPSAC Report also found that “menthol cigarettes are marketed disproportionately to younger people” and “disproportionately marketed per capita to African Americans.” *Id.* at 92. Further, it found that “youth choose menthol cigarettes, particularly at lower menthol yields, mainly because of the relative ease of smoking a menthol cigarette for the naive smoker and because they perceive menthol cigarettes to be less harmful than non-menthol cigarettes.” *Id.* at 116. The TPSAC Report concluded that “the availability of menthol cigarettes increases the likelihood of experimentation and regular smoking beyond the anticipated prevalence if such cigarettes were not available.” *Id.* at 217.

Continuing, the TPSAC Report pointed to evidence that “non-white smokers, particularly African American, of menthol cigarettes compared to non-menthol cigarettes experience more difficulty with cessation.” *Id.* at 149-150. Similarly, it found evidence that African-Americans and youth “are at high risk for poor cessation outcomes.” *Id.* at 150. The TPSAC Report also found that use of menthol cigarettes was prevalent among unemployed people, especially people with low income. *See id.* at 48.

The TPSAC Report concluded that “the availability of menthol cigarettes increases the numbers of people who initiate smoking, as well as leading to premature death from smoking caused diseases.” *Id.* at 221. If a ban on menthol-flavored cigarettes were in effect in 2010, TPSAC calculated that by 2020, 17,000 lives could be saved and 2.3 million people prevented from starting smoking; and by 2050, 327,000 premature death avoided and over 9.1 million people prevented from starting smoking. *Id.*

The FDA came to similar conclusions regarding the impact of menthol cigarettes on public health in its own scientific evaluation, *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes* (2013) (“FDA Menthol Report”).⁴ The FDA Menthol Report found that menthol cigarettes were associated with increased smoking initiation by youth and young adults, greater likelihood of progression to regular smoking, reduced success in smoking

⁴ Available at <https://www.fda.gov/media/86497/download>.

cessation, and greater addiction and greater nicotine dependency among smokers. The FDA therefore concluded that “menthol cigarettes pose a public health risk above that seen with nonmenthol cigarettes.” FDA Menthol Report at 6.

Both the TPSAC and FDA menthol reports leave no doubt that menthol cigarettes have far-reaching adverse impacts on public health in the United States, resulting in more smoking and more death and disease from tobacco use.

Not surprisingly, citizens urged the FDA to take action to protect Americans from the dangers of smoking menthol cigarettes. On April 12, 2013, the Tobacco Control Legal Consortium filed a Citizen Petition requesting the FDA to ban menthol cigarettes. Many comments were submitted in support of that petition. In July 2013, the FDA released an advance notice of proposed rulemaking regarding menthol in cigarettes, but took no further action.⁵ In November 2018, the FDA announced the agency’s intention to ban menthol cigarettes, but again took no action.⁶ On June 17, 2020, the African American Tobacco Control Leadership

⁵ U.S. Food and Drug Administration. Menthol in Cigarettes, Tobacco Products; Request for Comments, 21 C.F.R. § 1140 (2013), *available at* <https://www.federalregister.gov/documents/2013/07/24/2013-17805/menthol-in-cigarettes-tobacco-products-request-for-comments>.

⁶ In the November 15, 2018 press announcement, then-FDA Commissioner Scott Gottlieb, M.D. made the following comments concerning the availability of menthol cigarettes:

[M]enthol-flavored products represent one of the most common and pernicious routes by which kids initiate on combustible cigarettes. The menthol serves to mask some of the unattractive features of smoking that might otherwise discourage a child from smoking. Moreover, I believe that menthol products disproportionately and adversely affect underserved communities. And as a matter of public health, they exacerbate troubling disparities in health related to race and socioeconomic status that are a major concern of mine. Although I’m not proposing revisions to the compliance policy for the mint- and menthol flavors in e-cigarettes at this time, we need to address the impact that menthol in cigarettes has on the public health.

...

I noted that the popularity of menthol cigarettes with youth is especially troubling. In fact, youth smokers are more likely to use menthol cigarettes than any other age group. More than half (54 percent) of youth smokers ages 12–17 use menthol cigarettes, compared to less than one-third of smokers ages 35 and older. Prevalence of menthol use is even higher among African-American youth, with data showing that seven out of 10 African-American youth smokers select menthol cigarettes.

