



American
Heart
Association.



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Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

RE: Docket No. FDA-2017-D-3001, “Modified Risk Tobacco Product Applications for IQOS system with Marlboro HeatSticks, IQOS system with Marlboro Smooth Menthol HeatSticks, and IQOS system with Marlboro Fresh Menthol HeatSticks submitted by Philip Morris Products, S.A.”

The undersigned public health organizations submit these comments on the above-listed tobacco product modified risk applications submitted for the IQOS heated tobacco product system. See 83 Fed. Reg. 66282 (December 26, 2018). The subject applications should be denied for the reasons detailed in these comments.

I. SUMMARY OF REASONS THE IQOS APPLICATIONS SHOULD BE DENIED

Philip Morris International (“PMI”) has submitted applications under Section 911(g) of the Federal Food, Drug, and Cosmetic Act requesting a marketing order under both Section 911(g)(1) (risk modification order) and Section 911(g)(2) (exposure marketing order) for its Tobacco Heating System, marketed as IQOS with three different variants: Marlboro HeatSticks, Marlboro Smooth Menthol HeatSticks, and Marlboro Fresh Menthol HeatSticks. PMI proposes to make the following claims for these products:

“Switching completely from cigarettes to the *iQOS* system can reduce the risks of tobacco-related diseases”.

“Switching completely to *iQOS* presents less risk of harm than continuing to smoke cigarettes”.

“Switching completely from cigarettes to the *iQOS* system significantly reduces your body’s exposure to harmful and potentially harmful chemicals”.

The statute permits FDA to grant this application only if it determines that PMI “has demonstrated that [these products] as . . . actually used by consumers, will

(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and

(B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

The applications should be denied for insufficient evidence on the impact of the marketing of IQOS with modified risk claims on the increased likelihood of initiation of tobacco use by non-users, particularly youth.

- No accurate assessment of the impact on the health of the population as a whole can be made without consideration of actual data derived from studies of the perceptions of persons under age 18.
- Despite the fact that the modified risk claims PMI proposes to make could increase youth initiation of tobacco usage, PMI did not present these claims to persons under age 18 to determine how they would understand such claims.
- PMI failed to conduct any study of the effect of such claims on persons under 18 despite FDA’s draft guidance that expressly recommended that applicants present human studies that evaluate consumer perception of the product, including its labeling, marketing and advertising, and that are designed to determine the likelihood that consumers who have never used tobacco products, *particularly youth and young adults*, will initiate use of the product. (emphasis added)
- PMI’s proposed substitute for actually studying the perceptions of persons under the age of 18—oversampling of young adults—provides absolutely no evidence of how such claims actually affect the perceptions of persons under the age of 18.
- FDA cannot legally conclude on the record before it that the modified risk claims PMI proposes to make meet the statutory standard set forth in Section 911 and the grant of any application on this record would be arbitrary and capricious and an abuse of discretion.
- In light of the current epidemic of youth usage of products perceived to be “less harmful” than cigarettes, the grant of these applications in the absence of any direct examination of the actual perception of underage users would set a precedent disastrous for the public health.

PMI has submitted insufficient evidence that its marketing will target only adult smokers, particularly in light of its marketing of IQOS abroad, which reaches youth.

- PMI failed to provide a complete marketing plan that would permit FDA to determine how the products would be marketed in the United States.

- PMI's marketing of IQOS outside the United States demonstrates that the product has been marketed to attract underage users.
- PMI's use of social media based outside the United States has already reached U.S. consumers, including youth, despite the absence of a marketing order.
- Marlboro-branded HeatSticks may increase the risk of youth use.

The applications should be denied because PMI did not provide research on the impact of marketing menthol IQOS products with the proposed modified risk claims on the African-American population and youth.

- Two of the three products that are the subjects of this application are menthol flavored. A highly disproportionate share of African-American smokers use menthol cigarettes and a highly disproportionate share of smoking-related disease among African Americans is the result of menthol cigarettes. A highly disproportionate share of the advertising and marketing for menthol cigarettes targets African Americans.
- The failure of PMI to provide a complete marketing plan for the products that are the subject of these applications prevents FDA from evaluating the effect of such marketing on the African-American community.
- Similarly, menthol cigarettes contribute a disproportionate share of youth initiation and tobacco use. The failure of PMI to provide a complete marketing plan for these products prevents FDA from evaluating the effect of such marketing on youth initiation and usage of tobacco products.

The applications should be denied because the evidence indicates that the marketing of IQOS with modified risk claims will lead to greater dual use with cigarettes instead of leading substantial numbers of smokers to switch completely to IQOS.

