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FDA's reduced exposure marketing order for IQOS: why it is not a reliable global model

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Abstract

The US Food and Drug Administration (FDA) issued orders in July 2020 authorising Philip Morris Products S.A. to market its heated tobacco product (HTP) IQOS inside the USA with claims that it reduces exposure to some dangerous substances. FDA's 'reduced-exposure' orders explicitly prohibit the marketing of IQOS with claims that IQOS will reduce harm or the risk of tobacco-related diseases. Under US law, FDA's IQOS orders are problematic because FDA disregarded valid scientific evidence that IQOS increases exposure to other dangerous toxins and that Philip Morris Products S.A. failed to demonstrate that consumers understand the difference between reduced-exposure and reduced-harm claims. Unfortunately, both 'reduced-exposure' and 'reduced-harm' are classified as 'modified risk tobacco products' under US law. Exploiting this confusion, Philip Morris International used the FDA decision as the basis for marketing and public relations campaigns outside the USA to press governments to reverse policies that ban or regulate the sales and marketing of HTPs, including IQOS. Parties to the WHO Framework Convention on Tobacco Control should reject tobacco companies' unsubstantiated explicit or implied claims of reduced harm associated with HTPs and resist Philip Morris International's and other companies' calls to relax HTP regulations based on the FDA's actions. Instead, parties should adopt policies aligned with the Framework Convention on Tobacco Control when dealing with HTPs and other novel tobacco products.

The US Food and Drug Administration (FDA) issued orders in July 2020 authorising Philip Morris Products S.A. (PMPSA), the entity of Philip Morris International (PMI) that manufactures IQOS, to market its heated tobacco product (HTP) IQOS and three flavours of Heatsticks (Marlboro tobacco and two menthol flavours) in the USA with claims that it reduces exposure to some dangerous substances for users who switch 'completely' from conventional cigarettes to IQOS.[1] PMPSA submitted a modified risk tobacco product (MRTP) application to FDA and is responsible for clinical trials and postmarket studies and surveillance.[2] PMI entered into a licensing agreement with Altria Group to distribute

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and market IQOS in the USA with its subsidiary Philip Morris USA.[3] PMI, in turn, is using FDA's limited action to promote IQOS around the world, including efforts to pressure governments to allow IQOS' entry into markets and to adopt lax regulations for HTPs.[4–14] We examine the nuances of what FDA did and did not do as well as important differences between the US Family Smoking Prevention and Tobacco Control Act[15] (TCA, the US law governing FDA's authority over tobacco) and the WHO's Framework Convention on Tobacco Control (FCTC) in regulating new tobacco products.[16 17] Policy makers and advocates outside the USA need to understand these nuances to make informed decisions about IQOS, including maintaining existing regulatory frameworks banning the sales of the product or applying FCTC-based policies when bans do not exist.[18] In particular, FCTC Article 13.4(a)[19] commits parties to prohibit false, misleading or deceptive promotion of tobacco products (and HTPs are tobacco products) and Article 5.3[20] obliges parties to protect the setting of tobacco-control policies from tobacco industry interference.[17]

FDA'S ORDERS ARE BASED ON COMPLICATED US LAW THAT CAN BE EASILY MISREPRESENTED

In the USA, if a tobacco company wants to advertise its product as 'reduced harm' or 'reduced exposure', they need specific permission from FDA to do so. This decision is separate from authorising the *sale* of a tobacco product, something FDA did for IQOS in April 2019.[21] FDA's authority to permit tobacco companies to make such advertising claims falls under TCA[15] section 911, entitled 'Modified Risk Tobacco Products (MRTP)'. The law deals with 'reduced harm' and 'reduced exposure' claims in two different subsections of the MRTP. The requirements for obtaining reduced *harm* orders (permission to make such claims) are much more rigorous than for reduced *exposure* orders.

