PHILIP MORRIS INTERNATIONAL

May 25, 2020

PMI Responses to the OCCRP

Response from Dr. Moira Gilchrist, Ph.D. (Pharmaceutical Sciences), PMI's Vice President. Strategic & Scientific Communication:

"You should develop a safer product." For decades, that is what governments and the public health community have told the tobacco industry. PMI has invested billions of dollars in science and technology to achieve that precise objective.

A campaign of paid-for journalism supported by special-interest groups, including the openly prohibitionist Bloomberg Philanthropies – are dedicated to just one mission. Under the guise of promoting public health, they are working to rob adults who smoke of their right to choose scientifically substantiated better alternatives to continued smoking.

We have a question for those special interest groups: Why are they using an elaborate network of organizations, and paying journalists to confuse adults who smoke, elected officials, and the public health community? We can only conclude that they are pursuing a disastrous prohibition-only crusade.

We urge these groups to: STOP ignoring the rights of hundreds of millions of adults who would otherwise continue to smoke to find out about better alternatives; STOP ignoring science and evidence that doesn't fit with their dogma; and START having a real conversation.

This dangerous and misguided campaign has provided sponsored content that many people believe or will assume is independent. Ultimately, this undermines the goal of tobacco harm-reduction and confuses adults who smoke about better choices. And ironically, the campaign attacks the only company – PMI – that has publicly committed to eliminating cigarettes.

If people who smoke are denied accurate information – or worse yet, are misled about less-harmful alternatives, the vast majority will simply continue to smoke cigarettes.

To set the record straight we have addressed all of the allegations made against us by this global campaign on our website: PMI.com. We invite everyone to learn the facts, study our science and arrive at their own conclusions. We have nothing to hide.

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OCCRP Q1: In 2018, the Eighth session of the Conference of the Parties (COP8) decided to consider heated tobacco products as tobacco products, and so that the Parties must apply the WHO FCTC regulations. However, IQOS is promoted and advertised in public spaces, train stations and airports (art. 13 of the FCTC); IQOS' packs don't carry health warnings (art. 11 of the FCTC). Why is IQOS not regulated according to these WHO FCTC articles?

PMI Response:

The FCTC has no "regulations." It is a treaty between the countries which are 'Parties.' Those countries are responsible for the regulation of tobacco products within their respective jurisdictions. Philip Morris International affiliates comply with all local laws and regulations regarding the marketing of cigarettes and smoke-free products.

Questions regarding the requirements of the FCTC for the parties to the Treaty should be directed to the WHO.

OCCRP Q2: On PMI's website (pmiscience.com) it reads: "we welcome and encourage independent research on our products." What is your definition of independent study? For example, one article under your Independent Studies section is co-authored by Riccardo Polosa whose CoeHAR in 2018 was given two grants worth USD 205,805 in total from the Foundation for a Smoke-Free World (FSFW), an organization aimed at "accelerating the end of smoking", which is solely funded by Philip Morris International (PMI).

How would you comment on the status of independence of these two articles?

PMI Response:

These studies clearly state either that they are funded by Philip Morris International or that the authors are affiliated to Philip Morris International.

The independent study was conducted as part of a PMI Investigator Initiated Studies (IIS) pilot program, something that is stated clearly in the Funding section of the publication. Investigator Initiated Studies programs are common in the pharmaceutical industry and PMI ran a pilot program from June 2016 to January 2018. PMI accepted proposals under the pilot program to support external scientists to advance and verify smoke-free product science. The IIS pilot program was discontinued in 2018. The list of studies, guidelines and terms and conditions are still available on our science website.

