

POINT-BY-POINT RESPONSE TO QUESTIONS PUT TO PHILIP MORRIS INTERNATIONAL BY THE BUREAU OF INVESTIGATIVE JOURNALISM

ALLEGATION:

The key allegation is that Philip Morris International's "transformation" and "smoke-free" campaign is disingenuous as the majority of its profits still come from cigarettes and it is aggressively marketing cigarettes in countries with lax regulations. The campaign is simply a business strategy designed to market IQOS, increase the company's profits and rehabilitate its image so that it can regain a seat at the policy table, influence regulations and ensure the sustainability of its business.

PMI RESPONSE:

Response from Dr. Moira Gilchrist BSc (Hons) Pharmacy, PhD 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 coordinated by American special interest groups, all of whom are seemingly funded by the same source—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 them: Why are they using an elaborate network of organizations to deceive 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 smoke; 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 grants to media for journalism that many people believe is independent. Ultimately, this undermines the goal of harm reduction and confuses adults who smoke about better choices. And ironically, the campaign attacks the only company that has publicly committed to eliminate cigarettes.

If people who smoke are denied accurate information—or worse yet, are deceived—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."

1) PHILIP MORRIS INTERNATIONAL'S CONTINUED SALES OF CIGARETTES AND CONTINUED LEGAL ACTION AGAINST TOBACCO CONTROL POLICIES:

A

PMI claims it wants to phase out cigarettes but it sold more than 740m cigarettes in 2018 and is only reducing its production by 1% a year worldwide.

R

This information is out of date. Our publicly available 2019 fourth-quarter report shows that cigarette shipment volumes decreased by 33,606 million units in 2019, indicating a 4.5% decline (including the effect of deconsolidating RBH)

source: <https://philipmorrisinternational.gcs-web.com/static-files/a8eed5ab-aac5-410b-94ea-fa98bf659b0d>

A

Its revenues from alternative products shot up from 0.2% in 2015 to 14% in 2018, but the majority (86%) still came from cigarettes.

R

This is out of date. In 2019, Reduced-Risk Products² accounted for almost one fifth of total PMI Net Revenues.

who would otherwise continue to smoke away from cigarettes have increased from practically zero to almost one fifth of our total Net Revenues.

This growth demonstrates the strength of our commitment to a smoke-free future. In just a few short years since we announced our commitment to a smoke free future, revenues from products that are key to transitioning adult smokers

Surely, this should be regarded as concrete evidence of our sincerity rather than cause for cynicism from the unnamed critics you cite?

² "Reduced-risk products," or "RRPs," is the term PMI uses to refer to products that present, are likely to present, or have the potential to present less risk of harm to smokers who switch to these products versus continuing smoking. PMI has a range of RRP's in various stages of development, scientific assessment and commercialization. PMI RRP's are smoke-free products that produce an aerosol that contains far lower quantities of harmful and potentially harmful constituents than found in cigarette smoke.

A

Its 2019 investor presentation state it wants to remain a 'leader' in cigarettes.

R

As PMI—and the world—transitions away from cigarettes towards smoke-free products, PMI intends to maintain its market position.

cigarettes, the sooner we can stop making them.

Our vision is that one day smoke-free products will replace cigarettes. The sooner the world transitions away from

Our leadership position in the cigarette market gives us greater ability to convert adult smokers to smoke-free products and generates the revenues to fund our rapid transformation.

A

Its executives have explicitly said it will not give up market share of cigarettes to its competitors.

R

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A

PMI has acquired tobacco companies and launched subsidiaries since 2016 when it voiced ambitions to phase out cigarettes

R

We are unlikely to be interested in any acquisition that does not further our drive towards a smoke-free future. While not an acquisition, our recently announced global (ex- South Korea) collaboration agreement with KT&G is a case in point.

Through that transaction we are able to bring PMI's resources, knowledge and infrastructure as we launch KT&G's smoke-free products outside South Korea. Products sold under this agreement will give consumers across

multiple international markets access to KT&G's smoke free products for the first time; accelerating the achievement of PMI's vision of a smoke-free future while enabling KT&G to benefit from PMI's technical, scientific and international expertise in helping adult smokers switch to better alternatives. This collaboration will benefit adult smokers by providing greater choice and drive accelerated adoption of smoke-free products worldwide. Further information can be found [here](#).

A

PMI has launched new cigarette brands, flavours and limited editions since 2016

R

We have always been clear about our intention to maintain leadership in the combustible tobacco category until all adult smokers switch to smoke-free products.

In addition, 92% of our research and development is focused on smoke-free products, as is over 60% of our commercial expenditure.²

As PMI—and the world—transitions away from cigarettes towards providing smoke-

free products for adults who would otherwise continue smoking, PMI intends to maintain its market position.

Our vision is that one day smoke-free products will replace cigarettes. The sooner the world transitions away from cigarettes, the sooner we can stop making them.

Our leadership position in the cigarette market gives us greater ability to convert smokers to smoke-free products.

