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ABC MISSION:

To promote the prevention and treatment of cardiovascular disease including stroke, in Blacks and other minorities and to achieve health equity for all through the elimination of disparities.

August 2, 2022

Robert M. Califf, M.D.
Commissioner
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”

Dear Commissioner Califf:

The Association of Black Cardiologists appreciates the opportunity to submit comments in strong support of the proposed product standard prohibiting menthol as a characterizing flavor in cigarettes. This proposal, once finalized, will put an end the predatory practices of the tobacco industry on African Americans and young people who disproportionately use menthol-flavored products and will reduce disease and death from combusted tobacco product use, a leading cause of preventable cardiovascular death in the United States.

Founded in 1974, the ABC is a nonprofit organization representing cardiovascular specialists, cardiologists in training and other health professionals, as well as community health advocates. The ABC is dedicated to eliminating disparities related to cardiovascular disease for all people of color and adheres to the vision that all people regardless of race, ethnicity or gender should benefit equally from reduction in the frequency, duration and impact of diseases of the heart and blood vessels.

The ABC is pleased to have co-signed the comprehensive comment letter led and submitted by the Campaign for Tobacco-Free Kids to the FDA in response to this proposed rule. Given the detrimental effect of smoking on cardiovascular health, the ABC wishes to underscore several important points presented in that letter.

Prohibiting menthol cigarettes would decrease tobacco-related health disparities and advance health equity, especially among African Americans. The use of cigarettes is a leading cause of coronary heart disease, stroke, chronic obstructive pulmonary

disease, and peripheral vascular disease which can lead to limb amputation. These diseases affect African Americans at higher rates and contribute to health disparities in this country.

The proposed rule will have an enormous public health impact both in the short and long terms, including by contributing to the advancement of health equity.

For more than 60 years, the tobacco industry has targeted African Americans with marketing and price promotions for menthol cigarettes,ⁱ and, as a result, 85 percent of Black smokers smoke menthol cigarettes compared to 29 percent of White smokers.ⁱⁱ Consequently, African Americans are less likely to successfully quit smokingⁱⁱⁱ and suffer disproportionately from tobacco-related disease and death.^{iv} For example, smoking increases the development of diabetic foot amputation,^v and the rate of limb amputation in African Americans with peripheral arterial disease is two to four times the rate of white patients.^{vi} Contributing factors such as diabetes and renal disease drive this disparity. Despite accounting for 12 percent of the population, African Americans represented 41 percent of premature deaths caused by menthol cigarettes between 1980 and 2018.^{vii}

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.^{viii} Half of youth who have ever tried smoking started with menthol cigarettes^{ix} and menthol cigarettes were responsible for 10.1 million additional new smokers between 1980 and 2018.^x Bold steps, including a ban on menthol as a characterizing flavor in cigarettes are needed to prevent the next generation of smokers if we want to continue progress in reducing cardiovascular-associated disease and death in this country, and one of the most effective ways to do that is to prohibit the manufacturing and sale of flavored tobacco products.

A study published in the *New England Journal of Medicine* in April 2022 shows that youth smoking is associated with a 60 percent greater risk of a fatal cardiovascular event in adulthood.^{xi} Further, while cardiovascular events in children are rare, autopsies have shown pervasive histologic atherosclerotic plaque in the aorta and coronary arteries in young persons that were associated with dyslipidemia, elevated blood pressure, and smoking.^{xii} The study underscores the importance of public health efforts for maintaining cardiovascular health in children as a strategy for reducing the risk of premature cardiovascular disease in adulthood. Prohibiting menthol as a characterizing flavor in cigarettes to deter youth experimentation and addiction, as well as to increase the number of smokers who quit, is a sound, rational and necessary public health strategy.

Prohibiting menthol cigarettes will increase smoking cessation and save lives. Smoking cessation is one of the most important actions people who smoke can take, regardless of age, smoking duration or intensity, to reduce their risk for cardiovascular disease.^{xiii} The health benefits even extend to patients already diagnosed with coronary heart disease because when the toxic effects of nicotine are ceased, the risk for further damage is reduced. Further, it has been shown that those who quit smoking after a heart attack reduce their risk for another heart attack. Prohibiting menthol cigarettes, which are more difficult to quit than non-menthol cigarettes, will

reduce the burden of preventable cardiovascular disease by increasing smoking cessation.^{xiv} As described in the rule, modeling studies have estimated that 91,744 to 237,317 smoking attributable deaths among Blacks would be avoided by the year 2060 if menthol cigarettes were no longer available in the United States.^{xv}

The ABC urges the FDA to act swiftly to finalize this proposed rule. Questions or requests for additional information should be directed to Camille Bonta, ABC policy consultant, at cbonta@summithealthconsulting.com or (202) 320-3658.

Sincerely,



Anekwe E. Onwuanyi, MD
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Association of Black Cardiologists



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ⁱ 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.

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

ⁱⁱⁱ 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.

^{iv} 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/sg/1998/complete_report/pdfs/complete_report.pdf

^v Liu M, Zhang W, Yan Z, Yuan X. Smoking increases the risk of diabetic foot amputation: A meta-analysis. *Exp Ther Med*. 2018 Feb;15(2):1680-1685. doi: 10.3892/etm.2017.5538. Epub 2017 Nov 22. PMID: 29434753; PMCID: PMC5774386.

^{vi} Holman KH, Henke PK, Dimick JB, Birkmeyer JD. Racial disparities in the use of revascularization before leg amputation in Medicare patients. *J Vasc Surg*. 2011 Aug;54(2):420-6, 426.e1. doi: 10.1016/j.jvs.2011.02.035. Epub 2011 May 14. PMID: 21571495; PMCID: PMC3152619.

^{vii} 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.

^{viii} 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)

^{ix} 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.

^x 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.

^{xi} Jacobs DR Jr, Woo JG, Sinaiko AR, Daniels SR, Ikonen J, Juonala M, Kartiosuo N, Lehtimäki T, Magnussen CG, Viikari JSA, Zhang N, Bazzano LA, Burns TL, Prineas RJ, Steinberger J, Urbina EM, Venn AJ, Raitakari OT, Dwyer T. Childhood Cardiovascular Risk Factors and Adult Cardiovascular Events. *N Engl J Med*. 2022 May 19;386(20):1877-1888. doi: 10.1056/NEJMoa2109191. Epub 2022 Apr 4. PMID: 35373933.

^{xii} Ibid.

^{xiii} Centers for Disease Control and Prevention. Cardiovascular Care Settings and Smoking Cessation. <https://www.cdc.gov/tobacco/patient-care/care-settings/cardiovascular/index.htm>

^{xiv} 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).

^{xv} Levy, D.T., J. Pearson, A. Villanti, et al. “Modeling the Future Effects of a Menthol Ban on Smoking Prevalence and Smoking-Attributable Deaths zanbat@comcast.net in the United States.” *American Journal of Public Health*, 101:1236-1240, 2011. Available at <https://doi.org/10.2105/AJPH.2011.300179>.