To secure a *reduced harm* MRTP order (ie, permission to make a reduced harm claim), the tobacco company must demonstrate that the product, as actually used by consumers, will 'significantly reduce harms and the risk of tobacco-related disease to individual tobacco users' and 'benefit the health of the population as a whole' considering both users and non-users of tobacco products (Ref. 15, § 911(g)(1)). For products that cannot demonstrate reduced harm, FDA may issue a *reduced-exposure* order if the applicant demonstrates that the product 'would be appropriate to promote the public health' and the labelling and advertising are limited to representing that the product or its smoke contains or exposes users to a substantially reduced level of a harmful substance (Ref. 15, § 911(g)(2)). Additionally, the applicant must demonstrate that 'the product as actually used by consumers will not expose them to higher levels of other harmful substances compared with the similar types of tobacco products then on the market', that the labelling and marketing does not mislead consumers into believing that the product is less harmful than other tobacco products (Ref. 15, § 911(g)(2)(B)) and that the public comprehends the reduced-exposure marketing claims (Ref. 15, § 911(h)(1)). The TCA prohibits companies from making both explicit and implicit reduced-risk claims without obtaining specific FDA authorisation.[15] However, reduced-exposure claims may be inherently misleading because they may be interpreted by consumers as reduced risk claims, even in products like IQOS for which FDA explicitly rejected reduced risk claims. Before enactment of the TCA, the tobacco industry

lobbied for a regulatory system with separate tiers for exposure and risk recognising it would ease the process for obtaining at least one type of MRTP order,[22] and, as we describe below, continues to exploit this loophole.

FDA FOUND THAT PMPSA DID NOT DEMONSTRATE THAT IQOS IS SAFER OR REDUCES HARM

The FDA found that PMPSA did not meet its burden of demonstrating that IQOS is safer or reduces harm and did *not* permit PMPSA to market IQOS with claims that it is safer or less harmful than other tobacco products. Rather, the FDA marketing orders explicitly 'deny the marketing of (IQOS) with reduced risk claims'.[1] Specifically, FDA's review of PMPSA's MRTP application found:

> With respect [to] the risk modification order requests, the applicant **has not demonstrated** that, as actually used by consumers, the products sold or distributed with the proposed modified risk information will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and 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. [emphasis in original].[23]
>
> All that FDA allowed PMPSA to do was advertise IQOS with the following specific reduced exposure claim:
>
> AVAILABLE EVIDENCE TO DATE:
>
> - The IQOS system heats tobacco but does not burn it.
> - This significantly reduces the production of harmful and potentially harmful chemicals.
> - Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals.[1]

Additionally, FDA emphasised that the order 'does not mean FDA 'approved' the products', and stated, 'you [PMPSA] may not make any express or implied statement or representation directed to consumers that conveys, misleads, or would mislead consumers into believing' that '[IQOS products] are 'approved' by FDA… Moreover, because these products have not been authorised under section 911(g)(1) (risk modification order), you may not market these products with reduced risk claims.' [emphasis in original].[1]

As described above, FDA is statutorily required (Ref. 15, § 911(g)(2)(B)(ii)) to compare a proposed reduced exposure product to similar products currently on the market, but IQOS was not compared with e-cigarettes although there are many similarities between IQOS and e-cigarettes. This is significant because a 2020 study found higher odds of HTP awareness, trial and current use among current e-cigarette users and concurrent smoker-vapers.[24] FDA's failure to compare the health risks of IQOS to e-cigarettes[25] is a substantial omission in FDA's analysis.

IQOS PROMOTIONS OUTSIDE THE USA AND PMI-FUNDED 'FOUNDATION FOR A SMOKE-FREE WORLD' MISLEAD CONSUMERS AND POLICY MAKERS

In promoting IQOS outside the USA, PMI is taking advantage of the fact the public might think that a product marketed with reduced exposure claims and called a 'modified risk tobacco product' means it reduces risk of developing tobacco-related diseases. As described above, FDA made no such finding. PMI has used FDA's April 2019 marketing authorisation to market IQOS outside the USA as 'appropriate for the protection of the public health'.[25] The FDA's July 2020 MRTP decision about the harmfulness of IQOS created an opportunity for PMI to launch marketing and public relations campaigns urging governments to relax regulations and permit IQOS sales in an attempt to reverse existing policies that ban the sales and prohibit deceptive marketing of such novel tobacco products.[13] Since July 2020, PMI and FDA are cited in media reports in Hong Kong,[12] Korea,[11] the Philippines,[5] Malta,[4] several African countries[6–9] and elsewhere[14] mischaracterising FDA's MRTP order as evidence that IQOS is a reduced harm product. For example, PMI urged the Philippine government to use FDA's MRTP order as a basis of public health policymaking in the Philippines because 'FDA's decision has effectively differentiated IQOS from combustible cigarettes when it comes to health risk',[5] and in a Zimbabwe news report, the FDA decision was misrepresented as FDA certification of the marketing of IQOS as 'a reduced risk tobacco product with reduced smoking health risks',[8] capitalising on the confusion between risk and exposure.