² See our 2018 Sustainability report <https://www.pmi.com/sustainability/sustainability-report>

A

Since PMI announced it wanted to phase out cigarettes it has fought legal action against tobacco control policies while publicly claiming it wants to phase out cigarettes, a position which critics have called hypocritical

R

This is misleading.

PMI agrees that tobacco products should be subject to strict rules and enforcement. At times, we have objected forcefully to measures that would do nothing to dissuade people from starting to smoke or 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.

<https://www.pmi.com/who-we-are/our-views/regulation>

2) PHILIP MORRIS INTERNATIONAL'S CONTINUED YOUTH-FOCUSED ADVERTISING AND MARKETING OF CIGARETTES:

A

PMI has introduced cigarettes in coloured packaging attractive to children and young people. It has introduced flavours like Marlboro Tropical Mix, Marlboro Pacific Breeze, Marlboro Double Burst, Marlboro Fusion, Marlboro Mega Blast, Marlboro Ice Blast, Marlboro Splash Mega Purple, Marlboro Bright Beyond, Marlboro Vibe Beyond etc which appeal to children and young people.

R

A number of these brands—such as Marlboro Tropical Mix and Marlboro Pacific Breeze—are not part of PMI's product portfolio.

The others are not intended for children or young people. PMI only markets cigarettes to legal-aged smokers.

- PMI does not use images that have particular appeal to minors, including youth-oriented celebrities or cartoons.
- PMI does not use models who are or who appear to be under the age of 25.

- PMI only places advertising in media channels, venues or events that are not directed to minors and whose audience is reasonably estimated to be at least 75% adults.

- Advertising on television, in radio broadcasts, or in cinemas only appears in the later evening hours.

- PMI does not place advertising on the front or back cover of a printed publication for general circulation or general circulation to the trade.

A

In some countries PMI cigarettes appear at point of sale next to chocolates and sweets which appeal to children and young people, which violates some countries' tobacco control laws

R

We are committed to doing our part to prevent underage use of nicotine and tobacco products.

PMI neither owns nor has any means of control over the vast majority of the retail points of sale around the world where people buy our products.

However, we recognize that when we have the opportunity—for instance with our direct trade partners—we have a responsibility to set robust standards

and to work with them to guard against sales to underage purchasers. We have developed a set of tools for our affiliates to use to work more closely with their trade partners to guard against sales to underage purchasers, such as model clauses for contracts with trade partners, written communication to retailers reinforcing PMI's commitment to not sell its products to minors and PMI's expectation that all retailers who sell PMI products will comply.

A

PMI's subsidiary Sampoerna has created cigarette adverts that appeal to children, including youth focused imagery and slogans like "Go Ahead People" or "tapi gue jadi" ("but I did") representing teenage themes of freedom and rebellion. These adverts play on television, are visible on billboards and signs on shops next to schools. Logos are displayed in bars, cafes and restaurants.

R

These are not "youth focused" statements.

"Go ahead people" and "tapi gue jadi" are both campaign executions for our brand AMild. The advertising is aimed at legal-aged smokers and placement of our adverts across different channels follow

local regulation and PMI's marketing code.

In addition, when it comes to in-store point-of-sale materials placement, Sampoerna includes the youth access prevention program campaign materials.

A

Adverts for Sampoerna and PMI cigarettes play on children's channels like Cartoon Network and Nickelodeon Junior

R

This is incorrect. Neither PMI nor Sampoerna advertises or has advertised any tobacco products on Nickelodeon or the Cartoon Network or any other channel directed at minors.

Sampoerna complies fully with the applicable Indonesian law which permits television advertising for tobacco products between 9.30pm and 5.00am.

We require, by contract, that the agencies we work with to do the same and to ensure that the law is fully respected by the broadcasters they engage.

Following your inquiry we checked whether any of Sampoerna's agents or the broadcasters they work with had failed to meet the standards set by the law. Unfortunately, we discovered a single instance in July 2019 where an advert for a Sampoerna product appeared before the watershed, during an animated movie.

This was the result of a system error by the broadcaster for which they have accepted responsibility. We have informed the broadcaster that we will no longer be using their services with immediate effect.

A

PMI and Sampoerna sponsor youth-focused music events across Indonesia including Soundrenaline, the biggest music festival in South East Asia, and Djakarta Warehouse project, South East Asia's biggest dance music festival, which was headlined in 2019 by DJs Calvin Harris, Disclosure and Skillrex favoured by young people. During Djakarta Warehouse Project 2019 there was a Marlboro

Penthouse in which people could sit on sofas, watch television, play PlayStation games, and buy cigarettes. There was a Marlboro "Discover Room" with interactive red, blue and yellow booths, echoing cigarette-pack branding, and an arcade game where people could win prizes. Young attractive salesgirls in Marlboro-branded dresses roamed around the site selling cigarettes. These activities promote cigarettes to young people.

R

Sampoerna sponsors several music festivals, none of which are targeted at youth. We go to great lengths to prevent youth attending, including requiring attendees to register online and provide their date of birth, and full ID checks at the entrance. PMI only sponsors events that are not directed at minors meaning that 75% or more of the audience need to be reasonably expected to be adults.

