

**Improving the Health
of Pennsylvanians**

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pahealthpolicy.org

August 1, 2022

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Proposed Rule FDA-2021-N-1349: Tobacco Product Standard for
Menthol in Cigarettes**

The Pennsylvania Health Policy Coalition strongly supports the FDA's proposed tobacco product standard prohibiting menthol as a characterizing flavor in cigarettes.

The Pennsylvania Health Policy Coalition was established to represent the unified interests of Pennsylvania's local health departments and is recognized by the National Association of County and City Health Officials as Pennsylvania's state affiliate. The Coalition espouses a shared vision for improved public health and coordinated, sustained policy implementation at the local, state, and federal levels.

As the Tobacco Products Scientific Advisory Committee (TPSAC) clearly stated in its 2011 report to the FDA, "[r]emoval of menthol cigarettes from the marketplace would benefit public health in the United States."¹ The cooling and mildly anesthetic sensory effects from menthol additives in tobacco products mask and reduce the harshness of cigarette smoking, easing initiation into smoking, enabling deeper inhalations and regular smoking. In making it easier to inhale larger amounts of cigarette smoke, the menthol added to cigarettes also increases the amount of harmful chemicals absorbed into the body while smoking.² Menthol additives even enhance the addictive effects of nicotine in the brain, increasing the risk of nicotine dependence and reducing cessation success.^{3,4}

Tobacco use, in particular menthol cigarette use, creates significant health and economic burdens for residents, families, businesses, and communities in

¹ Tobacco Products Scientific Advisory Comm., U.S. Food & Drug Admin., Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations 225 (2011), *available*

at: <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf>.

² Ton HT, Smart AE, Aguilar BL, et al. Menthol enhances the desensitization of human alpha3beta4 nicotinic acetylcholine receptors. *Mol Pharmacol* 2015;88(2):256-64.

³ Alsharari, S.D., J.R. King, J.C. Nordman, et al. 'Effects of Menthol on Nicotine Pharmacokinetic, Pharmacology and Dependence in Mice.' *PLoS ONE*, 10(9): e0137070, 2015.

⁴ Zhang, M., E. Harrison, L. Biswas, et al. 'Menthol Facilitates Dopamine Releasing Effect of Nicotine in Rat Nucleus Accumbens.' *Pharmacology, Biochemistry and Behavior*, 175:47-52, 2018

Pennsylvania. The percentage of individuals who smoke in the Commonwealth is higher than the national average, while the average life expectancy at birth is lower.⁵ Tobacco kills 22,000 adults in Pennsylvania every year and an estimated 244,000 youth, currently under the age of 18, will die prematurely from smoking.⁶

Youth and young adults are particularly susceptible to the clutches of nicotine addiction. By reducing the harshness of cigarette smoking, menthol cigarettes make it easier for new users, particularly youth, to experiment and progress to regular tobacco use. A 1978 internal tobacco industry document about a traditionally menthol-only cigarette brand states that the brand is “being purchased by Black people (all ages), young adults (usually college age), but the base of our business is the high school student.”⁷

Teens who begin smoking with menthol products are twice as likely to become daily lifetime smokers than those who start smoking nonmentholated products.⁸ The human brain continues to develop until about age 25, making the adolescent brain more vulnerable to nicotine’s effects than the adult brain. The combined effects of nicotine and menthol in the developing brain make youth who smoke menthol cigarettes particularly vulnerable to the effects of menthol on nicotine dependence.⁹ In 2019, 26.7 percent of Pennsylvania high school youth reported currently using tobacco products. Compared to national statistics, more high school students in Pennsylvania smoked cigarettes on at least one day in the past 30 days, smoked cigarettes on 20 or more days during the past 30 days, smoked cigarettes every day, and smoked more than ten cigarettes per day. Less high school students, however, tried to quit using tobacco products in the past 12 months than did nationally.¹⁰

Tobacco-related health disparities particularly affect those who have also experienced systemic obstacles to health due to the inequitable distribution of social, political, economic, and environmental resources. In Pennsylvania, menthol cigarette smokers are significantly more likely to identify as Black, live in public housing, identify as LGBT, have less than a high school education, be female, and are younger than non-menthol smokers.¹¹ Menthol cigarette use is also higher among adults with behavioral health conditions or illness.¹² Young women who smoke menthol cigarettes have reported an increased likelihood of suffering anxiety or depression compared to non-menthol smokers.¹³ Higher levels of menthol cigarette smoking have

⁵ CDC, Behavioral Risk Factor Surveillance System, 2018.

