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April 23, 2020

BY EDIS

The Honorable Lisa R. Barton
Secretary to the Commission
U.S. International Trade Commission
500 E Street, S.W., Room 112
Washington, DC 20436

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Re: *Certain Tobacco Heating Articles and Components Thereof,*
ITC Docket No. 337-TA-3447

Dear Secretary Barton:

Enclosed please find as a courtesy filing the Public Interest Comments of the Reason Foundation.

Respectfully submitted,

/s/ Jamie D. Underwood

Jamie D. Underwood
of LATHAM & WATKINS LLP

Enclosure

cc: Service List

Philip Morris Products, S.A.

Guy Bentley, director of consumer freedom
Reason Foundation
April 23, 2020

The Honourable Lisa R. Barton
Secretary to the Commission
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

Re: Certain Tobacco Heating Articles and Components Thereof, DN 3447

Dear Secretary Barton,

I am writing on behalf of Reason Foundation to voice our concerns over the possible withdrawal of the IQOS tobacco heating system from the U.S. market. Reason Foundation advances a free society by developing, applying, and promoting libertarian principles, including individual liberty, free markets, and the rule of law. These comments are not intended to express a view on the merits or demerits of the specific claims brought before the International Trade Commission (ITC). Rather they are restricted to the public health and welfare implications of removing IQOS from the U.S. market.

Heated tobacco systems are part of a new generation of non-combusted products intended to give adult smokers the nicotine they desire without generating the smoke that may kill them. By heating instead of burning tobacco, these products emit much lower levels of harmful toxicants compared to cigarettes. Combustion at high temperatures causes emissions that expose cigarette smokers to complex and extremely hazardous chemicals, which when inhaled have numerous ill effects on the user's health. This problem was articulated by tobacco researcher Michael Russell who said: "People smoke for the nicotine, but they die from the tar."

Because there is no combustion in IQOS, levels of Harmful and Potentially Harmful Chemicals (HPHCs) in the vapor generated are, on average 54%–99.9% lower than reference cigarettes, according to an FDA review of independent and industry studies.¹ On January 25, 2018, the FDA's Tobacco Products Scientific Advisory Committee (TPSAC) unanimously endorsed the claim made by Philip Morris International (PMI) that switching completely from cigarettes to IQOS significantly reduces smokers' exposure to HPHCs.² On April 20, 2019, the FDA explained its reasoning for approving IQOS for sale: "Following a rigorous science-based review through the premarket tobacco product application (PMTA) pathway, the agency determined that authorizing these products for the U.S. market is appropriate for the protection of the public health because, among several key considerations, the products produce fewer or lower levels of some toxins than combustible cigarettes." IQOS has achieved significant success in international markets, with 14.6 million users, 73% of whom are classified as having "stopped smoking." While IQOS has been available in the U.S. for a relatively short time and in few locations, the initial results are promising, with 40% brand awareness among adult smokers in Atlanta and more than half of those who try the product proceeding to purchase it.

There are more than 34 million adult smokers in the U.S., the majority of whom say they would like to quit. In order to ensure a successful transition away from cigarettes for those who wish to do so, it is necessary to have a broad and diverse marketplace of safer alternatives. Some

¹ Center for Tobacco Products. "Technical Project Lead Review of PMI IQOS Premarket Tobacco Application." Food and Drug Administration. 2019. <https://www.fda.gov/media/124247/download>

² Food and Drug Administration. "Summary Minutes of the Tobacco Products Scientific Advisory Committee (TPSAC)." Center for Tobacco Products. January 24-25, 2018. <https://www.fda.gov/media/111455/download>

smokers succeed using traditional nicotine replacement therapy while others use e-cigarettes.

Unfortunately, a majority of the public is under the mistaken impression that e-cigarettes are just as or more dangerous than combustible cigarettes, which is deterring many smokers from switching. Heated tobacco products provide important option for smokers who have failed to quit using other tools or find current alternatives unappealing.

The availability of IQOS can assist in driving down U.S. cigarette sales, just as it has in other markets. A study conducted by the American Cancer Society (ACS) examined changes in Japan's cigarette sales from the time IQOS was launched in 2014 to 2018. During this period, there were no other major changes to Japan's tobacco policy. Before the introduction of IQOS, cigarette sales were declining at 1.8% per year. After the introduction of IQOS, cigarette sales declined at 9.5% per year. The authors concluded that "The introduction of IQOS likely reduced cigarette sales in Japan."³ Fortunately, IQOS has very little appeal to minors. According to surveys of 64,000 Japanese students, conducted by Prof. Y Osaki of Tottori University, Medical School, youth use of heated tobacco is close to zero.⁴ The percentage of high schoolers who had used a heated tobacco product at least once in the past month between December 2017 and February 2018 was 0.9% and daily use was 0.1%. As part of its decision to approve IQOS for sale, FDA also imposed stringent marketing restrictions to prevent youth access and

³ Stoklosa, M., Z. Cahn and A. Liber, et al. "Effect of IQOS introduction on cigarette sales: evidence of decline and replacement." *Tobacco Control*. June 17, 2019. <https://tobaccocontrol.bmj.com/content/early/2019/06/11/tobaccocontrol-2019-054998>

⁴ Kumamaru, Hiroya. "Update on Current Status in Japan on Tobacco Harm Reduction." *Global Nicotine Forum*. June, 2019. https://gfn.net.co/downloads/2019/presentations/Hiroya_Kumamaru.pdf

exposure.⁵ In conclusion, we urge you to consider the detrimental impact removing IQOS would have on reducing tobacco related harms.

Sincerely,

Guy Bentley
Director of consumer freedom, Reason Foundation

⁵ Food and Drug Administration. "FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway." April 30, 2019.
<https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobaccoheating-system-through-premarket-tobacco-product-application-pathway>

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