

August 1, 2022

Robert M. Califf, MD Commissioner U.S. Food and Drug Administration 10903 New Hampshire Ave. Silver Spring, MD 20993

RE: Tobacco Product Standard for Menthol in Cigarettes (Docket No. FDA-2021-N1349)

Dear Commissioner Califf,

The American College of Physicians (ACP) appreciates the opportunity to comment on the Tobacco Product Standard for Menthol in Cigarettes proposed rule. ACP is the largest medical specialty organization and the second largest physician membership society in the United States. ACP members include 160,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness. Internal medicine specialists treat many of the patients at greatest risk from COVID-19, including the elderly and patients with pre-existing conditions like diabetes, heart disease and asthma.

According to the Centers for Disease Control and Prevention, tobacco use is the leading preventable cause of mortality in the United States, and cigarette smoking is responsible for over 480,000 deaths annually. Smoking burdens almost every organ system and causes diseases that internal medicine physicians treat every day, including cancer, coronary heart disease, and chronic obstructive pulmonary disease. An estimated \$227 billion in U.S health care spending in 2014 was attributed to smoking. Although cigarette smoking rates have declined over the last 15 years, nearly 13% of the adult population reported smoking in 2020.

The American College of Physicians strongly supports the prohibition on the use of menthol as a characterizing flavor in cigarettes, cigarette components, and parts. ACP has long supported a ban on all flavored tobacco products because they attract young people and make it harder for established smokers to quit. From 1980 to 2018, menthol cigarettes were attributed to over 10 million new smokers, 3 million life-years lost, and nearly 380,000 premature deaths.

Menthol cigarettes are preferred by new smokers, including adolescents

Nearly half of young cigarette smokers used menthol cigarettes in 2018. For decades, tobacco companies have enticed young people and uninitiated smokers with flavored tobacco products. Tobacco companies have marketed menthol cigarettes as smoother, healthier alternatives to non-menthol products. The World Health Organization notes that menthol products are targeted at young people as "an attractive starter product for new smokers including youth and young adults." The literature shows that menthol's cooling, analgesic and anesthetizing effects help mask the harshness of cigarette smoke, making it easier for new smokers to inhale more nicotine and may increase smoking dependence and frequency among young people. According to the World Health Organization, "consumers perceive menthol cigarettes as offering some implicit health protection or medicinal benefit that non-menthol cigarettes do not provide."

## Menthol and health disparities

In 2011, the FDA concluded that menthol cigarettes are more addictive and harder to quit than non-menthol products, especially among Black smokers. The 2020 <u>Surgeon General report</u> on smoking cessation noted that "predatory marketing by the tobacco industry is common in geographic areas with large numbers of Black residents, which may negatively influence cessation." This alludes to the decades-long campaign by tobacco companies to market menthol cigarettes to Black Americans, including through targeted advertising and sponsoring music festivals. Targeting a dangerous, lethal product at a specific demographic is especially insidious. According to <u>Phillip Wilbur</u> of the Smoking Control Advocacy Resource Center, "when (tobacco companies) decide they want to sell to a certain segment of the population, what they are deciding is that they want that segment to die at a higher rate. That may not be their intention, but that's the effect." During consideration of the Family Smoking Prevention and Tobacco Control Act, a bipartisan group of antismoking advocates, including seven former federal health secretaries, sent <u>a letter</u> to the U.S. Congress recommending "(m)enthol should be banned so that it no longer serves as a product the tobacco companies can use to lure African American children."

Unfortunately, the tobacco industry's strategy has been successful: In the early 1950s, only about 5% of Black Americans favored menthol products; in 2018, 85% of Black American smokers used menthol cigarettes compared to 29% of White smokers. A <u>recent study</u> quantifies the harmful effects of menthol cigarettes on Black Americans over the last 40 years, including 1.5 million new smokers, 157,000 smoking-related premature deaths, and 1.5 million life years lost. Removing menthol cigarettes from the market would achieve two important goals — increasing cessation and helping to eliminate health disparities.

## Menthol and smoking cessation

Quitting smoking greatly reduces risk of coronary artery disease, cancer, stroke, and smoking-related mortality; decreases blood pressure, heart rate, and cough; and improves lung function and circulation. However, menthol may impede the ability for smokers to quit and experience these improved health outcomes. A meta-analysis concluded that Black Americans who smoke menthol cigarettes have a <u>lower likelihood of cessation</u> compared to those who use non-menthol cigarettes. Other evidence shows that across all racial and ethnic groups, persons who

smoke menthol are <u>less likely to achieve long-term cessation</u> of over 6 months than those who used non-menthol cigarettes. A ban on menthol cigarettes will increase cessation rates.

## A menthol ban will have a positive effect on public health

A ban on menthol in cigarettes is long overdue. The evidence is clear that prohibiting use of menthol as a characterizing flavor in cigarettes and cigarette components and parts would have a positive effect on public health. A 2017 systematic review concluded that banning menthol would likely to "reduce youth smoking initiation, improve smoking cessation outcomes in adult smokers, and in turn, benefit public health." A 2019 study concluding that a menthol ban would improve cessation rates among Black Americans and a 2020 meta-analysis concluded that "(f)indings of an association with lower likelihood of cessation among black/African American smokers, likely resulting from the tobacco industry's marketing influence, support the ban of menthol flavoring as part of a comprehensive tobacco control effort to increase cessation among black/African American smokers." In England, menthol smoking rates among young people dropped after a menthol cigarette ban was applied. After Canada implemented a menthol cigarette ban, quit attempts and quit success rates increased.

We strongly urge the FDA to swiftly implement a ban on menthol cigarettes. Thank you for the opportunity to comment on this proposed rule. Please contact Ryan Crowley, Senior Associate for Health Policy at rcrowley@acponline.org with comments or questions.

Sincerely,

Ryan Mire, MD, FACP

President

American College of Physicians