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LATHAM & WATKINS^{LLP}

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 Dr. Nikan H. Khatibi, MD.

Respectfully submitted,

/s/ Jamie D. Underwood

Jamie D. Underwood
of LATHAM & WATKINS LLP

Enclosure

cc: Service List

Philip Morris Products, S.A.

April 18, 2020

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

Re: Investigation No. 337-TA-3447

Dear Secretary Barton:

I am part of an informal, physician-led group of health professionals devoted to providing patients with devices to help them stop smoking traditional combustible cigarettes. Based on my experience in this area, I would like to offer thoughts regarding a request made by certain Reynolds entities in a Complaint filed with the U.S. International Trade Commission (“Commission”) on April 9, 2020. The Reynolds Complainants have asked the Commission to prevent the importation, and thus the availability to Americans, of the IQOS heated tobacco system. I do not believe this serves U.S. public health goals.

While the percentage of U.S. smokers has declined in the last half century, smoking remains the number one cause of preventable death, and tens of millions of Americans still smoke. The smoking cessation/reduction tools available to aid physicians in their quest to help patients quit or transition from traditional cigarettes have made some progress. It is time, however, to embrace new solutions.

Physicians, and all health professionals, live by the “first do no harm” oath, but complete elimination of risk is very hard in the realm of science, and also in patients’ lives. Reduction of risk is often the best solution. Not all potentially reduced risk smoking alternatives will work on every patient, however. Individual patients will respond differently to various therapeutic approaches. For these reasons, development and access to a range of potentially reduced risk products like IQOS is the key

to achieving a meaningful reduction in Americans' use of traditional cigarettes.

As the Surgeon General stated, the death and disease burden of tobacco in this country is overwhelmingly caused by cigarettes and other combusted tobacco products; rapid elimination of their use will dramatically reduce this burden. Therefore, a heated tobacco system such as IQOS, which is designed to deliver tobacco without combustion is an important development. Indeed, it should be of the upmost and immediate interest to public health to move current smokers away from combustible cigarettes. Other countries have offered IQOS as a non-combustible tobacco option for years, and with success. For example, a recent paper from the American Cancer Society found that the introduction of IQOS in Japan, the country with the highest number of IQOS users in the world, dramatically reduced cigarette sale in Japan. The researchers found that the decline in cigarette sales increased five-fold following the introduction of IQOS, without increasing the overall sales of tobacco products. IQOS now has almost 14 million users worldwide.

In the United States, IQOS has passed through the appropriate regulatory gates by receiving authorization for sale from FDA through the Premarket Tobacco Application (“PMTA”) process. To obtain this type of clearance, an applicant has to show its product is appropriate for the protection of the public health. No other heat not burn product or e-cigarette has been PMTA-authorized. In fact, e-cigarettes have gone largely unregulated. As major concerns mount regarding the rise of youth use of e-cigarettes and related marketing that targets this vulnerable group, FDA has recognized data showing low youth uptake of IQOS and, through its premarket order, closely restricts and inspects IQOS marketing.

The uncertainty and controversy around e-cigarettes and other novel tobacco and nicotine products is unlikely to abate any time soon. Therefore, more than ever, the healthcare providers must rely on FDA's regulatory review process to ensure that the products that are permitted to be sold on the market meet appropriate regulatory standards. While quitting all tobacco and nicotine use is the best choice for smokers, most smokers are unfortunately unable to achieve abstinence. In this

context, the continued availability of FDA-authorized products that have the potential to reduce smoking-related harms is a sensible strategy with a potential to move many more smokers off the nicotine delivery method that is by far the most harmful – lighting tobacco on fire.

In sum, IQOS is a non-combustible tobacco delivery system from which millions of Americans could benefit. That possibility goes away, however, should IQOS be banned from the U.S. market. If the United States is serious about reducing traditional smoking rates, it cannot deprive U.S. consumers of this popular, PMTA-cleared option.

Regards,

A handwritten signature in black ink, appearing to read 'N. Khatibi', with a long horizontal line extending from the end of the signature.

Dr. Nikan H. Khatibi, MD

CERTIFICATE OF SERVICE

It is hereby certified that copies of **PUBLIC INTEREST COMMENTS** were served on April 23, 2020 as follows:

<p>The Honorable Lisa R. Barton Secretary to the Commission U.S. International Trade Commission 500 E Street, SW, Room 112 Washington, DC 20436</p>	<p>By EDIS</p>
<p>David M. Maiorana Ryan B. McCrum JONES DAY 901 Lakeside Avenue Cleveland, OH 44114</p> <p>Stephanie E. Parker JONES DAY 1420 Peachtree Street, N.E. Suite 800 Atlanta, GA 30309</p> <p>Anthony M. Insogna JONES DAY 4655 Executive Drive Suite 1500 San Diego, CA 92121</p> <p>John J. Normile JONES DAY 250 Vesey Street New York, NY 10281 Tel: (212) 326-3939</p> <p><i>On Behalf of Complainants RAI Strategic Holdings, Inc., R.J. Reynolds Vapor Company, and R.J. Reynolds Tobacco Company</i></p>	<p>By Email dmaiorana@jonesday.com rhmccrum@jonesday.com separker@jonesday.com aminsogna@jonesday.com jjnormile@jonesday.com</p>

/s/ Erika J. Weinstein

Erika J. Weinstein

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