A Lost Opportunity for Public Health — The FDA Advisory Committee Report on Menthol

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A lthough some public health groups hailed as a public health victory the release of a report on menthol cigarettes by the Tobacco Products Scientific Advisory Committee (TPSAC) of the Food and Drug Administration (FDA), close examination of the report and its recommendations reveals that it actually represents a huge victory for Lorillard, the manufacturer of the leading brand of menthol cigarettes (Newport) — and a disappointing setback for the health of black Americans.

The TPSAC was created in 2009 by federal legislation, the Family Smoking Prevention and Tobacco Control Act, granting the FDA regulatory authority over tobacco products. The committee’s mandate was to examine the effects of menthol cigarettes on the public’s health and to issue a report and recommendations to the FDA. After studying the issue for the past year, the panel issued its long-awaited recommendations on March 23, 2011.

Although the report concluded that the addition of menthol (see diagram) to cigarettes does not increase their toxicity, it established unequivocally that menthol harms the public’s health by enhancing smoking initiation and impeding smoking cessation, thus increasing smoking prevalence by affecting both ends of the smoking continuum. Citing abundant scientific evidence, the report concluded that menthol masks the harshness of tobacco, making cigarettes more appealing, especially to young people who might otherwise be deterred by irritation or an unpleasant taste. The report also concluded that smokers of menthol cigarettes have a more difficult time quitting than smokers of nonmenthol cigarettes.

Despite these conclusions, the TPSAC did not recommend a ban on menthol cigarettes. Instead, the report simply stated, “Removal of menthol cigarettes from the marketplace would benefit public health in the United States.”

Thus, the committee’s basic “recommendation” is not a recommendation at all, but a conclusion that doesn’t suggest any particular action to the FDA.

That banning menthol cigarettes would benefit public health is self-evident. There are 19.2 million menthol-cigarette smokers in the United States, and if even a fraction of them quit smoking in response to a menthol ban, it would have a profound effect on public health. Moreover, approximately half of people who are just starting to smoke usually smoke a menthol brand, and if...
even a fraction of those people were to be deterred from initiating smoking, this, too, would have a profound public health benefit.

In fact, it is specifically because Congress knew that a menthol ban would substantially benefit the public's health (by decreasing tobacco sales) that politicians chose to exempt menthol from the Tobacco Act in the first place. It is because a menthol ban would actually reduce tobacco sales that an advocacy group called the Campaign for Tobacco-Free Kids and other health groups supporting the tobacco-regulation legislation ensured that such a ban was not included in it — since it would have risked the loss of Philip Morris’s support for the law and the crumbling of the deal that had been forged with the country's largest tobacco company. The mandate for the TPSAC to study the menthol issue was actually a compromise forged to appease the Black Congressional Caucus, which vigorously denounced the exclusion of menthol from the bill's flavoring ban. The Campaign for Tobacco-Free Kids, for its part, opposed an amendment that would have eliminated the menthol exemption, defending that opposition by warning that if menthol were banned, a black market in contraband cigarettes was likely to be created — an argument that had been made vigorously by Lorillard.

Adopting this line of thought, the TPSAC report, in its only actual recommendation, warns the FDA against banning menthol cigarettes because of the potential for a black market; it expresses this concern in language almost identical to that used by Lorillard and its consultants. Far from issuing a call for a ban on menthol cigarettes, then, the advisory committee has punted the issue back to the FDA.

If there were any doubts about whether the TPSAC’s actions should be expected to benefit Lorillard or the public’s health, by decreasing or increasing the prospects for a menthol-cigarette ban, they were resolved within hours after the report’s release, when the value of Lorillard stock shot up by 8%.

A number of political factors make it extremely unlikely that the FDA will ban menthol cigarettes. First, taking on a menthol ban is the last thing that the Obama administration needs, given that it is already fighting desperately to save its health care reforms and to stave off criticisms about a purported government “takeover” of health care.

Second, Congress has already made it clear that it has no intention of banning menthol cigarettes and that there would be no political backup for the administration if it chose to pursue such a policy. Had the political will existed for such a ban, it would have been accomplished in the context of the original Tobacco Act.

