



Federal Regulation of Menthol Tobacco Products: Frequently Asked Questions

Q. What is menthol flavoring in tobacco?

A. Menthol is an ingredient produced synthetically or found organically in plants of the mint family. For years, menthol has been used in products such as toothpaste, cold remedies, topical creams, and peppermint candies, because it provides a cooling sensation by stimulating the nerve endings that detect cold.¹ Recently menthol has come under scrutiny as an additive in cigarettes, because these same cooling properties reduce the harshness of tobacco smoke and the irritation of nicotine. As a result, menthol cigarettes have become a popular choice for those first starting to smoke.²

Q. Why is menthol tobacco flavoring a significant issue in federal tobacco regulation today?

A. Menthol cigarettes are smoked by approximately 19 million Americans, representing an estimated 33.9 percent (more than a quarter) of the U.S. cigarette market.³ Although cigarette use is on the decline in the U.S., sales of menthol cigarettes have steadily increased, especially among young people and new smokers.⁴ According to a 2009 [National Survey on Drug Use and Health](#), adolescents are particularly drawn to menthol cigarettes, with nearly 45% of smokers aged 12 to 17 using them. Most African American teenaged smokers, and 82.7% of black adult smokers, favor menthols.⁵

Public health concerns have been raised about the growth of the menthol cigarette market and the targeted marketing of menthols at specific populations, such as African Americans, women, and youth. Moreover, scientific studies show that because of its sensory effects and flavor, menthol may enhance the addictiveness of cigarettes.⁶ Menthol may also make it more likely for youngsters to start smoking, because (like other flavors) menthol may disguise the strong taste of tobacco, thus making the product more appealing to youth.⁷ Some experts even claim that menthol's "soothing" properties may mask the symptoms of respiratory disease, causing smokers to delay seeking medical attention or quitting.⁸

Q. Since menthol is a "flavor," why weren't menthol cigarettes outlawed along with other flavored cigarettes in September 2009?

A. In June 2009, President Obama signed the [Family Smoking Prevention and Tobacco Control Act](#) giving the Food and Drug Administration (FDA) the power to regulate tobacco products. The Act requires the FDA, within three months of enactment, to end the manufacture, marketing and sale of cigarettes that contain any artificial or natural characterizing flavoring, with one notable exception – menthol.⁹ Although menthol is excluded in the federal prohibition of cigarette flavors, the Act specifically states that the FDA has the authority (now and in the future) to regulate menthol and any other natural or artificial flavoring in cigarettes not specified in the Act.¹⁰

The Act required the FDA to assemble a Tobacco Products Scientific Advisory Committee, whose first task was to study menthol flavoring in tobacco products.¹¹ This advisory committee, which includes doctors, scientists, and public health experts, was asked to provide a report and recommendations on the impact of the use of menthol in cigarettes on the public health, particularly among youth, African Americans, Hispanics and other minorities.¹²

Q. How has the FDA handled the review of menthol cigarettes to date?

A. In March 2011, the Tobacco Products Scientific Advisory Committee released its [report](#) on the health impact of menthol cigarettes.¹³ The report concluded that the removal of menthol cigarettes from the market would benefit public health, finding that menthol has resulted in increased numbers of smokers, primarily among youth and minorities. FDA experts within the Center for Tobacco Products are currently reviewing the Committee's [report](#),¹⁴ a [tobacco industry perspective document](#), and related studies.¹⁵ In June 2011, the FDA announced that its Center for Tobacco Products would compile menthol research and conduct another independent review of scientific studies on the public health impact of menthol cigarettes. The studies include peer-reviewed literature, secondary data analyses, and independent analyses of relevant large data sets in the areas of chemistry, toxicology, and physiology; patterns of menthol smoking (such as initiation, dependence, and cessation); as well as biomarkers of exposure to toxic constituents.

The purpose of this extensive review process is to determine whether the FDA should regulate menthol tobacco products, and if so, how. The Center will submit its review to an external peer review panel this summer, and make the results of the peer review and preliminary scientific assessment available for public comment in the *Federal Register* by the fall of 2011.¹⁶

Q. What opposition has there been to the proposed removal of menthol cigarettes from the market?

A. The tobacco industry opposes the removal of menthol cigarettes from the market, arguing that the health impact of menthol cigarettes is no more adverse than that of non-menthol cigarettes.¹⁷ Lorillard, which manufactures menthol cigarette leader Newport, has framed the debate over regulating menthol cigarettes as a civil rights issue, releasing at least one promotional ad for menthol cigarettes with an African American woman and

a headline, “Freedom of Choice for Grown Folks.”¹⁸ The ad states that “[t]he history of African Americans in this country has been one of fighting against paternalistic limitations and for freedoms” and notes that adults should have the freedom to choose to smoke menthol cigarettes.¹⁹ Some members of the African American community, including leaders of the National Black Police Association and the National Organization of Black Law Enforcement Executives, oppose a ban on menthol cigarettes, expressing concerns that it would unfairly target black consumers and could lead to a contraband market of menthols.²⁰ Other organizations, such as the National African American Tobacco Control Network and the National Latino Tobacco Control Network, support the removal of menthol cigarettes from the market.

