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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 TechFreedom.

Respectfully submitted,

/s/ Jamie D. Underwood

Jamie D. Underwood
of LATHAM & WATKINS LLP

Enclosure

cc: Service List

Philip Morris Products, S.A.



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

Re: In the Matter of Certain Tobacco Heating Articles and Components Thereof,
Investigation No. 337-TA-3447

Dear Secretary Barton:

I am grateful for the opportunity to submit this public interest statement In the Matter of Certain Tobacco Heating Articles and Components. TechFreedom is a post-partisan think tank dedicated to promoting the progress of technology that improves the human condition. To this end, we seek to advance public policy that makes experimentation, entrepreneurship, and investment possible, and thus unleashes the ultimate resource: human ingenuity.

I. IQOS Technology is Innovation with Public Health Benefits

Traditional cigarettes are a known hazard to health, but the risks stem mainly from chemicals produced through the process of combustion. Products that heat nicotine solutions or tobacco, such as the IQOS, deliver nicotine without combustion and, as a result, lack most of the harmful and potentially harmful elements of traditional tobacco. Heat-not-burn alternatives provide substantially less hazardous options for individuals wishing to consume nicotine with an experience similar to smoking. In 2014, the FDA’s research determined, “the inhalation of nicotine (i.e. nicotine without the products of combustion) is of less risk to the user than the inhalation of nicotine delivered by smoke from combusted tobacco products.”¹

¹ Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products 81 FR 28973 (May 10, 2016), *available at* <https://www.gpo.gov/fdsys/pkg/FR-2016-05-10/pdf/2016-10685.pdf>.

TECH FREEDOM

The history of technology is full of examples where innovation moves consumers toward safer, more effective, and more user-friendly options. We've seen innovations in public health elsewhere, as telemedicine has increased access to medical services especially right now as our country is grappling with an unprecedented challenge of a pandemic. There is drone delivery being developed globally to help reach the most vulnerable population. Apple and Google are on track to release a privacy minded contact tracing tool to help reopen America.² These advances bypass conventional outmoded paradigms and create new ones, and they have occurred in all aspects of American life.

In his seminal 1976 British Medical Journal article, the late Professor Michael Russell noted that, "people smoke for nicotine, but they die from the tar."³ Yet, over 35 years later, smoked tobacco is still the primary source of nicotine and by far the largest cause of preventable death and disease.⁴ In an effort to stem such preventable deaths and to create a "smoke-free future," Philip Morris International (PMI) has introduced a new device in the U.S. utilizing a "heat-not-burn" (HNB) technology, which will significantly reduce the release of the chemical compounds as compared to the smoke created by the fire from conventional cigarettes. Results in other countries using IQOS are positive. Since IQOS was launched in the UK last December, for example, about 70% of people that use it are able to give up conventional cigarettes.⁵

Despite the benefits, only about 22% of all U.S. smokers have made the switch to healthier alternatives, suggesting that a large majority of the estimated 36.5 million current smokers in the

² Kaveh Waddell, *Apple, Google Could Alert You to Coronavirus Exposure*, Consumer Reports, (April 10, 2020), <https://www.consumerreports.org/coronavirus/apple-google-could-alert-you-to-coronavirus-exposure/>.

³ M.A.H. Russell, *Low-tar Medium Nicotine Cigarettes: A New Approach To Safer Smoking*, 1430 British Medical Journal 1976; 1431 (1976), <http://www.bmj.com/content/bmj/1/6023/1430.full.pdf>.

⁴ Centers for Disease Control, Smoking & Tobacco Use, *Fast Facts, Diseases and Death* (Nov. 16, 2017), https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm.

⁵ Reuters Staff, *Tobacco group Philip Morris sees IQOS as key to smokeless future in UK* REUTERS (June 30, 2017), <https://www.reuters.com/article/us-philipmorris-britain/tobacco-group-philip-morris-sees-iqos-as-key-to-smokeless-future-in-uk-idUSKBN19L1DU>.

U.S. do not view e-cigarettes, which have been around for some time, as an attractive alternative. According to one study, the principle reason for smokers not wanting to switch was because, in their view, e-cigarettes were less pleasurable than traditional cigarettes.⁶ This is the appeal of PMI's IQOS system: giving the user a taste and experience closer to smoking than other products could entice those stubborn smokers to switch to healthier alternatives. Also appealing to current smokers is the fact that the IQOS system delivers nicotine levels comparable to traditional cigarettes.⁷ Evidence shows that this is true, as PMI reports that there are nearly 14 million IQOS users worldwide⁸

Most critically, by heating rather than burning the tobacco, the IQOS system dramatically reduces the harmful chemicals ingested. In traditional cigarettes, the lit end can reach 1600° Fahrenheit; at such extreme temperatures, the breakdown of tobacco leaf also causes the release of what the FDA calls “harmful or potentially harmful constituents” (HPHCs) — the likely causes of smoking-related diseases.⁹ The IQOS system avoids the combustion altogether by heating the tobacco at a much lower temperature, which keeps many of the chemical reactions that release the HPHCs from occurring.¹⁰ This reduces the release of HPHCs overall and thus reduces the incidence of smoking-related diseases.¹¹

⁶ McKeganey N. & Dickson T., *Why Don't More Smokers Switch to Using E-Cigarettes: The Views of Confirmed Smokers*, International Journal of Environmental Research and Public Health, 2-12 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5486333/pdf/ijerph-14-00647.pdf>.

⁷ Philip Morris Int'l, Summary of Modified Risk Tobacco Product Application 5 (May, 2017), <http://pmiscienceusa.com/wp-content/uploads/Brief-Summary-of-PMIs-MRTP-Application-May-2017.pdf> [hereinafter MRTP Summary].

⁸ Philip Morris Int'l, 2019 Fourth-Quarter and Full-Year Results 19 (February 6, 2020), <https://philipmorrisinternational.gcs-web.com/static-files/156f7310-3ff7-4a6d-890f-3a7f663fee81>.

⁹ *Id.* at 2 (citing Department of Health and Human Services, Surgeon General's Report: How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease (2010)).

¹⁰ *Id.*

¹¹ *Id.*



Currently IQOS is the only FDA authorized heated tobacco product that has been through FDA's PMTA review process. Mitch Zeller, the director of CTP, noted that the PMTA process is a "critical part of our mission to protect the public...and to reduce tobacco-related disease and death," and that the review process made certain the IQOS' heat-not-burn technology is appropriate for the protection of the public health due to the product's potential to "completely move adult smokers away from use of combustible cigarettes."¹²

II. Excluding IQOS from the Market Would Stifle Innovation and Put Public Health in Jeopardy

As we move into this second section, it is important to remember that in July of 2017, the FDA announced a new comprehensive plan for tobacco and nicotine regulation. One element of this plan centered on fostering innovation that could lead to less harmful tobacco products, with the goal of achieving the public health benefits that would accrue if users of combusted tobacco products switch to novel, non-combusted forms of nicotine delivery.

The marketing order issued for IQOS authorized immediate commercial distribution of the product, subject to ongoing post-market oversight by FDA and the discretion to withdraw the marketing order upon a determination that continued marketing of IQOS is no longer appropriate for the protection of public health.

Decisions about product circulation in the market should be adopted and implemented in a manner that is consistent with their overarching objective: to strengthen the economy and give consumers choice. Removing IQOS will hurt both the consumers and the economy on many levels.

¹² Press release, FDA Permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway, FDA, (April 30, 2019), available at <https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway>.

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