- Health benefits to individual smokers occur only if smokers completely quit smoking. Dual use of cigarettes and other tobacco products does not produce a significant health benefit. PMI has failed to provide adequate evidence that smokers are likely to switch completely to IQOS rather than engage in dual use of cigarettes and IQOS.
- PMI's own studies show a likelihood that granting the application was more likely to increase dual use of cigarettes and IQOS than to cause smokers to switch completely.
- After evaluating the evidence, TPSAC determined that granting the application was more likely to increase dual use of cigarettes and IQOS than to cause smokers to switch completely.

The application should be denied because there exists considerable doubt about the extent of individual health benefits from complete switching from cigarettes to IQOS.

- FDA’s own preliminary analysis of the data submitted in this application does not demonstrate that smokers who switch from cigarettes to IQOS experience a significant health benefit.
- Independent research studies do not support the conclusion reached by PMI’s internal studies that there would be substantial health benefits to individuals from switching from cigarettes to IQOS.
- TPSAC determined that PMI had not shown that the reduction in exposure to HPHCs attributable to smokers’ switching to IQOS was “reasonably likely to translate to a measurable and substantial reduction in morbidity and/or mortality.”
- The available evidence indicates that reduced exposure claims for IQOS are likely to be misinterpreted as reduced risk claims.

II. SUMMARY OF STATUTORY MODIFIED RISK STANDARDS

The IQOS applications are governed by the standards set out in Section 911 of the Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act of 2009 (Section 911). Section 911 was enacted as a response to the tragic history of false and misleading tobacco industry claims that certain tobacco products were less dangerous than other products that persuaded health-conscious smokers to switch to the “reduced risk” products instead of quitting altogether.

In enacting the Tobacco Control Act, Congress made specific findings about the potential harm to public health from modified risk claims that should guide FDA in its consideration of any modified risk product application. Congress found that “unless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial harm to the public health. . . .” Sec. 2(37). Congress also found that “the dangers of products sold or distributed as modified risk tobacco products that do not in fact reduce risk are so high that there is a compelling governmental interest in ensuring that statements about modified risk products are complete, accurate, and relate to the overall disease risk of the product.” Sec. 2(40). Congress determined that it is “essential that manufacturers, prior to marketing such products, be required to demonstrate that such products will meet a series of rigorous criteria, and will benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products.” Sec. 2(36).

Under the Tobacco Control Act, a “modified risk tobacco product” is defined as a tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related

disease associated with commercially marketed tobacco products. A product is “sold or distributed” for such a use if, in relevant part,

- (1) [its] label, labeling, or advertising, either implicitly or explicitly [represents] that
 - (i) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;
 - (ii) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or
 - (iii) the tobacco product or its smoke does not contain or is free of a substance, or
- (3) . . . the tobacco product manufacturer has taken any action directed to consumers through the media or otherwise, other than by means of the label, labeling, or advertising. . . that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or its free of, a substance or substances.

Thus, a modified risk product is defined in terms of the manufacturer’s claims of reduced risk or reduced exposure in marketing the product, as well as its actions that may suggest to consumers that a product reduces risk or exposure to hazardous substances.

Under §911(g)(1), the burden is on the applicant seeking an order allowing the marketing of the product with a modified risk claim to demonstrate that the product “*as it is actually used by consumers* will (A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (B) benefit the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.” (emphasis added).

Sec. 911(g)(4) further requires FDA to take into account the following specific empirical factors in determining whether the (g)(1) standard has been met:

- (A) The relative health risks to individuals of the tobacco product that is the subject of the application;
- (B) The increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the tobacco product that is the subject of the application;
- (C) The increased or decreased likelihood that persons who do not use tobacco products will start using the tobacco product that is the subject of the application;

(D) The risks and benefits to persons from the use of the tobacco product that is the subject of the application as compared to the use of products for smoking cessation approved under chapter V to treat nicotine dependence.

Thus, FDA must consider not only the effects of the asserted modified risk product on those who use it, but also its population-wide impact on tobacco use initiation, cessation and relapse, including an assessment of the likelihood that smokers would actually switch to the modified risk product. It is not enough for an applicant to show that the product is less hazardous to users than other tobacco products; in order for a modified risk application to be granted, the applicant is required to show that the benefits of risk reduction (considering the likelihood of smokers completely switching to the modified risk product) outweigh the risks of increased initiation or diminished cessation. In short, the statute requires FDA to make scientific judgments not only about the physical effect of the product's use, but also about the likely responses of potential consumers (both smokers and non-smokers) to the product's marketing as a modified risk product.

III. RELEVANT HISTORICAL BASIS FOR SECTION 911

FDA's application of the statutory standards set out in Section 911 must be mindful of the historical context that led Congress to enact those standards, particularly with respect to the PMI application for IQOS.