Q. What are the next steps in the national debate over menthol tobacco regulation?

The Tobacco Control Act does not set a required deadline or timeline for the FDA to act on the Tobacco Product Scientific Advisory Committee’s recommendations.²¹ Any actions that the FDA takes to regulate the sale or distribution of menthol cigarettes or establish a tobacco product standard for menthol cigarettes will require rule making that includes public notice and the [opportunity for public comment](#).²²

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NOTES

¹ Deirdre Lawrence et al., *Sensory Properties of Menthol and Smoking Topography*, 9(1) TOBACCO INDUCED DISEASES S3 (2011), available at <http://www.tobaccoinduceddiseases.com/content/pdf/1617-9625-9-S1-S3.pdf>.

² See Philip Gardiner & Pamela Clark, *Menthol Cigarettes: Toward a Broader Definition of Harm*, 12 NICOTINE TOBACCO RESEARCH S85 (2010), available at http://ntr.oxfordjournals.org/content/12/suppl_2.toc. This issue contains several recent studies and commentary on the public health impact of menthol cigarettes.

³ Gary A. Giovino et al., *Epidemiology of Menthol Cigarette Use*, 6 NICOTINE & TOBACCO RESEARCH S67 (2004), available at <http://www.bvsde.paho.org/bvsacd/cd53/giovino.pdf>.

⁴ Substance Abuse & Mental Health Services Admin., National Survey on Drug Use and Health, *The NSDUH Report: Use of Menthol Cigarettes* (Nov. 19, 2009), available at <http://oas.samhsa.gov/2k9/134/134MentholCigarettes.htm> (last visited July 20, 2011) (“Overall, the rate of smoking menthol cigarettes among past month smokers increased from 31.0 percent in 2004 to 33.9 percent in 2008. Rates of menthol use increased from 43.5 to 47.7 percent among adolescents aged 12 to 17 and from 34.1 to 40.8 percent among young adults aged 18 to 25.”).

⁵ *Id.*

⁶ Henningfield et al., *Does Menthol Enhance the Addictiveness of Cigarettes? An Agenda for Research*, 5 NICOTINE & TOBACCO RESEARCH 9 (2003), available at <http://ntr.oxfordjournals.org/content/5/1/9.extract>.

⁷ Kunal K. Gandhi et al., *Lower Quit Rates Among African American and Latino Menthol Cigarette Smokers at a Tobacco Treatment Clinic*, 63 INT. J. OF CLINICAL PRAC. 360 (2009); Charyn D. Sutton & Robert G. Robinson, *The Marketing of Menthol Cigarettes in the United*

States: Populations, Messages, and Channels, 6 NICOTINE & TOBACCO RESEARCH S83 (2003), available at <http://www.bvsde.paho.org/bvsacd/cd53/sutton.pdf>.

⁸ Giovino, *supra* note 3.

⁹ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (codified, in relevant part, at 15 U.S.C.A. §§ 1333-34 and 21 U.S.C.A. § 301 et seq. (West 2010)), available at <http://www.govtrack.us/congress/billtext.xpd?bill=h111-1256>. The provision of the Act prohibiting the manufacture, marketing and sale of flavored cigarettes took effect September 22, 2009. 21 U.S.C.A. § 387g(a)(1)(A) (2009).

¹⁰ *Id.*

¹¹ *Id.*; see also FOOD & DRUG ADMIN., *Tobacco Products Scientific Advisory Committee*, <http://www.fda.gov/advisoryCommittees/CommitteesMeetingMaterials/tobacoproductsScientificAdvisoryCommittee/default.htm>.

¹² 21 U.S.C. § 387g(e)(1)-(2).

¹³ FOOD & DRUG ADMIN., TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE, MENTHOL REPORT AND RECOMMENDATION (2011), available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM247689.pdf>.

¹⁴ FOOD & DRUG ADMIN., *Menthol Report Overview*, <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm247605.htm> (last visited July 19, 2011).

¹⁵ Jonathan Daniel Heck et al., *Menthol Cigarettes: No Disproportionate Impact on Public Health* (2011) available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM249320.pdf>.

¹⁶ FOOD & DRUG ADMIN., *Menthol Update*, <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm260911.htm> (last visited July 21, 2011).

¹⁷ See Heck, *supra* note 15.

¹⁸ See Rita Rubin, *FDA Weighs Ban on Newports, Other Menthol Cigarettes*, USA TODAY, Mar. 14, 2011, <http://yourlife.usatoday.com/health/story/2011/03/FDA-weighs-ban-on--Newports-other-menthol-cigarettes/44877538/1>.

¹⁹ See *id.*

²⁰ See *id.*

²¹ See *Menthol Report Overview*, *supra* note 14.

²² See *id.*