A

In Argentina Marlboro cigarettes were being promoted at festivals primarily targeted at young people including Lollapalooza and Rock at Baradero festivals in Buenos Aires. PMI cigarettes are promoted at beachfront nightclubs where PMI runs promotions for combinations of cigarettes and alcoholic drinks, eg a reduced price for a drink and a cigarette compared to just a drink

R

During 2019 Massalin Particulares was present at events such as Lollapalooza and Rock in Baradero (Events). On both occasions, a point of sale (POS) of tobacco products was implemented in strict compliance with national law 26,687 "Regulation of advertising, promotion and consumption of tobacco products" and with its Implementing Decree N° 602/2013 (Regulations).

Regulations prohibit the advertising of tobacco products except: inside POS or outlets of tobacco products or through direct communications addressed to individuals over eighteen (18) years old, provided their prior consent had been obtained and their age had been verified. Tobacco products' display is not prohibited nor regulated.

Even though Regulations do not prohibit minors accessing POS where tobacco products are sold, Massalin Particulares implemented an age verification gate so only adults over 18 could access the POS inside the Events. Those who were under the legal age were not admitted.

Regards marketing executions inside the POS located at the Events, Massalin Particulares only displayed tobacco products and engaged with legal aged smokers according to the Regulations. In addition Massalin Particulares placed a hospitality spot inside its POS for its adult guests, but no purchase of tobacco products was required to access to it. Lastly, Massalin Particulares never promoted its tobacco products associating them with alcoholic beverages.

3) PHILIP MORRIS INTERNATIONAL'S "NORMALIZATION PLAN"

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- Internal Philip Morris International (PMI) documents 2014 obtained by Reuters in 2017 reveal a 10-year "normalization" plan. Its objective was to "Establish PMI as a trusted and indispensable partner, leading its sector and bringing solutions to the table"

- The strategies and actions involved being "for something", establishing a "forward looking, motivational and credible" purpose statement.

- PMI strategized to "balance the debate" around nicotine by exposing "double standards" of anti-tobacco opponents and amplifying the voices of people supporting harm reduction rather than "prohibitionists"

- PMI strategized to build on existing and foster future, stakeholder relations with international organizations, politicians, NGOs, academics, scientists, researchers and the media, etc. to further expand communications and engagement opportunities.

- PMI strategized to make this "normalization" strategy a priority. Changing the company's reputation should be a key objective for senior staff and communications managers.

- PMI planned to hire company ambassadors to spread this narrative and represent Philip Morris International on issues beyond tobacco.

R

We are transitioning our Company, our industry, and the world away from cigarettes. Our communications and regulatory engagement strategy is completely and transparently aligned with this aim.

We understand the scepticism towards our industry and have become accustomed to vocal mischaracterizations of how we make our views known.

To be clear, we do not "interfere" with governments, we interact with governments.

Like every other business, governments meet with PMI to discuss a wide range of issues, such as taxation, international trade and product regulation. It's a basic element of policy making to allow multiple points of view. For example, when working on the FTC, the WHO had open hearings and received hundreds of submissions. There wasn't a rule that said, "All opinions welcome so long as you agree with us."

Governments make their own decisions.

Just because we interact with governments, does not mean that governments cannot act independently. Silencing those who disagree never makes sense and simply does not work. Open dialogue is the only way to solve a complex problem.

Decisions on the future of public health are often made behind closed doors without any public accountability or scrutiny. Where we are excluded, we work hard to ensure that our views are heard and we offer our opinions proactively.

To move forward in the best interests of public health and adult smokers, we believe that tobacco policies should continue to focus on keeping people from starting to smoke and on helping people quit. An essential third element is to ensure that adults who continue to smoke have access to, and information about, smoke-free products that are a much better choice.

4) EVIDENCE OF “NORMALIZATION” IN ACTION

A

PMI has increased its media appearances with executives appearing on prominent television and radio shows, advertising campaigns in major newspapers, funding of content with Vice (Change Incorporated) and Gay Star News and sponsorship of articles, videos and events with other publications.

R

PMI is committed to a smoke-free future in the UK and around the world. Not surprisingly we communicate to media about our vision, mission and purpose.

problem that smoking prevalence is high within the LGBTQ+ community, a fact highlighted in the Government’s Tobacco Control Plan for England.

In 2019, we sponsored a page on the Gay Star News website to cover a range of health issues which included the

We had no editorial control of the content created.

A

PMI has sought relationships with politicians. From 2017 - 2019 there was a PMI stand at the Conservative party conference, allowing the company to promote its messages to British politicians and their teams.

R

For many years the Conservative Party has a Conference where organisations, companies, charities can book space in an exhibition hall. For the past three Conferences, Philip Morris has booked

such a space, in order to share our ideas for achieving a smoke-free UK. For transparency, this stand was clearly attributed to Philip Morris.

A

In July 2018 PMI held an event in Westminster, sponsored by Scottish MP Ross Thompson, to present how it could work with MPs to “deliver a smoke-free future” and to provide new data it had analysed on the number of smokers in each constituency.

R

In 2019, Mr Ross Thomson MP sponsored a room booking in Parliament, which enabled us to hold a drop-in event for MPs.