The provisions of Section 911 were enacted in response to a massive evidentiary record of fraudulent health and "reduced risk" claims made by tobacco product manufacturers over the course of more than fifty years. Those claims caused millions of Americans to initiate cigarette smoking who otherwise would not have done so and caused millions of American smokers to continue smoking when they otherwise would have quit. In the absence of this massive industry fraud, literally millions of deaths, and untold suffering, would have been avoided.

The voluminous evidence of the industry's use of these false health-related claims was presented to the United States District Court for the District of Columbia in *United States v. Philip Morris, U.S.A., Inc.*¹ and furnished critical support for the court's conclusion that the defendant tobacco companies had engaged in a conspiracy to defraud the American public so massive as to constitute racketeering under federal law. A central component of the fraud was the representation of "light" and "low-tar" cigarettes as safer than other cigarettes, when the companies knew, as actually used by smokers, such cigarettes were no less hazardous. The court found:

Even as they engaged in a campaign to market and promote filtered and low tar cigarettes as less harmful than conventional ones, Defendants either lacked evidence to substantiate their claims or knew them to be false. Indeed, internal

¹ 449 F. Supp.2d 1 (D.D.C. 2006), *aff'd in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009), *cert. denied*, 130 S.Ct. 3501 (2010).

industry documents reveal Defendants' awareness by the late 1960s/early 1970s that, because low tar cigarettes do not actually deliver the low levels of tar and nicotine which are advertised, they are unlikely to provide any clear health benefit to human smokers, as opposed to the FTC smoking machine, when compared to regular, full flavor cigarettes.²

It is worth noting that applicant PMI³ was, at the time of the court's ruling, a subsidiary of Philip Morris Companies, Inc. (now Altria), a defendant in the *Philip Morris* case and, as such, a subject of the court's conclusion that the defendants had violated civil racketeering laws in perpetrating decades-long fraudulent conduct that included the "light" and "low-tar" fraud. Indeed, defendant Altria will be the exclusive distributor of the IQOS product in the U.S.⁴

In addition to enacting safeguards against future claims of reduced risk or exposure, Section 911 also specifically prohibits the use of the descriptors "light," "mild," "low" or similar terms in the absence of an order from FDA finding that the requirements of Section 911 have been met. However, tobacco companies, including Philip Morris, began using color-coding schemes to evade the statute's restrictions and terms like "gold" and "silver" have replaced "light" and "ultra-light." For example, consumers who previously smoked Marlboro Lights were told that they could now purchase "Marlboro Gold" and "Marlboro Silver."⁵ Philip Morris placed notes on packs of Marlboro Lights reading "Your Marlboro Lights package is changing, but your cigarette stays the same" and directing customers to "in the future, ask for Marlboro in the gold pack."⁶ Indeed, in rejecting industry arguments that the restrictions on these descriptors in Section 911 render unnecessary the corrective statements ordered by the District Court as a remedy for the Racketeer Influenced and Corrupt Organizations Act (RICO) violations of the major cigarette companies, the U.S. Court of Appeals for the D.C. Circuit specifically noted Altria's use of packaging colors to continue to mislead consumers.⁷

The District Court found the corrective statements remedy necessary because the defendants, including Altria, were likely to continue their fraudulent conduct into the future. It therefore ordered them to sponsor the corrective statements as a remedy to deter such fraud, in newspapers, on television, on company websites and on package inserts, including this statement to remedy the "light" and "low-tar" fraud:

² *Id.* at 430-31.

³ Although the applications refer to Philip Morris Products S.A. as "the MRTP applicant," the applications also refer to PMI as an entity which includes Philip Morris Products S.A. and use the designation PMI throughout. Therefore, these comments will refer to PMI as the applicant.

⁴ LaVito, A, "Philip Morris outlines its plan for IQOS' introduction in the US," *CNBC*, November 2, 2017, <https://www.cnbc.com/2017/11/02/philip-morris-outlines-its-plan-for-iqos-introduction-in-the-us.html>.

⁵ Wilson, D, "Coded to Obey Law. Lights Become Marlboro Gold," *New York Times*, Feb. 18, 2010.

⁶ Wilson, D, "FDA seeks explanation of Marlboro Marketing," *New York Times*, June 17, 2010.

⁷ *U.S. v. Philip Morris USA Inc.*, 786 F.3d 1014,1024 (D.C. Cir. 2015).

A federal court has ordered Altria, R.J. Reynolds Tobacco, Lorillard, and Philip Morris USA to make this statement about low tar and light cigarettes being as harmful as regular cigarettes.

- Many smokers switch to low tar and light cigarettes rather than quitting because they think low tar and light cigarettes are less harmful. They are **not**.
- “Low tar” and “light cigarette smokers inhale essentially the same amount of tar and nicotine as they would from regular cigarettes.
- **All** cigarettes cause cancer, lung disease, heart attacks, and premature death – lights, low tar, ultra lights, and naturals. There is no safe cigarette.

