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March 23, 2018

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

Re: Global Marketing of iQOS by PMI

Dear Mr. Zeller:

By this letter, we seek to bring to the attention of the Food and Drug Administration (FDA) information about how Philip Morris International (PMI) is marketing the iQOS heated tobacco product in foreign countries. This material bears directly on two PMI applications currently pending at FDA: (1) PMI's application for a marketing order (PMTA order) for iQOS under Section 910 of the Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act); and (2) PMI's application under Section 911 of the Tobacco Control Act to allow iQOS to be marketed as a modified risk tobacco product (MRTP). We ask that the material presented with this letter be considered by FDA in its evaluation of the PMI PMTA; we also have filed this letter and the supporting material in Docket No. FDA-2017-3001 concerning PMI's MRTP application for iQOS.

As explained below, this material about the marketing of iQOS abroad raises significant questions about the credibility of various public claims made by the applicant and its affiliates to FDA in support of the iQOS application and requires a thorough investigation by FDA before the agency makes a final disposition of either application. As slide 2 indicates, there is a wealth of real-world marketing experience for iQOS in countries around the world. According to PMI, iQOS is available in at least 37 countries.

**PMI Representations to TPSAC about Marketing of iQOS in the U.S.**

At the January 24-25 meeting of FDA's Tobacco Product Scientific Advisory Committee (TPSAC) to consider PMI's MRTP application for iQOS, Sarah Knakmuhs, Vice President of Heated Tobacco Products for Philip Morris USA, spoke in support of the application. Ms.

Knakmuhs described her role as “to lead the commercialization efforts of iQOS in the U.S.” and she spoke to TPSAC “about plans to introduce iQOS in the U.S.” As Ms. Knakmuhs explained, her company, Philip Morris USA (“Philip Morris”), is licensed to sell iQOS in the United States. From the outset, Ms. Knakmuhs acknowledged the relevance of PMI’s marketing abroad to its plans to market the product in the U.S., observing that “we’ve also had the opportunity to learn from PMI’s introduction of iQOS in markets outside the U.S.”

As the following discussion shows, FDA also can learn much from PMI’s marketing of iQOS in other parts of the world. Indeed, the material we submit with this letter strongly suggests that, before either pending PMI application can be granted, FDA must thoroughly investigate PMI’s world-wide marketing of iQOS to determine if the marketing that is actually occurring is consistent with the representations these companies have made to FDA and TPSAC concerning the domestic marketing plans. It is also a stark reminder that the public health impact of any marketing order concerning iQOS will be impacted by how and to whom it is marketed.

A recurring theme of the TPSAC presentations by Ms. Knakmuhs and others on behalf of PMI is that PMI and Philip Morris USA intend to limit the domestic marketing of iQOS to adult smokers and to limit its reach to unintended audiences such as nonsmokers and youth. As Ms. Knakmuhs told TPSAC in describing the “challenge” of selling iQOS in the U.S.: “On 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.” Ms. Knakmuhs then proceeded to explain Philip Morris’s plans to use print and digital advertisements “only in publications with predominantly adult readership” and to use direct mail and e-mail to reach only adult smokers “by identifying them from our adult tobacco consumer database, which we have built over many years.” The slides attached to this letter demonstrate that PMI’s actions outside the U.S. are not consistent with these representations, and support the need for FDA to understand how iQOS has been marketed in other countries. FDA should recognize that the representations that PMI and its affiliates have made to FDA cannot be taken at face value in light of this extensive experience.

### **iQOS Retail Stores**

Slides 3 and 4 show images of iQOS retail stores in Canada, the United Kingdom and South Africa. These reflect prominent and sophisticated efforts to replicate the appeal of Apple computer retail outlets and similar stores selling technologically advanced products to the general public. These sleek stores are in locations that are highly visible to broad audiences, including youth and young adults, with images that mirror those used by technology companies and others to make their products highly appealing to youth and young adults. Certainly nothing about their appearance suggests an intention to appeal only to adult smokers. Although the Philip Morris presentation to TPSAC speaks of the company’s plans to limit retail interaction to age-verified adults and to smokers, the design and existence of these outlets in other countries

gives FDA the opportunity to evaluate whether PMI's commercial conduct is actually consistent with the Philip Morris representations about U.S. marketing of the product. It also makes it critical that FDA examine what is happening in these countries.

### **iQOS Advertising to General Public**

Several slides depict iQOS advertising to the general public. For example, slide 5 depicts an outdoor ad for iQOS on the sidewalk of a shopping area in Berlin, Germany. Slide 6 shows iQOS-branded automobiles seen around Russia and Ukraine. By its very nature, such advertising reaches a general audience, including non-smokers and youth. Indeed, slide 7 shows a young child in front of an iQOS display in Greece. Such advertising is inconsistent with a claimed strategy of targeting only adult smokers. It demonstrates what happens without clear legal restrictions to prevent PMI from placing highly attractive ads in locations where they will be seen by large numbers of youth and non-smokers. PMI's behavior outside the United States demonstrates that, in the absence of strong legal requirements preventing this type of advertising, there is no way to stop this kind of marketing. Voluntary marketing restrictions have never been effective with this industry, and voluntary assurances by PMI and Philip Morris cannot be counted on in the U.S.