The purpose of the event was to highlight the inequality in smoking prevalence across constituencies in Great Britain. The data are available on our public website: <https://www.smokefreefuture.co.uk/smokingmapofbritain/>

For transparency, the event was clearly attributed to Philip Morris Limited (PML).

A

PMI is a founding member of an industry group, the UK Vaping Industry Association (UKVIA), which funds an All Party Parliamentary Group on Vaping, giving PMI access to British politicians. UKVIA has called for a relaxation of the cap on nicotine strength after Brexit among other things.

R

PML is one of many members of UK Vaping Industry Association (UKVIA). We support their work to engage with a range

of stakeholders on policy issues, and we support their work with the wider vaping community

A

Some British researchers have reported an increase in requests to collaborate with PMI and appear at PMI-affiliated events

R

The Bureau of Investigative Journalism would not reveal the number of researchers or their identities and would not provide any facts relating to the increase (e.g. number of occasions) that

they have received requests to appear at PMI-affiliated events. Nor, has there been a timescale over which this allegation has alleged to happen. This is conjecture and not based on facts

A

Critics say the above points represent the normalization strategy in action

R

We are working to provide better alternatives to smoking, which is a well-recognized element of tobacco control. The negative characterization

of “normalization” misses the key point that the many people who will otherwise keep smoking should have access to such alternatives.

5) FOUNDATION FOR A SMOKEFREE WORLD

A

Critics call the Foundation a “front group” for PMI, working to further its interests

R

According to the WHO and other sources, a “front group” is one that masks or doesn’t properly disclose tobacco-company source. PMI’s financial support of the Foundation is crystal clear.

So this is simply untrue.

The Foundation for a Smoke-Free World is an independent, non-profit organization dedicated to reducing the

health impacts from smoking. 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 are precluded from having any influence over how the foundation spends its funds or focuses its activities. All inquiries about the Foundation’s activities should be directed to the Foundation.

A

The World Health Organization says the Framework Convention for Tobacco Control guidelines are explicit that governments should not accept financial or other contributions from the tobacco industry or those working to further its interests, such as the Foundation.

R

This misrepresents both the Foundation and the Framework Convention on Tobacco Control.

The Foundation for a Smoke-Free World is an independent, non-profit organization 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 are precluded from having any influence over how the Foundation

spends its funds or focuses its activities. All inquiries about the Foundation’s activities should be directed to the Foundation.

It is absolutely incorrect to suggest that the FCTC prohibits “contributions from the tobacco industry”. This is a frequent mischaracterization. Such a prohibition is not supported by the letter, nor the spirit, of the Treaty. Treaty guidelines, such as those referred to here, are non-binding, as the FCTC Secretariat has made clear:

“Guidelines constitute a non-binding instrument adopted by an international body to provide assistance to countries in addressing specific issues at the national or international level.” - FCTC Secretariat, January 2006 ([link](#))

A

Academics say Moira Gilchrist, PMI’s VP of Strategic and Scientific Communications approached them to sit on the Foundation’s board, calling into question its independence from PMI

R

The Bureau of Investigative journalism was unable or unwilling to specify to

which academics they refer to here and has withdrawn this allegation.

A

An analysis of the Foundation's tax returns reveals it has spent more on hiring PR and communications agencies than scientific research, leading to critics to say it performs a key communications function for PMI

R

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any influence over how the Foundation spends its funds or focuses its activities. 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 public record.

A

Critics say the Foundation is promoting PMI's rhetoric on harm reduction, "reduced risk" products and what the industry's role should be in science and policymaking without the listener/reader being aware that message is funded by PMI

R

The premise of the question is wrong. An element of tobacco control – including as the FCTC defines it – is that tobacco companies should develop less harmful alternatives.

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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 are precluded from having any influence over how the foundation spends its funds or focuses its activities. All inquiries about the Foundation's activities should be directed to the Foundation.

6) HEALTH CLAIMS AND POLICY AROUND IQOS

A

Critics question why, if PMI's stated desire to be part of the solution to smoking is genuine, its flagship product Iqos is a heated tobacco product, which offers less harm reduction than an e-cigarette.

R

Tobacco control aims to reduce the well documented health effects of smoking. Many public health authorities have acknowledged that it is the burning of tobacco that produces/releases that majority of the toxicants that cause smoking-related diseases.

Scott Gottlieb, M.D., then Commissioner of Food and Drug Administration (July 28, 2017) said: "Nicotine is by no means a completely safe and benign compound. But a family and population-focused approach to reducing tobacco-caused disease and death must start from the premise that, as far as nicotine is concerned, the problem isn't just the nicotine. The bigger problem is the delivery mechanism -- how the nicotine gets delivered. Attach it to smoke particles created by burning cigarettes and the mechanism is deadly (emphasis added). But attach the very same nicotine to a medicinal product without the other chemicals found in tobacco products and these therapeutic products have been found to be safe and effective by FDA in helping smokers quit. In fact, for nicotine replacement products such as gum, lozenges and patches, FDA doesn't even require a doctor's prescription for them."

