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FDA Puts Kids, Public Health at Risk by Allowing Philip Morris to Market IQOS Heated Cigarette as Modified Risk Tobacco Product

Statement of the Campaign for Tobacco-Free Kids, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association and Truth Initiative

WASHINGTON, D.C. – Setting a dangerous precedent that puts kids and public health at risk, today the U.S. Food and Drug Administration authorized the marketing of Philip Morris' IQOS heated cigarette as a "modified risk tobacco product" despite the FDA's acknowledgement that Philip Morris failed to show that IQOS presents a reduced risk of tobacco-related disease and without requiring Philip Morris to provide evidence, based on any U.S. data, that the product's marketing won't appeal to kids. With today's action, the FDA has created a real danger that kids and adults will falsely believe IQOS has been proven to present a lower health risk and that kids will be exposed to marketing that portrays IQOS, a highly addictive tobacco product, as an appealing, cool alternative to cigarettes, in much the same way as e-cigarettes.

In its decision, the FDA acknowledges that the impact on youth of allowing IQOS to be marketed as a modified risk product is "unclear." Such doubts should be resolved by protecting our kids, not by treating them like guinea pigs in a Philip Morris marketing experiment. The last thing we need is yet another tobacco product that puts kids at risk for nicotine addiction and misleads consumers about health risk.

Specifically, the FDA allowed Philip Morris to market IQOS with a claim that switching completely from conventional cigarettes to IQOS significantly reduces "exposure" to harmful or potentially harmful chemicals, despite the FDA's own finding that "the overall body of evidence was not sufficient to demonstrate that completely switching from combusted cigarette to the IQOS system reduces the risk of tobacco-related disease or harm." It is likely that consumers will be misled by the claim allowed by the FDA and interpret it to mean that completely switching from cigarettes to IQOS will reduce the risk of disease – despite the FDA's conclusion to the contrary.

The FDA's failure to require that Philip Morris present evidence about the impact of its marketing on America's youth repeats an egregious error the FDA has made in the past, one that undermines a core goal of the Tobacco Control Act. It is especially troubling that the FDA granted Philip Morris' application without regard to how IQOS will be marketed – and whether that marketing will appeal to kids – despite examples of marketing outside the U.S. that mirrors

the type of advertising Philip Morris has long used to attract youth to cigarettes. Our organizations on multiple occasions have raised concerns with the FDA that Philip Morris International has marketed IQOS in other countries in ways that clearly appeal to kids, including through social media, sponsorships of events like beach parties and fashion shows, and slick stores and kiosks that look like they're selling tech gadgets, not addictive tobacco products. This marketing presents IQOS as a fun lifestyle product, using imagery and themes that will attract kids (see examples of IQOS marketing <u>here</u> and <u>here</u>). If the FDA fails to prevent such tactics in the U.S., there is a serious risk that IQOS will join e-cigarettes in addicting a new generation of kids.

As our organizations pointed out in our <u>comments to the FDA</u> on Philip Morris' application, the company failed to demonstrate that the marketing of IQOS with modified risk claims will not increase initiation of tobacco use by non-users, particularly youth, or that the marketing for the product will target only adult smokers. The evidence also indicates that the marketing of IQOS with modified risk claims will lead to greater dual use with cigarettes instead of leading substantial numbers of smokers to switch completely to IQOS – similar to how e-cigarettes have led to dual use with no health benefits. Philip Morris also did not provide research on the impact of marketing menthol IQOS products with modified risk claims on African Americans, including youth, risking a repeat of the targeted marketing of menthol cigarettes that has caused so much harm to the health of African Americans.

The FDA should have denied Philip Morris' application in its entirety because of the company's failure to provide sufficient scientific evidence to support its claims and to demonstrate that the product will not be marketed in ways that appeal to kids.