

7 May 2025

Philip Morris International's Response to "Understanding Heated Tobacco Products: Current Issues and Recent Findings" (STOP – April 2025 - the "Report")

Dear Prof. Anna Gilmore; Dr. Sophie Braznell & Colleagues

We are writing regarding "Understanding Heated Tobacco Products: Current Issues and Recent Findings"—a report recently published by Stopping Tobacco Organizations and Products (STOP), with contributions from authors at the Tobacco Control Research Group (TCRG). Put simply, the report is yet another piece of biased, pseudoscientific rhetoric, published without peer review or oversight, and designed to stoke hysteria and mislead policymakers. A vast number of factors are absent from your Report, including scientific integrity and, as importantly, the voices of adults who have switched to a smoke-free product and stopped smoking. It is shameful that you continue to ignore facts and science that do not align with your lobbying positions and consistently disregard the existence of the millions of people whose lives are impacted by your efforts.

Instead, you continue to mislead the public by ignoring or misrepresenting the overwhelming body of scientific and real-world evidence that supports the role that heated tobacco products (HTPs) can play in helping to reduce and ultimately eliminate the demand for cigarettes. As you seek to reach your goal of "stopping tobacco organizations and products", we urge you to refocus on the right objective: reducing disease and death caused by smoking. In this regard, we were shocked that you disseminated a quote from Dr. Braznell that "...there is no clear evidence that they [HTPs] are safer or less safe than other tobacco and nicotine products, **even cigarettes**." On the contrary, there is a wealth of clear evidence. However, a reader who smokes cigarettes could easily assume that Dr. Braznell's position is that it is "safer" to continue to do so than to switch to an HTP.

Detailed below are responses to some of the main themes in the many inaccurate and misleading claims that have been made in your Report. We will publish this response on our website and share it with others to raise awareness of the inaccurate and misleading manner in which your conclusions have been constructed, as well as your obvious conflicts of interest, which sows confusion and misleads the public. Our CEO's recent remarks for BBC World on the illogical opposition to smoke-free products reflect the challenges posed by lobbying organizations like yours, whose stances often contradict scientific evidence and hinder meaningful progress in public health initiatives.



1. General background on PMI's smoke-free future strategy

Everyone knows that smoking is harmful and addictive. Yet, despite this, there are still around one billion people who smoke, according to the WHO. We all agree that the best choice for health is to quit smoking, but the reality is that most people don't. These men and women deserve better choices than continuing to smoke. This is why, since 2008, Philip Morris International and its subsidiaries (PMI) have invested over \$14 billion in the development and responsible commercialization of smoke-free products such as *IQOS*. As of the end of 2024, smoke-free products accounted for almost 40% of our total net revenues. Our ambition is to be a predominantly smoke-free business by 2030, with over two-thirds of our revenues coming from our smoke-free business. We are committed to delivering a smoke-free future and, as our CEO has said, cigarettes belong in museums.

2. Overview of IQOS science

As we have made consistently clear publicly (including on our website), we agree the best choice for any adult smoker is to quit altogether and those not already using tobacco products should not start. However, we are clear that switching completely to a smoke-free alternative is a better choice for any adult than continuing to smoke. To be clear, PMI has never claimed heated tobacco products are safe or risk-free.

PMI's science and <u>numerous independent studies</u> were included in an extensive review by the U.S. Food and Drug Administration (FDA), leading to it <u>authorizing IQOS</u> as a <u>Modified Risk Tobacco Product (MRTP)</u> and confirming that two versions of our heated tobacco product provide a significant reduction of the harmful and potentially harmful compounds (HPHCs) found in cigarette smoke.

The totality of <u>scientific evidence</u> so far demonstrates that the *IQOS* system, while addictive and not risk-free, is a better choice for adults who would otherwise continue smoking cigarettes and that switching completely to *IQOS* presents less risks compared to continued smoking.

For years, STOP and the TCRG have consistently and systematically ignored any scientific evidence—whether independent, from a government agency, or the industry—which does not suit the narrative you and your funders wish to portray to the public and policymakers. This is evident from your persistent, decontextualized message that HTPs are harmful. As we explain below, HTPs are addictive and they are not risk-free, but by omitting the comparison to cigarette smoke for smokers who switch completely, your message is fundamentally flawed and seriously misleading. There is an increasing consensus, as highlighted by the BBC in their recent enquiry to us, that a significant portion of public health researchers agree *IQOS* is less harmful than conventional cigarettes for adults who switch to it and stop smoking. Despite this, it is evident that your position remains



misaligned with this emerging perspective, fostering unnecessary confusion, undermining the valuable shift towards harm reduction and most importantly - ignoring the consumers, also referenced by the BBC, who switched away from cigarettes to a smoke-free alternative.

