US panel rejects marketing plan for heated tobacco device

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This undated image provided by Philip Morris in January 2018 shows the company's iQOS product. U.S. government experts have rejected a proposal from Philip Morris International to sell its "heat-not-burn" tobacco device as a lower-risk alternative to cigarettes that reduces disease. But the panel of advisers to the Food and Drug Administration endorsed a lesser claim that the product reduces exposure to harmful chemicals in cigarettes. The mixed review suggests Philip Morris will be able to market its device to U.S. smokers, but on limited terms. (Philip Morris via AP)

Government advisers dealt a blow Thursday to Philip Morris International's hopes to sell its heat-not-burn device in the United States as a less-harmful alternative to cigarettes.

The penlike device heats Marlboro-branded sticks of tobacco but stops short of burning them. It is already sold in more than 30 countries and Philip Morris aims to make it the first "reduced risk" tobacco product ever sanctioned by the U.S.

The votes Thursday by the panel of Food and Drug Administration advisers on the marketing of the iQOS device are nonbinding. The FDA will make a separate decision on whether to allow the product on the market, and—if so—how it could be marketed to consumers.

FDA clearance would mark a major milestone in efforts by both the industry and government officials to provide alternative tobacco products to U.S. smokers. The adult smoking rate has fallen to an all-time low of 15 percent, though smoking remains the nation's leading preventable cause of illness and death.

The nine-member panel voted on several statements that Philip Morris wants to use to market iQOS. According to the company, the heat-not-burn approach reduces exposure to tar and other deadly byproducts of cigarettes.

But panelists expressed doubts that company studies, primarily from animals and laboratory experiments, could predict lower rates of diseases and death in humans. They voted unanimously, with one abstention, that the studies did not show that the device reduces deadly diseases tied to smoking.

"I voted no because, based on the evidence presented to us, it was premature to make such a claim," said Deborah Ossip, of the University

of Rochester's public health department.

The panel only supported one of the company's proposed statements: that switching completely to iQOS from cigarettes reduces exposure to harmful chemicals. That claim was considered the least significant because it does not establish a health benefit.

This week's meeting and FDA's ultimate ruling are being closely watched by both the tobacco industry and the public health community amid debate over whether alternative products, including electronic cigarettes, should play a role in reducing the enormous toll of smoking, which contributes to 1 in 5 U.S. deaths.

Philip Morris believes its product is closer to the experience of smoking than e-cigarettes, which will make it more attractive to smokers. iQOS produces a tobacco vapor that includes nicotine. The FDA is in the process of beginning to regulate e-cigarettes, which did not come under the agency's authority until 2016. E-cigarettes don't use tobacco but vaporize liquid usually containing nicotine.

The United Kingdom is one of the more than 30 countries where iQOS is sold.

Richard Etrata, a London tailor, said iQOS has helped him cut down on smoking.

"I haven't smoked a single cigarette for two and a half weeks," said Etrata, visiting a retail store in downtown London where Philip Morris sells the device. "I did vape for a week but it was useless. The scent didn't do anything for me."

Unlike the U.K. and most other countries, the U.S. government has broad authority to regulate a number of aspects of the tobacco industry,

including new products. Under a 2009 law the FDA can permit sales of new tobacco products shown to be less dangerous than what's currently available and to approve marketing claims about reduced harms.

The FDA itself has much at stake in the review of iQOS and similar tobacco products in development.

Last July, FDA Commissioner Scott Gottlieb laid out a proposal to begin pushing U.S. consumers away from traditional cigarettes toward products that deliver nicotine without all the harms of cigarettes. But the FDA has not yet allowed any company to market a tobacco product as "reduced risk," compared to cigarettes.

If cleared in the U.S., iQOS would be marketed by Altria, the largest U.S. cigarette maker.