

Scott Gottlieb, M.D., Commissioner
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. ID: FDA-2017-D-3001-0002 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 Dr. Gottlieb:

The Competitive Enterprise Institute (CEI) welcomes the opportunity to offer comments regarding modified risk tobacco product applications (MRTP), particularly in the case of the MRTP for the iQOS System and its associated variety of its product, Heatsticks.

Interest of the Commenters: CEI is a non-partisan, non-profit public policy organization with a long history of research and advocacy with an emphasis on promoting rational risk regulation and consumer choice. Throughout our decades of research, we have frequently observed that attempts to limit exposure to certain risks—however well-intentioned—often unintentionally increase exposure to other, possibly more hazardous risks. In the case of tobacco harm reduction, anxieties about an absence of total certainty about the long-term effects of tobacco alternatives (along with resentment toward the companies offering such products) has obscured the established short-term and potential long-term public health benefits of maintaining a competitive market that offers current smokers a wide variety of less harmful nicotine products.

Background: Despite the efforts of public health campaigns, smoking continues to contribute to more than 7 million deaths worldwide each year.¹ In the U.S. alone, over 16 million Americans suffer from smoking-related diseases and half a million die each year as a result of health effects arising from their habit.² As with other public health crises, we ought to embrace *all* avenues of harm reduction rather than focus on an ineffective “abstinence only” approach. As the harmful nature of traditional cigarettes stem from their use of combustion to burn tobacco, heat-not-burn (HNB) products, like the iQOS System, are intrinsically less harmful than traditional cigarettes.³ Regardless of the smaller level of risk such products might eventually be shown to pose, the inherent risk-reducing nature of HNBs should compel the U.S. Food and Drug Administration (FDA) to preserve and increase current smokers’ access to such products as an option.

Reduced-Risk Products and Public Health: The FDA granting approval to the iQOS would allow the provision of a new and less risky cigarette alternative and help counter years of misinformation—from government and non-governmental health bodies—communicated to the American public.

Since their introduction to the U.S. market, alternative tobacco products (electronic cigarettes) have been viewed by the U.S. public health community as being potentially as—or more—harmful than cigarettes. They have even been characterized as a ploy by cigarette companies to lure non-smoking minors.⁴

While these non-combustible products were initially embraced by the smoking public as a way to reduce exposure to the harmful chemicals in traditional cigarettes or as a way to transition off nicotine use entirely, the continued emphasis by the FDA, the Centers for Disease Control, the Campaign for Tobacco-Free Kids, the American Academy of Pediatrics, and others on these products' unknown harms—coupled with misinformation about the risks of nicotine, irrespective of its delivery method—has stymied the wider adoption of such products by skewing public understanding of the *relative risk* non-combustible products pose. For example, a 2015 poll conducted by researchers at Georgia State University's School of Public Health found that 35 percent of adults incorrectly believed that vaping was as harmful as combustible cigarettes—a massive increase from 2012, when only 11.5 percent of adults surveyed held this misguided opinion.⁵ This shift in opinion occurred despite the increasing scientific evidence to the contrary and as health advocates other nations, like the United Kingdom, fully embraced such products as part of their approach to tobacco harm-reduction.⁶

In 2009 Congress vested the FDA with the authority to regulate tobacco products while charging the FDA to “promote and encourage the development of innovative products and treatments” to advance “total abstinence from tobacco use ... reductions in consumption of tobacco ... [and] reductions in the harms associated with continued tobacco use.”⁷ During your April 2017 confirmation hearing, you asserted that “there should be reduced harm products available to consumers to transition them off of combustible cigarettes.”⁸ There is sufficient scientific evidence to indicate that the iQOS and its associated products—while perhaps not *risk free*—are such harm-reducing products. Compliance with the FDA's statutory obligation to promote less harmful tobacco alternatives and fulfillment of the Commissioners' promises require the FDA to approve the iQOS for consumer use.

Conclusion: Adult consumers deserve access to a free market that provides them an array of nicotine-consumption choices. By stepping out of the way, the FDA can fulfill its obligation to support tobacco and tobacco-alternative technological innovations, thereby allowing the market to do what decades of public health campaigns have failed to accomplish: provide smokers with satisfying alternatives to fully quit tobacco or practically eliminate tobacco-related harms.

We strongly urge the FDA to approve the iQOS and to support Americans' access to this and other harm-reducing combustible cigarette alternatives.

Respectfully,
Michelle Minton
Senior Fellow

Competitive Enterprise Institute

¹ World Health Organization, Tobacco Fact Sheet, updated May 2017, <http://www.who.int/mediacentre/factsheets/fs339/en/>.

² Centers for Disease Control and Prevention, Fast Facts and Fact Sheets: Smoking and Tobacco Use, accessed September 8, 2017, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm.

³ American Cancer Society, Harmful Chemicals in Tobacco Products: Tobacco smoke, accessed September 8, 2017, <https://www.cancer.org/cancer/cancer-causes/tobacco-and-cancer/carcinogens-found-in-tobacco-products.html>.

⁴ American Academy of Pediatrics, “Booming Market of Candy-Flavored E-Cigarettes and Cigars Threatens to Hook a New Generation of Kids, New Report Warns,” news release, March 15, 2017, <https://www.aap.org/en-us/about-the-aap/aap-press-room/pages/Booming-Market-of-Candy-Flavored-E-Cigarettes-and-Cigars-Threatens-to-Hook-a-New-Generation-of-Kids,-New-Report-Warns.aspx>.

⁵ Ban A. Majeed, Scott R. Weaver, Kyle R. Gregory, et al, “Changing perceptions of harm of e-cigarettes among U.S. adults,” *American Journal of Preventive Medicine*, Vol. 52, Issue 3 (March 2017), pp. 331-338, <http://www.sciencedirect.com/science/article/pii/S0749379716304433>.

⁶ Bradley J. Fikes, “UK medical group endorses vaping for smokers,” *San Diego Union-Tribune*, April 30, 2016, <http://www.sandiegouniontribune.com/business/biotech/sdut-royal-college-physicians-vaping-smoking-2016apr30-story.html>.

⁷ Family Smoking Prevention and Tobacco Control Act of 2009 Public Law 111-31, 111th Congress, <https://www.gpo.gov/fdsys/pkg/PLAW-111publ31/html/PLAW-111publ31.htm>.

⁸ Dr. Scott Gottlieb testimony, Food and Drug Administrator Confirmation Hearing, April 5, 2017, <https://www.c-span.org/video/?426502-1/fda-commissioner-nominee-scott-gottlieb-defends-accusations-conflicts-interest&start=8732>.