And, ... there’s no evidence to suggest that menthol-flavored cigarettes may play a role in harm reduction for adult smokers.

Council and Action on Smoking and Health filed a lawsuit against the FDA alleging unreasonable delay on the part of the agency in banning menthol in cigarettes.⁷ To resolve the pending Citizen Petition and the lawsuit, the FDA now states that it will provide a final response to the citizen petition by January 29, 2021.

In light of the slow pace of these developments and the urgency of the issue, the undersigned state attorneys general submit this letter to urge the FDA to finalize rulemaking and prohibit menthol cigarettes. We particularly bring the following matters to your attention.

1. Youth Initiation

The effect of menthol cigarettes on youth smoking initiation has been well-documented. Both the TPSAC and the FDA menthol reports concluded that menthol cigarettes increase the number of children who experiment with cigarettes and the number of children who become regular smokers, thus increasing overall youth smoking. These young people who initiate using menthol cigarettes are more likely to become addicted and long-term daily smokers.

Studies published after the publication of the TPSAC and FDA menthol reports reach the same conclusions. For instance, despite decades of public health campaigns directed at youth, 2019 data estimates that more than half a million middle and high school-aged smokers (46.7%) use menthol cigarettes.⁸ Such cigarettes continue their longstanding role as a gateway to addiction—more than half of all adult smokers aged 18–34 were introduced to smoking through menthol cigarettes.⁹ And, notably, the younger the population considered, the stronger the

Statement from FDA Commissioner Scott Gottlieb, M.D. (Nov. 15, 2018), *available at* <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access>.

⁷ *African American Tobacco Control Leadership Council et al. v. United States Department of Health and Human Services et al.*, Case No. 3:20-cv-04012 (N.D.Cal. June 17, 2020).

⁸ Wang TW, Gentzke AS, Creamer MR, et al. Tobacco Product Use and Associated Factors Among Middle and High School Students—United States, 2019. *MMWR Surveill. Summ.* 2019; 68(No. SS-12):1–22. DOI: <http://dx.doi.org/10.15585/mmwr.ss6812a1>.

⁹ D'Silva, J, Cohn AM, Johnson AL, et al. Differences in Subjective Experiences to First Use of Menthol and Nonmenthol Cigarettes in a National Sample of Young Adult Cigarette Smokers. *Nicotine & Tob. Research* 2018 Sep; 20(9): 1062–1068. DOI: <http://dx.doi.org/10.1093/ntr/ntx181>.

influence of menthol cigarettes on continued smoking behavior: a higher percentage of smokers aged 18–24 initiated smoking through menthols than smokers in the older 25–34 cohort.¹⁰

Other recent studies show that youth menthol smokers are more likely to perceive menthol cigarettes as easier to smoke than regular cigarettes,¹¹ that youth menthol smokers have significantly higher levels of certain measures of dependence,¹² and that initiation with a menthol-flavored cigarette is associated with a higher relative risk of daily smoking.¹³

According to the FDA’s own evaluation of scientific evidence in 2018, “[y]outh and young adult smokers are disproportionately more likely to smoke menthol than nonmenthol cigarettes” and there is “a greater use of menthol cigarettes by younger smokers and less usage among older smokers.”¹⁴

A ban on menthol cigarettes would substantially reduce youth cigarette use. Studies show a decrease in youth cigarette use after the 2009 ban on other flavors in cigarettes. Unfortunately, the effects of the 2009 flavor ban were diminished by the continued availability of menthol-flavored cigarettes.¹⁵

2. Reduced Cessation

¹⁰ *Id.*

¹¹ Cohn, AM, Rose SW, D’Silva J, et al. Menthol Smoking Patterns and Smoking Perceptions Among Youth: Findings from the Population Assessment of Tobacco and Health Study. *Am J Prev Med.* 2019 Apr; 56(4): e107–e116. DOI: <http://dx.doi.org/10.1016/j.amepre.2018.11.027>.