3. False claims that *IQOS* produces smoke and misleading statement on emissions such as carbon monoxide

Absence of smoke & fine solid particles

The term "fine particles" refers only to particle size, without consideration of other important characteristics, such as whether the particles are solid or liquid or their chemical composition. The generation of smoke from tobacco combustion leads to the formation of solid particles, with a median diameter below 100 nm. Conversely, the *IQOS* aerosol contains liquid droplets comprised of mainly water and glycerin. *IQOS* does not generate solid particles (see also Investigation of solid particles in the mainstream aerosol of the Tobacco Heating System THS2.2 and mainstream smoke of a 3R4F reference cigarette - P Pratte, S Cosandey, C Goujon Ginglinger, 2017).

Numerous independent studies and reviews, including by the U.S. FDA, confirm key elements of our science showing that there is significant reduction in HPHCs compared to cigarette smoke. Our studies show that *IQOS* emits on <u>average 90-95 percent lower levels</u> of harmful chemicals compared with cigarettes.¹

While the reduction in HPHCs in *IQOS* aerosol compared to cigarette smoke has been clearly established, we have also been transparent that a small number of constituents are found to be higher in *IQOS* aerosol, due to fundamental differences in product design. The differences in these constituents are detected at thresholds below 100 nanograms/item and the low total concentration was not considered to be a risk in authorizing the products as "modified risk" by the FDA. Furthermore, analysis on the aerosol has demonstrated a significantly lower toxic potential overall, compared to cigarette smoke. The toxicological risk of any of the constituents found at low levels in *IQOS* aerosol is significantly outweighed by the reduction in exposure to known HPHCs which cause smoking-related diseases in cigarette smoke.

The significant reductions in HPHCs, such as benzo[a]pyrene and carbon monoxide, is due to *IQOS* heating tobacco rather than burning it. This has been confirmed by both PMI's science and numerous independent studies confirming *IQOS* does not produce smoke, including:

- https://doi.org/10.1016/j.yrtph.2016.10.001
- https://doi.org/10.1016/j.tca.2019.178475
- https://doi.org/10.3390/toxics11120947



These findings are further supported by the U.S. FDA, which concluded in granting an MRTP order with reduced exposure claims in July 2020 that available evidence demonstrates *IQOS* "heats tobacco but does not burn it."

The statement that "PMI described the emissions of its *IQOS* prototype as smoke" in published research from 2012 is inaccurate and obviously misleading without context. While the emissions in this research were accurately described as "smoke", the authors were referencing a completely different prototype product developed in the first part of the century, not the *IQOS* system that was launched from 2014 onwards. The prototype referred to is a K-series Electrically Heated Cigarette Smoking System (EHCSS) from 2008, which heated tobacco, but to temperatures up to 500Cⁱⁱ. It is disingenuous and misleading to apply these statements to the *IQOS* system, which is an entirely different product, including the heating system, temperature range and overall product design approach. *IQOS* does not cause combustion of tobacco, nor does it generate smoke.

Harmful and potentially harmful compounds

A systematic review conducted by independent researchers based in the U.K. evaluated clinical trials that could demonstrate the effectiveness and safety of HTPs in quitting smoking. Comparing tobacco specific nitrosamines levels (NNAL) among HTP users compared to smokers, the authors concluded there was "moderate certainty evidence" that NNAL levels were lower among HTP users compared to smokers. It is important to note that the moderate certainty grade was downgraded from "high certainty" because of a perception of high risk of bias suggesting that a 'worst-case scenario' still shows evidence of a reduction in exposure to nitrosamines. (Heated tobacco products for smoking cessation and reducing smoking prevalence - Tattan-Birch, H - 2022 | Cochrane Library).

Furthermore, the U.S. FDA, German Federal Institute for Risk Assessment (BfR), and many others have conducted actual emissions tests that consistently support reductions in toxicants from HTPs compared to cigarettes. The BfR <u>concludes</u> that "levels of major carcinogens are markedly reduced in the emissions of the analyzed HNB [heat-not-burn] product in relation to the conventional tobacco cigarettes and that monitoring these emissions using standardized machine smoking procedures generates reliable and reproducible data which provide a useful basis to assess exposure and human health risks."

