FDA attempt at prohibiting menthol flavoring part of long campaign

By Richard Craver Winston-Salem Journal

For anti-tobacco advocates, securing a ban on menthol flavoring in tobacco and nicotine products would be tantamount to cutting the head off a dangerous snake.

Menthol styles, which are mint-flavored, have proven controversial for decades because they are considered a smoother way to smoke traditional cigarettes, and because of their specific appeal to minority consumers.

In 2009, Congress exempted menthol from banned flavorings in traditional cigarettes in the federal Tobacco Control Act.

Yet, advocates and public-health officials continued to argue that without menthol, many smokers would choose not to smoke a tobacco-flavored product and quit, a potential major public-health victory.

Last October, the Food and Drug Administration requested approval from the federal Office of Management and Budget for several changes to federal tobacco regulations. OMB serves as the White House’s clearinghouse for reviewing regulatory changes.

One of the changes that wasn’t made public called for placing the current form of menthol on a list of flavorings that would be prohibited in such tobacco and nicotine products as electronic cigarettes, vaporizers, hookahs, traditional cigars and little cigars.

The FDA would have left a door open for menthol, but manufacturers would have had to go through an expanded, lengthy and costly regulatory gauntlet with no assurances of approval.

If the FDA proposal had been approved, menthol and other flavored products would have been removed from the marketplace by early November.

The federal Office of Management and Budget did approve FDA's request to add, tighten and enhance several regulations that were disclosed May 5 and are set to go into effect.
Aug. 8, pending lawsuits.

However, OMB stripped restricting flavored tobacco products from the regulations.

FDA officials did not disclose OMB’s removal of the potential flavor regulations when they held a teleconference with media on May 5 in unveiling the new regulations. The request to prohibit menthol became public May 27 when OMB released a “red-lined” version of the FDA proposal.

Included in OMB’s mission is “ensuring that regulations are based on sound analysis and serve the purposes of the statutes that authorize them and the interests of the public.”

There is an indication that FDA officials are not through with regulatory requests on flavorings and how electronic cigarettes, vaporizers and hookahs could be marketed and advertised.

Both agencies said last week they “do not comment on changes made during the review process.”

The FDA’s overarching reasoning for moving against menthol, according to its request, is that “as a general matter, it is more likely that a tobacco product with a characterizing flavor would appeal to youth and young adults than a product without a characterizing flavor.” It listed menthol as a characterizing flavor.

The FDA cited federal research indicating the popularity of flavorings with youths, acknowledging more so with candy and fruit flavors than menthol. Menthol was cited as playing a potential gateway role for youths to other tobacco products, as well as leading to higher smoking usage.

OMB apparently was not persuaded by FDA’s pledge that it “is not including any specific restrictions in this final deeming rule regarding flavored tobacco products, nor is it including a ban on flavored tobacco products.”

Matt Myers, president of the Campaign for Tobacco-Free Kids, called the OMB decision “deeply disappointing.”

“Given the weight of the evidence cited by the FDA, it is difficult to imagine a public health justification for the ... decision.”

**Companies’ perspective**

Menthol’s popularity with smokers led Reynolds American Inc. to spend $29.25 billion in June 2015 to acquire Newport, the top-selling U.S. menthol brand and No. 2 traditional cigarette brand, from Lorillard Inc. Reynolds now holds 57 percent of the U.S. menthol cigarette market share.

Susan Cameron, Reynolds’ chief executive, said before the manufacturer gained federal regulatory approval to buy Lorillard that she believed the FDA would not clamp down severely on menthol.

Brian May, a spokesman for Philip Morris USA, said “we believe the science and evidence doesn’t support restricting or banning menthol cigarettes.”

David Howard, a spokesman for R.J. Reynolds Vapor Co., restated the company’s opinion that “we agree that some flavors currently available in the market are not appropriate, as they are not adult-oriented in nature. These would include flavors like bubble gum, cotton candy and gummy bear.”

Scott Ballin, past chairman of the Coalition on Smoking or Health, predicted in 2014 that Reynolds’ takeover of Newport would spur some public-health advocates to “use this merger as a means of calling on the FDA to move quickly to ban menthol.”

Myers said last week the FDA “must move forward immediately, and its proposal must be strengthened to include e-cigarettes and end the use of menthol in all tobacco products.”

Part of Reynolds’ confidence in acquiring Newport comes from how much federal and state governments depend on cigarette excise taxes for a steady revenue source. Several states, including North Carolina, have instituted an excise tax on e-cigs.

There’s also the dependence that 46 states have on the landmark Master Settlement Agreement. Those states agreed in 1998 to not pursue further legal action against tobacco manufacturers. In exchange, the manufacturers agreed to pay about $206 billion over more than 20 years to help the states recover smoking-related health-care costs.

However, most states, including North Carolina, have siphoned MSA payments away from health care toward their General Fund or other projects.

If the FDA were to be successful in banning menthol, tobacco analysts project a potential
surge in demand for smoking-cessation products made by pharmaceutical companies since 30 percent of all adult smokers and more than 40 percent of all youth smokers consume a menthol style.

There also could be increased demand for nicotine replacement therapy gum Zonnic, made by Reynolds subsidiary Niconovum USA.

Mitch Zeller, director of the FDA's Center for Tobacco Products, has acknowledged the potential role that e-cigs and vaporizers could play in weaning smokers from traditional cigarettes.

Flavorings are a big appeal of e-cigs and vaporizers for smokers, several studies have determined. Those studies found that restricting or banning flavors in e-cigs and vaporizers could encourage smokers to return to traditional cigarettes.

Other recent studies, have determined e-cigs and vaporizers could be as much as 95 percent less harmful than traditional cigarettes since they don't burn the tobacco leaves.

Zeller said May 5 the FDA concluded "that while there may be anecdotal reports that e-cigarettes are helping individual smokers get off of cigarettes, the Preventative Services Task Force and the published literature at this point don't provide support for e-cigarettes being effective cessation aids."

“There are still many open questions about are e-cigarettes a gateway to smoking more harmful products,” Zeller said. “Nicotine can be highly addictive and no kid should be inhaling an aerosol or a vapor that contains nicotine that is capable of addicting.”

Research record
Dr. Michael Siegel, an anti-smoking advocate and a professor at the Boston University School of Public Health, said that “rather than serving as a gateway toward cigarette smoking, e-cigarettes may actually be acting as a diversion away from cigarettes.”

“If electronic cigarette flavors are banned, the percentage of smokers who progress to regular e-cigarette use will plummet.”

Gregory Conley, president of the American Vaping Association, said he is puzzled why Zeller dismisses as anecdotal “the experiences of millions of adult ex-smokers who quit by using flavors in e-cigs and vaporizers.”

“The agency has spent tens of millions of dollars researching new nicotine products, but has thus far utterly failed to study the issue of flavors and smoking cessation,” Conley said.

“While the White House should have never approved the FDA's disastrous deeming ban, putting the brakes on this particular aspect was the right thing to do. The FDA is out of control and needs to be reined in.”

Mitch Kokai, a policy analyst with the libertarian think tank John Locke Foundation, said it is possible that OMB officials considered banning flavorings within the new rules “to be a bridge too far.”

“It's one thing for the federal government to place a product under the burden of new regulations. It's another to place an outright ban on that product.”

craver@wsjournal.com (336) 727-7376 @rcraverWSJ