Jamie D. Underwood
Direct: +1.202.637.3365
jamie.underwood@lw.com

555 Eleventh Street, N.W., Suite 1000
Washington, D.C. 20004-1304
Tel: +1.202.637.2200 Fax: +1.202.637.2201
www.lw.com

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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

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 Spark MD.

Respectfully submitted,

/s/ Jamie D. Underwood

Jamie D. Underwood
of LATHAM & WATKINS LLP

Enclosure

cc: Service List

April 21, 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: *In the Matter of Certain Tobacco Heating Articles and Components Thereof*

Dear Secretary Barton:

I write to relay my thoughts regarding the Public Interest Statement that was filed in conjunction with the above-referenced matter at the U.S. International Trade Commission on April 9, 2020. Banning the IQOS heated tobacco system is *not* in the best interest of U.S. public health. I strongly urge the Trade Commission to allow marketing and sales of IQOS in the United States and would like to explain why this product is important as a public health tool of smoking cessation.

I have been a family physician for fourteen years. In that time, I have used many different tools in my efforts to help people quit smoking traditional cigarettes. Notwithstanding my dedication to the task, less than five-percent (5%) of my smoking population has had any real success with cessation. My colleagues would share the same data. Until learning about heat-not-burn products, I had come to accept that smoking cessation was not an area where I was able to offer my patients much in terms of realistic, effective cessation tools.

The vast majority of people who smoke are well aware that they should quit. However, cessation options presently available in the United States are woefully inadequate. Nicotine replacements such as lozenges, patches and gum do not replicate, biochemically, the nicotine delivery of a cigarette. Many smokers try them and say, quite uniformly, “they don’t work”. Medications such as Wellbutrin and Chantix can be cost-prohibitive and often cause side effects intolerable to the user. In the U.S, using all

available options, in the most motivated of people, under the most ideal situation, we have a less than 18% cessation rate. The "average" smoker must try to quit an average of eight times before he or she might be successful. In fourteen years, following all training and guidelines and trying every trick I can think of, I have not found a product or strategy that truly helps people transition away from combustible cigarettes and move toward cessation. Our all-or-nothing approach does not accommodate gradual modifications in human behavior that lead to sustained change. Because of this, patients who smoke fail in their cessation efforts time and time again.

One of the beautiful things about humans is we often do what feels best right now, not what is in our long-term interest. Solving problems 'right now' is one reason all-or-nothing approaches don't work. With virtually every other detrimental health condition including diabetes, obesity, unprotected intercourse, opiate addiction and many more, we have therapeutic options to help people ***transition***. This has not been the case with smoking. In the U.S, our approach to smoking cessation is akin to telling a person who is one-hundred pounds overweight that they must lose one-hundred pounds. Right now. Offering two behavioral options – continue where you are or modify everything to end-goal right now – sets up a success or failure paradigm that leaves no room for gradual improvement.

Incremental change – as with the weight loss metaphor encouraging that even a reduction of twenty-five pounds is a marked health improvement – until recently did not exist as part of our dialogue about smoking cessation. New non-combustible nicotine delivery systems such as heat-not-burn tobacco products offer the possibility of a gradual modification in nicotine exposure and smoking behaviors while a person works toward full cessation. In this way these new products open up an entirely different approach to smoking cessation. Heat-not-burn products provide another option for the U.S. healthcare system, and the physicians within it, to rethink our dialogue around motivational change for our smokers.

I was extremely skeptical of heat-not-burn options prior to learning about the research and utility of the IQOS in early 2019. I had never thought about the option of helping smokers in a transitional way.

After learning about how the IQOS delivers nicotine and reduces a patient's exposure to the toxic products of combustion released with a traditional cigarette, I had a paradigm shift. It may sound strange, as a physician, to say I became extremely excited about the option to start to work with my patients on a *transition* away from traditional cigarettes. I became excited to have something new to offer people who have failed every other method of smoking cessation time and again. And I became hopeful, after forty-four years of inhaling my father's KOOL menthol second-hand smoke, that maybe there was something out there to help him quit, too.

I began to think, if I can't help people quit all the way…can I help them quit part way? Does shifting towards the road of cessation move people through the hardest first part of change? Leading a conversation that looks towards cessation as a matter of incremental change differs from the long-held culture of saying that smoking is deleterious for health and quitting is the only option. The absolutism of that strategy towards cessation has been and remains woefully ineffective. Is continuing a harmful habit that can be modified to be less harmful better than no change at all? As a physician and daughter of a smoker, I think it is.

The IQOS allows for a gradual reduction in nicotine and an instant reduction in exposure to the harmful byproducts of traditional cigarette smoke- both for the smoker and the people around him or her. I have discussed the IQOS with patients. Based on the biochemistry of the device, I have been eagerly awaiting this as an effective option to assist my patients in smoking cessation. I purchased an IQOS overseas for my father in 2019. He began using it, was committed, was (after 60 years!) believing he could quit smoking, and then stopped using it because he cannot purchase IQOS compatible supplies where we live in the U.S.

Taking away the IQOS - the only novel alternative nicotine product reviewed by the U.S. Food and Drug Administration and found to be appropriate for the protection of public health- would be a massive step backward in U.S smoking reduction. The IQOS is a tool to help patients on the road to

behavioral change. It is a tool people can use to improve their quality of life as they work toward 'perfect' wellness. IQOS has been available, and extremely successful, in dozens of countries for more than three years with many success stories of transition leading to cessation.

The medical community in the U.S. desperately needs more options to effectively advocate for change when it comes to traditional smoking. Cessation, while ideal, is not an effective approach straight-out-of-the-gates for virtually any detrimental health condition. Working *with* people and helping them down a path is what leads to change. Absolute declarations of this-or-that simply don't work. The IQOS is a novel transitional device, FDA approved after years of thoughtful hard-won research and a necessary tool towards helping smokers transition away from traditional cigarettes. To change the absolutist strategy towards cessation, a wide choice of potentially reduced-risk products is needed. Excluding IQOS as a product available to US smokers would be a step in the wrong direction.

Thank you,

Julie K. Gunther, MD, FAAFP
sparkMD, Owner, Physician
2402 West Jefferson Street
Boise, Idaho 83702
drg@sparkmd.com

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