The FDA has identified a list of HPHCs that are linked to the most serious smoking-related diseases. Regarding benzo[a]pyrene, analysis conducted by PMI as part of our *IQOS* PMTA submission to the U.S. FDA shows a 93-95 percent reduction of the quantity of the compound in the *IQOS* aerosol compared to reference cigarette smoke (https://doi.org/10.1016/j.yrtph.2016.10.001).

Regarding carbon monoxide, analysis shows a reduction by over 99 percent compared to reference cigarette smoke, with the remaining <1.0 percent likely to be due to environmental background. This



is because *IQOS* does not combust tobacco and does not produce carbon monoxide (https://doi.org/10.1016/j.yrtph.2016.10.001). The U.S. FDA recognized this when it decided to remove the requirement to include the Surgeon General Warning on Carbon Monoxide exposure in *IQOS* labeling requirements, stating that it would be misleading:

"Removal of the warning: 'SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide' from the required warnings to be displayed on the product package labels and advertisements under FCLAA. Based on a fair evaluation of all material facts, the warning is misleading with respect to these products which, although categorized as cigarettes, do not produce carbon monoxide above environmental levels and do not increase CO-related health risks [emphasis added]." https://www.fda.gov/media/124247/download (see page 98)

The FDA also noted this decision in its press release:

https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway

It is clear that products like *IQOS* are addictive, and they are not risk-free, but switching completely to a scientifically substantiated smoke-free alternative is the better choice for any adult smoker than continuing to smoke cigarettes. This is also reflected in our U.S. FDA authorized MRTP claim for *IQOS*: "Scientific studies have shown that switching completely from conventional cigarettes to the *IQOS* system significantly reduces your body's exposure to harmful or potentially harmful chemicals." FDA stated that "the issuance of the order is expected to benefit the health of the population." FDA Authorizes Marketing of IQOS Tobacco Heating System with 'Reduced Exposure' Information | FDA

Auer research

The research letter by Dr. Auer from 2017 referred to in the Report [source 28] has several methodological flaws and its reliability has been questioned by highly respected institutions, including the FDA in their 2020 MRTP authorization. However, despite knowing this, in subsequent years, the TCRG and STOP continue to falsely rely on the Auer research letter to support your misleading narrative on heated tobacco products. The weight of scientific evidence (including numerous scientific studies as outlined above) supports the view that the *IQOS* system does not produce smoke.

It is misleading to reference this 2017 study without placing due prominence on the FDA's 2020 conclusions about it. Its review of the Research Letter from Auer and his colleagues concluded that:

"Auer et al conducted the analysis over two consecutive days and some of the data included too few replicates. Data published in the article lack the appropriate number of replicates, and do not include testing of some compounds in cigarettes, such as acenaphthene. In addition, the identity of some of



the compounds, such as acenaphthene, cannot be confirmed since the method used is not selective. The data published is not considered adequate for comparing the levels of HPHCs between the IQOS products and combusted cigarettes. There are significant analytical issues in the Auer study, such as lack of testing reference samples, low number of replicates, lack of selectivity on some analytical methods. In comparison, we have not identified specific issues with the applicant's [PMI's] methods." https://www.fda.gov/media/110387/download (see page 13).

And:

"...the [FDA] chemists concluded the data published by Auer et al. are not considered adequate for comparing the levels of [harmful and potentially harmful constituents] between the IQOS products and [conventional cigarettes] due to analytical issues— specifically lack of testing reference samples, low number of replicates, and a lack of sensitivity on some analytical methods." https://www.fda.gov/media/124247/download (see page 21).

We wrote to the authors at the time to encourage a dialogue to better understand the obvious incongruities in the research, but that good faith request has been consistently mischaracterized by groups such as the TCRG and STOP. Although the letter has been published on our website for several years, we take the opportunity to attach and publish it again to avoid any ambiguity as to our intentions or the serious methodological and analytical issues with the research.

In conclusion, there is overwhelming evidence, including from numerous government agencies, that *IQOS* significantly reduces the average levels of HPHCs compared to cigarette smoke and your continued persistence in ignoring this scientific evidence, misleads the public and shows your Report is neither objective nor fact based.