PMI also recognizes that combustion and the production of smoke is the primary cause of smoking related disease, therefore is developing a portfolio of products that deliver nicotine without burning tobacco. Some of these products use heated tobacco and others do not

and are more similar to e-cigarettes. The idea is to maximize the number of current adult smokers that completely stop smoking, and therefore need products that are less harmful and satisfy adult smokers enough so that they completely abandon cigarettes.

The two principal categories of smoke free alternatives are heated tobacco, which makes up around 70% of the total international retail value of \$23 billion, and e-vapor at 30%, all based on our latest estimates. We also note that heated tobacco is growing faster than e-vapor, helped by the quality of consumer experience and consequent better rates of conversion away from cigarettes.

In keeping with this portfolio approach, we have commercialized e-cigarettes in parallel with IQOS for several years. We have recently announced that later this year we plan to launch the latest generation of e-cigarette products, IQOS Veev at scale in Europe.

Many adult smokers have used e-cigarettes to successfully stop smoking cigarettes, but many have not. For these smokers a product that more closely mimics the smoking experience (sensory, taste, ritual, etc.), may be an alternative that can help. What is most important is that adult smokers have access to a product that they are able to switch to and completely quit smoking cigarettes.

A

PMI's studies and independent studies agree that levels of 56 harmful and potentially harmful constituents (HPHCs) were lower in Iqos' emissions than in cigarette smoke. However an analysis by Neal Benowitz and colleagues published by the BMJ in 2018 shows levels of 56 other constituents which are not included in PMI's or the US FDA's list of HPHCs were higher in Iqos' emissions than cigarette smoke. The authors say the impact of these substances on the overall toxicity or harm of Iqos is not known. Other studies also show the presence of other chemicals in Iqos emissions whose long term health risks are unknown.

R

PMI conducted targeted assessments of the IQOS aerosol which specifically looked at the US FDA's list of HPHCs. In addition, PMI performed and submitted to the US FDA the results from a non-targeted differential screening of the IQOS aerosol. In this assessment over 80% of the compounds were confirmed by reference standards resulting in 99.7% of the total mass of IQOS aerosol being of known composition.

In the assessment 51 compounds were identified that were present at higher levels and 3 compounds that were unique in the aerosol of IQOS compared to the smoke of the reference cigarette. An evaluation for the likely origins of the constituents more abundant demonstrated that the majority are either: 1) flavors that are naturally found in cured tobacco or added to the tobacco, or 2) plant metabolites or 3) compounds that are the result of sugar (naturally present in tobacco) transformation upon heating. These results were expected since the IQOS variants are flavored, while the reference cigarette used for testing is not.

Of the compounds found that were unique to or in higher quantities than the smoke of the reference cigarette, we identified and reported 4 compounds of

potential toxicological concern. Based upon published inhalation toxicology literature, we determined that the level of exposure to these compounds through IQOS are below the level of toxicological concern.

The U.S. FDA reviewed all of this data, as well as performing its own tests on the product and in their technical review of the Premarket Tobacco Application (PMTA) for IQOS, they stated that the "aerosol contain some chemicals which are different from those found in combusted cigarettes". "Although some of the chemicals are genotoxic or cytotoxic, these chemicals are present in very low levels and potential effects are outweighed by the substantial decrease in the number and levels of HPHCs found in CC [conventional cigarettes]". ([link](#))

Further information can be found at:

<https://www.fda.gov/tobacco-products/advertising-and-promotion/philip-morris-products-sa-modified-risk-tobacco-product-mrtp-applications>

https://www.pmisience.com/resources/docs/default-source/news-documents/pmi-tpsac_final-sponsor-presentation.pdf?sfvrsn=15dcce06_4

A

The World Health Organization also maintains that there is no evidence to demonstrate that heated tobacco products or e-cigarettes are less harmful than conventional tobacco products and conclusions cannot yet be drawn about their ability to assist in quitting smoking

R

The WHO recently withdrew this statement.

IQOS is not a cessation product, and therefore not intended for, or marketed to, smokers who would like to quit nicotine and tobacco products all together. IQOS is designed for, and marketed to, 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 million IQOS users, of which over 70%—close to 10 million people—have stopped smoking cigarettes all together.

The totality of evidence available on IQOS supports 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 products in the US as modified risk tobacco products. Those applications remain pending with the FDA.

However, 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, “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 in the US does not mean that IQOS is safe, risk-free or “FDA approved.” All tobacco products are potentially harmful and addictive and those who do not use tobacco products should continue not to.

A

PMI says it is only targeting the world's 1.1 billion adult smokers with Iqos, but an [Italian study](#) found nearly half of people who had tried the product had never smoked.

R

Based on the data up to the end of 2019, we estimate that there are approximately 14 million IQOS users, of which over 70%—close to 10 million people—have stopped smoking cigarettes all together. According to the FDA's PMTA authorization of IQOS for commercialization in the US: "available data, while limited, also indicate that few non-tobacco users would be likely to choose to start using IQOS, including youth."

The research looked at a 3086-person sample of the Italian population aged ≥ 15 years, and then extrapolates the results from the sample (2009 never smokers, of which 20 had tried IQOS) to the entire population of 52.4 million despite the fact that the authors stated that one limitation of the study is "the relative small size that does not allow us to obtain stable prevalence estimates in subgroups".

