



AMERICAN ASSOCIATION FOR RESPIRATORY CARE
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Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

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

The American Association for Respiratory Care (AARC) appreciates the opportunity to submit comments in strong support of the proposed product standard prohibiting menthol as a characterizing flavor in cigarettes, which will reduce youth smoking, save lives, and advance health equity. The proposed rule will have an enormous public health impact in the short and long term.

The AARC is a national professional organization with a membership of 40,000 respiratory therapists who specialize in providing pulmonary diagnostics and treatment for patients who suffer from respiratory conditions like chronic obstructive pulmonary disease (COPD), asthma, pneumonia, lung trauma and other respiratory-related diagnoses. Respiratory therapists are educated and trained in all aspects of pulmonary medicine and are acutely aware of the devastating impact of tobacco use on public health.

Prohibiting menthol cigarettes will increase smoking cessation and save lives. Smoking remains the leading cause of preventable disease and death in the United States.¹ Prohibiting menthol cigarettes, which are more difficult to quit than non-menthol cigarettes, will reduce this burden by increasing smoking cessation.² As described in the rule, modeling studies have estimated that 324,000 to 654,000 smoking attributable deaths would be avoided by the year 2060 if menthol cigarettes were no longer available in the United States.³ Tobacco use is a major risk factor for COPD, which is a leading cause of death in the United States and accounts for increased hospital readmission rates due to acute exacerbations of the disease. Smoking at a young age can result in respiratory disease later in life that can seriously impact quality of life. As the lung health experts in their hospitals and in their communities, respiratory therapists are the key practitioners in helping people quit smoking.

Prohibiting menthol cigarettes will reduce youth smoking. Menthol cools and numbs the throat, reduces the harshness of tobacco smoke, and makes cigarettes more appealing to new smokers, particularly young people. As is well-documented in the proposed rule, menthol facilitates experimentation, progression to regular smoking of menthol cigarettes and contributes to greater nicotine dependence.⁴ Half of youth who have ever tried smoking started with menthol cigarettes⁵ and menthol cigarettes were responsible for 10.1 million additional new smokers between 1980 and 2018.⁶ According to the Centers for Disease Prevention and Control (CDC), smoking and secondhand smoke exposure during childhood and teenage years can slow lung growth and development which can increase the risk of developing COPD in adulthood. The proposed product standard to prohibit menthol in cigarettes is an important and critical step in preventing youth from becoming new smokers.

Prohibiting menthol cigarettes would decrease tobacco-related health disparities and advance health equity, especially among Black Americans. Menthol cigarettes have caused substantial harm to public health, and particularly to Black Americans. For more than 60 years, the tobacco industry has targeted Black Americans with marketing and price promotions for menthol cigarettes,⁷ and as a result, 85% of Black smokers smoke menthol cigarettes compared to 29% of White smokers.⁸ Consequently, Black Americans are less likely to successfully quit smoking⁹ and suffer disproportionately from tobacco-related disease and death.¹⁰ Despite accounting for 12% of the population, Black Americans represented 41% of premature deaths caused by menthol cigarettes between 1980 and 2018.¹¹ In addition to youth and Black smokers, preference for menthol is also disproportionately high among Hispanic and Asian smokers, lesbian, gay, and bisexual smokers, smokers with mental health problems, socioeconomically disadvantaged populations, and pregnant women.¹² Importantly, the proposed product standard is expected to substantially decrease tobacco-related health disparities and to advance health equity across population groups.

On behalf of the American Association for Respiratory Care, we urge the FDA to act swiftly to issue this lifesaving rule in final form.

Respectfully submitted,



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¹ U.S. Department of Health and Human Services (HHS). The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014

² Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. 26396, 26466-26468 and 26473-26477 (proposed May 4, 2022) (to be codified at 21 C.F.R. pt. 1166).

³ Levy, D.T., J. Pearson, A. Villanti, et al. "Modeling the Future Effects of a Menthol Ban on Smoking Prevalence and Smoking-Attributable Deaths in the United States." *American Journal of Public Health*, 101:1236-1240, 2011. Available at <https://doi.org/10.2105/AJPH.2011.300179>. Levy, D.T., R. Meza, Z. Yuan, et al. "Public Health Impact of a US Ban on Menthol in Cigarettes and Cigars: A Simulation Study." *Tobacco Control*, 2021. Available at <https://doi.org/10.1136/tobaccocontrol-2021-056604>.

⁴ Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. 26396, 26463-26466 and 26469-26470 (proposed May 4, 2022) (to be codified at 21 C.F.R. pt. 1166)

⁵ Ambrose, BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014," *Journal of the American Medical Association*, published online October 26, 2015.

⁶ Le, TT, "An Estimation of the Harm of Menthol Cigarettes in the United States from 1980 to 2018," *Tobacco Control*, published online on February 25, 2021.

⁷ Gardiner, PS, "The African Americanization of menthol cigarette use in the United States," *Nicotine & Tobacco Research*, 6(S1): S55-S65, 2004. Yerger, VB, et al., "Racialized geography, corporate activity, and health disparities: Tobacco industry targeting of inner cities," *Journal of Health Care for the Poor and Underserved*, 18: 10-38, 2007. Hafez, N. & Ling, P.M. "Finding the Kool Mixx: how Brown & Williamson used music marketing to sell cigarettes," *Tobacco Control* 15: 359-366, 2006.

⁸ Delnevo, CD, et al., "Banning Menthol Cigarettes: A Social Justice Issue Long Overdue," *Nicotine & Tobacco Research*, 22(10): 1673-1675, 2020.

⁹ CDC, "Current Cigarette Smoking Among Adults—United States, 2005-2015," *Morbidity & Mortality Weekly Report*, 65(44): 1205-1211, November 11, 2016, http://www.cdc.gov/mmwr/volumes/65/wr/mm6544a2.htm?s_cid=mm6544a2_w.

¹⁰ CDC, "Vital Signs: Disparities in Tobacco-Related Cancer Incidence and Mortality—United States, 2004-2013," *Morbidity & Mortality Weekly Report*, 65(44): 1212-1218, <http://www.cdc.gov/mmwr/volumes/65/wr/mm6544a3.htm>; See also American Cancer Society. *Cancer Facts & Figures for African American/Black People 2022-2024*. Atlanta: American Cancer Society, 2022. HHS, "Tobacco Use Among US Racial/Ethnic Minority Groups—African Americans, American Indians and Alaskan Natives, Asian Americans and Pacific Islanders, and Hispanics: A Report of the Surgeon General," 1998, http://www.cdc.gov/tobacco/data_statistics/sgr/1998/complete_report/pdfs/complete_report.pdf

¹¹ Mendez, D and Le, TT, "Consequences of a match made in hell: the harm caused by menthol smoking to the African American population over 1980-2018," *Tobacco Control*, published online September 16, 2021.

¹² Delnevo, CD, et al., "Banning Menthol Cigarettes: A Social Justice Issue Long Overdue," *Nicotine & Tobacco Research*, 22(10): 1673-1675, 2020.