1050 17th Street, N.W.
Suite 1150
Washington, DC 20036
202.525.5717

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Aug. 23, 2017

Docket No. FDA-2017-D-3001
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Modified Risk Tobacco Product Applications: Applications for IQOS System with Marlboro Heatsticks, IQOS System with Marlboro Smooth Menthol Heatsticks, and IQOS System with Marlboro Fresh Menthol Heatsticks Submitted by Philip Morris Products S.A.; Availability

Dear Commissioner Gottlieb,

I write to you on behalf of the R Street Institute, a Washington-based nonprofit public policy research organization dedicated to free markets and real solutions. Exploring ways that tobacco harm reduction strategies could address the thousands of smoking-related deaths the United States continues to experience annually has been a major focus of R Street research since the institute opened its doors five years ago. It is in light of that prior research that we urge the Food and Drug Administration to allow the IQOS system to be available to consumers as a reduced risk tobacco product.

As an addiction researcher at The Scripps Research Institute, I led studies examining neurophysiological changes that occur in the early and late stages of drug use and addiction. The Scripps Research Institute continues to produce groundbreaking insights into potential treatments of addiction, including vaccines that target drugs to prevent entry into the brain; deep brain stimulation that mediates compulsive drug seeking; treatments that target the stress response system that perpetuates the cycle of addiction; and targeted drug delivery that prevents the initiation of addiction. Unfortunately, as is often the case, these treatments are many years away from being available and will not help everyone who may benefit from them. One of the frustrating aspects of addiction is that treatments that are efficacious in a lab or clinical setting rarely are effective in real-world settings. Real-world solutions must be available to mitigate the harms that come from risky behaviors, and they must be palatable to the intended audience.

Responsible for 480,000 deaths a year, cigarette smoking is the leading cause of preventable death in the United States. While nicotine replacement products are available for those who wish to quit, they have not been terribly effective at transitioning smokers to complete cessation; between 25 and 35 percent of smokers relapse within six months. Electronic delivery of tobacco, including IQOS, represents a new and likely more attractive alternative for people who are either unsuccessful in quitting using traditional nicotine replacement or who might not otherwise quit smoking.

We predict that, with the burgeoning technology of electronic devices, many of those who do not want to quit smoking eventually will transition to these safer products. This will further decrease the incidence of smoking-related diseases. We further believe we likely have reached the maximum quit rates possible with the existing products and public health efforts, with further reductions among current smokers likely to be minimal. Newer technologies like IQOS provide an opportunity to increase quit rates drastically.

Smoking is, by far, the most common way to use nicotine, as well as the most harmful way to use it. Because combustion contributes to at least 90 percent of the more than 7,000 chemicals that are inhaled in smoking traditional cigarettes, noncombustible tobacco products have an inherently reduced risk profile, which is reflected in the IQOS application. Furthermore, allowing the user to deliver nicotine via the preferred route of administration—in this case, inhalation—increases the likelihood that smokers will continue to use this product, rather than revert back to combustible cigarettes. Data estimating that between 54 and 72 percent of IQOS users in other countries convert to exclusive use shows that inhalation of heated/noncombusted tobacco can substitute for combustible cigarettes.

Smokers have adopted e-cigarettes as a way to transition both from traditional cigarettes and eventually to cease nicotine use altogether. Using Centers for Disease Control and Prevention data, it recently was reported that e-cigarettes are the most popular product for adults who quit smoking. However, those who dislike e-cigarettes as an alternative to smoking often cite the unnatural taste and liquid composition as primary factors in their decision not to switch to these safer products. The availability of a tobacco-heated system that tastes like tobacco and does not require the use of liquids can ameliorate some of these issues.

Complete abstinence is certainly the best way to reduce the burden of disease among smokers. Unfortunately, not only is that very difficult to do successfully, but some people have no desire to quit smoking. Among the reasons that people do not wish to quit are addiction and dependence, behavioral patterns and emotional stability – people who choose not to quit may view the potential for disease as less risky than the benefits that come with smoking. For these people, nicotine replacements will not suffice and the availability of alternative products might be a safer way to use nicotine.

In light of the FDA's recent proposal to begin a dialogue that will eventually lead to cigarettes with reduced nicotine content (to levels that are considered “nonaddictive”), it is necessary that the FDA approve products that can serve as acceptable alternatives to current smokers. Mandating very low nicotine cigarettes before beginning this conversation about safer alternatives will make difficult to adopt such a strategy and likely would result in a proliferation of black market cigarettes and dangerous adulteration of VLNCs to increase nicotine content.

In the commissioner's statement on the future of tobacco, he called for “innovations that have the potential to make a notable public health difference.” Approving IQOS is the first step in a race to innovation whose ultimate outcome could be drastic improvements in the health of smokers.

Sincerely,

Carrie Wade, PhD, MPH
Harm Reduction Policy Director

Edward Anslem, MD
Senior Fellow