FDA Proposes Rule Prohibiting Menthol Cigarettes

Tobacco control researchers say this proposed change could have the greatest impact on youth and African American smokers.

July 13, 2022 By National Cancer Institute

Menthol cigarettes could soon be prohibited in the United States if new tobacco product standards proposed by the Food and Drug Administration (FDA) are finalized and take effect.

Prohibiting menthol as a "characterizing flavor" in cigarettes is expected to make them less appealing, reducing diseases and deaths caused by cigarette smoking. Tobacco control researchers say this proposed change could have the greatest impact on youth and African American smokers, who smoke menthol cigarettes at a far higher rate than other smokers.

FDA also proposed a rule prohibiting all characterizing flavors (e.g., grape, cotton candy)—except tobacco flavoring—in cigars to help curb their appeal.

The proposed rules, announced on April 28, are open for public comment through August 2.

"This is a very large public health step," said Priscilla Callahan-Lyon, M.D., senior science advisor in FDA's Center for Tobacco Products. "If finalized, this rule will make the manufacturing and sale of menthol cigarettes illegal in the United States. Combined with continued efforts at prevention and cessation, these actions will have significant public health benefits."

The proposed rule aligns with the Biden Administration's Cancer Moonshot℠ goal of reducing deaths from cancer by at least 50% over the next 25 years, Dr. Callahan-Lyon said. Smoking is estimated to account for 30% of all cancer deaths in the United States.

"This is one of the most important opportunities we've had in tobacco control in a long time," said Michele Bloch, M.D., Ph.D., chief of NCI's Tobacco Control Research Branch.

"We anticipate that once menthol cigarettes are prohibited, there will be fewer adolescents and young adults who initiate smoking and go on to become regular smokers," Dr. Bloch said. "And we think a substantial portion of African American smokers will take this opportunity to quit."

The evidence against menthol

Tobacco manufacturers add menthol to cigarettes to provide users with a cooling sensation that masks the irritation and harshness of smoking.

Menthol also interacts with nicotine in the brain to enhance the addictiveness of nicotine, making it harder for people to quit smoking, explained Rachel Grana Mayne, Ph.D., a program director in NCI's Tobacco Control Research Branch.

In the proposed rule, FDA noted that in 2019 an estimated 18.5 million people in the United States aged 12 and older smoked menthol cigarettes, a disproportionate number of whom were youths, young adults, and African Americans.

"Menthol cigarettes are often the first cigarette that youth and young adults try," Dr. Grana Mayne said. "Prohibiting these products will reduce smoking's appeal to youth and young adults and is expected to decrease the likelihood that they will continue to experiment with and use cigarettes."

The tobacco industry has aggressively targeted menthol cigarettes to the African American community for many decades, Dr. Callahan-Lyon said. That has contributed to the heavy use of menthol cigarettes by African Americans who smoke (85%) and why disease and death caused by menthol cigarettes falls heavily on this community, she explained.

One NCI-supported study estimated that although 12% of the US general population is African American, they made up 41% of premature deaths from menthol cigarettes between 1980 and 2018.

In 2009, as part of the Family Smoking Prevention and Tobacco Control Act, Congress banned all flavored cigarettes, except for menthol. However, Congress charged FDA's Tobacco Products Scientific Advisory Committee with reviewing the scientific evidence on the harms of menthol in cigarettes and making a recommendation to FDA. In July 2011, the committee issued a report concluding that removing menthol cigarettes from the market would benefit public health in the United States.

Shortly after, FDA's Center for Tobacco Products conducted its own evaluation of the available science on the public health impact of menthol cigarettes. Their analysis concluded that menthol cigarettes are likely associated with numerous problems, including increasing the number of people who start smoking and progress to regular smoking, and a lower likelihood of quitting smoking, particularly among African Americans.

Since then, FDA has continued to evaluate menthol's effects on smoking, including initiation and cessation. "We have come to the conclusion that we have enough science to support prohibiting menthol in cigarettes," said Dr. Callahan-Lyon.

