



STOPPING TOBACCO
ORGANIZATIONS & PRODUCTS

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Brief



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FDA does not rule that IQOS reduces tobacco-related harm, yet PMI still claims victory

On July 7, 2020, the U.S. Food and Drug Administration (FDA) published the outcome of Philip Morris International's (PMI) application to market IQOS, its heated tobacco product, as a "modified risk tobacco product" in the U.S.

***Summary:** On July 7, 2020, the U.S. Food and Drug Administration (FDA) published the outcome of Philip Morris International's (PMI) application to market IQOS, its heated tobacco product, as a "modified risk tobacco product" in the U.S. The FDA has two standards for assessing modified risk. It agreed that the data submitted by PMI showed that IQOS **may reduce exposure** to harmful substances, but that IQOS **does not reduce risk** of disease and death when compared to cigarette smoking. Nevertheless, PMI immediately launched a global PR campaign, hailing the decision as a "milestone for public health" and encouraging other countries to follow the FDA's lead. This misrepresents the FDA's decision.*

Furthermore, the documents setting out the FDA's decision reveal concerns about potential youth and non-smoker uptake of IQOS and request more research on the impacts of the product and its use. PMI knows that the FDA's dense, technical language creates room for confusion, especially outside the U.S. The only way to prevent the company from capitalizing on this confusion is to clarify the FDA's decision. This brief sets out the facts, which we believe are a matter of urgent public interest.

On July 7, 2020, the U.S. Food and Drug Administration (FDA) reached its judgement on whether Philip Morris International's (PMI) flagship heated tobacco product (HTP)¹, IQOS, should be considered a "modified risk tobacco product" (MRTP) [3].

Even though IQOS failed to meet an important standard for assessing MRTP status, PMI lost no time in proclaiming victory. The company issued a video on Twitter in which Vice President of Scientific and Strategic Communications, Dr. Moira Gilchrist, stated: "This is a milestone for public health. This decision clearly demonstrates that IQOS is fundamentally different to cigarettes and is a much better choice for adults who'd otherwise continue to smoke." [4]

PMI's PR push misrepresents the outcome of the FDA's judgement

The FDA has two standards for assessing MRTP status: the higher and far more important "risk modification" standard and the lower "exposure modification" standard. PMI met the lower standard, but it failed to meet the higher one, which is to "demonstrate that the product, as it is actually used by consumers, will:

1. Significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and
2. Benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products." [5]

Since PMI was unable to demonstrate reduced harm, reduced risk of disease and benefit to the population [3], the FDA instructed PMI that it "may not market these products with reduced risk claims." [3]

There is no evidence that IQOS is safer than cigarettes

Independent analyses of PMI's own data submitted to the FDA suggest IQOS may be as harmful as smoking [6-8]. For example, an analysis of PMI's clinical trials showed the risks of developing serious illness such as heart disease and chronic obstructive pulmonary disease (COPD), are not consistently reduced in IQOS users compared to those smoking cigarettes [6]. Analyses of PMI's animal and human data found the lung and immunosuppressive effects of switching to IQOS were indistinguishable from continuing conventional cigarettes [7]. Similarly, another analysis of PMI's animal and human data found hepatotoxic (harmful to the liver) effects of switching to IQOS, an effect which is not usually observed with conventional cigarettes [8]. **In short, there is currently no evidence that IQOS is safer than cigarettes.**²

Even PMI quietly acknowledged this: In its MRTP application to the FDA, PMI gave an "important warning" (Figure 1): "It has not been demonstrated that switching to the IQOS system reduces the risk of developing tobacco-related diseases compared to smoking cigarettes" [15].

Figure 1

Extract from Philip Morris International's Modified Risk Tobacco Product Application to the US Food and Drug Administration [15, p18].

PMI IMPORTANT WARNING:

- It has not been demonstrated that switching to the *iQOS* system reduces the risk of developing tobacco-related diseases compared to smoking cigarettes.
- *HeatSticks* contain nicotine, which is addictive.
- Using the *iQOS* system can harm your health.

1 HTPs are products which heat tobacco leaf using an electronic heating device or lit carbon tip to produce a nicotine aerosol [1,2]

2 This contrasts with the evidence on e-cigarettes which suggests both they that they are substantially lower risk than cigarettes (although not risk free) [9-11], but also that they can help smokers quit [12-14].

Less exposure to some toxic substances is not “a milestone for public health”

Because PMI could not demonstrate *risk* modification, the FDA instead considered, and subsequently granted, an *exposure* modification order [3]. For this order, PMI had to demonstrate IQOS has the *potential* to benefit overall population health by proving it substantially reduced *exposure* of harmful substances to users and those around them [5].

