May 14, 2019

Mr. Mitchell Zeller
Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Marketing order for IQOS

Dear Director Zeller:

Our organizations are writing in connection with the April 30 action by the U.S. Food and Drug Administration (FDA) issuing a marketing order to Philip Morris International (PMI) and Philip Morris Products S.A. allowing the U.S. marketing of IQOS heated tobacco products, to be distributed in the U.S. exclusively by Altria Client Services LLC (Altria).

FDA states that its action in issuing this marketing order is premised on representations that Altria and PMI made that the IQOS products will be marketed only to adult smokers in the U.S. for the purpose of encouraging them to switch completely from the use of conventional cigarettes, while avoiding marketing to audiences like non-smokers and youth. Indeed, the marketing order itself refers to two amendments to the IQOS Premarket Tobacco Applications (PMTAs) submitted by PMI (dated September 5, 2018 and March 25, 2019) in which "you include representations about your marketing plan for your products in the United States and indicate that you intend to focus marketing on adult cigarette smokers while limiting reach to unintended audiences."[1] Moreover, PMI made express representations to the Tobacco Product Scientific Advisory Committee (TPSAC) during its January 24-25, 2018 meeting to consider the separate IQOS modified risk tobacco product application that it would market these products to adult smokers, not youth and nonsmokers. On that occasion, Sarah Knakmuhs, Vice President of Heated Tobacco Products for PM USA, assured TPSAC that "[o]n the one hand, we're committed to maximizing our reach to adult smokers and supporting them so they can switch completely to IQOS. On the other hand, we want to limit our reach to unintended audiences such as nonsmokers and youth."[2]

In connection with PMI's PMTA and its pending modified risk product application, we repeatedly have submitted evidence to FDA that PMI's marketing of IQOS across the globe is

[1] FDA Marketing Order Letter from Matthew R. Holman, Ph.D, Director Office of Science, to Philip Morris Products S.A., April 30, 2019, at 2.
[2] PMI Presentation to TPSAC, January 24, 2018, Transcript, https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM599234.pdf

entirely inconsistent with a marketing focus on adult smokers. Instead, in numerous countries, PMI has pursued a strategy of marketing these products to the broadest range of consumers, with messaging and imaging presenting IQOS as a fashionable and trendy lifestyle product – precisely the kinds of images that appeal to young people. This is demonstrated by a representative sample of IQOS global marketing, including social media marketing, submitted with this letter, showing:

- IQOS retail stores attempting to replicate the appeal of other high-tech retail outlets, in locations highly visible to broad audiences, including youth;
- IQOS advertising to the general public;
- IQOS kiosks in shopping malls;
- IQOS sponsored social events and parties;
- IQOS marketing at public events, including music events;
- IQOS partnerships with trendy fashion magazines and designers, clearly associating IQOS with publications and products popular among young women;
- IQOS marketing at cultural events; and
- IQOS marketing through social media "brand ambassadors" or "influencers" with images showing IQOS as part of an exciting and youthful lifestyle.

It is instructive that, late last week, PMI announced that is has suspended its global promotion of IQOS through "influencers" on social media, but only after it was exposed in a Reuters story[3] and, even then, PMI distorted the extent to which it was using "influencers" on social media. The company, however, has made no commitment to permanently end this type of marketing or to avoid the tactics or images cited in the Reuters story in the U.S. marketing of IQOS; nor has it disavowed its sponsorship of beer fests, beach parties, fashion shows and other tactics to reach young people with its marketing.

In the Technical Project Lead Review that accompanied its IQOS PMTA decision, FDA ignored and failed to consider the evidence provided it of how PMI had marketed IQOS in country after country. These marketing tactics cannot be reconciled with an expressed intent to limit IQOS marketing to adult smokers who may use the IQOS products as an alternative to cigarettes.

Given the tobacco industry's long history of marketing its products to youth, a history that the tobacco companies have never acknowledged, and the recent impact on so many American families of the irresponsible marketing of e-cigarettes, resulting in an epidemic of youth usage of those products, we are deeply concerned that similar marketing of IQOS in the US would have a devastating impact on public health, particularly on the health of young people.

[3] Chris Kirkham, "Exclusive, Philip Morris suspends social media campaign after Reuters exposes young 'influencers,' Reuters, May 10, 2019, https://www.reuters.com/article/us-philipmorris-ecigs-instagram-exclusiv/exclusive-philip-morris-suspends-social-media-campaign-after-reuters-exposes-young-influencers-idUSKCN1SH02K

This concern is increased by how FDA addressed the mandatory legal consideration of the evidence provided by the applicant with regard to the risk to youth. The experts at FDA in social science issues concluded as follows:

> The social science review concludes that based on the information submitted by the applicant, we have concerns with respect to: the lack of information about youth under age 18, as well as the lack of a discussion of submitted data's applicability to youth and the lack of presentation of the data in stratified categories that would allow us to make inferences about youth, the potential for initiation among young adult never smokers, and the potential for dual use among current smokers with only a one cigarette per day decrease in use frequency. **Philip Morris Products S.A.'s premarket tobacco product applications do not contain sufficient information to address these concerns from a Social Science perspective.** [4]

Yet this expert observation and conclusion was overruled by the Technical Project Lead of the Office of Science,[5] and the IQOS PMTA was granted by FDA, based on two studies and limited experience in two different countries (Japan and Italy) with different cultures, different marketing rules and different circumstances. There was no meaningful data or analysis to demonstrate the applicability of the limited experience in those countries to the American setting.

In light of the experience with e-cigarettes and youth in the United States, and the examples that demonstrate that PMI has marketed IQOS in many countries using the same marketing techniques, strategies and images that have fueled the e-cigarette epidemic in this country, the decision by the Office of Science reviewer, and the FDA, to discount the conclusions of the social science review team is not only arbitrary, it is dangerous long term.

Given FDA's reliance on PMI's assurances about the intended marketing of IQOS in the U.S., and the decision of the senior leadership at FDA to ignore the findings of the Social Science review team, our organizations urge FDA to issue a public commitment that, if the agency becomes aware of IQOS marketing in the U.S. that reflects any of these marketing strategies and tactics used by PMI in other countries, FDA will revoke forthwith the marketing order issued on April 30, 2019.

We look forward to your prompt response.

Respectfully submitted,

American Academy of Pediatrics
American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
Campaign for Tobacco-Free Kids
Truth Initiative

[4] FDA, Technical Project Lead Review for PMI heated tobacco products (April 29, 2019), at 83 (emphasis added).
[5] Id.