PHILIP MORRIS PRODUCTS S.A.

To: [redacted];
[redacted]

December 4, 2020

Article published on Tobacco Tactics Website—*PMI Promotion of IQOS Using FDA MRTP Order*—https://tobaccotactics.org/wiki/pmi-iqos-fda-mrtp-order/ last edited November 13, 2020

Dear [redacted],

We recently became aware of an article "PMI Promotion of IQOS Using FDA MRTP Order"[1] (the **Article**) published on the Tobacco Tactics website (the **Website**), of which you are the Managing Editor. We note that the Website provides the Right of Reply[2] and with this letter, we are putting you on notice that the Article contains significant factual errors and misleading statements. We request that you correct these immediately. To assist you in this matter, important contextual information for your consideration and guidance is provided in Annex 1, and a non-exhaustive list of examples of factual errors and misleading statements in the Article is provided in Annex 2.

We note that the Website provides a guide to writing[3] (the **Guide**) and request that you revisit the Article in its totality and implement corrections forthwith, in line with your commitment to provide information that is "*objective, factual and well referenced, not subjective or judgemental*". We believe, and hope you do as well, that readers should not be misinformed or misled by the content of the Article and therefore look forward to seeing an updated version that is in line with your stated editorial principles.

In keeping with Philip Morris International's (PMI) commitment to fostering open and transparent dialogue, we will make our correspondence regarding the Article available to the public via our own website and through our owned media channels.

As our review of the Website continues, we may ask for additional corrections. All of our rights are hereby reserved.

Sincerely,

Dr. Moira Gilchrist

VP Strategic and Scientific Communications

[1] https://tobaccotactics.org/wiki/pmi-iqos-fda-mrtp-order/ accessed December 03, 2020
[2] https://tobaccotactics.org/wiki/right-of-reply/ accessed December 03, 2020
[3] https://tobaccotactics.org/wiki/guide-to-writing/ accessed December 03, 2020

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Annex 1

Contextual Information Regarding the Subject Matter of the Article

On July 7, 2020, the U.S. Food and Drug Administration (FDA) authorized the marketing of Philip Morris Products S.A.'s *IQOS* Tobacco Heating System as modified risk tobacco products (MRTPs)[4]. In their accompanying press release[5], FDA stated that these were *"the first tobacco products to receive "exposure modification" orders, which permits the marketing of a product as containing a reduced level of or presenting a reduced exposure to a substance or as being free of a substance when the issuance of the order is expected to benefit the health of the population."* FDA's press release also notes that *"There are two types of MRTP orders the FDA may issue: a "risk modification" order or an "exposure modification" order. The company had requested both types of orders for the IQOS Tobacco Heating System. After reviewing the available scientific evidence, public comments and recommendations from the Tobacco Products Scientific Advisory Committee, the FDA determined that the evidence did not support issuing risk modification orders at this time but that it did support issuing exposure modification orders for these products. This determination included a finding that issuance of the exposure modifications orders is expected to benefit the health of the population as a whole."*

FDA's authorization[6] states that, *"[t]he scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies (section 911(g)(2)(A) of the FD&C Act)."* The authorization explains why *IQOS* is fundamentally different from cigarettes. FDA is clear that reduced exposure to harmful chemicals does not render the *IQOS* Tobacco Heating System harmless. Nevertheless, reduced exposure statements are permitted for products authorized under the MRTP pathway and FDA has now allowed use of reduced exposure statements related to our *IQOS* tobacco heating system—the first and only electronic nicotine product to be granted marketing orders through the FDA's MRTP process. With this authorization, FDA has explicitly permitted that exposure reduction information be made available to consumers.

PMI makes clear that *IQOS* is not risk free; it is addictive; it is not a cessation aid and we do not present or market it as such; the best choice any smoker can make is to quit tobacco and nicotine altogether. Those adult smokers who do not quit deserve access to and accurate information about better alternatives, such as *IQOS*. Governments, regulators, scientists and the public health community deserve to hear the truth about U.S. FDA's historic decision in order that they can decide for themselves how best to modernize tobacco regulation and leverage innovations like *IQOS* in the interests of public health.

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[4] https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-orders accessed December 03, 2020

[5] https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-iqos-tobacco-heating-system-reduced-exposure-information

[6] https://www.fda.gov/media/139796/download

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Annex 2

Non-Exhaustive List of Factual Errors and Misleading Statements in the Article

Of the Article's numerous inaccuracies, the most serious and misleading are detailed below. In addition to addressing these points, we respectfully request that the authors of the Article review it in its entirety and correct any additional factual errors or misleading statements.

(1) The Article states that "*The US Tobacco Products Advisory Committee (TPSAC) recommended **against** approving PMI's application to market IQOS as a reduced risk product.*[3]" ***(emphasis added by the Website)***

(a) TPSAC's title is incorrect. The correct title is "Tobacco Products Scientific Advisory Committee". **Please change "The US Tobacco Products Advisory Committee (TPSAC)" to "Tobacco Products Scientific Advisory Committee (TPSAC)"**.