After years of litigation and other delaying tactics by the defendants, including Altria, these corrective statements have now appeared in newspapers and on television, as well as being set forth in inserts on cigarette packs. They serve as reminders of the history of false claims of “reduced risk” products by the tobacco companies, including PMI’s former affiliates and its intended IQOS U.S. distributor. In light of that history, particularly the finding by a federal court that Altria and the other RICO defendants are likely to continue their fraudulent conduct, making corrective statements necessary as an antidote to that fraud, FDA should ensure that the statutory standards, enacted by Congress to prevent a similar public health disaster from ever repeating itself, are rigorously applied to PMI’s IQOS applications.

IV. THE APPLICATIONS SHOULD BE DENIED FOR INSUFFICIENT EVIDENCE ON THE IMPACT OF THE MARKETING OF IQOS WITH MODIFIED RISK CLAIMS ON THE INCREASED LIKELIHOOD OF TOBACCO USE INITIATION BY NON-USERS, PARTICULARLY YOUTH

As noted above, in evaluating the IQOS modified risk applications, FDA is required to determine whether granting the applications will lead to an “increased or decreased likelihood” that non-users of tobacco products will initiate use of IQOS or some other tobacco product. Because initiation of tobacco products typically occurs when users are young, it is particularly important for FDA to assess the likelihood that the marketing of IQOS and HeatSticks with modified risk claims will lead to initiation by young people. Because PMI’s applications offer no evidence of youth perception of the proposed modified risk claims, they should be denied on that ground alone.

- A. The current epidemic of youth usage of e-cigarettes underscores the importance of requiring that PMI present evidence that there is little risk of youth initiation from marketing IQOS with modified risk claims

Although IQOS is not an e-cigarette, and has not yet been authorized to be marketed in the U.S., FDA’s consideration of the IQOS modified risk applications must take into account the implications of the on-going crisis of youth e-cigarette use.

FDA is considering these applications at a time when both the Commissioner of the FDA,⁸ and the Surgeon General of the United States,⁹ have declared that e-cigarette use by the young has reached “epidemic” proportions. Data from the National Youth Tobacco Survey shows that, among high school students, current e-cigarette use increased from 1.5 percent (220,000 students) in 2011, to 20.8 percent (3.05 million students) in 2018. Indeed, e-cigarette use among high school students rose a remarkable 78 percent from 2017-2018. The growing use of e-cigarettes has now reached middle school kids as well, increasing from 0.6 percent in 2011 (60,000 students) to 4.9 percent (570,000 students) in 2018, with a 43 percent increase from 2017-2018 alone.¹⁰

There is little doubt that the current epidemic of e-cigarette use among teens is largely the result of the extraordinary appeal to this age group of JUUL, an e-cigarette with a high-tech design that resembles a USB flash drive. In a rare advisory issued in December of last year, U.S. Surgeon General Jerome Adams cited JUUL as “a new type of e-cigarette” that “has become increasingly popular among our nation’s youth,” citing its 600 percent surge in sales during 2016-2017, giving it the greatest market share of any e-cigarette in the U.S. by the end of 2017, as the epidemic of e-cigarette use among kids began to take hold. The current e-cigarette youth epidemic demonstrates that there is a serious risk that new products like IQOS, marketed as modified risk products, may attract significant usage among young people, many of whom may never have used a tobacco product. In particular, a new study of U.S youth found significantly high levels of awareness, interest in trying, and susceptibility to trying IQOS among experimental, former, and current vapers, compared to never vapers.¹¹

Thus, it is critical that FDA require substantial evidence that the marketing of IQOS as a modified risk product would not lead to increased youth initiation of tobacco products before it grants the application.

⁸ Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency’s continued efforts to address growing epidemic of youth e-cigarette use, including potential new therapies to support cessation, November 2, 2018.

⁹ Surgeon General’s Advisory on E-Cigarette Use Among Youth, December 18, 2018 (SG Advisory).

¹⁰ U.S. Centers for Disease Control and Prevention (CDC), “Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students—United States, 2011-2018,” *Morbidity and Mortality Weekly Report (MMWR)*, 67(45):1276-1277, November 16, 2018, https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm?s_cid=mm6745a5_w. Current use defined as any use in the past month.

¹¹ Czoli, CD, et al., “Awareness and interest in IQOS heated tobacco products among youth in Canada, England and the USA,” *Tobacco Control*, Published Online First, doi:10.1136/tobaccocontrol-2018-054654, January 29, 2019 (Czoli, CD, et al.).

