



The Association for Nonsmokers-Minnesota

July 1, 2022

Commissioner Robert M. Califf M.D.
c/o Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20825

Re: Proposed tobacco product standard eliminating menthol as a characterizing flavor in cigarettes

Docket No. FDA-2021-N-1349

Dear Commissioner Califf,

On April 28, 2022, the U.S. Food and Drug Administration proposed an historic rule to prohibit menthol as a characterizing flavor in cigarettes. The Association for Nonsmokers-Minnesota (ANSR) from Saint Paul, Minnesota is pleased to submit these comments to the U.S. Food and Drug Administration 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 both in the short and long term.

Founded in 1975, ANSR is a 501(c)(3) nonprofit organization dedicated to reducing the human and economic costs of commercial tobacco use. ANSR is Minnesota's oldest nonprofit dedicated solely to tobacco control and has a proven track record of passing bold tobacco control policies. Our core commitments are to reduce the number of young smokers, combat health inequities, and advocate for the health of all Minnesotans and have a strong history of collaboration with diverse partners and community groups to advance policy change at the city, county, and state level. ANSR has led efforts in several cities across the state to restrict or end the sale of menthol and all flavored tobacco products. While the decision is long overdue, this action is a powerful and crucial step toward mitigating some of the disparities in health outcomes for minority communities in our state, especially among Black Minnesotans.

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,¹ and as a result, 85% of Black smokers smoke menthol cigarettes compared to 29% of White smokers.² Consequently, Black Americans are less likely to successfully quit smoking³ and suffer disproportionately from tobacco-related disease and death.⁴ Despite accounting for 12% of the population, Black Americans represented 41% of premature deaths caused by menthol cigarettes between 1980 and 2018.⁵ 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.⁶ Importantly, the proposed product standard is expected to substantially decrease tobacco-related health disparities and to advance health equity across population groups.

Smoking remains the leading cause of preventable disease and death in the United States.⁷ Prohibiting menthol cigarettes, which are more difficult to quit than non-menthol cigarettes, will reduce this burden by increasing smoking cessation.⁸ A research study led by the African American Leadership Forum in 2016 found that U.S.-born African Americans confirm menthol tobacco is a serious threat to their health with 84% of surveyed smokers smoke a brand that is menthol and 72% of surveyed smokers agreed menthol makes it harder to quit. The 2016 research also showed that a majority of African American community members support new laws to reduce tobacco's harm with 69% of surveyed smokers supporting more laws to reduce the harms of smoking and 60% of surveyed smokers said they would quit if menthol was no longer sold in stores. This data clearly illustrates that removing menthol and flavored tobacco from the marketplace will address health disparities caused by Big Tobacco's lethal tactics. Racism is a public health crisis. Clearing the market of menthol and all flavored products will directly improve the health of Black communities and other groups targeted by Big Tobacco.

¹ Gardiner, PS, "The African Americanization of menthol cigarette use in the United States," *Nicotine & Tobacco Research*, 6(S1): S55-S65, 2004. Yeger, 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.

² Delnevo, CD, et al., "Banning Menthol Cigarettes: A Social Justice Issue Long Overdue," *Nicotine & Tobacco Research*, 22(10): 1673-1675, 2020.

³ 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.

⁴ 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>.

⁵ 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.

⁶ Delnevo, CD, et al., "Banning Menthol Cigarettes: A Social Justice Issue Long Overdue," *Nicotine & Tobacco Research*, 22(10): 1673-1675, 2020.

⁷ 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

⁸ 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).

Menthol makes smoking easier and more attractive for youth. Menthol makes experimentation easier because it can mask irritation from smoking. Menthol flavoring makes it easier for kids to start smoking and harder for adults to quit.^{9,10} Menthol tobacco products appeal to youth. More than a third of Minnesota adolescent smokers (34 percent) report smoking menthol cigarettes, compared to 28 percent of Minnesota adult smokers.^{11,12} There is more that can be done to prevent youth from becoming addicted to commercial tobacco products and the predatory practices of the tobacco industry.

There is local support and momentum for menthol restrictions. In Minnesota, 17 cities have passed strong ordinances to restrict or end the sales of menthol tobacco products. ANSR has created and led the community-driven campaign, Beautiful Lies Ugly Truth (www.beautifullieuglytruth.org), to engage with communities that have been disproportionately impacted by tobacco use and encourage decision makers to pass comprehensive policies to reduce access to menthol tobacco products. Since 2017, ANSR has worked with some of the biggest cities in the metro area such as Minneapolis, Saint Paul, Bloomington, Edina and Roseville to pass some of the first comprehensive restrictions on the sale of all menthol-flavored tobacco products in the country. These cities have successfully adopted and implemented restrictions to sell menthol tobacco products and substantially reduced access and availability of these products. The number of outlets selling menthol tobacco products decreased by 76% in Minneapolis and 62% in St. Paul.¹³ There are several more municipalities that continue to show support for comprehensive regulation of menthol tobacco products in their communities.

Prohibiting menthol as a characterizing flavor in cigarettes will help to reduce the tremendous toll of tobacco in Minnesota:¹⁴

- High school students who smoke: 3.2% (9,300)
- Additional kids (under 18) who become new regular, daily smokers each year: 1500
- Adults in Minnesota who smoke: 13.8% (598,500)
- Adults who die each year in Minnesota from their own smoking: 5900
- Kids alive in Minnesota today who will ultimately die from smoking: (given current smoking levels): 102,000

⁹ U.S. Food & Drug Administration. Preliminary scientific evaluation of the possible public health effects of menthol versus non-menthol cigarettes. <http://www.fda.gov/downloads/UCM361598.pdf>.

¹⁰ U.S. Department of Health and Human Services. The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General. 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.

¹¹ Minnesota Department of Health. Teens and Tobacco in Minnesota: Highlights from the 2017 Youth Tobacco Survey. February 2018.

¹² ClearWay Minnesota, Minnesota Department of Health. Minnesota Adult Tobacco Survey, 2018 Update. 2019.

¹³ Bosma, Linda M et al., "Restricting Sales of Menthol Tobacco Products: Lessons Learned from Policy Passage and Implementation in Minneapolis, St. Paul, and Duluth, Minnesota." *Health equity* vol. 5,1 439-447. published online June 18, 2021.

¹⁴ Campaign for Tobacco-Free Kids, The Toll of Tobacco in Minnesota, <https://www.tobaccofreekids.org/problem/toll-us/minnesota>.

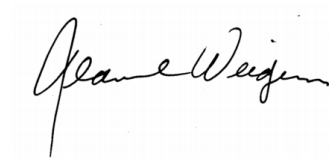
- Annual health care expenditures in Minnesota directly caused by tobacco use: \$2.51 billion

The FDA has proposed that this rule would take effect one year after the final rule is issued. Given the number of lives that the rule would save, the Association for Nonsmokers-Minnesota strongly urges the FDA to act more quickly to get the final regulation in place.

In the proposed rule, it is apparent that the FDA is considering exempting heated cigarette products like iQOS or so-called Very Low Nicotine (VLN) cigarettes from this rule. Given the potential harm of these products, it is critical that they not be exempted from the proposed standard.

Finally, the proposed rule indicated that the FDA is considering establishing a process by which a manufacturer could request an exemption from the standard for a particular product on a case-by-case basis. The Association for Nonsmokers-Minnesota strongly discourages any exemptions to ensure the strongest possible public health benefit from the final rule.

Respectfully,



Jeanne Weigum, Director
Association for Nonsmokers-Minnesota