(b) During the meeting to discuss the MRTP applications for the IQOS system (the **TPSAC Meeting**), TPSAC did not make the recommendation as stated. TPSAC were requested to vote on a number of important questions. This question was not one of them. The TPSAC Meeting Materials and Information[7], including transcripts and minutes confirm this. On January 24 and 25, 2018, experts from Philip Morris International Inc. (PMI) and Philip Morris USA Inc. presented to the TPSAC as part of the FDA's review of PMI's request to commercialize *IQOS* in the U.S. as a "Modified Risk Tobacco Product". The FDA reviews modified risk tobacco product applications (MRTPAs) and it is FDA that makes the determination as to whether to authorize an MRTP. FDA takes into consideration TPSAC recommendations, along with public comments and other information made available to them, before making a determination on any MRTP application. **Please correct the statement about TPSAC's recommendations accordingly to make these important facts clear to readers.**

(c) In accordance with your Guide, in order to provide readers with "*enough objective material – hard facts about what the person or organisation said or did, including quotes from the target person or from critics etcetera, to enable readers to make their own reasoned judgement*", **please include a complete overview of the TPSAC Meeting based on and referencing the TPSAC meeting minutes and other official materials from the hearing**.

[7] https://www.fda.gov/advisory-committees/tobacco-products-scientific-advisory-committee/2018-tpsac-meeting-materials-and-information

(d) It is perplexing that the authors of the Article chose to substantiate their statement by referencing a news article from Reuters[8], which in turn refers to a letter signed by a group of U.S. senators after the TPSAC Meeting. While apparently seen by Reuters, the letter has neither been published by them, nor anyone else to our knowledge. The overall relevance of this article as an accurate source of information for the Article's statement is unclear. **Please change this reference to a more definitive and public source of information, such as the TPSAC Meeting Materials and Information.**

(e) The U.S. Federal Food, Drug, and Cosmetic Act (FDCA) does not recognize the term 'reduced risk product' as used in the Article. The FDCA refers to 'modified risk tobacco products' (MRTP), see FDCA section 911(b)(1). **When addressing correction (b) above, please utilize the official terminology from FDCA section 911(b)(1) to address this inaccuracy**.

(2) The Article states *"The FDA **denied** PMI a 'risk modification' order, for which PMI originally applied. A 'risk modification' order requires a burden of proof that products "(1) Significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (2) Benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products". PMI "did not demonstrate" that IQOS met these standards." **(emphasis added by the Website)***

The Article misrepresents the facts by failing to mention that in December 2016, PMI applied for both "risk modification" and "exposure modification" orders, and that while '*the FDA determined that the evidence did not support issuing risk modification orders at this time',* it did *'support issuing exposure modification orders for these products. This determination included a finding that issuance of the exposure modifications orders is expected to benefit the health of the population as a whole."* **Please adopt the following corrections to address this misrepresentation:**

(a) **Clarify that PMI applied for both "risk modification" and "exposure modification" orders.**
(b) **Clarify that FDA denied a risk modification order "at this time".**
(c) **Clarify that a "risk modification" order requires that an applicant has demonstrated that a product, as it is actually used by consumers, will – *"(1) Significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (2) Benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products."* Notably, this is the statutory standard that must be cleared, but it is not a "burden of proof" as that phrase is typically understood in a legal context.**
(d) **Note that the Agency's determination "included a finding that issuance of the exposure modifications orders is expected to benefit the health of the population as a whole."**

[8] https://www.reuters.com/article/us-health-tobacco-philipmorris/u-s-senators-ask-fda-to-reject-philip-morris-iqos-application-idUSKBN1FR1WH?feedType=RSS&feedName=topNews&utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+reuters%2FtopNews+%28News+%2F+US+%2F+Top+News%29

(3) The Article states that *"[t]he exposure modification standard that PMI was awarded "establishes a lower standard" than that of risk modification*", referencing the Scientific Review of Modified Risk Tobacco Product Application (MRTPA) Under Section 911(d) of the FD&C Act -Technical Project Lead document (the **TPL Document**).

Whilst the TPL Document is a factually accurate source, the authors of the Article selected only one phrase ("*establishes a lower standard*") from a much wider and more complex observation by the FDA: "*section 911(g)(2) establishes a lower standard, which allows FDA to issue an order when risk reduction has not yet been demonstrated but is reasonably likely based on demonstrated reductions in exposure (e.g., a finding that a reduction in morbidity or mortality among individual users is reasonably likely in subsequent studies; a finding that issuance of an order is expected to benefit the health of the population as a whole)*." **Please adopt the following corrections to address this misrepresentation:**

(a) **Change "awarded" to authorized. FDA does not "award" marketing orders.**
(b) **Clarify the full breadth of FDA's decision, including that it "is reasonably likely based on demonstrated reductions in exposure (e.g. a finding that a reduction in morbidity or mortality among individual users is *reasonably likely* in subsequent studies; a finding that issuance of an order is *expected* to benefit the health of the population as a whole)."**

(4) The Article references a statement[9] produced by Stopping Tobacco Organizations and Products (STOP) from July 2020, authored by Sophie Braznell, Anna Gilmore and Andy Rowell of the University of Bath, with editorial review from Vital Strategies (the **Briefing Paper**). It is important to note that, given their affiliations, neither the authors nor the editors are impartial contributors.