The second study is a PMI-conducted study and is clearly marked as such. It is not listed as an independent study on our website:

"Affiliations: Philip Morris International Research and Development, Philip Morris Products S.A, Quai Jeanrenaud 3, 2000, Neuchâtel, Switzerland

Mark C. Bentley, Martin Almstetter, Daniel Arndt, Arno Knorr, Elyette Martin, Pavel Pospisil & Serge Maeder"

The Foundation for a Smoke-Free World is an independent, non-profit organization. It is dedicated to fund research and encourage innovative measures to reduce the harm caused by smoking, to evaluate the impact that smoke-free alternatives can have on smokers and public health, to assess the effect of reduced cigarette consumption on the industry value chain, and to measure overall progress towards a smoke-free world. While PMI has provided initial funding, the foundation is seeking and expects to receive funding from other sources as well. PMI and the tobacco industry, or any third party, are precluded from having influence: the Foundation's decisions are its own. All inquiries about the Foundation's activities should be directed to the Foundation. PMI's funding of the Foundation is well known and a matter of record.

OCCRP Q3: Philip Morris was accused of manipulation by Medical Academy officials in different countries, when its officials promoted the IQOS as a cessation or medical device during medical conferences. What is your position in this regard?

> **Additional information: Two senior officials of the Romanian Academy and the Romanian Academy of Medical Science signed an official letter in 2018, accusing Philip Morris of "using the same manipulative techniques as in the last century to convince doctors to accept and even recommend these products." The letter was a reaction to Philip Morris employees promoting the Heat Tobacco Products during medical conferences.**

PMI Response:

PMI does not – and never has – promoted *IQOS* or any smoke-free product as cessation devices or medical devices.

We have legitimately presented the science behind reduced-risk products at medical conferences, when we were invited, but do not promote *IQOS* products at these events.

On one occasion in 2018, the organizers of a medical conference mistakenly printed the *IQOS* logo on a banner, instead of PMI Science, as they had been instructed. This led to the decision by the Philip Morris International affiliate to withdraw from that conference in order to avoid any misunderstanding.

OCCRP Q4: Do you consider that IOQS should be accepted and regulated as a smoking cessation device? If so, could you please explain why?

PMI Response:

IQOS is not a cessation device, and therefore not intended for smokers who are looking for a means to quit nicotine and tobacco products all together – the best choice for any smoker. Please see our Good Conversion Practices for more information.

IQOS is designed for adult smokers who would otherwise continue to smoke cigarettes. Based on the data up to the end of 2019, we estimate that there are approximately 14.6 million IQOS users, of which more than 10 million have stopped smoking completely, with the balance in various stages of conversion."

The totality of evidence available on *IQOS* confirms that it presents less risk of harm compared to continued smoking. This evidence was submitted in support of our applications for authorization to commercialize the *IQOS* and three variants of HeatSticks in the US as modified risk tobacco products. Those applications remain pending with the FDA.

The U.S. FDA authorized the commercialization of *IQOS* in the US under the premarket tobacco product application pathway in April 2019, and in its decision made the following statements relevant to your inquiry: "Through the FDA's scientific evaluation of the company's applications, peer-reviewed published literature and other sources, the agency found that the aerosol produced by the IQOS Tobacco Heating System contains fewer toxic chemicals than cigarette smoke, and many of the toxins identified are present at lower levels than in cigarette smoke. For example, the carbon monoxide exposure from *IQOS* aerosol is comparable to environmental exposure, and levels of acrolein and formaldehyde are 89% to 95% and 66% to 91% lower than from combustible cigarettes, respectively."

This is in line with the World Health Organization's (WHO) "Tobacco Product Regulation – Basic Handbook" published in August 2018, where it is recognized on page 7, that "If overall exposure to tobacco product toxicants is reliably lowered, population harm may be reduced even if large numbers continue to use these products."

This decision from the U.S. FDA to authorize the marketing of *IQOS* as a new tobacco product in the U.S. does not mean that *IQOS* is safe, risk-free or "FDA approved." All tobacco products are potentially harmful, they are addictive and those who do not use tobacco products should continue not to.

OCCRP Q5: OCCRP reporters discovered that two companies (UBC and ICONPLC) are contacting doctors in several countries around the world to accept to participate in a clinical study financed by Philip Morris International.

PMI Response:

Our research protocols conform to international standards and practices that assure the quality and integrity of clinical and non-clinical laboratory processes.

