FDA Finding May Curb Mentholated Cigarette Availability

By Merrill Goozner

The availability of menthol cigarettes increases the likelihood that youths and African Americans will become habitual smokers, making menthols a greater public-health hazard than regular brands, the U.S. Food and Drug Administration’s Tobacco Products Scientific Advisory Committee (TPSAC) said at its mid-March meeting. “The availability of menthol cigarettes has an adverse impact on public health by increasing the number of smokers and increasing the number of avoidable deaths and premature mortality,” said committee member Mark Stuart Clanton, M.D., chief medical officer of the American Cancer Society’s High Plains Division.

However, the committee found insufficient evidence to conclude that smoking menthols increases the likelihood of addiction among all adults. Nor did evidence indicate that mentholated brands are more dangerous than regular cigarettes, which increase lung and other cancers, heart disease, emphysema, and other chronic conditions.

The TPSAC’s conclusions came after a year-long review of epidemiological and physiological studies of menthol smokers in the past decade. The committee’s findings could lead to stepped-up FDA regulation of mentholated brands, which could go as far as a ban. The FDA has until mid-June to issue its final review of the evidence.

Agency officials were noncommittal about what actions they might take in response to the TPSAC report. “We do recognize the strong interest in this issue,” said Lawrence Deyton, M.D., director of the Center for Tobacco Products at FDA. “Now it’s up to us to do our job.”

The 2009 Tobacco Control Act, which created TPSAC and gave the FDA the authority to regulate tobacco, targeted menthol cigarettes as the first product for heightened scrutiny because of mounting evidence that mentholated brands ultimately lead to lifelong smoking by youths and minorities. The consensus statement of the eight-member panel (three industry representatives on the committee were not allowed to vote on the final recommendations) said the evidence was sufficient to reach that conclusion.

The committee found that menthol brands increase experimentation and regular smoking, as well as increase the likelihood of addiction in young smokers and African-Americans, 80% of whom prefer menthols. It also found that smoking menthols makes the success of smoking-cessation programs less likely.

“Youths who initiate with menthol cigarettes are more likely to become daily, regular smokers than those who initiate with nonmenthol cigarettes, [and] adolescent menthol smokers have a higher prevalence of addiction than those who smoke nonmenthol cigarettes,” Clanton said. Also, “the availability of menthol cigarettes results in lower likelihood of smoking cessation in African-Americans [than that for] nonmenthol cigarettes.”

Interpreting the Science

The committee asked David Mendez, Ph.D., of the School of Public Health at the University of Michigan to construct a model that estimated how mentholated brands affect public health. Using data from the studies, he estimated that 45% of youths who experiment with tobacco do so with menthol brands, which led to a 21.8% overall smoking initiation rate. He estimated that just 16.7% of youths would take up smoking if mentholated brands were not available, given the lower experimentation-to-initiation ratio of youths who experiment with non-mentholated brands.

Mendez also found that menthol would lead to excess deaths. “We estimate 327,000 excess deaths [will be] attributable to menthol between 2010 and 2050, since over 9 million additional Americans would take up smoking over that period,” Mendez told the committee. “When we run the model, we see 66,000 excess deaths from the 1.6 million extra initiators by 2050 in the African-American community.”

However, a recent study published in this issue of the Journal found that lung cancer incidence and mortality actually decreased among older adult smokers of menthol cigarettes compared with regular cigarettes. William J. Blot, Ph.D., of the International Epidemiology Institute, conducted a retrospective cohort study from March 2002 to September 2009 of more than 85,000 racially diverse adult smokers of both menthol and nonmenthol cigarettes. “Our take on this is that smoking is bad. There is no doubt about that. We’ve known it for years and years,” he told Reuters. But “to single out mentholated cigarettes compared to other types of cigarettes may not be necessary.”

The tobacco industry representatives on the committee, who issued their own report...
in response to the TPSAC report, challenged the finding that 68% more experimenters take up smoking if their first taste of tobacco was mentholated. That finding was drawn from the report “Menthol Cigarette and Youth Smoking Uptake,” done by RTI International for the FDA. “This variable is drawn from a single paper of 100 youths, only a dozen of whom were African-American,” said Jonathan D. Heck, Ph.D., a senior researcher for Lorillard Tobacco, which markets Newports, the most popular menthol brand. “It was not statistically significantly different for nonmenthol smokers compared to menthol smokers from experimentation to initiation. This is a frail basis to employ in making such projections and calculations.”

The final report hammered the industry for its menthol marketing campaigns, which over the years used powerful images to associate smoking mentholated brands with refreshment, reduced harm, less harshness, youthfulness, and fun. The campaigns often targeted their messages to young people and African Americans, the committee found. “There was abundant evidence that menthol cigarettes are disproportionately marketed to younger smokers,” said Melanie Wakefield, Ph.D., director of the Centre for Behavioural Research in Cancer at the Cancer Council in Victoria, Australia. “Evidence from tobacco industry documents [showed] that the tobacco industry designed menthol cigarettes with lower menthol yield and an awareness within the industry that lower menthol can reduce the harshness of cigarettes.”

