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Comments re Tobacco Products Scientific Advisory Committee Meeting, January 24-25, 2018.

The Progressive Policy Institute (PPI) strongly favors the approval of innovative products that reduce risks to consumers. In that regard, we would like to submit comments in support of modified risk tobacco product applications (MRTPAs), submitted by Philip Morris Products S.A. for its IQOS system and HeatSticks.

Founded in 1989, PPI started as the intellectual home of the New Democrats. Many of its mold-breaking ideas have been translated into public policy and law and have influenced international efforts to modernize progressive politics.

Today, the Progressive Policy Institute is developing fresh proposals for stimulating U.S. economic innovation and growth; equipping all Americans with the skills and assets that social mobility in the knowledge economy requires; modernizing an overly bureaucratic and centralized public sector; and, defending liberal democracy in a dangerous world.

In particular, one of our main policy interests is regulatory improvement—that is, improvement in the regulatory system so that it yields better outcomes for consumers, without blocking innovation. This places us solidly in the pragmatic center.

Moreover, the Progressive Policy Institute strongly supports science-based regulatory policy, no matter where the evidence leads us. This means tackling tough problems with an open and pragmatic mind to achieve the best possible outcomes.

From this perspective, our best assessment is that PMI's application fits squarely in our main mission of promoting innovation and growth, while improving the health of both smokers and the population as a whole. Innovation, at its base, provides a way of altering trade-offs for the better. The IQOS Tobacco Heating System proposed by PMI is an innovation that reduces harm to current smokers by inducing them to switch to a product that produces much less harmful and potentially harmful chemicals—that's a win-win proposition.

This conclusion is supported by the recent toxicological assessment of "novel heat-not-burn" products done by the United Kingdom's Committee on Toxicity (COT). The COT evaluated two such products, including PMI's IQOS Tobacco Heating System. According to the COT,

...For both products, there were some HPHCs where the reduction was approximately 50%, but the reduction in a number of other HPHCs was greater than 90%, with many of the compounds being below the limits of detection or quantification for the assays used

The COT also noted that:

...there would be a likely reduction in risk for smokers deciding to use heat-not-burn tobacco products compared with continuing to smoke cigarettes as the exposure to HPHCs is reduced.

FDA's Draft Guidance for Modified Tobacco Product Applications specifically encourages innovation: "The modified risk tobacco product provisions of the FD&C Act may be valuable tools in the effort to promote public health by reducing the morbidity and mortality associated with tobacco use, particularly if companies take advantage of these provisions by making bold, innovative product changes that substantially reduce, or even eliminate altogether, either the toxicity or addictiveness of tobacco products, or both."

Innovative products such as IQOS and other non-combustible products can help meet this goal. As Commissioner Gottlieb recently noted, "[t]he overwhelming amount of death and disease attributable to tobacco is caused by addiction to cigarettes." To provide a much less harmful alternative, the FDA should make a timely decision on PMI's application, and also do all it can to truthfully inform consumers of the reduction in risk from these and other non-combustible products.



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Finally, we are strongly supportive of the FDA's implementation of the Tobacco Control Act. The FDA has a pivotal role to play in promoting innovation and improving public health, and we believe that the FDA has struck the right balance.

Sincerely,

A handwritten signature in black ink that reads 'Michael Mandel'.

Michael Mandel, PhD
Chief Economic Strategist
Progressive Policy Institute