This decision was made largely on the basis of research produced or funded by PMI, which the company supplied to the FDA. Independent researchers have raised concerns over the completeness of these data, noting that when assessing IQOS aerosol PMI typically only analyses 40 [16] of the 93 harmful or potentially harmful substances recognised by the FDA [17]. More comprehensive data from PMI’s analyses show that up to 56 other substances are in fact higher in IQOS aerosol than cigarette smoke, some more than 1000% higher [16, 18]. It is not certain all these data have been seen by the FDA. The FDA has requested additional research on the potential impact of these higher exposures [19]. Moreover, independent aerosol analyses of IQOS found users’ daily intake of some harmful chemicals could be near or above maximum daily dose guidelines [20].

In addition, there is no evidence that IQOS helps smokers quit 2. There are no randomized controlled trials of smoking cessation using HTPs. This is perhaps unsurprising because, despite PMI’s widely promoted claims of a commitment to harm reduction [21], the company has made it clear that IQOS is not intended to be a quit product [22].

Other countries agree IQOS is not reduced risk

Because of the many concerns raised regarding IQOS, other jurisdictions have **not** approved PMI’s attempts to have IQOS officially recognised as a reduced risk tobacco product. For example, the Italian Ministry of Health denied PMI’s application to have IQOS recognized as a reduced exposure and reduced risk product on the grounds of insufficient substantiating evidence [23].

The Italian National Health Institute report, which was originally suppressed and only obtained through work of

investigative journalists, Report and OCCRP, as part of their investigations into IQOS, [24] and to which we have had exclusive access, concluded “that the available evidence is not sufficient to demonstrate” that use of IQOS “is associated with effective risk reduction” [25].

Some countries, such as Australia, Singapore, Finland and Thailand, have used existing nicotine product laws to outright ban HTPs [26]. Scientific and regulatory bodies in the U.K. [9], the Netherlands [27] and Germany [28] recognize that HTPs emit lower levels of harmful substances than cigarettes, but that the extent to which this can reduce disease and death remains unclear.

Warning: PMI will use the FDA decision to mislead governments and consumers

Past behavior suggests that PMI will misrepresent the FDA’s decision to other governments and consumers. In April 2019, the FDA granted a premarket authorization for IQOS that allowed PMI to start selling IQOS in the U.S. [29]. This premarket authorization did not include any decisions on the harmfulness of IQOS, but did not stop PMI from using the authorization as an official endorsement of their “reduced-risk” product. PMI deliberately used the 2019 authorization to lobby governments to open their markets for IQOS [30], to promote the product outside the U.S. [31], and, as a talking point, advancing the company’s disingenuous commitment to a smoke-free future [21, 32]. With the FDA’s recent ruling, it is not a matter of whether PMI will use the ruling to mislead governments and the public but, rather, how quickly.

Don’t be misled by PMI’s spin

The FDA’s assessment [3] is largely in line with existing evidence that IQOS can reduce emissions of [33] and exposure to harmful substances, [34] but that there is currently no evidence that this translates to reduced harm [6-8, 33-34], which is key to reducing the health and economic costs of tobacco use.

Buried deep in its judgement the FDA states that HEETS, the tobacco sticks inserted into an IQOS device, “are novel tobacco products for which long term health consequences have not been established” [19]. The FDA also expresses concern about any increase in the use of IQOS among

young people and non-smokers [19]. There is evidence of PMI targeting exactly these segments in other countries [21].

Governments in other countries should not take the FDA's ruling as an endorsement that IQOS reduces harm. Even though the FDA has instructed PMI that it cannot tell or mislead consumers to believe that IQOS is FDA-approved [19], there is a risk that PMI's spin of the FDA decision may have done exactly that.

Key Takeaways

- The FDA has not ruled that IQOS is safer than cigarettes.
- In its own words, PMI acknowledges, "It has not been demonstrated that switching to the IQOS system reduces the risk of developing tobacco-related diseases compared to smoking cigarettes."
- Analyses by independent researchers and by other governments have **not** found that IQOS reduces disease or death.
- Based on available evidence, several countries have banned the product or restricted its sales.
- There is no level of tobacco exposure that has been found to be safe.
- Governments should be alert to PMI's spin on the FDA ruling—it is not an endorsement of IQOS.
- Governments and civil society should monitor PMI's PR and marketing to ensure that consumers are not being misled on the FDA decision or the safety of IQOS.
- There is currently no evidence that IQOS helps smokers quit. Smokers wishing to quit should use products shown to be safe and effective in line with national and international guidance [35].

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