TAXPAYERS PROTECTION ALLIANCE

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The Taxpayers Protection Alliance (TPA), on behalf of our members across the country, submit the following comments to the Tobacco Products Scientific Advisory Committee in support of approving the **Modified Risk Tobacco Product Application** (Docket FDA-2017-D-3001), published on June 15, 2017, and issuing market orders under both §911(g)(1) (risk modification order) and §911(g)(2) (exposure modification order) for Philip Morris International's (PMI) novel Tobacco Heating System (THS), "iQOS," to be marketed with the requested claims for all three variants as submitted.

TPA is a non-profit, non-partisan organization dedicated to educating the public through the research, analysis and dissemination of information on the impact of government intervention. It is our view that innovation without intervention empowers the economy and gives consumers choice.

TPA appreciates the FDA's efforts to reexamine processing times in accordance with the 2009 Family Health and Smoking Prevention Act ("Tobacco Act"). Bringing safer tobacco products to the market expediently will undoubtedly offer significant health benefits for consumers.

At the same time, TPA recognizes that the Act's intention was not to prevent, but protect users and the public from the risks of using tobacco. In line with those goals, PMI diligently incorporates those same principles of consumer safety throughout the iQOS design process. Delaying approval timeframes will discourage future ambitions of creating safer tobacco products while ultimately depriving users of the ability to take advantage of a lower-risk alternative.

We would also like to remind the Center for Tobacco Products that Congress clearly intended for the FDA to develop rules and processes designed to bring reduced risk tobacco products to market in order to diminish the harm to public health caused by smoking. To date, the FDA has not demonstrated a respect for this clearly stated congressional intent to institute a harm reduction regulatory framework which would consider the continuum of risk which exists for various nicotine-containing products and then provide a path for ultimately allowing manufacturers to disclose or "claim" this reduced risk to consumers, if it is shown to be a scientifically sound claim.

It is our assertion that amongst the more than 2.3 million pages of scientific evidence presented in their application, PMI has more than demonstrated a scientifically sound basis for making reduced harm claims on THS products. Other countries such as Japan and South Korea have concurred with that evidence and welcomed iQOS into their markets with outstanding success.

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In addition, independent analyses reach similar conclusions about the safety of iQOS. Two years ago, a research team led by Dr. Reto Auer of the University of Bern in Switzerland examined the level of carcinogens emitted from an IQOS puff, compared to the traditional cigarette brand Lucky Strike. The team found that amounts of polycyclic aromatic hydrocarbons (PAH) found in IQOS smoke were far lower than for cigarette smoke. Of the thirteen PAHs studied for which output data is available, only one PAH (Acenaphthene) contains a per-cigarette dosage over 10 nanograms (ng). By way of comparison, ordinary cigarette smoke contained doses of over 100 ng for the majority of PAHs studied. Trace amounts of PAHs are all over the place, in the food we eat and the liquids we drink. While "acceptable" levels of PAH in water vary depending on the source, most authorities conclude that a concentration of less than 10 ng per liter is acceptable. Based on these figures, a small/moderate amount of IQOS smoking per day seems to be fairly harmless.

American consumers have a right to truthful disclosure of the potential harms (or benefits) of products they consider in the marketplace. With knowledge that an innovative alternative to combustible cigarettes with reduced risks is available, smokers have demonstrated their tendency to migrate to less risky tobacco products. Indeed, iQOS was designed out of the recognition that users' commitment to safer alternatives presents benefits dually for consumers and untapped market potential for companies. Withholding this information, thereby leading Americans to believe untruths which prompts them to choose deadly products over safer innovative technologies, is not in line with the mission of the FDA. It is important that regulatory staff do not lose sight of both the overall FDA mission and the tobacco harm reduction philosophy which Congress prescribed when it gave the FDA regulatory oversight of tobacco.

That there is a backlog of many promising new technologies and product innovations, which could very well be life-saving for millions of American smokers, is an unnecessary risk to the public as a whole.

A broad definition of tobacco used in language written by Congress understandably presents challenges to FDA's interpretation. It is concerning that Congress used such a broad interpretation of "tobacco" such that the FDA could, on a political whim, deem what is really technology to be "tobacco." Be that as it may, we find the technology of "heat not burn" to be a true testament to human ingenuity and a stunning innovation that could quickly evolve the adult nicotine-consumption market.

If combustible cigarettes could truly be replaced entirely by a less harmful nicotine delivery system such as iQOS, the impact would be a historical milestone in the population-level improvement of Americans' health. Lower healthcare costs and longer lifespans are just some of the many benefits iQOS has the ability to offer to the public.

The ability for consumers to make this revolutionary choice to abandon their combustible cigarettes in favor of innovative new technology, such as iQOS, requires access to information such that they can make that informed choice. For this to happen, though, the FDA must decide to see their role in tobacco regulation as objective expert science gatekeepers when considering industry-provided studies. They also must find a way to critically judge the submissions on their merit rather than by the company name on the title of the docket.

TPA applauds the FDA's new leadership for pursuing similar innovative policies that promote consumer choice like those in the area of digital health. Now, the FDA has an opportunity to take that a step further

by allowing consumers to have access to honest information and safer alternatives. The end result could lead to a tidal wave of nationwide reduction in smoking and tobacco-related diseases.

TPA agrees with the FDA that information leads American consumers to make better decisions. American consumers generally make better decisions when they have better information. We believe it is the duty of the FDA to permit scientifically-substantiated reduced risk claims be made when warranted by scientific evidence so Americans will have access to this potentially life-saving information on which to base their own decision to switch to a reduced-risk tobacco product. The three claims which PMI requests permission in their MRTP application to use in marketing iQOS are reasonable and entirely reflective of the evidence established through sound scientific methodology.

TPA urges the FDA to expediently assess the evidence found in this application and allow this innovative technology to be truthfully described by the manufacturer to adult smoking consumers who are struggling to quit but still desire to make healthier decisions.

TPA urges the FDA to approve Philip Morris International's Modified Risk Tobacco Product application for all three variants of the iQOS Tobacco Heating System and issue marketing orders which allow any of the three proposed claims.

Every adult smoker in America has the right to know that iQOS is not just "interesting technology," but could be the innovation they have long sought as a way to live a healthier lifestyle while still enjoying nicotine.

Sincerely,

David Williams
President