B. Without justification, PMI has failed to present evidence on youth perception of the IQOS modified risk claims

FDA should reject PMI's applications because they provide no data whatsoever on youth perceptions of IQOS and no evidence regarding the potential for adolescent use. No accurate assessment of the impact on the health of the population as a whole can be made without consideration of actual data derived from studies of the perceptions of those under age 18. The total absence of data on youth perception of IQOS should—standing alone—preclude granting PMI's applications. Indeed, the grant of these applications in the absence of that data would set the worst possible precedent and be wholly inconsistent with FDA's statutory mission to protect the public health.

As noted above, FDA's assessment of an MRTP application must consider the population-wide impact of the product on both users and non-users of tobacco products, which includes its impact on tobacco use initiation. Despite the fact that the effect of modified risk claims on underage users must be a central focus of FDA's evaluation of an MRTP application, PMI's MRTP applications provide no evidence whatsoever on the impact of the modified risk claims made for IQOS on adolescent risk perception or adolescent use of tobacco products. PMI seeks to explain the absence of such data by the conclusory statement that "PMI internal policy prohibits the conducting of studies relating to tobacco products, which involves under legal age of smoking, a policy that is consistent with recommendations from the FDA."¹²

This statement is based on a misreading of FDA's Draft Guidance for the preparation of Modified Risk Tobacco Product Applications. As that draft guidance makes clear, FDA requires only that "all study subjects *receiving tobacco products* are current daily tobacco product users at least 21 years of age"¹³ (emphasis added). Not only is this limitation not applicable to studies of promotional material such as modified risk claims to determine the effect of such materials on adolescent risk perception or interest in using the product, but the draft guidance makes clear that inclusion of the effect on adolescent perception should be an essential feature of such studies. The draft guidance states:

To address the effect of the MRTP on tobacco use initiation, FDA recommends that applicants submit:

- Human studies that evaluate consumer perception of the product, including its labeling, marketing and advertising.

These studies should be designed to provide evidence regarding the likelihood of population benefit or harm from the proposed product, including...:

¹² PMI, Sec. 2.7, at 126.

¹³ FDA, Draft Guidance, Modified Risk Tobacco Applications, March 2012, at 29 (FDA 2012 Draft Guidance).

- The likelihood that consumers who have never used tobacco products, *particularly youth and young adults*, will initiate use of the tobacco product,¹⁴ (emphasis added)

Moreover, the draft guidance instructs companies to “estimate the attributable risk of all of the various health effects for various types of individuals in the U.S. population, as well as the total number of individuals of each type.” The draft guidance goes on to state, “The types of individuals may include, but are not limited to, the following ... Non-users who initiate tobacco use with the proposed product, *such as youth*, never users, former users” (emphasis added).¹⁵

Thus, far from prohibiting the testing of such messages on adolescents, the FDA draft guidance characterizes such testing as particularly important. In this light, PMI’s failure to provide any evidence of the effect of these messages on adolescent risk perception is an inexplicable omission that ignores FDA’s specific instruction to include that analysis.

Contrary to PMI’s assertion that FDA’s policy precludes research regarding consumer perception of youth, FDA’s draft guidance on MRTP applications describes how such research should be done. Recognizing that research among non-smokers, and non-smoking youth in particular, requires care, FDA offered applicants an opportunity to work with the agency to determine the best way to conduct studies involving youth:

When designing consumer perception studies, applicants should take care that the studies themselves do not promote use of the product, particularly among vulnerable populations, such as youth, non-users of tobacco products, and pregnant women. FDA recommends that applicants meet with FDA to discuss research plans before embarking on research with vulnerable populations. Section IX.B of this guidance provides information on requesting a meeting with FDA.¹⁶

PMI’s decision not to assess the impact of the marketing of IQOS on youth also contravenes recommendations made by the Institute of Medicine’s (IOM) 2012 report, *Scientific Standards for Studies on Modified Risk Tobacco*, which recommended that “FDA should require studies to include populations of special relevance, including (but are not limited to) ... adolescents”¹⁷ and included an assessment of the effects on youth as “an essential element in establishing the public health benefit of an MRTP.”¹⁸ The report included research on adolescents in three of its “Evidence domains relevant to an MRTP application.”¹⁹ The need to consider the effects of promotional statements on youth is vitally important in light of the

¹⁴ *Id.* at 20.

¹⁵ *Id.* at 22.

¹⁶ *Id.* at 26.

¹⁷ Institute of Medicine, *Scientific Standards for Studies on Modified Risk Tobacco Products*, December 2011, at 14 (IOM report).

¹⁸ IOM report, at 50.

