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Caryn Cohen
Office of Science
Center for Tobacco Products
Food and Drug Administration
Document Control Center
Bldg. 71, Rm. G335
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002
Submitted via email to TPSAC@fda.hhs.gov and by mail

RE: Tobacco Products Scientific Advisory Committee Meeting regarding “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.”

Ms. Cohen:

I appreciate this opportunity to provide comments¹ to the Tobacco Products Scientific Advisory Committee (TPSAC) regarding the modified risk tobacco product applications submitted by Philip Morris Products S.A.

For the many smokers who want to quit using cigarettes, there is now genuine hope that this goal can be achieved. The private sector has made this hope possible by developing nicotine delivery systems that are appealing enough to help smokers quit while also being significantly less harmful than cigarette smoking. One of the key innovations is e-cigarettes. In the most comprehensive government report of its kind, Public Health England described e-cigarettes in 2015 as “95% less harmful than tobacco cigarettes”²

Fortunately, the innovations do not end with e-cigarettes as evidenced by the heat-not-burn products that are the subject of the modified risk tobacco product applications at issue. These products more closely mimic the act of smoking thus providing a very appealing alternative to cigarette smokers who may find that e-cigarettes do not work for them. Increasing choices for consumers means having a greater chance of identifying those products that will appeal to an even greater number of cigarette smokers.

The IQOS products already have an impressive record of getting cigarette smokers to switch to this less harmful alternative. According to Philip Morris regarding their innovative IQOS heating system, “over three million consumers have already chosen to switch from cigarettes to this product: our tobacco heating system *IQOS*.”³

¹ The views I have expressed in this comment are my own, and should not be construed as representing any official position of The Heritage Foundation.

² News release, “E-cigarettes Around 95% Less Harmful Than Tobacco Estimates Landmark Review,” Public Health England, <https://www.gov.uk/government/news/e-cigarettes-around-95-less-harmful-than-tobacco-estimates-landmark-review> (accessed February 21, 2017).

³ <https://www.pmi.com/smoke-free-products/iqos-our-tobacco-heating-system>

The FDA should be commended for embracing tobacco harm reduction⁴ and recognizing that cigarette smokers should not be faced with an all-or-nothing proposition: smoke cigarettes or stop smoking cigarettes without the use of viable alternatives to make cessation feasible.

On July 28, 2017, the FDA explained regarding its regulatory plan on tobacco-related disease and death:

A key piece of the FDA's approach is demonstrating a greater awareness that nicotine—while highly addictive—is delivered through products that represent a continuum of risk and is most harmful when delivered through smoke particles in combustible cigarettes. ... The FDA is committed to encouraging innovations that have the potential to make a notable public health difference and inform policies and efforts that will best protect kids and help smokers quit cigarettes.⁵

The FDA now has an opportunity to put this well-stated philosophy in action by allowing these innovations to quickly get onto the market; smokers should have access to these potentially life-saving products without unwarranted government obstacles. TPSAC, through its recommendations to the FDA, can help to make this happen. This is not to dismiss any concerns that may exist regarding use of these products by children. These products can be made available to smokers while still addressing any legitimate concerns that might exist regarding use by children.

The timing of the application process is also extremely critical. The faster these innovative products can get onto the market, the sooner cigarette smokers can have access to the alternatives that can change their lives. Further, other companies and entrepreneurs who could develop future innovations are watching as this process plays out. If the process is timely, predictable, and not costly and burdensome, those who would provide future innovations will be encouraged to move forward. If the process is the exact opposite, then future innovations may never see the light of day.

Tobacco harm reduction is a philosophy that will ultimately win the day; as discussed, the FDA itself has already embraced this philosophy. TPSAC should help lead the way.

Sincerely,

Daren Bakst
Research Fellow in Agricultural Policy
Thomas A. Roe Institute for Economic Policy Studies
The Heritage Foundation
daren.bakst@heritage.org
202.608.6163

⁴ Across the federal government, agencies need to embrace tobacco harm reduction. See http://www.heritage.org/government-regulation/report/rethinking-tobacco-policy-the-federal-government-should-stop-blocking?_ga=2.237782601.854564098.1505313112-265824330.1488984476

⁵ <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm568923.htm>