4. Allegations of youth marketing and uptake

It is simply not true that our heated tobacco products are being marketed to young people. For example, *IQOS* is not used in the sponsorship of any sporting events (Formula 1 or otherwise), PMI does not have official accounts on TikTok for marketing or otherwise, and X (formerly Twitter) is only used by *IQOS* for customer care. Any third-party event we sponsor has a clear requirement for at least 75% of the audience to meet the legal age for purchasing tobacco products within the country and digital marketing is directed at legal age adults on platforms with age verification measures in place. Additionally, PMI's <u>robust marketing code</u> does not allow marketing that appeals to minors (e.g., we don't use cartoons, youth-oriented celebrities, or models who are or appear to be under the age of 25 nor engage in product placement in movies or on television—and we decline every request we receive in relation to the same).

In the U.S., when reviewing the available data, the FDA, as part of its scientific review process to grant Premarket Tobacco Product Application authorization (PMTA) of *IQOS* for commercialization ("the



PMTA Review"), noted: "Available data, while limited, also indicate that few non-tobacco users would be likely to choose to start using *IQOS*, including youth."

Furthermore, available evidence shows that unintended use among youth is very low in the 70 markets where *IQOS* is currently available. For example, in Japan (our biggest and most mature market for heated tobacco products where independent data shows that cigarette sales have declined five times faster since the introduction of *IQOS* in 2014), the 2022 Lifestyle Survey of Adolescents—a nationwide cross-sectional survey of Japanese youth conducted for comprehensive research on lifestyle-related diseases by the Ministry of Health, Labour and Welfare, Health Science Research Fund—found 0.3% of junior and senior high-school students report current use of HTPs.

Allegations on youthful demographics of *IQOS* users are plainly wrong and not supported by data. In fact, the data show (see p. <u>46 of our investor information</u>) that 82 percent of *IQOS* consumers are over the age of 29, illustrating that *IQOS* is being adopted by its intended audience—legal age adults who were formerly smoking.

5. Allegation of dual usage & gateway to smoking

The allegation that the majority of *IQOS* users continue smoking is false. Real life observations in Japan show that smoking rates and cigarette sales are decreasing, not increasing. The data from millions of consumers around the world consistently show that *IQOS* is a gateway out of smoking, with over 70% of legal age users of *IQOS* globally having switched completely away from cigarettes. In short: it is not causing people to start smoking. Our data demonstrate a conversion rate of 72% (see slide 42), where legal age smokers have fully switched to *IQOS* and stopped smoking. The remaining percentage of users are dual users, normally in various phases of switching fully away from cigarettes. Clearly, this is not the "vast majority of users", or even the majority.

Data from Japan, our biggest *IQOS* market, clearly demonstrates that cigarette sales are in rapid decline, with the Japanese Ministry of Health data showing exclusive smoking at a record low of around 10% of the adult population. Additionally, total tobacco sales (cigarettes and heated tobacco products combined) are not increasing, illustrating that those using heated tobacco are not using them in addition to cigarettes in large numbers.

To give some sense of perspective, there were over 32 million *IQOS* legal age users in the world at the end of 2024—a large proportion in Japan alone—which shows there is more than enough real-world data to demonstrate that this claim is false.

6. Initial high-level commentary on <u>new research from TCRG</u> authors on impact of HTP on biomarkers of potential harm

The recent review on the impact of HTPs on biomarkers of potential harm (BoPH) concludes that there is a need to have more independent studies to understand the health impacts of HTPs. We



agree it is important to have evidence coming from a variety of institutions, including academic and government-funded research programs. However, we disagree that there is limited evidence of "benefits" compared to continued smoking. In the TCRG's own analysis, the direction of effect in the majority of BoPHs was beneficial with a clearer picture coming from the confinement studies where confounding from other factors that may impact clinical measures is minimized.

Furthermore, <u>we</u> and <u>others have studied</u> biomarkers of exposure to HPHCs which can provide more insights into the relative risk between HTPs and cigarettes in the shorter term. When taken together, studies assessing reductions in biomarkers of exposure and potential harm show a clear indication that HTP use is a better alternative than continued smoking.

7. Japanese "whistleblower" allegations

These 2024 allegations are false and based on the inaccurate statements of a disgruntled former employee of Philip Morris Japan whose employment was lawfully terminated in 2019 after evaluation of his performance during his six-month probationary period. His allegations were taken seriously and investigated thoroughly at the time. His allegations of unlawful conduct were found to be without merit and were not the basis for the termination of his employment.

Allegations that PMI was not transparent with the universities mentioned are also untrue. For example, one of the studies in question was a feasibility study and it was never intended to be published in a peer-reviewed journal, which is perfectly normal for this type of study. Nevertheless, PMI employees did present the study at a harm reduction conference in Greece in 2020 and our involvement was clear. We also have email correspondence from Kyoto University acknowledging our role.