Had the TPSAC come out with a clear and strongly stated recommendation that the FDA ban menthol cigarettes to protect the public’s health, it would have exerted substantial enough pressure on the agency to make serious consideration of such a policy possible. Instead, the FDA now has the explicit acknowledgment of its advisory committee that “a black market for menthol cigarettes could be created, criminal activity could ensue, and different methods might be used to supply such a black market.” The agency can thus avoid making the politically toxic move of banning menthol cigarettes without having to act in direct opposition to the stated recommendations of its advisory committee.

Moreover, by recommending that the FDA undertake an extensive study of potential black-market effects, the committee may have tied the hands of the agency for years to come. Any rule-making process is unlikely to be initiated until the agency completes such a review. More important, the wind has been taken out of the sails of the menthol issue; it is no longer a dominant concern on the agenda of the advisory committee, which is quickly moving on to other matters.

At the end of the day, it is difficult to understand the rationale for a policy that bans every other type of cigarette flavoring — including chocolate, strawberry, banana, pineapple, cherry, and kiwi — yet exempts the one flavoring that is actually used extensively by tobacco companies to recruit and maintain smokers, a finding that has been documented extensively by the TPSAC itself. Ironically, it is because removing menthol would actually improve the public’s health by reducing the consumption of cigarettes that we are not going to see such an action from the federal government. There is no political risk in banning chocolate and strawberry cigarettes, since no companies are currently selling such products and they play no role in smoking ini-
The Threat of Menthol Cigarettes to U.S. Public Health

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The 2009 Family Smoking Prevention and Tobacco Control Act gave the Food and Drug Administration (FDA) authority to regulate certain tobacco products with the goal of protecting public health.¹ The law provides the FDA with regulatory tools for reducing harm to health from products that cause nicotine addiction and disease. It specifically banned flavored cigarettes, except those containing menthol, which account for about 30% of the current U.S. cigarette market. It also created the Tobacco Products Scientific Advisory Committee (TPSAC), consisting of nine voting members and three nonvoting members representing the tobacco industry, and charged it with preparing a report on “the impact of use of menthol cigarettes on the public health including such use among children, African Americans, Hispanics, and other racial and ethnic minorities.”

Menthol, a naturally occurring monocular terpene alcohol, has long been used in consumer and medicinal products because of its minty taste and aroma and its cooling and anesthetic properties. It acts primarily on transient receptor potential channels that contribute to the detection of physical stimuli, including temperature and chemical irritation. Mentholation of cigarettes resulted from a chance discovery made in the 1920s by Lloyd “Spud” Hughes, an Ohio man who smoked cigarettes that had been stored in a tin containing menthol crystals. Hughes accidentally identified an additive whose pharmacologic actions reduce the irritating properties of smoke generally and nicotine specifically. Menthol contributes to perceptions of cigarettes’ strength, harshness or mildness, smoothness, coolness, taste, and aftertaste. Research also shows that menthol has druglike characteristics that interact at the receptor level with the actions of nicotine.

The TPSAC, on which we serve, submitted its menthol report to the FDA on March 23, 2011, with a conclusion that menthol cigarettes damage public health and a general recommendation that “removal of menthol cigarettes would benefit public health in the United States.”² The report has generated controversy that reflects misunderstanding of the roles of the TPSAC and the FDA.

For its report, the TPSAC drew on sources including the peer-reviewed literature, presentations and submissions from the tobacco industry and its consultants, internal industry documents, and analyses of relevant data and modeling. Industry members of the committee provided their perspectives throughout the review process and submitted their own report. The TPSAC review was directed at answering key questions related to both individual smokers and impact on the population; we used a conceptual framework defining points in the processes of smoking initiation, continuation, addiction, and attempted cessation at which menthol cigarettes’ availability could theoretically harm health (see flow chart). The committee classified the relevant evidence in terms of its strength with regard to equipoise, assessing its sufficiency to determine whether a relationship between menthol cigarettes and a specific effect was at least as likely as not.

In assessing menthol cigarettes’ effect on public health, the TPSAC considered whether their...