¹² Cwalina, SN, Majmundar A, Unger JB, et al. Adolescent menthol cigarette use and risk of nicotine dependence: Findings from the national Population Assessment on Tobacco and Health (PATH) study. *Drug and Alcohol Dependence.* 2020 Jan 1; 206:107715. DOI: <http://dx.doi.org/10.1016/j.drugalcdep.2019.107715>.

¹³ Villanti, AC, Johnson AL, Glasser AM, et al., Association of flavored tobacco use with tobacco initiation and subsequent use among US youth and adults, 2013–2015. *JAMA Network Open.* 2019 Oct; 2(10): e1913804. DOI: <http://dx.doi.org/10.1001/jamanetworkopen.2019.13804>.

¹⁴ Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12,294, 12,296 (proposed Mar. 21, 2018) (to be codified at 21 C.F.R. pt. 1100, 1140, 1143) (“Advance Notice of Proposed Rulemaking”), *available at* <https://www.govinfo.gov/content/pkg/FR-2018-03-21/pdf/2018-05655.pdf>.

¹⁵ Courtemanche CJ, Palmer MK, Pesko MF. Influence of the flavored cigarette ban on adolescent tobacco use. *Am J Prev Med.* 2017; 52(5):e139–46. DOI: <http://dx.doi.org/10.1016/j.amepre.2016.11.019>.

It is also important to emphasize menthol's adverse effects on cigarette smoking cessation. This was documented in the TPSAC and FDA menthol reports, and is supported by research conducted since that time. Scientific studies show that the sensory effects and flavor of menthol can make cigarettes more addictive.¹⁶ Menthol smokers show greater signs of nicotine dependence and are less likely to successfully quit smoking than non-menthol smokers.¹⁷ Compared to adults who smoke non-menthol cigarettes, adults who smoke menthol cigarettes make more attempts to quit smoking and have a harder time quitting.¹⁸ Pregnant women who smoke menthol cigarettes have lower quit rates than non-menthol smokers and decreased likelihood of quitting smoking.¹⁹

Significantly, while the available data shows reductions in non-menthol cigarette use among youth in the past decade, menthol cigarette use among youth has not decreased. Indeed, over 90% of the cigarette consumption decline between 2009 and 2018 is attributed to non-menthol cigarettes; nevertheless, sales of menthol cigarettes have increased by nearly 10% from 2000 to 2018.²⁰ The percentage of smokers who currently smoke menthol cigarettes has increased for all age groups.²¹

Studies of recent policy changes show that the devastating health impacts of menthol cigarettes can be turned around by implementing a ban on these products.

¹⁶ Wickham RJ. How Menthol Alters Tobacco-Smoking Behavior: A Biological Perspective. *Yale J Biol Med.* 2015 Sep; 88(3): 279–287. Published online 2015 Sep 3, *available at* <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4553648/>.

¹⁷ Villanti AC, Collins LK, Niaura RS, et al. Menthol cigarettes and the public health standard: a systematic review. *BMC Public Health* 2017; 17:983, DOI: <https://doi.org/10.1186/s12889-017-4987-z>.

¹⁸ Smith, SS, Fire MC, Baker BB. Smoking cessation in smokers who smoke menthol and non-menthol cigarettes. *Addiction.* 2014 Dec; 109(12): 2107–2117. DOI: <https://doi.org/10.1111/add.12661>.

¹⁹ Stroud LR, Vergara-Lopez C, McCallum M, et al. High Rates of Menthol Cigarette Use Among Pregnant Smokers: Preliminary Findings and Call for Future Research. *Nicotine Tob Res.* 2020 Oct; 22(10): 1711–1717. DOI: <https://doi.org/10.1093/ntr/ntz142>.

²⁰ Delnevo CD, Giovenco DP, Villanti AC. Assessment of menthol and nonmenthol cigarette consumption in the US, 2000 to 2018. *JAMA Netw Open.* 2020; 3(8):e2013601. DOI: <https://doi.org/10.1001/jamanetworkopen.2020.13601>.

²¹ Villanti AC, Mowery PD, Delnevo CD, et al. Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004–2014. *Tob Control.* 2016 Nov; 25(Suppl 2):ii14–ii20. DOI: <https://doi.org/10.1136/tobaccocontrol-2016-053329>.