This feasibility assessment for a clinical study is part of our commitment to continue building the scientific evidence related to *IQOS*. Clearly the best thing any smoker can do is to quit tobacco and nicotine altogether. However, independent reports from the U.S. and Europe show that approximately 40 percent of smokers diagnosed with COPD continue to smoke. We are investigating the feasibility of conducting a study in COPD patients who do not quit smoking. If the study goes ahead, it would include smoking cessation as the first option before enrolling in the study, and throughout the study during study visits. Smokers who continue to smoke cigarettes would be offered the opportunity to switch to *IQOS* to assess the impact compared to continuing to smoke on the progression disease. The study would be conducted in accordance with Good Clinical Practice, under the oversight of country-specific independent ethics boards/institutional review boards, and would be published on clinicaltrials.gov to ensure that there is complete transparency and oversight.

OCCRP Q6: What is the budget that PMI allocated to UBC Studies and Iconplc for the three-year clinical study "Effect of switching from cigarette smoking to THS on lung function parameters in mild to moderate COPD patients" and in what countries PMI is looking for doctors and patients with COPD?

PMI Response:

The budget of individual elements of PMI's Research & Development are confidential and not publicly disclosed, however, the study budget would be in the benchmark range for similar clinical studies. Since 2008, PMI has invested over USD 7.2 billion to develop and scientifically substantiate smoke-free alternatives

OCCRP Q7: In some countries, your company promoted and encouraged the use of IQOS during the Covid 19 lockdown referring to it as an alternative to continuing smoking and staying at home. This is an example: "Your house does not need smoke and ash. Consider this when you think of leaving home to buy cigarettes." Due to the fact that also the Food and Drug Administration has not decided yet on the separate modified risk tobacco product (MRTP) applications that the company also submitted for these products to market them with claims of reduced exposure or reduced risk, IQOS cannot be considered less harmful than combustible cigarettes and that smoking is most likely associated with the negative progression and adverse outcomes of COVID-19, how do you comment on these marketing strategies?

Additional information: Romania – the message was used in online advert in two of the biggest online news platforms in the country.

Additional information: For example, in Japan, advertisements were published in hardcopy editions of major newspapers and in Romania in the Iqos official website.

PMI Response:

The provisions of the United States Tobacco Control Act (2009) set a U.S.-specific legislative standard to determine whether any product is a "modified risk tobacco product". However, the totality of evidence available on *IQOS* confirms that it presents less risk of harm compared to continued smoking. See PMI's Response to Question 4, setting out the relative risk profile of *IQOS* compared to combustible cigarettes and the FDA's findings to date. PMI affiliates comply with local laws regarding the marketing of smoke-free products in each country where they are sold.

One example mentioned was part of a paid media campaign in April 2019. The landing page was to the "Try IQOS For Free" section on iqos.ro (which is age-gated). The translation you have provided is incomplete; the exact translation is "Your house does not need smoke and ash. Consider this when you think about going to buy cigarettes. Try IQOS for free 21 days."

Some communications to consumers during the COVID-19 pandemic are aimed at existing adult *IQOS* customers, informing them that *HEETS* can be sent to their home address.

OCCRP Q8: In 2019 Philip Morris International publicly announced that the company's internal "marketing standards" prohibits the promotion of tobacco products with youth-oriented celebrities or models who are, or appear to be, under the age of 25. Recently, several Philip Morris subsidiaries admitted the use of over-19-years-old teenager employees to promote *IQOS* and *HEETS* on social media. How do you explain this double standard?

PMI Response:

Although you reference "several subsidiaries" when pressed, we note you were able to refer only to Philip Morris Romania. You have not been clear as to the incident you refer to. We would be happy to respond if you provide more information.

OCCRP Q9: Did Philip Morris International or its subsidiaries submit a request to market the *IQOS* as a reduced risk product in other countries than the U.S.? If so, please indicate the countries and what is the status of your submissions.

PMI Response:

The modified risk tobacco product pathway (MRTP) is unique to the U.S. PMI follows the law in every country in which we operate, following the appropriate process to bring the products to market.