The result, said Dorothy Hatsukami, Ph.D., a professor of psychiatry at the Tobacco Use Research Center at the University of Minnesota, was that although cigarette smoking is becoming less prevalent among adolescents, “menthol smoking is declining at a slower rate than nonmenthol smoking. . . Less experienced adolescent smokers may in fact be experimenting with menthol cigarettes,” she said. “Tobacco companies were aware of the appeal of menthol cigarettes to younger smokers because these cigarettes are easier to smoke.”

Top tobacco industry officials also challenged that finding during the 2-day meeting. “There is continuing confusion about prevalence and preference and its public-health impact,” said William R. True, Ph.D., senior vice president for research at Lorillard. He pointed to evidence that the smoking prevalence rate among African Americans is 21.3% compared with 22.1% in the general population, even though 80% of blacks who smoke prefer menthols, compared with 30% of the general population. “Evidence of higher menthol preference among certain demographic groups does not translate to higher smoking prevalence or overall smoking harm.”

Creating a Black Market?

Though TPSAC members strongly endorsed the public-health benefits of restricting access to menthol brands, which could range from an outright ban to restrictions on marketing, the full committee cautioned against taking precipitous action that might foment a black market. “The issue of contraband needs attention,” said Jonathan M. Samet, M.D., shortly after the meeting. “Depending on what actions the FDA would take, they would need to consider the impact on contraband.”

Several outside speakers raised the issue during public comments at the meeting. “A ban on menthol would be ineffective and create a significant contraband market,” said Scott Ramninger, chief executive officer of the American Wholesale Marketers Association, which represents distributors of tobacco and other products to the convenience-store market. “If menthol cigarettes have the same health risk as regular cigarettes, how can the FDA justify a ban? Common sense tells us that an unscientific ban would be ignored by the public and exploited by the contraband market.”

But some committee members minimized the risk of a large black market’s emerging after a ban of menthols. “Most contraband between states [involves] legitimate products to avoid taxes,” said committee member Jack Henningfield, Ph.D., vice president of research at Pinney Associates. “To come anywhere close to providing menthol cigarettes that are 30% of the market, you’re talking about truckloads a day delivered to thousands of outlets.”

Clanton questioned industry’s claim that a black market would accelerate teen smoking. “There would be an increased cost on the black market,” he said. “A 10% increase in cost would lead to a 1% overall decrease in smoking rates. A 50% increase in costs on the black market would lead to a 3.5% overall decrease in smoking.”

The effect of rising costs has already been seen in response to recent tax increases on tobacco products. The federal government in 2009 raised tobacco excise taxes from 39 cents to $1.01 per pack. Though federal revenues from tobacco taxes will rise this year to $17.5 billion, the higher rate of smoking cessation associated with higher costs will reduce tax revenue to $15.5 billion per year by the end of this decade, according to estimates from the Office of Management and Budget.

A similar trend is under way in the states, many of which have raised their levies on tobacco in the past 2 years to cope with the recession’s large budget deficits. State tobacco taxes now range from a low of 17 cents per pack in Missouri to $2.75 per pack in New York. But according to data from the Campaign for Tobacco-Free Kids, revenue from tobacco taxes—including collections from the 1998 state attorneys general lawsuit settlement with the tobacco industry—will decline 2.3% this year to $25.3 billion.
The tobacco industry is not just questioning the science in its efforts to hold on to its menthol brands. One month before TPSAC issued its report, Lorillard and R.J. Reynolds sued the FDA for putting scientists with alleged conflicts of interest on the committee.

The suit claimed that Neal Benowitz, M.D., a professor of clinical pharmacology at the University of California, San Francisco, Henningfield, and Samet had over the past decade testified multiple times on behalf of plaintiffs suing the tobacco industry. The trio also consulted for drug companies that manufactured smoking-cessation products, according to the suit. The FDA, which refused to comment on the litigation, issued no conflict-of-interest waivers for the March TPSAC meeting that issued the final consensus report.

The tobacco industry’s willingness to challenge FDA actions in court drove financial markets’ reaction. Tobacco company stocks, including that of Lorillard, rose shortly after the TPSAC action. Suggesting that the weak scientific basis for banning menthol would encourage companies to sue to protect their franchises if the FDA took that action, stock analysts at UBS AG and Goldman Sachs urged clients to purchase tobacco stocks, according to Bloomberg News. The FDA “may not want to face any serious legal challenges,” Goldman Sachs analyst Judy Hong told clients in a research note.

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