⁶ Campaign for Tobacco Free-Kids. The Toll of Tobacco in Pennsylvania. Available at: <https://www.tobaccofreekids.org/problem/toll-us/pennsylvania>

⁷ Achey, Ted L. “U.S Exhibit 22,357, Memo, ‘Product Information’ TED L. ACHEY, LORILLARD INC., August 30, 1978.” Depositions and Trial Testimony (DATTA); RICO Privilege Downgrades Collection. 1978.

⁸ Nonnemaker J, Hersey J, Homs G, Busey A, Allen J, Vallone D. Initiation with menthol cigarettes and youth smoking uptake. *Addiction* 2013; 108(1): 171-178.

⁹ Goriounova, N.A. and H.D. Mansvelder. “Short- and Long-Term Consequences of Nicotine Exposure During Adolescence for Prefrontal Cortex Neuronal Network Function.” *Cold Spring Harbor Perspectives in Medicine*, 2: a012120, 2012.

¹⁰ CDC, Youth Risk Behavioral Surveillance System, 2019.

¹¹ Research & Evaluation Group at PHMC, June 2022; Tobacco User Survey, 2021. Presented at the June 8, 2022 PADOH, Division of Tobacco Prevention and Control Technical Assistance Conference.

¹² FDA, “Memorandum of Summary of Internal Analyses Using Data From the 2019 National Survey on Drug Use and Health on Menthol Cigarette Smoking.” Silver Spring, MD: HHS, FDA, Center for Tobacco Products, 2022.

¹³ Cohn, A.M., A.L. Johnson, E. Hair, et al. “Menthol Tobacco Use Is Correlated with Mental Health Symptoms in a National Sample of Young Adults: Implications for Future Health Risks and Policy Recommendations.” *Tobacco Induced Diseases*, 14(1), 2016.

also been reported in pregnant smokers with lower educational attainment and lower household income than their counterparts.¹⁴

Black smokers have the highest percentage of menthol cigarette use compared to other racial and ethnic groups.¹⁵ More than seven out of ten Black youth, ages 12-17 years, who smoke use menthol cigarettes.¹⁶ According to a 2018 National Survey on Drug Use and Health, 85 percent of Black smokers smoked menthol cigarettes, compared to 30 percent of White smokers. Black children and adults are also more likely to be exposed to secondhand smoke than any other racial or ethnic group.¹⁷ Menthol cigarette smokers, especially Black smokers, also have lower rates of smoking cessation success than non-menthol smokers. Among Black daily smokers, menthol smokers also had 53 percent lower odds of quitting smoking compared to nonmenthol smokers.¹⁸

This increased prevalence of menthol cigarette smoking has contributed to a disproportionate burden of tobacco-related morbidity and mortality among members of underserved communities. Among Black Americans, tobacco use is a major contributor to the three leading causes of death - heart disease, cancer, and stroke.^{19,20} The risk of developing diabetes, the fourth leading cause of death among Black Americans, is 30–40 percent higher for cigarette smokers over nonsmokers.²¹

Greater use among certain populations is no accident, but the result of the predatory marketing of highly engineered menthol cigarettes to specific groups. Targeted marketing of these products in urban communities has occurred through print advertisement placements in magazines with Black and younger readership, price discounts, point-of-sale marketing in Black and lower-income communities, and lower prices for menthol cigarettes near public schools.²² Areas with underserved populations tend to have more tobacco retailers per capita, leading to greater tobacco advertising exposure. Menthol products are given more shelf space in retail outlets within Black and other minority neighborhoods.²³

Tobacco also has a significant, negative impact on Pennsylvania's economy. Annually, cigarette smoking costs Pennsylvania more than \$6.4 billion in annual health care costs and \$5.7 billion in productivity losses.

¹⁴ Stroud, L.R., C. Vergara-Lopez, M. McCallum, et al. "High Rates of Menthol Cigarette Use among Pregnant Smokers: Preliminary Findings and Call for Future Research." *Nicotine & Tobacco Research*, 22(10):1711–1717, 2020.

¹⁵ Giovino GA, Villanti AC, Mowery PD et al. Differential Trends in Cigarette Smoking in the USA: Is Menthol Slowing Progress? *Tobacco Control*, doi:10.1136/tobaccocontrol-2013-051159, August 30, 2013.

¹⁶ Gardiner PS. The African Americanization of Menthol Cigarette Use in the United States. *Nicotine and Tobacco Research* 2004; 6: Suppl 1: S55-65.