IQOS MARKETING OUTSIDE THE USA VIOLATES THE FCTC

The FCTC[16] requires parties to protect public health by taking evidence-based measures to reduce tobacco use and nicotine addiction, to prevent false or misleading labelling, advertising and promotions about a product's health effects and to prevent tobacco industry interference in the development and implementation of public health policies. The USA is not a party to the FCTC and the FDA's orders do not reflect FCTC goals. Instead of reducing tobacco use and nicotine addiction, the IQOS MRTP order permits the marketing of a new nicotine product, allows misleading claims about IQOS's health impacts and has been used by the industry to promote policies it favours. FCTC parties should enact measures that support FCTC's goals, rather than replicating FDA's actions.

The FCTC applies to HTPs,[18] including IQOS. Further, in July 2020, the WHO issued an updated information sheet on HTPs[26] and a statement[17] urging full implementation of the FCTC. WHO reiterated that FDA's decision did not mean that IQOS reduced risk or was harmless, saying that IQOS's reduced-exposure claims may be misleading as users' health may be affected by exposure to additional toxins.[17]

Marketing IQOS with unsubstantiated reduced-exposure claims or labelled as a 'modified-risk' product in countries that are parties to FCTC would violate several of its legally binding provisions,[27] including provisions that ban all forms of false or misleading tobacco advertising promotion, and sponsorship,[19] prohibit packaging and labelling that promote

false, misleading or erroneous impressions about the health effects of the product[28] and protect policies from tobacco industry interference.[20] Several countries, including Canada, Singapore and Finland, have imposed strict regulations on IQOS marketing and sales,[29] and Australia[30] (with some exceptions), Brazil and Thailand[31] banned their entry into market. Other parties to FCTC should follow their lead as recommended by the Conference of the Parties to the FCTC in its October 2018 Decision on 'Novel and emerging tobacco products'.[18]

EVEN UNDER US LAW, FDA'S IQOS REDUCED-EXPOSURE ORDERS ARE NARROW AND DO NOT ALLOW IQOS TO BE MARKETED AS REDUCED-RISK PRODUCTS

FDA's reduced exposure orders[1] as well as FDA's April 2019 Premarket Tobacco Product Application (PMTA) orders[21] raised significant concerns. In our view, FDA disregarded valid scientific evidence and misapplied the law because PMPSA failed to meet its statutory burden to demonstrate that IQOS is 'appropriate for the protection of the public health',[25 32–35] failed to demonstrate that IQOS exposes users to substantially reduced levels of dangerous substances[36] and failed to show that consumers will not be misled by the claim.[37 38]

First, allowing the marketing of IQOS—with or without reduced-exposure claims—is not good for the public health; PMPSA failed to demonstrate reduction in long-term disease risks and failed to adequately address potential carcinogenic, genotoxic, cytotoxic, hepatotoxic, cardiovascular and pulmonary risks.[25 39–42] Second, the MRTP claim authorised by FDA that IQOS 'significantly reduces the production of harmful and potentially harmful chemicals' is on its face inaccurate. Although IQOS may reduce exposures to *some* harmful and potentially harmful chemicals compared with conventional cigarettes, IQOS aerosol produces *higher levels* of harmful and potentially harmful chemicals than conventional cigarettes for dozens of other toxins, including glycerol and propylene glycerol,[36] which FDA has proposed adding to the current list of harmful and potentially harmful chemicals.[43] Third, PMPSA failed to demonstrate that consumers, especially adolescents, understand the difference between reduced-exposure and reduced-harm claims and will not be misled by the labelling and advertising claims to believe that IQOS reduces harm[37 38] and, fourth, their studies did not address youth use.[44 45] Moreover, the reduced-exposure claim is premised on the unsubstantiated statement that smokers will 'switch completely' to IQOS and understand what 'switching completely' means. PMPSA also failed to adequately address the likelihood of poly-use of IQOS with other tobacco products.[46 47] FDA's own scientists acknowledged many of these deficiencies in FDA's Technical Project Lead (TPL) Scientific Review of PMPSA's MRTP application.[23] In its Assessment of Potential Health Risks to Tobacco Users and Non-Users, the TPL found that 'disease or mortality risk is unlikely to be substantially reduced as a result of exposure reduction in dual users of cigarettes and IQOS', having noted that dual use is the most common pattern of use (Ref. 23, p. 42). Indeed, current research shows that dual use of IQOS and cigarettes is common.[24 48 49]

FDA's TPL stated that FDA's Tobacco Products Scientific Advisory Committee unanimously voted that PMPSA did not demonstrate that consumers accurately understand the risks of IQOS (Ref. 23, p. 50). Because the TPL acknowledged that 'consumers need to switch completely to achieve the benefits of reduced exposure', FDA's MRTP order[21] requires PMPSA to conduct and report post market surveillance **'to ensure consumers understand that the benefits of reduced exposure cannot be achieved by continuing to smoke combusted cigarettes in addition to using IQOS**. [emphasis in original]' (Ref. 23, p. 52).

