From:	Takao Ohki
To:	TPSAC
Subject:	TPSAC Public advisory committee meeting
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Food and Drug Administration, Document Control Center
Office of Science, Center for Tobacco Products
Bldg. 71, Rm. G335, 10903 New Hampshire Ave.
Silver Spring, MD 20993-0002, 1-877-287-1373,

December 24th, 2017

Dear Ms. Cohen,

My name is Takao Ohki, MD, Chairman and Professor of Surgery and Chief of Vascular Surgery at the Jikei University School of Medicine in Tokyo, Japan. These comments are related to a forthcoming public advisory committee meeting of the Tobacco Products Scientific Advisory Committee taking place on January 24 and 25, 2018, to discuss modified risk tobacco product applications, submitted by Philip Morris Products S.A. for IQOS system.

As known, smoking is one of the leading causes of fatal vascular diseases including PAD (Peripheral Artery Disease) and AAA (Abdominal Aortic Aneurysm). Having been a vascular surgeon in the US for 12 years, I have personally treated countless patients who suffered from such diseases. This reality grieves me even though I'm currently in Japan.

Smoking is not only associated with increased occurrence of PADs and AAAs but also is a risk factor for acceleration of the disease condition. To reduce the number of patients suffering from such diseases, I sincerely hope that all smokers quit smoking immediately and completely. However, many smokers fail to quit smoking. It is easy to blame them, but as a clinician, I strongly believe that we should not desert them. They are still our patients whom we should help. If IQOS is identified as a better alternative, it can be a trigger for them to consider their own health and smoking behavior.

As a scientist and a physician, I have read numerous papers that have dealt with IQOS pre-clinical and clinical data, which indicate that the risk profile of IQOS is dramatically different from cigarette, and the potential of IQOS to be a less harmful alternative has been suggested strongly. Even though clinical trial data is limited, and occasionally surrogate endpoints are used, it is clear that IQOS is less harmful than cigarette. During pharmaceutical and medical device review process, FDA approval is often granted based on such surrogate endpoints and in absence of true population based endpoint which is later evaluated during the post-marketing phase. This is since if one waits for the true endpoint to become available, millions will miss the opportunity of a new product that has potential benefit. The current situation of IQOS resembles this condition. Since IQOS is already available with convincing evidence that it is less harmful compared with cigarette, we should not wait until data completion of a true endpoint such as population impact that will take decades to manifest.

Looking at Japan, already close to 3 million smokers have quit smoking and switched to IQOS and this suggests high acceptance of the product as a cigarette replacement for smokers. Although my ultimate wish is to have all the smokers to quit using all tobacco products, it should be the upmost and immediate interest of the public health to move the current cigarette smokers away from the most harmful cigarettes to something less harmful as soon as possible.

I sincerely hope that the committee members consider this viewpoint at the upcoming TPSAC meeting. Please do not hesitate to contact me if you have any questions/concerns regarding my letter.

Best regards,

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