This is further conflated by the fact that the study looked at ever-tryers and intention to try, without considering how many will actually start using the product on a regular basis.

To minimize potential biases and misinterpretations of the results from a study like this, it would be more appropriate to express the results as a percentage of the total sample size and indicate the level of precision by including confidence intervals for the various point estimates. And to continue to monitor the population overtime.

Despite the conclusion the results of the study suggest that IQOS is, in fact, more appealing to current adult smokers than to ex- and never smokers and these results are in line with PMI studies in the US that PMI submitted to the US FDA as part of their application. From which the US FDA concluded that the "available data, while limited, also indicate that few non-tobacco users would be likely to choose to start using IQOS, including youth"

Other Studies you should take into consideration to balance the reference to the study you cite include the following: PMI: presented the first 2 years of data from their cross-sectional survey ... The survey shows a fairly stable tobacco use prevalence, with the majority (~98.7%) of IQOS users transitioning from other tobacco products, primarily cigarettes. ([link](#))

Sutanto et al. data showed that the majority of HTP users are current and former cigarette smokers, with only 1.0% of HTP users who have never smoked cigarettes. (Int. J. Environ. Res. Public Health 2019, 16, 4630) ([link](#)).

TP (IQOS) store customers are predominantly current and former smokers, with the majority having quit smoking. A small minority are never smokers who do not subsequently initiate smoking. (Chest Volume 155, Issue 6, Supplement, June 2019, Page A387) ([link](#))

A

Critics say PMI's promise not to target non-smokers or teenagers is disingenuous. They argue if PMI's stated aim was achieved, and it convinced its customers to switch to Iqos without attracting any new ones, the company would go out of business once that generation of former smokers had died out. They say PMI's business model relies on young people beginning to use Iqos to create a new market. It also functions to prevent smokers from quitting but to continue consuming PMI products instead

R

For PMI, the long-term business opportunity is to convert adult smokers who would otherwise continue to smoke cigarettes to better alternatives. There are over 1 billion adult smokers worldwide. As of December 2019, we estimate IQOS is being used by close to 14 million legal-age smokers, with close

to 10 million of these fully converted and another 4 million in various stages of conversion. For e-cigarettes, there are around 40 million global users, of which we estimate fewer than 10 million are converted. The approximate total of 20 million converted users represents only 2% of the world's smokers.

A

Independent studies and PMI's own data shows that rather than completely switching from cigarettes to Iqos most people become "dual users" - both smoking and using Iqos. Experts say it is likely that these users do not receive any health benefits

R

This is inaccurate.

Based on data up to the end of 2019, we estimate that there are approximately 14 million IQOS users, of which over 70% have stopped smoking cigarettes all together.

PMI is clear that adult smokers who do not quit and would otherwise continue to smoke should fully switch to these products.

The FDA, commenting on PMI's data, said: "The toxicological and clinical studies do not show an increase in HPHC exposures when consumers are using both IQOS and [cigarettes] and, although the decreases are not statistically significant, some HPHC exposures appear to be decreased", but the "available evidence shows no increase in HPHC exposures for those who dual use".

A

Dr Reto Auer and colleagues set up a study to characterize Iqos emissions, and found many of the same chemicals found in regular cigarette smoke, and higher levels of other chemicals which may be harmful to health. He maintains that a process of pyrolysis, producing smoke, occurs during use of Iqos. He and his team maintain Iqos emits smoke, not vapour. He says PMI is "dancing around" the definition of smoke to avoid indoor smoking bans.

R

External authorities have reviewed the paper and concluded that the data published were not considered adequate for this comparison.

According to the FDA:

"The chemistry reviewers conducted a search of peer-reviewed literature and identified eight additional studies reporting results of chemical analyses of "heat-not-burn" tobacco products. The individual studies are described in the chemistry PMTA review. Auer et al.²⁷ compared the concentrations of eight volatile organic compounds (VOCs), 16 PAHs, three inorganic compounds, and nicotine in mainstream aerosol generated

at 330 °C in the IQOS system with Heatsticks and in mainstream cigarette smoke at 684 °C. **Although the results indicated significantly elevated levels of acenaphthene and formaldehyde in the IQOS product, the chemists concluded the data published by Auer et al. are not considered adequate for comparing the levels of HPHCs between the IQOS products and CC [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.**" (Premarket Tobacco Product Marketing Order, Technical Project Lead Review (TPL) April 30, 2019, p.21, emphasis added).

7) IQOS MARKETING

A

PMI has launched “try it for free” promotions across many countries. In the UK customers can try the device for just £10.

R

We are committed to helping those who would otherwise continue to smoke, to convert to smoke-free alternatives. For many smokers, switching to smoke-free alternatives represents a significant change in ritual, and to help overcome the barriers to switching, we provide them

the opportunity to ‘try before you buy.’ Under this programme, consumers pay for HEETS (tobacco sticks) and they are given the opportunity to use the device for a 14-day period. If they don’t return the device, they are charged the sales price.