### **iQOS Kiosks in Shopping Malls**

Slide 8 depicts a particularly significant form of promotion to the general public: iQOS kiosks in shopping malls. The kiosks shown are in Greece and Russia. They function to promote the brand and the product to the general public; in no sense do they represent marketing carefully targeted to adult smokers.

### **iQOS-Sponsored Social Events**

Slides 9 and 10 depict iQOS "launch events" in South Africa. The Philip Morris presentation to TPSAC indicated the company's intention to have "consumer events" for iQOS in the U.S. and suggests that age verification will be required for these events. Ms. Knakmuhs also indicated that "[t]o have a guided trial, consumers must confirm they are current smokers."

These events bear strong similarities to events that PMI and other tobacco companies have used in the past to make cigarettes look cool and appealing to youth and young adults. It is inevitable that these types of events will attract youth and young adults; they always have before. These events don't educate; they renormalize and reglamorize tobacco use. Even if their format has been altered and the products are different, history has demonstrated that claims by PMI and other tobacco companies that certain events and activities will be for adults only have more often been honored in the breach and/or that underage youth have had an easy time gaining entrance. Anything short of rules with meaningful penalties and effective enforcement that limits events to

“adults only,” and requires government-issued photo identification age verification is inadequate. Moreover, FDA should determine exactly what is being done by PMI to confirm that attendees are current smokers. Slide 11 also depicts an iQOS-sponsored party at a dance/night club in Catania, Italy, featuring pop performer Saturnino Celani. Events like this do not appear to be consistent with PMI’s representations.

### **iQOS Marketed at Public Events, Including Music Events**

Slides 12 and 13 depict the marketing of iQOS at a street food festival in Kyiv, Ukraine. This is not the kind of marketing that represents a serious effort to restrict the marketing of a tobacco product to verified adult smokers seeking to make a transition to a less harmful product. The brand and product obviously are being broadly promoted to the attendees at the festival in a manner to glamorize the product and it is clear from the images that there are minors and non-smokers in attendance. The distribution of free samples at the festival (slide 13) is particularly notable; even though this activity would be prohibited in the U.S., PMI’s willingness to use this form of marketing abroad belies any claim of a sincere effort by the company to avoid exposing “unintended audiences” to iQOS.

Even more troubling is the marketing of iQOS at music events, such as the 2017 Estereo Picnic music festival in Bogotá, Colombia, <https://www.songkick.com/festivals/387188-estereo-picnic/id/28202039-festival-estereo-picnic-2017> (slide 14) and a concert featuring the popular group “Leningrad” in St. Petersburg, Russia (slide 15) – whether or not there was any effort to limit the event to adult smokers only. Although the Estereo Picnic event claims to be limited to persons 18 and above, young adults, including non-smokers attending the event, would have been exposed to the iQOS promotions.

### **iQOS Partnerships to Create Broad Market Appeal**

Several of the slides are evidence of partnerships PMI has formed internationally to market iQOS to as wide an audience as possible. Thus, slides 16 and 17 depict a partnership with the fashion magazine Marie Claire, clearly intended to associate the iQOS brand with a publication popular among young women, with an appeal obviously not limited to adult smokers. Similarly, slide 18 shows an event hosted by Interview Magazine Russia and iQOS, featuring interviews with celebrities and artists. Slide 19 is a press release issued in February 2018, announcing a PMI partnership with Ferrari to promote the iQOS brand. Although the tobacco brand sponsorship of a race car would be prohibited in the U.S., PMI’s use of this tactic abroad is further evidence of the company’s strategy to appeal to the widest possible consumer audience.

### **Brand Association with Cultural Activities with Broad Market Appeal**

Finally, several slides reflect efforts to associate the iQOS brand with sophisticated cultural activities having broad appeal. For example, Slide 20 shows an iQOS sponsored photographic art event in Zurich, Switzerland, with no indication that attendance was limited to adult smokers. Slides 21 and 22 depict Creative Hub “Qreators” by iQOS, which are presented as branded spaces providing information about iQOS, as well as product testing, at a venue that would also host various cultural events. This appears to be a highly sophisticated effort to make the iQOS brand appealing to the creative community, not simply to smokers.

### **Conclusion**

Even this limited collection of images reflecting the marketing of iQOS in other countries is sufficient to raise significant concerns about the credibility of PMI’s representations to FDA and TPSAC concerning its planned marketing of the product in the U.S. In light of the marketing of iQOS abroad, it is essential that FDA not take these representations at face value. Rather, prior to issuing any kind of marketing order, whether it be a PMTA order or an MRTP order, it is incumbent on FDA to thoroughly investigate the marketing of this product overseas, and to recognize that such marketing is not consistent with PMI’s claimed intention to market only to adult smokers in the U.S. and to avoid marketing to unintended audiences like non-smokers and youth. Moreover, the use of these marketing tactics abroad is surely sufficient to require that, if any marketing orders are issued to PMI for the U.S. market, they be expressly conditioned on the adoption of legally binding enforceable obligations preventing PMI and Philip Morris from using similar images and strategies in the U.S. and provisions for the ongoing monitoring of such marketing to ensure their compliance with these commitments.

Respectfully submitted,



Matthew L. Myers  
President