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April 27, 2020

VIA EDIS

The Honorable 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*,
Dkt. No. 337-3447

Dear Secretary Barton:

On Thursday, April 23, 2020, Latham and Watkins LLP ("Latham") filed timely comments to Complainants' Public Interest Statement in the above-referenced matter on behalf of Nextera Healthcare ("Nextera"). Latham had full permission to do so and submitted the filing as a courtesy to Nextera.

On Friday, April 24, 2020, the ITC's docketing team rejected the filing because a law firm may not file a document on behalf of a person or entity that it does not formally represent. Neither Latham nor Nextera received notice of this issue in time to address the concern.

The undersigned represents Nextera for purposes of perfecting the filing of its public interest comments. Nextera respectfully submits that there is good cause for the Commission to accept and consider its public interest filing out of time. The filing, in fact,

was made in a timely fashion but was rejected based on a technical imperfection in the manner of its filing. Moreover, given the statutory provisions and Commission rules governing consideration of the public interest, it is important that the Commission consider to the greatest extent possible all such submissions. Finally, neither the Commission Staff nor Complainants will be prejudiced by acceptance of the filing at this time, given that it was served on the Commission Staff and Complainants on the day it was originally filed.

For the foregoing reasons, Nextera respectfully requests that the Commission accept and consider its public interest submission out of time.

Sincerely,

/s/ Benjamin Levi
_____
Benjamin Levi

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

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