For example, foreign jurisdictions where cigarette menthol bans have been implemented show as high as a 24% cessation success rate among daily menthol smokers within one year of the ban's implementation, providing evidence that menthol prohibition leads to positive smoking cessation outcomes.²²

Closing the menthol exception will benefit public health because it will likely cause a significant number of menthol cigarette users to quit smoking.

3. Disparities in Use

It is important to protect vulnerable populations, and in this regard disparities in menthol cigarette use demand action. As noted before, both the TPSAC and FDA menthol reports concluded that menthol is favored by discrete segments of the population and that this has been driven by targeted advertising, pricing and promotions. A majority of African-American smokers smoke menthol cigarettes, and other minority groups are also more likely to use these products. Moreover, among African-Americans, menthol cigarettes are associated with increased dependence on smoking and reduced success in smoking cessation.

More recent research bolsters findings that menthol cigarettes disproportionately harm the health of vulnerable populations, in particular African-Americans. The prevalence of menthol use is highest among African Americans—89% of all African-American smokers smoke menthol cigarettes, compared to 26% of white smokers.²³ Over 93% of African-American smokers initiated cigarette use with menthol cigarettes.²⁴ Studies also show that female and African-American menthol smokers are less likely to quit smoking.²⁵ African-American female menthol smokers have the lowest quit rates.²⁶

²² Chaiton MO, Nicolau I, Schwartz R, et al. Ban on menthol-flavoured tobacco products predicts cigarette cessation at 1 year: a population cohort study. *Tob Control*. 2020 May; 29(3):341-347. DOI: <https://doi.org/10.1136/tobaccocontrol-2018-054841>.

²³ Smith PH, Akpara E, Haq R, et al., Gender and Menthol Cigarette Use in the United States: A Systematic Review of the Recent Literature (2011–May 2017). *Curr. Addict Rep*. 2017 Dec; 4(4): 431–438. DOI: <https://doi.org/10.1007/s40429-017-0175-6>.

²⁴ See *ftn.* 9.

²⁵ See *ftn.* 17.

²⁶ See *ftn.* 18.

Women smokers present a uniquely vulnerable population because they are more likely to use menthol cigarettes—approximately 40% of women smoke menthol cigarettes compared to 31% of men.²⁷ The prevalence of menthol cigarette smoking continues to be higher in pregnant women, especially racial minorities.²⁸ Menthol cigarette use is also disproportionately high among LGBTQ smokers, smokers with mental health problems, and socioeconomically disadvantaged populations.²⁹

The FDA should act now because extensive data shows that a ban on menthol cigarettes will protect public health and advance health equity.

4. Illicit Trade

The available evidence shows that the public health benefits from banning menthol cigarettes outweigh concerns about illicit tobacco trade. Protecting the public from dangerous products, including tobacco products prohibited by the FDA, is one of the States' utmost priorities and an area of enforcement in which the state attorneys general have long and extensive experience.

The tobacco enforcement expertise and experience of the state attorneys general goes back decades. Since the 1990s, state attorneys general have been at the forefront of the fight against the tobacco industry's predatory and fraudulent practices that addicted millions to smoking and caused devastating health consequences. For over two decades, state attorneys general have regulated cigarettes through the MSA and related statutes. These efforts include enforcing the provisions to stop youth targeting in advertising, marketing and promotions; free sampling; tobacco product placement in the media; brand name sponsorships; outdoor advertising; and use of cartoons. The state attorneys general established tobacco litigation and enforcement units in every state to ensure that the tobacco industry complied with the MSA and applicable laws. Robust enforcement mechanisms exist on state and multi-state levels to investigate and prosecute violations of tobacco laws, including illicit trade in tobacco products. States also hold the tobacco industry accountable by requiring them to obtain and maintain

²⁷ See *ftn.* 23.

²⁸ See *ftn.* 19.