In addition to finding deficiencies with the reduced-exposure claim, the TPL's Toxicological Assessment noted other 'significant limitations' in the studies presented concerning the relative health risks of using IQOS (Ref. 23, p. 33) that further demonstrate that IQOS is not 'appropriate for the protection of the public health' regardless of whether it reduces exposure to some toxins compared with conventional cigarettes. Additionally, the TPL found 'the health effects due to nicotine exposure may not be substantially different between use of IQOS and cigarettes, including risks to the fetus and the potentially negative effect of nicotine on the developing brain in youth' (Ref. 23, p. 42). Furthermore, a PMI-funded report[50] found that most of the world's largest tobacco companies are not phasing out cigarette sales, suggesting that dual use will continue to predominate for decades.

The TPL's assessment of impacts to non-users noted that PMPSA 'did not provide any direct data on the potential for use or appeal among U.S. youth' (Ref. 23, p. 62). The TPL found that given the uncertainty about youth uptake and the fact that youth are at increased risk for initiating tobacco use (Ref. 23, p. 75), FDA's MRTP order[21] should require PMPSA to provide postmarket studies demonstrating that IQOS continues to benefit the health of the population as a whole by monitoring the impact of IQOS's advertising and marketing on youth to ensure that youth exposure to PMPSA's marketing will not lead to increased youth initiation and use. Research has found a high level of interest in trying HTPs among youth and young adults,[24 51] even when only assessing unflavoured IQOS. Levels of interest and susceptibility among youth may be higher in the USA and other countries where IQOS menthol flavours are available and where IQOS is marketed aggressively[52] and promoted as 'reduced risk'. Finding that FDA granted premarket authorisation of IQOS without sufficient evidence of its impact on youth, tobacco control experts called on FDA to require companies to submit research showing the impact on youth and young adults before issuing any future PMTA or MRTP orders.[44]

CONCLUSION

FDA's reduced-exposure order for IQOS was narrow and explicitly stated that it should not be interpreted as concluding that IQOS is a reduced-risk product. Indeed, FDA specifically concluded that the evidence PMPSA submitted did not support a reduced risk claim. FDA should not have issued the order because of the inherent confusion between reduced-exposure and reduced-risk products and because PMPSA failed to meet its burden to demonstrate that IQOS exposes users to substantially reduced levels of dangerous substances, that consumers will not be misled by the reduced-exposure claims and that IQOS protects public health. Unless and until additional evidence is produced, FDA should

revise its MRTP order for IQOS. In the future, FDA should not issue any reduced-exposure or reduced-risk MRTP order unless the applicant provides sufficient scientific evidence to support its claim, including clear and convincing evidence that reduced-exposure orders will not be misunderstood by consumers as reduced risk statements. Other countries should reject tobacco companies' unsubstantiated claims of reduced harm associated with HTPs and resist PMI's and other companies' calls to relax HTP regulations based on the FDA's actions. Countries should, instead, adopt policies aligned with the FCTC goals when dealing with HTPs and other novel tobacco products.

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What this paper adds

- The US Food and Drug Administration (FDA) issued orders authorising Philip Morris Products S.A. to market its heated tobacco product IQOS in the USA with claims that it reduces exposure to some toxicants, but denied the company's request to market IQOS with claims that it reduces harm or the risk of tobacco-related diseases.
- Under US law, products marketed with either 'reduced-exposure' or 'reduced-harm' claims are categorised as 'modified risk tobacco products', which creates confusion.
- Philip Morris International has exploited this confusion and used FDA's orders to market and promote IQOS outside the USA and to press governments to reverse policies that ban or regulate the sales and marketing of heated tobacco products, including IQOS.
- Parties to the WHO Framework Convention on Tobacco Control (FCTC) should reject Philip Morris International's and other tobacco companies' unsubstantiated explicit or implied claims of reduced harm associated with heated tobacco products and resist their calls to relax heated tobacco product regulations based on the FDA's actions; instead, countries should adopt policies aligned with the FCTC.