
BEFORE THE
U.S. FOOD AND DRUG ADMINISTRATION
Washington DC

In the Matter of:

Docket No. FDA-2017-D-3001-0002

Modified Risk Tobacco Product Applications:
Applications for iQOS System with Marlboro Heatsticks,
iQOS System with Marlboro Smooth Menthol Heatsticks,
and iQOS System with Marlboro Fresh Menthol Heatsticks

Comments of
Thomas A. Giovanetti, President
Institute for Policy Innovation (IPI)
Supporting the Applications

January 11, 2017

On behalf of the Institute for Policy Innovation (IPI), a free-market public policy research organization that closely follows health care and regulatory policy, I write to express our support for the modified risk tobacco product application submitted by Phillip Morris International (PMI) for a new product technology called the iQOS system, and three types of “heatstick” products currently pending before the agency.

We believe the innovative iQOS technology has the potential to be a transformational product that could save countless lives within the population that has been unable or unwilling to curtail smoking. We therefore urge that these applications be reviewed and approved without unnecessary delays caused by extraneous factors in defiance of Congress’ clear intention to encourage tobacco harm reduction by stimulating the development of reduced risk products.

Congress established the Modified Risk Tobacco Product (MRTP) approval pathway in 2009 as part of the Tobacco Control Act in recognition of the problem that some tobacco consumers would continue to use tobacco products despite availability of tobacco cessation therapies and thorough public awareness campaigns about the dangers of smoking. The MRTP pathway was designed to encourage innovation of less dangerous products, and several companies, including Phillip Morris International, have made huge investments in developing new products that have dramatically reduced risk profiles, including the iQOS products described in this application.

Based on the voluminous research that PMI has submitted along with its application, it appears that the iQOS family of products significantly reduces a user’s exposure to the carcinogenic compounds found in cigarettes, while maintain the flavor and nicotine that attracts smokers to

cigarettes. This suggests legitimate scientific basis for iQOS to fit well within Congress' intentions for reduced risk products.

The iQOS combination of reduced risk with comparable user experience suggests that it is an acceptable replacement for cigarettes, and the markets in which iQOS is available have borne this out. According to PMI, three million users have already switched from cigarettes to iQOS.

A reduced risk product that users find to be an acceptable substitute for a higher risk product should be viewed as very constructive from a public health perspective.

We believe the approximately 36 million remaining smokers in the United States deserve to have access to the best reduced risk alternative to cigarettes available, which is why we believe that the iQOS products should be approved for sale in the United States.

In the years just prior to and following after the Tobacco Master Settlement Agreement, the public health movement to discourage cigarette smoking has partially morphed into a movement that is simply in opposition to tobacco companies. We expect groups like the Truth Initiative to express firm opposition to reduced risk products such as iQOS, but we urge the FDA to resist such political pressures.

Indeed, we are quite impressed at the dedication and research of Phillip Morris International to spend billions of dollars transforming the company and developing tobacco products with dramatically reduced risk. Such corporate behavior is to be commended, not condemned.

Further, we observe that it is more than a little ironic that, at the same time that public policy is becoming more open to granting the possibility that there are health or social benefits to decriminalizing many substances and re-opening research into previously banned substances, that groups like the Truth Initiative would argue that tobacco itself is inherently to be opposed.

While we support technologies and public relations campaigns to discourage smoking and to help smokers stop smoking, we resist the idea that tobacco use is inherently to be discouraged. If a product such as iQOS dramatically reduces the cancer risk of tobacco use, such a reduced risk product would more resemble other, socially acceptable products that adults choose to consume from a public policy and regulatory perspective.

In conclusion, we believe there is compelling evidence and argument for the FDA to approve the iQOS family of products through its MRTP pathway, and urge the FDA to do so. Such an approval would be consistent with the FDA's announced policy of encouraging the development of noncombustible, reduced risk tobacco products.

We would be happy to answer any further questions the Commission might have on this matter, and would pledge to work constructively with the Commission to encourage the substitution of reduced risk tobacco products such as iQOS for cigarettes.

Sincerely,



Tom Giovanetti
President