# 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 |

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

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.

**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
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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

"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


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