(a) Contrary to statements in the Article, the Briefing Paper does not summarize "*the evidence from academic research on IQOS*". It mentions selected statements from individuals with well-known opinions about PMI and *IQOS* and fails to mention PMI's public responses and positions on these (e.g. PMI's response[10] to a study by Stanton Glanz[11]), and the growing body of other independent studies related to *IQOS*[12]. The Briefing Paper also misleadingly portrays the state of the scientific evidence regarding *IQOS*, as well as FDA's evaluation of it. Of particular concern, the Briefing Paper falsely states that "*In short, there is currently no evidence that IQOS is safer than cigarettes*" using an FDA webpage (which has since moved[13])– about heated tobacco products in general, not *IQOS* specifically—as a reference to support

[9] https://exposetobacco.org/wp-content/uploads/STP054_FDA_IQOS_Brief_v3.pdf
[10] https://www.pmiscience.com/resources/docs/default-source/news-documents/the-difference-between-switching-to-iqos-and-continued-smokingef07ae852f88696a9e88ff050043f5e9.pdf
[11] https://tobaccocontrol.bmj.com/content/27/Suppl_1/s9
[12] https://www.pmiscience.com/whats-new/independent-studies
[13] https://www.fda.gov/tobacco-products/products-ingredients-components/how-are-non-combusted-cigarettes-sometimes-called-heat-not-burn-products-different-e-cigarettes-and#:~:text=A%20non%2Dcombusted%20cigarette%20consists,aerosol%20that%20the%20user%20inhales.

this statement. The FDA actually states that "*There is no safe tobacco product. Non-combusted cigarettes may help reduce the risk of tobacco-related harms for adult smokers who switch completely from combusted cigarettes, but all tobacco products can lead to nicotine addiction and contain toxic, cancer-causing chemicals that can cause serious health problems*." **Please adopt the following corrections to address these false and misleading statements:**

i. **Remove all information and references derived from the Briefing Paper; and/or**
ii. **Include the following from PMI: "With respect to the Stopping Tobacco Organizations and Products (STOP) Briefing Paper, PMI notes that it misleadingly portrays the state of scientific evidence regarding *IQOS*, as well as FDA's evaluation of it. FDA's press release can be found here [link to FDA press release], while other documents relating to the authorization can be found here [link to FDA MRTP Orders]. In particular, FDA affirmed that scientific studies have shown that switching completely from conventional cigarettes to the *IQOS* system significantly reduces your body's exposure to harmful and potentially harmful chemicals.**

(b) The Article's authors state that the Briefing Paper highlights *"the potential for the misrepresentation of the* partial *approval applying to the marketing of IQOS, which only applies in the US[8]".* The FDA does not approve tobacco products. FDA authorizes tobacco products if they meet the standard outlined in U.S. Federal Food, Drug, and Cosmetic Act. It does not recognize the concept of partial authorization. **Please adopt the following corrections to address this misrepresentation:**

i. **Remove all information and references derived from the Briefing Paper; and/or**
ii. **Delete or change the above mentioned sentence to be factually accurate.**

(5) The Article references a University of Bath Tobacco Control Research Group "*peer-reviewed paper in BMJ highlighting how the decision increases confusion around the safety of HTPs.*" This British Medical Journal editorial (the **BMJ Editorial**) makes unwarranted attacks on the expertise of one of the world's leading regulatory agencies and attempts to undermine better choices for adults who smoke. The BMJ Editorial elicited several responses, including one from PMI[14] and the Article should reflect this for completeness and transparency. **Please amend this section to make the facts clear to readers:**

(a) **Remove the reference; and/or**
(b) **Include PMI's and others' responses to the BMJ Editorial for completeness and transparency.**

(6) The Article states: "*In an interview with Forbes in Mexico, Mario Masseroli, President of PMI Latin America and Canada, said PMI had "been in contact with the Mexican authorities trying to show*

[14] https://www.bmj.com/content/370/bmj.m3528/rr

the difference between IQOS and conventional cigarettes" and that "you cannot ignore a decision like the FDA" (translated from original Spanish).[40]*"*

Quotes have been selected from the referenced article and taken out of their original context giving a misleading impression. Mario Masseroli's full quotes from the *Forbes* article are: *"We believe that it is something that cannot be ignored if you are an authority in any country seriously thinking about solving the problem of public health, such as diseases related to smoking, you cannot ignore a decision like the FDA," "We have been in contact with the Mexican authorities trying to show the differences between IQOS and the conventional cigarette, we believe it is important to have such a discussion based purely on scientific arguments."*

Please amend this section to make the facts clear to readers by either deleting or providing the quotes in their entirety.

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