"Research funded and conducted by NCI played an important role in building the evidence base for

the proposed rules," Dr. Bloch said.

Lessons from other countries

Evidence from menthol bans around the world informed FDA's proposed rule, Dr. Callahan-Lyon said.

In 2016, for example, an expert group convened by the World Health Organization found that youth who regularly smoked menthol cigarettes had a harder time quitting than youth who smoked nonmenthol cigarettes. The report recommended that countries ban the use of menthol and related flavorings in cigarettes and possibly all tobacco products. Many countries have done just that, Dr. Bloch said.

The preponderance of evidence from published studies indicates that a ban on menthol cigarettes would profoundly decrease smoking rates, said Geoffrey T. Fong, Ph.D., of the University of Waterloo.

One NCI-funded study, for example, showed that after Canadian health authorities banned menthol cigarettes, people who primarily smoked menthol cigarettes were more likely to quit smoking than nonmenthol cigarette smokers. Extrapolating these findings to the United States, the researchers estimated that a US prohibition on menthol cigarettes could lead to more than 1.3 million US smokers quitting, with a large proportion of them being African American.

A similar study looking at outcomes of a menthol cigarette ban in England found that the number of youth who smoked menthol cigarettes declined substantially after the ban took effect.

A ban on menthol cigarettes in the United States would be "a landmark policy that's likely to lead to tremendous public health benefits, including reductions in cancer," said Dr. Fong, who led the Canadian study. "Anything we can do to get smokers to quit is going to lead to reductions in the overall burden of the number-one preventable cause of cancer."

Beefing up prevention and cessation resources

Helping people quit smoking is the best way to ensure that these rules have maximum benefit for public health, Dr. Callahan-Lyon said. So FDA is working with other federal partners to make sure the support is there for those who are trying to stop.

Other organizations, such as the African American Tobacco Control Leadership Council (AATCL), have led efforts across the United States to prohibit menthol and other flavored tobacco products. Valerie Yerger, N.D., of the University of California, San Francisco, and an AATCL cofounder, said that, for the ban to have the biggest impact, resources from the federal government need to be accompanied by efforts at the state, local, and community levels.

“If you don’t have boots on the ground at the community level, then you don’t have anybody countering” the persistent marketing by the tobacco industry, Dr. Yerger said.

Dr. Yerger also noted the need for investments to address the underlying barriers that contributed to people smoking. “How do we alleviate the inequities that are driving people to smoke?” she asked.

Dr. Grana Mayne agreed, noting that there is a window of opportunity to make sure smoking cessation programs are easily accessible with adequate resources and few barriers to their use.

“The reality is that the communities that are at highest risk and most likely to be affected by prohibiting menthol cigarettes often have limited resources available to them,” she continued. “We need to ensure that people can get help quitting smoking when they decide that they need it, and without any barriers at all.”

NCI offers free, evidence-based resources to help people quit smoking, Dr. Bloch said. NCI’s Smokefree.gov, for example, offers a suite of smoking cessation resources, such as text messaging programs that offer 24/7 support and articles on how to handle the challenges of quitting smoking.

No time to waste

FDA held public listening sessions in June to hear from affected communities. After the public comment period for the proposed rules ends, the agency will review the comments and decide what, if any, changes should be made to the proposed rules, Dr. Callahan-Lyon explained.

Based on the comments FDA receives, the agency may decide to end the rulemaking process, issue a new proposed rule(s), or issue a final rule(s). FDA is currently proposing that any final rule would become effective 1 year after it is published, she said.

In the meantime, it’s important to continue focusing on prevention and cessation, Dr. Callahan-Lyon noted. “Most people who smoke regret ever starting,” she said. “They smoke because they’re addicted. What we need to do is to make it easier for them to quit.”

This story was published by National Cancer Institute on June 22, 2022. It is republished with permission.

© 2026 Smart + Strong All Rights Reserved.