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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

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 Nextera Healthcare.

Respectfully submitted,

//s/ Jamie D. Underwood

Jamie D. Underwood
of LATHAM & WATKINS LLP

Enclosure

cc: Service List

April 16, 2020

United States International Trade Commission, Washington DC

In the Matter of Certain Tobacco Heating Articles and Components Thereof

Investigation No. DN 3447

Public interest comment submitted by Clint Flanagan,

M.D., Founder & CEO, Nextera Healthcare

I welcome the opportunity to provide comments to the U.S. International Trade Commission in response to the Public Interest Statement filed on April 9, 2020, by Complainants RAI Strategic Holdings, Inc.; R.J. Reynolds Vapor Company; and R.J. Reynolds Tobacco Company. I understand that the complainants seek to exclude IQOS heat not burn systems from the U.S. market and I am concerned that such a ban would have a serious negative impact on the public health and welfare of U.S. consumers.

As a primary care physician, I routinely see patients who smoke and suffer from chronic illnesses related to their smoking. Without question, the first course of treatment for these patients is counseling on smoking cessation. We work hard with patients to get them to quit. For a

multitude of reasons, however, many patients just cannot or will not stop smoking cigarettes. Even with proper counseling, prescription nicotine replacement therapy, or other methods, some of my patients just can't stop. There are also some who will not stop. They've either made a conscience decision to disregard the risks, or have other behavioral health issues which make quitting less of a priority. Many of them are, of course, self-medicating with nicotine.

The truth is that smoking remains the leading preventable cause of premature disease and death in the United States. So, what can we as physicians do for the patients who cannot stop? Primary care physicians and behavioral health specialists are in need of new strategies to help in this effort. That's why I was very pleased to see the Food and Drug Administration take steps to develop a new comprehensive plan for tobacco and nicotine regulation that will recognize that although nicotine is addictive and can be harmful, it certainly is most harmful when delivered through smoke particles in combustible cigarettes. In the New England Journal of Medicine (NEJM) published August 16, 2017, then-FDA Commissioner Scott Gottlieb wrote:

> The regulatory framework for reducing harm from tobacco must include nicotine – the chemical responsible for addiction to tobacco products – as a centerpiece. Nicotine, though not benign, is not directly responsible for the tobacco-caused cancer, lung disease, and heart disease that kill hundreds of thousands of Americans each year. The FDA's approach to reducing the devastating toll of tobacco use must be rooted in this foundational understanding: other chemical compounds in tobacco, and in the smoke created by combustion, are primarily to blame for such health harms.

As Commissioner Gottlieb pointed out in the NEJM, the law provides the FDA with a regulatory tool to do just that. The Family Smoking Prevention and Tobacco Control Act of 2009 lets FDA review scientific evidence behind new tobacco products and also gives the FDA the power to bring potentially reduced risk products to market as long as they are appropriate for the protection of public health.

The advent of non-combustible alternative tobacco products does raise significant questions for physicians and their patients. If there are products that deliver the nicotine patients crave, in a form that is pleasing to them, with significantly reduced harm to themselves and the rest of the population, then such products could play a significant part in a patient's journey to quitting. Both patients and their physicians, however, will need to look to the FDA to provide an evidence-based review of these products on an ongoing basis to ensure that there aren't any other unintended harms that may come as result of a transition from traditional cigarettes. It's also important that the FDA review these products over time to ensure that public health is continually protected.

In April 2019, the FDA for the first time authorized one such novel potentially reduced risk non-combustible product – IQOS tobacco heating system – for sale in the United States. In its review of the company's applications, FDA made the following key observations:

- FDA's scientific evaluation of the company's applications, peer-reviewed published literature and other sources found that the aerosol produced by the IQOS tobacco heating system contains fewer toxic chemicals than cigarette smoke, and many of the toxins identified are present at lower levels than in cigarette smoke.
- Clinical studies of up to six months in duration demonstrated improved biomarkers of exposure, which indicates reduced exposure to harmful and potentially harmful constituents. Although these studies did not demonstrate reduction in long-term disease risks, the

currently available evidence indicates that smokers of combusted cigarettes who switch completely to IQOS will havereducedtoxic exposures and this is likely to lead to less risk of tobacco-related diseases.

- IQOS delivers nicotine in levels close to combustible cigarettes suggesting a likelihood that IQOS users may be able to completely transition away from combustible cigarettes and use IQOS exclusively.
- Available data, while limited, also indicate that few non-tobacco users would be likely to choose to start using IQOS, including youth.

IQOS tobacco heating system is fundamentally different from e-cigarettes and combustible cigarettes. A heated tobacco product such as IQOS consists of a heating source and tobacco. The tobacco may be wrapped in paper, which makes it a type of cigarette. However, the tobacco is heated to a lower temperature than a combusted cigarette to create an aerosol that the user inhales. On the other hand, an e-cigarette uses an e-liquid that may contain nicotine, glycerin, propylene glycol, flavorings, and other ingredients. The device has an electric heat source that heats thee-liquid to create an aerosol that the user inhales.

Because IQOS uses tobacco and tastes like tobacco, one can expect that millions of smokers in the United States who are looking for a potentially less harmful alternative will be interested in this product. This includes a large segment of the smoker population who have tried e-cigarettes but rejected them, including my patients. Equally, a large portion of e-cigarette users continue to smoke, undermining any potential benefits from switching toe-cigarettes.

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