²⁹ Delnevo CD, Ganz O, Goodwin RD. Banning Menthol Cigarettes: A Social Justice Issue Long Overdue. *Nicotine & Tobacco Research*, Volume 22, Issue 10, October 2020, Pages 1673–1675. DOI: <https://doi.org/10.1093/ntr/ntaa152>.

applicable licenses, pay excise taxes, keep detailed records, and document the movement of tobacco products from the point of manufacture through distribution to retail outlets and consumers.³⁰ In short, states maintain extensive and effective regulation over cigarettes.

In addition, the Prevent All Cigarette Trafficking Act (“PACT Act”) (15 U.S.C. §§ 375–378 and 18 U.S.C. § 1716E) helps federal and state authorities regulate interstate cigarette deliveries. Persons who sell, transfer, or ship cigarettes in interstate commerce are required to register and file monthly reports with the tobacco tax administrator of the state into which shipments of cigarettes are made. These persons are also required to comply with state and federal tax payment requirements. The PACT Act subjects illegal sellers to stringent penalties, allows the attorneys general of states where tobacco products are delivered to enforce provisions of the Act, and provides other enforcement tools to enable federal and state enforcement officials to collaborate, detect, and stop illegal sales of cigarettes.

The Contraband Cigarette Trafficking Act (“CCTA”) (18 U.S.C. §§ 2341–2346) prohibits shipment, transportation, receipt, distribution, or purchase of “contraband cigarettes” (*i.e.*, a quantity in excess of 10,000 cigarettes without the payment of applicable state or local cigarette taxes in the state or locality where such cigarettes are found). The CCTA imposes various recordkeeping and reporting requirements on persons who ship any quantities of cigarettes in excess of 10,000 (or 500 cigarette packs). Strict penalties are imposed on those who violate provisions of the CCTA, including imprisonment of up to five years. The state attorneys general are authorized to obtain appropriate relief in a civil action asserting violations of the CCTA, including civil penalties, money damages, and injunctive or other equitable relief.

Further, although this letter focuses on state authority and actions, the framework of federal regulation and enforcement is even more important when considering the effects of a menthol ban. Federal enforcement ranges from U.S. Customs and Border Protection Agency actions to prevent the importation of prohibited products, to Alcohol and Tobacco Tax and Trade Bureau inspections of cigarette

³⁰ Several states also use advanced digital tax stamp systems specifically tailored to monitor and trace movement of cigarettes in their jurisdictions. These systems provide full visibility regarding cigarette brands and styles distributed and allow the States to detect illicit trade practices such as tax evasion and distribution of unauthorized cigarettes.

manufacturers, and to the FDA’s own requirements that manufacturers report ingredients. Also, the FDA’s Office of Enforcement and Compliance operates a nationwide tobacco retailer inspection and enforcement program, inspecting tens of thousands of stores every year. Thus, at all levels—manufacturing, importing and selling—there are nationwide programs that make it unlikely that an illicit trade in menthol cigarettes will emerge.

Indeed, with more than 100 state and local jurisdictions already banning menthol-flavored cigarettes, an FDA-led ban of menthol products is more likely to reduce trafficking than increase it.³¹ Presently, localities with menthol bans work against the backdrop of national and state-level distribution programs that make retail-level bans more complicated to administer. Local bans balkanize distribution networks for tobacco products, leading to higher rates of accidental or intentional illegal deliveries to retail stores and their customers. A national ban, in contrast, addresses these products before they enter the lawful distribution chain, significantly reducing the potential for mistake and the ease of access to illicit products for scofflaw sellers. Considering the States’ consistent, longstanding, and rigorous enforcement and the extensive state and federal tobacco enforcement regimes, it is unlikely that a national ban on menthol cigarettes will result in the creation of a significant illicit trade for these products.

Further, studies of foreign jurisdictions that banned menthol cigarettes show that the prohibition on menthol cigarettes did not create a black market for menthol cigarettes. For example, the evaluation of Nova Scotia’s tax data after the implementation of a menthol ban did not reveal evidence of increased seizures of menthol as opposed to non-menthol cigarettes, suggesting Nova Scotia’s ban on menthol cigarettes did not result in an illicit market.³² Studies also indicate that tobacco manufacturers are likely to comply with the prohibition on menthol cigarettes.³³

³¹ <https://www.tobaccofreekids.org/assets/factsheets/O398.pdf>

³² Cadham JC, Sanchez-Romero LM, Fleischer NL, et al. The actual and anticipated effects of a menthol cigarette ban: a scoping review. *BMC Public Health*. 2020; 20: 1055. DOI: <https://doi.org/10.1186/s12889-020-09055-z>.