¹⁹ IOM report, at 7 (Summary).

industry’s documented history of marketing tobacco products in ways that attract adolescents and the role that youth initiation has played—and continues to play—in the recruitment of long-term adult smokers.²⁰

According to IOM, perceptions of and intentions to use a given MRTP are also likely to differ by age group. Thus, IOM noted that it is “critical that studies include participants in the following age groups: children (\leq 12 years old), adolescents (13–17 years old), young or emerging adults (18–25 years old), adults (\geq 25 years old).”²¹ As noted by IOM, “adolescents’ perceptions of the risks and benefits of cigarette smoking play an important role in adolescents’ decisions to smoke. Given that adolescence is a period of heightened vulnerability for the initiation of tobacco use, it is important to evaluate whether adolescents accurately understand the purported benefits of an MRTP. Of particular importance are adolescents’ perceptions of the risks and benefits of using the product, and whether they intend to initiate tobacco use with the MRTP rather than a traditional tobacco product because they believe the former is a “safe” alternative.”²²

Similarly, the IOM report detailed ideas for how research on youth perceptions of risk of MRTPs can be conducted consistent with ethical standards of research.²³ For example, IOM suggests that such research could be appropriately done under the supervision of an independent third party.²⁴ Such a procedure would make it possible for an applicant to develop evidence regarding the effect of the marketing of a product on this population. IOM noted that, “Survey research or perception/messaging research among non-smokers is acceptable where the non-smokers are not being exposed to the product.”²⁵ Even in the case of studies that include exposure to a particular tobacco product among non-users (which is not critical in this case), IOM concluded, “Experimental research that exposes non-users to products is ethically problematic; but such research cannot completely be ruled out because it could provide critically valuable information. The ethics, risks, and benefits need to be determined on a case by case basis.”²⁶

Despite the express instructions in FDA’s draft guidance on the preparation of modified risk applications, the extensive discussion in the IOM report on how research on youth risk perception could appropriately be conducted, evidence of high rates of youth usage of IQOS in Japan,²⁷ and an explosion of youth usage of e-cigarettes in the United States in 2018, PMI has

²⁰ U.S. Department of Health and Human Services (HHS), *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012, at 530-41, 603-27 and sources cited therein (2012 Surgeon General’s Report); *U.S. v. Philip Morris*, 449 F. Supp. 2d, at 561-691.

²¹ IOM report, at 174.

²² IOM report, at 165.

²³ IOM report, at 10.

²⁴ IOM report, at 57.

²⁵ IOM report, at 52.

²⁶ IOM report, at 52-53.

²⁷ Tabuchi, T, et al., “Awareness and use of electronic cigarettes and heat-not-burn tobacco products in Japan,” *Addiction* 111:706-713, 2015.

submitted applications that ignore the effects of the proposed modified risk claims on youth and provides a disingenuous rationale for doing so. Applications that present no evidence on the effect of modified risk claims on youth initiation or perception of risk cannot possibly meet the public health standard.

PMI purports to justify its refusal to provide such data by citing FDA's responses to questions submitted in 2013.²⁸ Although FDA erred in not stating categorically that PMI's applications would not be granted in the absence of the submission of data based on reliable surveys of the perceptions of youth—data clearly called for in FDA's draft guidance for the submission of MRTP applications—nothing in FDA's responses indicates that FDA intended to discourage PMI from submitting such data; on the contrary, FDA's responses invited PMI to consult with it on how such studies could best be formulated and conducted but PMI failed to take advantage of this opportunity.

Moreover, although FDA improperly failed to state that it would categorically reject an application that lacked data derived directly from a study of the perceptions of youth under 18 years it did so only on the basis that in some cases evidence about such perceptions could conceivably be inferred from studies of young adults in the 18-25-year old cohort.²⁹ FDA's statement contemplates that an applicant seeking to take advantage of such inferences must persuasively demonstrate how the information concerning young adults could adequately substitute for the lack of direct evidence regarding the perceptions of youth under 18 and what adjustments would have to be made in the information presented for such inferences to constitute an acceptable substitute for direct evidence. PMI has not even attempted to provide any such rationale or to explain what inferences it draws or why such inferences are valid beyond a vague statement that young adult populations were oversampled in their surveys. Such an oversampling does nothing to support a reliable inference that the results reflect the perceptions of the under-18 population. No application so utterly devoid of evidence regarding the effect of modified risk claims on a critically important segment of the population should be granted. Having decided to take the risk of submitting an application devoid of evidence on one of the most crucial issues, PMI cannot legitimately complain if its applications are found deficient.

FDA should have responded to PMI's questions by stating directly that no MRTP application could be granted in the absence of direct evidence about youth perception of the proposed modified risk claims based on an actual survey of people in the target age group. Such a response would have been consistent with FDA's own draft guidance on the preparation of MRTP applications and with the extensive examination of this issue by the Institute of Medicine. Nevertheless, nothing in the responses FDA provided indicated in any way that FDA would approve an application devoid of evidence about youth perception or the impact on youth. It

²⁸ PMI, Response to November 22, 2017 Information Request, submitted as part of PMI's amended application, at 48-50.

