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Center for Tobacco Products
Food and Drug Administration
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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 Members of the Committee:

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, our approach to tobacco harm reduction must not be myopically focused only on an ineffective "abstinence only" stance, but rather should embrace *all* avenues of harm reduction. Because the harmful nature of traditional cigarettes stems primarily 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] While they may eventually be shown to have some risk, all evidence indicates it is far less than traditional cigarettes. For example, after reviewing the available evidence, the UK Committee on Toxicity recently noted that since "exposure to compounds of concern in the aerosol is reduced compared to conventional cigarette smoke, it is likely that there is a reduction in risk, though not to zero, to health for smokers who switch completely to heat-no-burn tobacco products."[4]

Whatever smaller risks remain, the inherent risk-reducing nature of HNBs should compel the U.S. Food and Drug Administration (FDA) to preserve smokers' access to such products as an alternative option.

Reduced-Risk Products and Public Health: The FDA granting approval to the iQOS would facilitate development in and access to 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 (mainly electronic cigarettes) have been viewed by the U.S. public health community as being potentially as harmful as, or even more harmful than, than cigarettes. They have even been characterized as a ploy by cigarette companies to lure non-smoking minors.[5] Their fears, though unjustified by the bulk of scientific research on the matter, pose a much greater threat to public health than the risks associated with such new products.

Initially, the American public embraced the entry of non-combustible products on the market; viewing them as a way to exposure to the harmful and potentially harmful chemicals in traditional cigarettes or as a way to transition off nicotine use entirely. But, 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 the "unknown" harms of such products—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, while in 2012 only 11.5 percent of adults held this misguided opinion.[6] This shift in opinion occurred despite the increasing scientific evidence to the contrary and as health advocates other nations, like the United Kingdom, have embraced such products as part of their approach to tobacco harm-reduction.[7]

Yet, there is a history of success when public health authorities embrace an "all of the above" approach as opposed to abstinence only. In the European Union, for example, only one nation allows the sale of snus (a moist tobacco chew): Sweden. As a result of preserving access to this harm-reducing alternative, Swedes have the lowest rates of smoking in the EU at just 7 percent while in the nation with the next lowest rate, the UK, 17 percent of adults continue to smoke.[8] Consequently, Sweden has among the lowest rates of smoking-related cancers, including lung and oral, of any EU nation.[9] Given the widespread understanding of the risks associated with smoking, consumers appear willing and even eager to switch to lower-risk alternatives, when access to such alternatives exists. U.S. authorities should take heed of the Swedish experience.

In 2009 Congress vested the FDA with the authority to regulate tobacco products. However, Congress also charged the Agency 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."[10] Though the scientific evidence is limited, it is sufficient to conclude the iQOS and its associated products qualify as harm-reducing products compared to traditional cigarettes.

Compliance with the FDA's statutory obligation to promote less harmful tobacco alternatives require the FDA to approve the iQOS for consumer use.

Conclusion: Regardless of the potential risks associated with novel HNB products, all of the available evidence indicates they meet the qualification as "modified risk" products when compared to traditional cigarettes. Adult consumers deserve access to these new choices, to a free market offering an array of nicotine-consumption choices, and the freedom to decide for themselves what risks they are comfortable taking; especially as they endeavor to transition away from traditional tobacco products toward risk-reducing alternatives. 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 Committee to recommend the FDA approve the iQOS and support Americans' access to this and other harm-reducing alternatives to combustible tobacco.

Respectfully,
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[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] Committee on Toxicity, "Statement on the toxicological evaluation of novel heat-not-burn tobacco products," December 11, 2017, https://cot.food.gov.uk/cotstatements/cotstatementsyrs/cot-statements-2017/statement-on-heat-not-burn-tobacco-products.
[5] 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.
[6] 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.
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[8] European Commission, "Attitudes of Europeans toward tobacco and electronic cigarettes," Special Eurobarometer 458, May 2017.
[9] World Health Organization International Agency for Research on Cancer, "Estimated incidence and mortality, 2012," http://eco.iarc.fr/EUCAN/Cancer.aspx?Cancer=1.
[10] 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.