It is also worth noting that the TCRG, STOP, and/or Vital Strategies paid the investigative journalists responsible for this story, and as such the content cannot be regarded as editorially independent. See more on conflicts of interest below.

8. Allegations that IQOS is a way to undermine public smoking bans

PMI has invested over \$14 billion since 2008 in the development and responsible commercialization of smoke-free products. Our goal is to one day replace cigarettes entirely with a range of less harmful, smoke-free products. We do this because innovation and technological advances have enabled us to develop better alternatives that adults who smoke want to switch to, and because it is the right thing to do—not just for our company, but for public health.

PMI operates in compliance with all local laws and regulations. We respect the authority of governments to implement appropriate measures that protect public health, including by restricting smoking in public places. We ensure that our marketing and sales practices for our products adhere to these regulations, including to the extent applicable to smoke-free products which are



fundamentally different from traditional cigarettes because they do not burn tobacco or create smoke.

9. Call to action that IQOS should be treated like cigarettes (such as for tax)

We note the Report includes a direct call to action (i.e. lobbying) for governments not to differentiate HTPs for tax purposes.

We have always been clear that regulations should continue to dissuade people from starting to smoke and encourage cessation. But it's equally clear that millions of men and women will continue to smoke, and they should have the opportunity to switch to better alternatives. Regulation is a key enabler for innovation and consumer innovations driven by science and require a commonsense regulatory approach that distinguishes the most harmful products, such as cigarettes, from better alternatives to encourage those adult smokers who don't quit to switch to them. Products like *IQOS* are fundamentally different from cigarettes and represent a better choice for adults than continuing to smoke and, as such, should be recognized for their potential for improving public health.

10. Conflicts of interests of STOP & TCRG authors

STOP is an anti-tobacco lobbying and public relations group with no legal entity status.

STOP is neither unbiased nor objective and, since 2018, the TCRG claims to have received over \$17million from Bloomberg Philanthropies who have a well-known agenda to see smoke-free products banned or treated like cigarettes. STOP appears to be focused on publishing inaccurate and misleading "research" aimed at discrediting the industry and its science, with PMI and *IQOS* a consistent target of unwarranted criticism. For example, a BBC podcast was removed from publication by the BBC Editorial Complaints team after Professor Anna Gilmore made several inaccurate and misleading statements about PMI and *IQOS*. On many occasions we have written to the TCRG/STOP citing inaccuracies in your public communications and your response has been to ignore our correspondence and repeat your misstatements.

The TCRG, STOP, Campaign for Tobacco Free Kids, and Vital Strategies are all significant beneficiaries of Bloomberg Philanthropies, which has awarded grants of hundreds of millions of dollars over the past 10 years, funding all of these groups to advocate and lobby for bans on smoke-free products (like heated tobacco and e-cigarettes), which are widely acknowledged by independent science to be far less harmful than traditional cigarettes. These groups are often active in countries that need smoke-free products the most due to disproportionately high numbers of smokers. The effect of this lobbying means that there are many countries, such as Turkey, Thailand, Vietnam, Argentina, Brazil



and India, where cigarettes and other combustible tobacco products can legally be sold—yet better alternatives for adult smokers are banned.

It is important that the Report is seen in the context of your clear conflict of interest. It is yet another attempt by a highly partial group of researchers who appear to be paid to advance the interests of their funders, rather than objectively progressing science for the good of public health. The unfortunate outcome of this work is that it creates confusion and risks perpetuating smoking for many millions of people around the world.

As noted above, PMI has previously written to you on numerous occasions asking that you correct falsities. However, these requests have been ignored. The lack of action to correct factual inaccuracies and biased, misleading claims gives the impression that your work is subjective commentary, and not objective scientific exploration.

We, of course, would welcome the opportunity to discuss this matter with you at any time. In our view, the current absence of dialogue is severely hindering the creation of a workable, reality-based plan to end smoking globally.

Yours faithfully,

Dr. Moira Gilchrist

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Chief Communications Officer

Philip Morris International

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ⁱ The approach used by PMI to substantiate reduced emissions for consumer-facing product statement is based on the World Health Organization (WHO) 9 list. This is a list of nine priority HPHCs proposed by the WHO Study Group on Tobacco Product Regulation for mandated lowering in cigarette smoke, which does not include nicotine.