³³ Brown J, DeAtley T, Welding K, et al. Tobacco industry response to menthol cigarette bans in Alberta and Nova Scotia, Canada. *Tob Control*. 2017; 26:e71-e74, available at <https://tobaccocontrol.bmj.com/content/26/e1/e71.long>.

Moreover, there were no reports of significant increases of illegal sales of flavored cigarettes following the 2009 ban on flavored cigarettes. While there is illicit trade in cigarettes between states with high and low excise tax rates, that arises in quite different circumstances—differential tax rates between nearby states—from a national prohibition on all menthol cigarettes. And while a ban on menthol cigarettes may lead to some level of illegal sales, the vast majority of menthol smokers are likely to comply with the law. A recent study shows that up to 46% of adult menthol smokers and up to 65% of young adult menthol smokers would quit smoking in response to a menthol ban instead of turning to purchasing menthol cigarettes on a black market.³⁴ Studies analyzing the impact of the 2017 Ontario, Canada ban on menthol cigarettes found that, one month after the ban was implemented, 29% of menthol smokers attempted to quit smoking.³⁵ A follow-up study relating to Ontario’s menthol ban found that, a year after the ban was implemented, 56% of all smokers had made at least one quit attempt and 19% reported no current tobacco use.³⁶

There is little reason to suggest that prohibiting menthol cigarettes will cause the emergence of an illicit market that will threaten the public health gains from prohibiting menthol cigarettes or that that state and federal authorities will be unable to prevent the emergence of such illicit activity. The FDA should not be swayed by the tobacco industry’s doomsday predictions of an increase in illicit trade.

IV. CONCLUSION

The compelling and consistent scientific evidence shows that removing menthol cigarettes from the U.S. market will likely reduce youth smoking initiation, improve smoking cessation outcomes in adult smokers, advance health equity, and benefit public health. Every year of inaction relating to menthol flavor prohibition costs thousands of lives and adversely impacts the health of the public. Prohibiting menthol cigarettes will not create a significant black market and enforcement

³⁴ See *ftn.* 32.

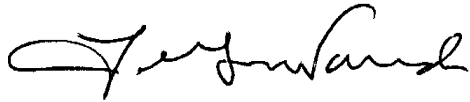
³⁵ Chaiton M, Schwartz R, Cohen JE, et al. Association of Ontario’s Ban on Menthol Cigarettes With Smoking Behavior 1 Month After Implementation. *JAMA Intern Med.* 2018 May 1; 178(5):710–711. DOI: <https://doi.org/10.1001/jamainternmed.2017.8650>.

³⁶ See *ftn.* 22.

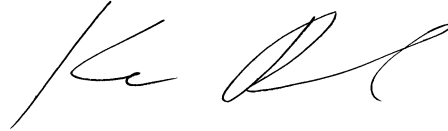
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authorities are well-equipped to safeguard against illicit trade in menthol cigarettes. For all these reasons, the FDA should no longer delay its rulemaking to remove menthol cigarettes from the United States market.

Respectfully submitted,



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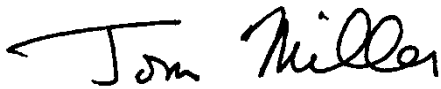
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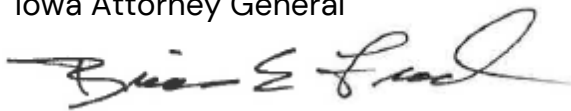
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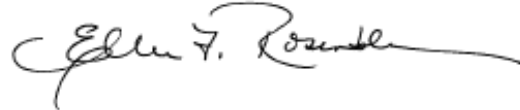
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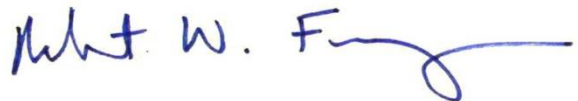
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