²⁹ PMI, Response to November 22, 2017 Information Request, submitted as part of PMI's amended application, at 48-50.

would be arbitrary and capricious for FDA to grant these defective applications on the record presented and no such action could withstand judicial scrutiny if FDA were so unwise as to do so.

C. Marketing IQOS with modified risk claims is likely to led to youth initiation of tobacco products.

Not only did PMI fail to include a study of youth perception of its modified risk claims, but it also failed to provide a review of existing literature regarding youth e-cigarette or other tobacco use in the U.S. Nor did it examine data on youth use in countries where IQOS is already being used. Like IQOS, e-cigarettes are high-tech, marketed as alternatives to cigarettes, available in flavors, and the devices are attractively designed. E-cigarettes are also the most popular tobacco product used by youth after rapid growth in just the ten years that it has been on the market in the U.S.,³⁰ and research shows that adolescents' perceptions about the health risks of the products are tied to initiation and use.

Even though no e-cigarettes have been the subject of an MRTP order, there is no doubt that many users, including young users, perceive these products as safer than cigarettes and that this perception has contributed to their widespread use.³¹ Data from the 2016 National Youth Tobacco Survey found that, among middle and high school students who were current e-cigarette users, the phrase, “[t]hey are less harmful than other forms of tobacco, such as cigarettes” was the fourth most commonly cited reason to use e-cigarettes, and the third most common reason among middle and high school ever users of e-cigarettes.³² In other comments submitted to this docket, researchers highlighted studies that show that youth perceptions of reduced harm from e-cigarettes compared to cigarettes are linked to starting and using e-cigarettes. The comments state, “Despite studies showing negative health effects of e-cigarettes, adolescents report believing that e-cigarettes are safer than cigarettes, can help people quit smoking conventional cigarettes, and contain none or just limited amounts of nicotine. Adolescents also consider e-cigarettes to be trendier, more prevalent, and more acceptable than conventional cigarettes. Adolescents who have used e-cigarettes have reported the lowest perceptions of harm and more positive attitudes regarding e-cigarettes.”³³ Thus, based on the on-going experience with e-

³⁰ CDC, “Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students—United States, 2011-2018,” *MMWR*, 67(45):1276-1277, November 16, 2018, https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm?s_cid=mm6745a5_w. Current use defined as any use in the past month.

³¹ Amrock, SM, et al., “Perceptions of e-Cigarettes and Noncigarette Tobacco Products Among U.S. Youth,” *Pediatrics* 138(5), doi: 10.1542/ped.2015-4306, 2016.

³² Tsai, J, “Reasons for Electronic Cigarette Use Among Middle and High School Students — National Youth Tobacco Survey, United States, 2016,” *MMWR* 67(6):196-200, February 16, 2018.

³³ Comments by Halpern-Felsher, B, et al., Docket No. FDA-2017-D-3001, tracking number 1k1-908n-holz. “The evidence cited in PMI’s MRTP Application indicates that the proposed labeling and warnings for IQOS will mislead consumers, particularly youth, about the product,” December 8, 2017, available at <https://www.regulations.gov/document?D=FDA-2017-D-3001-0149>.

cigarettes alone, there is substantial reason to believe that a reduced risk message for IQOS would make those products more attractive to youth.

Beyond the likely perceptions of the proposed modified risk messaging, the products themselves have many of the elements that attract youth. As outlined in a recently published study, the product packaging, sleek design, and IQOS stores resemble products that are attractive to youth.³⁴ The packaging looks very similar to iPhone packaging, just as the IQOS stores are structured and designed like Apple stores or Microsoft stores. The IQOS device looks high-tech and fashionable, and could be easily concealed, like JUUL e-cigarettes, the product, as noted previously, that has spurred the dramatic growth in youth e-cigarette use. As the authors of a recent study of youth perceptions of IQOS commented, “[q]ualitative evidence suggests that IQOS packaging and marketing may have particular appeal among youth and young adults, given the important role that technology plays in their lives.”³⁵

The available evidence of IQOS use in other countries shows that the product has the potential to facilitate high rates of youth tobacco usage. Data from one Japanese study published in 2015 showed higher ever use rates of IQOS and Ploom (another heat-not-burn product) among adolescents and young adults than among older adults.³⁶

A just-published study showed adolescents aged 16-19 images of the IQOS device and a pack of regular HeatSticks branded HEETS (unlike the products in these applications, which are branded as Marlboro HeatSticks) in the U.S., Canada, and England. Not unexpectedly, the authors found that experimental, current, and former smokers were “significantly more likely to report interest in trying IQOS and susceptibility to trying IQOS,” but they also found that among youth never-users (never smokers and never vapers) in the U.S., susceptibility to trying IQOS was higher than for traditional cigarettes but lower than for e-cigarettes. About one in five never-users (21.8%) in the U.S. were interested in trying IQOS and more than one quarter of never-users (27.0%) showed susceptibility to trying IQOS. Moreover, this study demonstrates the type of research that should have been submitted by PMI in this application. The participants were not provided with the products, but rather an image of the products, and the findings are directly relevant to these applications.³⁷

Given this evidence, and the on-going youth e-cigarette epidemic, PMI’s failure to present evidence regarding youth perception of the proposed modified risk claims should preclude the grant of its IQOS applications.