A

Dr Robert Jackler, of Stanford University, has released a report documenting marketing of Iqos all over the world. The report documents Iqos’ use of brand ambassadors called coaches, models, influencers, events, parties, brand affiliations and stores to market the product.

Experts say it is clear from the contents of this report that Iqos is not being targeted at non-smoking adults, and is being targeted at the general population. They fear this means non-smokers could become addicted to a heated tobacco product, increasing their risk of smoking-related diseases.

R

You have admitted that this report has not been published although it seems you have a copy. You have refused to provide us with a copy of the report. It is not the practice of reasonable journalism to ask PMI to comment on your representation of this report’s contents when we have not been able to see the basis of these allegations, or any supporting facts or evidence.

Unnamed “experts” may make unsubstantiated comments on unpublished reports and responsible independent journalists should challenge this.

A

It was revealed in May 2019 that PMI was using models under the age of 25 - which it against its internal guidelines - and so it suspended its influencer

campaign. Yet Stanford researchers uncovered an Armenian account - @iqostyle.arm - which appears to be linked to PMI which has continued to use attractive young influencers posting about Iqos.

R

The @iqostyle.arm account is independent of PMI. PMI has nothing to do with it.

A

Gabriele Gzimailaite, a London-based blogger and Instagrammer with a following of more than 120,000, was paid and/or given travel and hospitality from PMI to promote Iqos. In her blog she says she is a social smoker. Experts said PMI should not be targeting social smokers as they may become more addicted by regularly using Iqos.

R

Gabriele Gzimailaite is a blogger. She was invited to several events, between 2017 and 2018. At this time, she identified as

a smoker. No fee or payment was given. Gabriele maintained full editorial control over any content she chose to publish.

A

Some of the Iqos advertising, in countries including Ukraine, Armenia, Italy and Japan, features young-looking models or posts featuring pastel-coloured Iqos' on a backdrop of cupcakes and

lipstick, appearing to target teenagers and young women. Experts fear young people who may not have smoked could begin using Iqos, raising their risk of smoking-related diseases and other health effects of nicotine on the developing brain.

R

This "fear" is unfounded and is clearly scaremongering.

According to a study conducted under a Japanese Ministry of Health research grant from 2017-2019, 0.1% of high-school students were daily users of heated tobacco products.

Children should not use our product or any other tobacco or nicotine and we do not market or sell the product to them.

A

Some advertising shows Iqos with surfers and runners, implying it is a product to suit healthy, outdoors-y lifestyles when in fact it has health risks for non-smokers.

R

This is a ridiculous assertion. Adult smokers run too. Adult smokers surf too. Adult smokers are "outdoorsy". In fact, adult smokers do all the things non-smokers do.

We make clear in our communications that IQOS is not risk free and addictive. IQOS is not a product for non-smokers.

A

PMI adapts its message for each country's culture and regulations. While in the US PMI is forbidden from claiming Iqos is a smoking cessation device, in Japan Iqos adverts make explicit health claims things like "Iqos

Spot: a place where you can use Iqos while quitting". A post from Iqos' Instagram page in Japan promotes Iqos as a way to avoid lung cancer, emphysema and myocardial infarction. Public health experts said PMI does not have the evidence to make this claim

R

The post you refer to is not connected with PMI or its affiliates. We did not make this claim.

A

PMI has already faced regulatory action due to its marketing of Iqos. In 2018 the UK Department of Health wrote to the company ordering it to take down posters in shop windows describing Iqos as "healthier" than cigarettes and hosting pop up displays at public events. In 2017 Russia's Moscow Federal Agency fined PMI for promotion of Iqos

R

The Department of Health (DoH) wrote to us regarding some of our posters displayed in shop windows. This was on the back of a Telegraph article in which our activities were described as, "marketing [IQOS] as a healthier alternative to cigarettes." This is not language used by PML and neither

featured in the posters.

In 2017 Moscow division of the Federal Antimonopoly Agency fined the local affiliate for using Internet banner ads leading to the IQOS website where heated tobacco sticks were sold. PM Russia is no longer using such banners.

8) PHILIP MORRIS INTERNATIONAL'S LOBBYING OUTSIDE THE UK

A

PMI has embarked on a global lobbying campaign to prevent Iqos from being banned and to ensure Iqos is taxed at a lower rate than cigarettes, including launching legal action in order to sell Iqos in Mexico. It lobbied senators of the Ways and Means committee in the Philippines for a tax band for Iqos that was 95% lower than cigarettes, which it claims is proportionate to the reduced risk. It has conducted meetings with government officials in Vietnam and also lobbied the Argentinian government (which has banned heated tobacco products) to lower the taxes on the Iqos device.

R

We are vocal and transparent: Products like e-cigarettes and heated tobacco products should not be banned. They should be regulated in a way that will allow adult smokers to have access to, and accurate information about them so they are encouraged to switch to them rather than continuing to smoke. In some countries, laws never really contemplated these innovative smoke-free alternatives, and this is the reason they can unintentionally constrain better consumer choice.

We advocate for appropriate, non-discriminatory and risk-proportional regulation in all product spheres including where taxation is concerned.

