

## US sales OK'd for cigarette alternative that heats tobacco

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In this Oct. 22, 2018 file photo, visitors try out a pen-like "heat-not-burn" device at an IQOS store at Ginza in Tokyo. On Tuesday, April 30, 2019, the U.S. Food and Drug Administration said it will allow Philip Morris International to sell the cigarette alternative that heats tobacco without burning it. (AP Photo/Eugene Hoshiko)

U.S. health officials on Tuesday said Philip Morris can sell a cigarette alternative that heats tobacco without burning it, opening the door for the company's effort to shift smokers toward newer products.

The Food and Drug Administration has not yet decided whether to allow the device, IQOS (EYE-kose), to be advertised as less harmful than cigarettes. A decision on that key marketing pitch could come later this year.

The cigarette alternative is the centerpiece of Philip Morris International's effort to move the shrinking number of U.S. smokers toward other products, including heating and vaping devices.

FDA regulators stressed that IQOS is neither safe nor "FDA approved." But they acknowledged that studies submitted by the company did show IQOS produces fewer toxic byproducts than traditional burning cigarettes.

"All tobacco products are potentially harmful and addictive and those who do not use tobacco products should continue not to," the FDA said in a statement.

Altria, maker of Marlboro cigarettes, will sell IQOS in the U.S. for Philip Morris International. The device will be subject to laws that ban television and radio advertising of cigarettes. The FDA said it will impose extra restrictions on online and social media advertising to discourage use by teenagers.

Philip Morris said in a statement it will comply with FDA restrictions "so that IQOS is reaching the right audience—current adult smokers." The product is already sold in over 40 other countries.

Tobacco control experts have long argued that products like IQOS will

only benefit public health if they are solely used by smokers who are unable or unwilling to quit cigarettes.

Eric Lindblom of Georgetown University law school said the FDA could have made more explicit that IQOS is only to be used as a smoking substitute.

"Instead of requiring constructive labeling and preventing harmful advertising, FDA is hoping that Altria and (Philip Morris) will market IQOS responsibly," said Lindblom, who previously worked in FDA's tobacco center.

About 14 percent of U.S. adults smoke despite decades of tax hikes, smoking bans and public health campaigns aimed at reducing the deadly habit. Smoking causes more than 480,000 deaths each year.

The battery-powered IQOS heats sticks of tobacco but stops short of burning them, producing a tobacco aerosol that includes nicotine. This is different from e-cigarettes, which don't use tobacco at all but instead vaporize liquid usually containing nicotine. Philip Morris argues its product is closer to the experience of smoking a cigarette and will therefore help more smokers switch.

But the product will come under intense scrutiny from anti-smoking groups and public health advocates amid a recent surge in underage vaping by high school and middle school students.

The American Lung Association said it was "deeply concerned," by the decision and stated: "FDA must take steps to protect youth from beginning a tobacco addiction with this product."

Recently departed FDA Commissioner Scott Gottlieb spent the last year of his tenure at the agency trying to reverse the trend, while

acknowledging that underage vaping could climb even higher.

The company's U.S. partner, Altria, said Tuesday it will begin selling IQOS in Atlanta at a specialty store. The tobacco sticks will be sold at convenience stores and other retailers in the region.

Wells Fargo analyst Bonnie Herzog called the FDA decision a "big win," for the tobacco giants and predicted annual sales of \$4.5 billion by 2025.

Philip Morris had hoped to launch IQOS as the first "reduced risk" tobacco product sanctioned by the FDA. But regulators are still reviewing the company's data and proposed claims. Congress gave the FDA the power to regulate key aspects of the tobacco industry in 2009, including designating new tobacco products as "reduced risk."

Last year, a panel of FDA medical and scientific advisers delivered a mostly negative review of IQOS. The panel said the company had not shown that using IQOS reduced the deadly diseases associated with smoking.

An endorsement from the FDA would mark a major milestone in efforts by both the industry and government to provide less harmful tobacco products to smokers who can't or won't quit cigarettes.

Shares of Altria Group Inc. rose 84 cents to \$54.35 in trading.

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