

Judge lets challenge to FDA tobacco panel proceed

August 1 2012, by MICHAEL FELBERBAUM

(AP) — A challenge by two of the largest U.S. cigarette makers alleging conflicts of interest in the Food and Drug Administration advisory panel's review of tobacco products can move forward, a federal judge has ruled.

In an order posted Wednesday, U.S. District Court Judge Richard Leon in Washington denied the FDA's motion to dismiss the suit filed by Lorillard Inc. and R.J. Reynolds [Tobacco](#) Co. The suit filed last year alleges financial conflict of interest and bias by several members of the Tobacco Products Scientific Advisory Committee and asks the court to stop the federal agency from relying on the panel's recommendations.

The panel is tasked with advising the FDA on tobacco-related issues, including the public health impact of menthol cigarettes and dissolvable tobacco, two industry growth areas.

"Because of the limited number of viewpoints on these issues, the scientific — as opposed to political — nature of those viewpoints, and the distinct responsibilities of the committee, I believe I have sufficient standards which I can evaluate the agency's discretion," Leon wrote in his order.

Representatives for the FDA and R.J. Reynolds would not comment on pending litigation.

In a statement, Lorillard said: "The practice of appointing members to a

government scientific advisory committee who have financial interests that violate conflict-of-interest laws and regulations should be subject to judicial review, as the court has now recognized."

The FDA won the authority to regulate tobacco in 2009. The law doesn't let the FDA ban nicotine or tobacco, just regulate what goes into tobacco products, require the ingredients be publicized and limit how tobacco is marketed, especially to young people. The agency's panels advise it on scientific issues. It doesn't have to follow their recommendations, but usually does.

In the suit, the tobacco companies allege that the panel fails to meet the federal requirements that committee members should be fairly balanced and not inappropriately influenced by any special interest. The suit specifically alleges that some committee members have conflicts of interest because they were paid expert witnesses in anti-tobacco lawsuits and have financial ties to pharmaceutical companies that make smoking-cessation products.

The agency, however, argued that the panel meets federal standards and that the cigarette makers' "alleged injuries are entirely speculative," and "not fairly traceable." The FDA also argued that the court lacks jurisdiction to review the conflict of interest challenged raised by the companies.

Several cigarette makers, including Altria Group Inc., parent company of Philip Morris USA, had previously asked the federal agency to remove members of the panel for conflicts of interest. Altria is not part of the suit.

Lorillard, based in Greensboro, North Carolina, holds about 35 percent of the U.S menthol market with its top-selling Newport brand. R.J. Reynolds and its parent company, Reynolds American Inc., based in

Winston-Salem, North Carolina, sell brands like Camel and Pall Mall, as well as several dissolvable tobacco products — is finely milled tobacco pressed into shapes like tablets that slowly dissolve in a user's mouth.

Vince Willmore, a spokesman for the Campaign for Tobacco-Free Kids, said the suit is an effort by the tobacco companies to "obstruct effective policies to reduce tobacco use and to discredit anyone who advocates such policies."

The suit comes amid two advisory panel reports mandated by the law that gave the FDA authority to regulate the tobacco industry.

A panel report issued last March said removing menthol cigarettes from the market would benefit public health because the flavoring has led to an increase in smokers__ particularly among teens, African Americans, and those with low incomes. It also said that they make it harder for them to quit. The report, however, said menthol smokers are not likely to be at a higher risk of disease or exposed to a greater number of toxins. The FDA is conducting an independent review on the issue.

In a report earlier this year, the panel said that dissolvable tobacco products could reduce health risks compared with smoking cigarettes but also have the potential to increase the overall number of tobacco users. Dissolvable [tobacco products](#) are gaining the attention of tobacco companies looking to make up for a decline in cigarette use as smokers face tax hikes, growing health concerns, smoking bans and social stigma

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