We are stakeholders with significant expertise and will continue to actively partake in democratic processes so our voice is heard.

We are just one stakeholder and can only hope that our arguments are heard and fairly and objectively assessed by those who make decisions.

Please take note that we do not claim that our products reduce risk by 95%, the new tax law in the Philippines differentiates tobacco products based on combustion, or the lack of it, and we commercialized IQOS in Mexico under existing applicable laws.

PHILIP MORRIS INTERNATIONAL'S LOBBYING IN THE UK

PMI supports the Government's commitment to make England smoke-free by 2030. To realise this ambition, millions of current adult smokers need to be persuaded to quit altogether or switch to less harmful alternatives. Critical to this will be putting in place a regulatory

framework that ensures adult smokers have the facts about alternatives and that tobacco companies are pushed to phase out cigarettes. We have made this point time and time again to MPs, civil servants, local councilors, journalists and the broader public.

A

In the UK PMI has offered to fund local authority smoking cessation services, which was rebuffed by then-health minister Steve Brine, who said he did not believe such a partnership would be "ethical" and deemed any further meeting with PMI as "inappropriate". Despite this, PMI has since contacted local authorities directly with its proposal.

R

PML made a clear commitment in a 2018 New Year advertisement (available [here](#)) to offer support to Local Authority cessation services where smoking rates are highest. This advert was placed in

three national newspapers. We followed up on this commitment by contacting the local authorities with high prevalence rates.

A

During a meeting with public health officials at the Royal Borough of Windsor and Maidenhead, PMI representatives discussed the possibility of doing some work around smoking cessation in schools. A PMI representative explained that having had "a couple of initial conversations with other councils", it was still "in the development stage of how a partnership could work."

R

A PML representative went to a meeting with officials from Windsor Council to get their perspective on the smoking issues in their community which need to be

prioritized. They told us what mattered to them and we relayed other experiences that other Councils are going through.

A

In email exchanges with officials at Burnley council, PMI shared images of a "quit/switch mobile cabin" and a PMI report on the role of heated tobacco in reducing smoking rates.

R

Burnley Council reached out to PML in response to our letter after our New Year advertisement. There was a meeting and as part of the follow up to this, a number of documents were requested, so we shared links to Public Health England

reports, our science (publically available) and reports we commissioned from Frontier Economics. We also included an early stage mock-up of a 'Quit/Switch' cabin.

A

In 2018, PMI claimed to have had more than 40 approaches at the Local Government Association

Conference, during some of which it was discussed potentially

“partnering to end smoking locally”.

It has also contracted C|T Group, a lobbying firm run by Sir Lynton Crosby, to contact local authorities on its behalf.

R

Yes. This was communicated in correspondence to Burnley Council. We are happy to share this information.

Yes, we tasked C|T Group to write to some local authorities reiterating PML's offer to engage.

A

In one letter, a C|T Group consultant said: “PML [Philip Morris Limited] are looking to meet with representatives from Local Authorities with the

responsibility for public health and smoking cessation services to explain what they are seeking to do and in what ways they can help to reduce smoking rates in local areas.”

R

Yes. As above, this was reiterating the offer PML had already made publicly.

A

Leaked internal emails show Philip Morris attempting to use this offer of local funding as a way to leverage weaker rules on advertising heated tobacco products.

R

Philip Morris supports the Government's commitment to make England smoke-free by 2030. To realise this ambition, millions of current smokers need to be persuaded to quit altogether or switch to less harmful alternatives. Critical to this will be putting in place a regulatory

framework that ensures smokers have the facts about alternatives and that tobacco companies are pushed to phase out cigarettes. We have made this point time and time again to MPs, civil servants, local councilors, journalists and the broader public.

A

PMI funded a Westminster reception in September 2019 hosted by Public Policy Project, an advisory firm run by former Conservative health minister Stephen Dorrell. It was not disclosed to attendees, which included local authority public health chiefs, stop smoking officials and NHS staff, that the event was sponsored by PMI

and attended by its lobbyist James Barrow. By not disclosing PMI's sponsorship of the event, public health officials attending unwittingly breached article 5.3 of the World Health Organisation's Framework Convention on Tobacco Control, which ensures policies are protected from commercial and other vested interests of the tobacco industry.

R

The event was organized by Public Policy Projects (PPP). They have told us that Philip Morris' sponsorship of the reception was made clear to anyone interested in attending, ahead of the event.

A

Philip Morris has been accused of running a secretive campaign around the world to block or weaken provisions in the treaty, which is designed ultimately to protect public health and save lives. According to a 2014

internal Philip Morris document, previously reported on by Reuters in 2017, the company sees it as a “regulatory runaway train” driven by “anti-tobacco extremists”.

R

It is absurd to call our campaigning for a smoke-free future “secretive”. We are open about our science, our communications and our ambition to replace cigarettes with better smoke-free alternatives.

Regarding the treaty, we believe that open dialogue is the only way to solve a complex problem. Decisions on the future of public health are often made behind closed doors without any public accountability or scrutiny. Where we are excluded, we work hard to ensure that our views are heard and we offer our opinions proactively.