¹⁷ Tsai J, Homa DM, Gretzke AS, et al. Exposure to Secondhand Smoke Among Nonsmokers — United States, 1988–2014. *Morbidity and Mortality Weekly Report*, 2018;67(48):1342–1346.

¹⁸ Babb S, Malarcher A, Schauer G, et al. Quitting Smoking Among Adults—United States, 2000–2015. *Morbidity and Mortality Weekly Report*, 2017;65(52):1457-64

¹⁹ U.S. Department of Health and Human Services. Tobacco Use Among U.S. Racial/Ethnic Minority Groups—African Americans, American Indians and Alaska Natives, Asian Americans and Pacific Islanders, and Hispanics: A Report of the Surgeon General. U.S. Department of Health and Human Services, CDC, Office on Smoking and Health, 1998.

²⁰ Kochanek KD, Murphy SL, Xu J, Tejada-Vera B. Deaths: Final Data for 2014. *Natl Vital Stat Rep*. 2016 Jun;65(4):1-122. PMID: 27378572.

²¹ Heron M. Deaths: leading causes for 2010. *Natl Vital Stat Rep*. 2013 Dec 20;62(6):1-96. PMID: 24364902.

²² Wailoo K. *Pushing Cool: Big Tobacco, Racial Marketing, and the Untold Story of the Menthol Cigarette*. University of Chicago Press; 2021.

²³ Centers for Disease Control and Prevention. No Menthol Sunday. Available at: <https://www.cdc.gov/tobacco/features/menthol/index.html>



These amounts do not include health costs caused by exposure to secondhand smoke nor by smoking-caused fires.

The American Lung Association's annual "State of Tobacco Control" report evaluates and grades state government actions in enacting proven-effective tobacco control laws and policies necessary to save lives. The 2022 State of Tobacco Control report gave Pennsylvania a failing grade for levels of tobacco prevention and program funding, restrictions on flavored tobacco products, levels of state tobacco taxes and access to cessation services. Pennsylvania received a 'D' in smoking restrictions.ⁱⁱ

Several states and localities have also attempted to restrict the sale of tobacco products. To date, at least 345 localities nationwide have passed restrictions on the sale of flavored tobacco products, more than 160 of which also restrict the sale of menthol cigarettes.ⁱⁱⁱ In Pennsylvania however, there are no restrictions on menthol flavoring and state preemption laws severely limit any measures local health departments and localities can take to restrict the sale of tobacco products.

Comprehensive tobacco control policies help achieve health equity by reducing disparities among groups most affected by tobacco use and secondhand smoke exposure. A multiyear analysis of the National Survey on Drug Use and Health report data found that the 2009 Tobacco Control Act, which prohibited the use of characterizing flavorings in cigarettes, except for menthol, was associated with a 43 percent decline in smoking among youth, ages 12 to 17, and a 27 percent decline in smoking among young adults, ages 18 to 25. The study also found an increase in smoking of menthol cigarettes among youth immediately after the ban took effect, suggesting a substitution effect between flavored tobacco products.^{iv}

As the Tobacco Products Scientific Advisory Committee Report concluded: the "removal of menthol cigarettes from the marketplace would benefit public health in the United States." While we have made strides in local tobacco control and cessation efforts, federal regulation of menthol cigarettes is essential to improving equity in coverage and health benefits for populations at greatest risk.

Given the incredible and intentional harm caused by menthol cigarettes, we urge the FDA to enact the proposed regulation to prohibit menthol as a characterizing flavor in cigarettes as expeditiously as possible.

Sincerely,

Handwritten signature of Debra Bogen in black ink.

Debra Bogen, MD
Director
Allegheny County
Health Department

Handwritten signature of Garry Ritter in black ink.

Garry Ritter
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ⁱ Campaign for Tobacco-Free Kids, Broken Promises to Our Children: a State-by-State Look at the 1998 State Tobacco Settlement 22 Years Later FY2021, 2020.

ⁱⁱ American Lung Association. State of Tobacco Control 2022. Available at: <https://www.lung.org/research/sotc>

ⁱⁱⁱ Bach, Laura. Campaign for Tobacco-Free Kids. States & localities that have restricted the sale of flavored tobacco products. June 2022. Available at: <https://www.tobaccofreekids.org/assets/factsheets/0398.pdf>

^{iv} Rosshem ME, Livingston MD, Krall JR, et al. Cigarette Use Before and After the 2009 Flavored Cigarette Ban. The Journal of adolescent health: official publication of the Society for Adolescent Medicine. 2020.