



The U.S. FDA Ruling on IQOS: Spin vs Truth

September 10th, 2020

Definitions

The United States Food and Drug Administration (U.S. FDA)

- Regulatory government agency responsible for, among other areas including food, drugs and cosmetics, [regulating the manufacturing, marketing and distribution](#) of tobacco products in the U.S.

IQOS

- Heated tobacco product (HTP) created by Philip Morris International (PMI)
- Contains nicotine and tobacco, unlike e-cigarettes which contain nicotine, but no tobacco
- Users inhale an aerosol created by heating the tobacco materials

Modified Risk Tobacco Product (MRTP)

- A classification tobacco companies can apply for; the FDA may choose to grant the product this classification or not
 - Two standards are evaluated to determine MRTP status: risk modification and exposure modification
 - Risk modification is a more important and meaningful standard
 - Even if only one of these standards is met, a company might claim MRTP status, which creates confusion as to whether a product actually reduces risk
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The terminology used in the FDA’s July 2020 ruling on IQOS as a Modified Risk Tobacco Product is confusing and creates room for misinterpretation and inaccurate representation. This resource explains what the FDA ruled and debunks the public relations spin PMI is using to portray this ruling as a win for health.

PR Spin vs. Truth

SPIN: The FDA "approved" IQOS.

TRUTH:

The FDA ruled that IQOS met its lower "exposure modification" standard, but did not meet its more important "risk modification" standard.

- This means that while IQOS may reduce exposure to harmful substances, it has not been proven to reduce the risk of disease and death compared with smoking cigarettes.
- IQOS did not meet the "risk modification" standard because [PMI "...has not demonstrated that... \[IQOS\].... will significantly reduce harm](#) and the risk of tobacco-related disease."

The FDA ruled [that PMI may not market IQOS](#) with reduced-risk claims.

SUBMISSION INFORMATION	
Applicant	Philip Morris Products S.A.
Product Manufacturer	Philip Morris Products S.A.
Submission Date	November 18, 2016
FDA Receipt Date	December 5, 2016
Purpose	<input checked="" type="checkbox"/> Risk Modification (911g(1)) order <input checked="" type="checkbox"/> Exposure Modification (911g(2)) order
Proposed Modified Risk Claims	Modified Risk Claim #1: 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 can reduce the risks of

SPIN: The FDA's ruling is a step forward for public health.

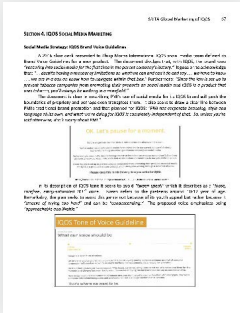
TRUTH:

- PMI called the decision a "[historic public health milestone](#)," even though it included this warning in its MRTP application: "Using the IQOS system can harm your health."
- PMI has a [history of targeting young people and non-smokers](#), justifying the FDA's concern about a [potential increase in IQOS use](#) among these groups.
- If taken up in large numbers, especially by those who otherwise wouldn't have smoked, HTPs could harm public health.

SPIN: The FDA's ruling means consumers will have access to a safer product.

TRUTH:

- There is no such thing as a safe tobacco product.
- PMI showed reduced exposure to only 40 of the 93 potentially harmful substances recognized by the FDA; yet 56 other substances are *higher* in IQOS aerosol than cigarette smoke.¹
- IQOS has not been shown to help smokers quit and does not carry significantly less risk than smoking.²



"In particular, I find that the claims 'Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system can reduce the risks of tobacco related diseases.' and 'Switching completely to IQOS presents less risk of harm than continuing to smoke cigarettes.' are not substantiated"

–Technical Project Lead on FDA's review of PMI's MRTP application

PMI's Aggressive IQOS Promotion Scheme

- The FDA ruling is the latest tool PMI is using to urge governments to allow the sale of IQOS and to relax HTP regulations.
- PMI [markets IQOS heavily on social media](#) platforms that have a strong youth audience, causing concern for increased youth uptake. PMI has been found to use influencers and celebrities to push IQOS, attempting to portray the device as an upscale lifestyle product associated with glamor, hearkening back to decades-old cigarette ads.
- PMI can be expected to start using modified risk claims when promoting IQOS to governments, regulators and users.

Recommendations

- **Be aware of PMI promoting a misleading portrayal of the FDA ruling.**
- **Governments should resist PMI's pressure to open their markets to IQOS.**
- **Where IQOS is already present, governments should regulate it and other HTPs as tobacco products.**
- **Learn more about the ruling and PMI's current and past attempts to addict as many users as possible:**
 - [FDA's Full Ruling](#)
 - [FDA Does Not Rule that IQOS Reduces Tobacco-Related Harm, Yet PMI Still Claims Victory](#)
 - [Inside the Philip Morris Campaign to "Normalize" a Tobacco Device](#)
 - [Addiction at Any Cost: Philip Morris International Uncovered](#)
 - [US Regulator Adds to Confusion Around Heated Tobacco Products](#)

¹ St.Helen G, Jacob Iii P, Nardone N, et al. IQOS: examination of Philip Morris International's claim of reduced exposure. *Tobacco Control* 2018;27(Suppl 1):s30. doi: 10.1136/tobaccocontrol-2018-054321 pmid:30158205

² Jankowski M, Brożek GM, Lawson J, et al. New ideas, old problems? Heated tobacco products - a systematic review. *Int J Occup Med Environ Health* 2019;32(5):595-634. doi: 10.13075/ijomh.1896.01433 pmid:31584041

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STOP's Rapid Engaged Action Team (REACT)

REACT provides tobacco industry monitoring, research, expertise in industry arguments and strategic communication, customized to the local context. Learn more at www.exposetobacco.org/react



Acknowledgements and Authorship

Stopping Tobacco Organizations and Products (STOP) is a global tobacco industry watchdog whose mission is to expose the tobacco industry strategies and tactics that undermine public health. STOP is funded by Bloomberg Philanthropies (www.bloomberg.org) and is a partnership between The Global Center for Good Governance in Tobacco Control, The Tobacco Control Research Group at the University of Bath, International Union Against Tuberculosis and Lung Disease and Vital Strategies. This brief was prepared for STOP by The Tobacco Control Research Group at the University of Bath.