³⁴ McKelvey, K, et al., “Heated tobacco products likely appeal to adolescents and young adults,” *Tobacco Control* 27:s41–s47, 2018.

³⁵ Czoli, CD, et al. at 5.

³⁶ Tabuchi, T, et al., “Awareness and use of electronic cigarettes and heat-not-burn tobacco products in Japan,” *Addiction* 111:706-713, 2015.

³⁷ Czoli, CD, et al.

V. PMI HAS SUBMITTED INSUFFICIENT EVIDENCE THAT ITS MARKETING WILL TARGET ONLY ADULT SMOKERS, PARTICULARLY IN LIGHT OF ITS MARKETING OF IQOS ABROAD, WHICH REACHES YOUTH

PMI's proposed marketing plan provides FDA with wholly insufficient evidence that its intended U.S. marketing will reach only adult smokers and avoid youth exposure to its modified risk claims. This is particularly significant in light of the known marketing of IQOS to broader audiences around the globe and PMI's social media marketing, which is now reaching U.S. consumers, including youth.

The indefiniteness and incompleteness of PMI's marketing plan is shown, for instance, in the description of its proposed direct mail pieces. PMI states, "Additional derivative promotional materials will be developed closer to the time of commercial distribution of THS. These derivative materials will differ from the submitted materials by channel, format, and layout but they will have several common elements."³⁸ The channel, format, and layout are important elements needed to assess effectiveness and impact of the advertisement. PMI also leaves itself open to further options by stating, "These channels include, but are not limited to, the following..."³⁹ This could very well mean that the company would advertise initially in age-restricted or adult-only channels, but then expand to media with wider audiences—a strategy PMI has used in other countries. Until PMI can commit itself to a marketing plan that will limit its modified risk messages to the claimed target – adult smokers – and require the company to submit any expansion or plan changes to FDA for approval before implementation, the applications should be denied.

- A. Current global marketing of IQOS undercuts the credibility of PMI's assurances to FDA that its U.S. marketing would reach only adult smokers.

The lack of detail in PMI's marketing plan submitted in the application makes it imperative for FDA to evaluate how PMI has been marketing its IQOS products in countries where it is already being sold, not merely what it claims it will do in the U.S. In fact, PMI's assurances to FDA that its U.S. marketing of IQOS will target only adult smokers have little credibility in light of its broad-based global marketing of the IQOS product.

PMI's experience in marketing IQOS in other countries has informed and shaped its approach to marketing in the United States. As Sarah Knakmuhs, Vice President of Heated

³⁸ PMI application, Module 4, Labels, Labeling and Advertising – Redacted, at 5.

³⁹ PMI application, Module 4, Labels, Labeling and Advertising – Redacted, at 9.

Tobacco Products for PM USA, commented at the January 24-25 TPSAC meeting, “we’ve also had the opportunity to learn from PMI’s introduction of IQOS in markets outside the U.S.”⁴⁰

A recurring theme of the TPSAC presentations by Ms. Knakmuhs and others on behalf of PMI is that PMI intends to limit the domestic marketing of IQOS to adult smokers and to limit its reach to unintended audiences such as nonsmokers and youth. As Ms. Knakmuhs told TPSAC in describing the “challenge” of selling IQOS in the U.S.: “On one hand, we’re committed to maximizing our reach to adult smokers and supporting them so they can switch completely to iQOS. On the other hand, we want to limit our reach to unintended audiences such as nonsmokers and youth.”

Despite her claims that PMI intends to limit the domestic marketing of IQOS to adult smokers and to limit its reach to unintended audiences such as nonsmokers and youth, it is clear that PMI wants to present the product as a fashionable and trendy lifestyle product – precisely the kinds of images that appeal to young people.

In March 2018, the Campaign for Tobacco-Free Kids filed a letter in this docket to bring to FDA’s attention examples of PMI’s marketing for IQOS in other countries and demonstrated the wide distribution of images, messages, and experiences that are not confined to adult smokers.⁴¹ That letter, and its attached images, highlights IQOS retail stores, advertisements visible to the general public, IQOS kiosks in shopping malls, IQOS-sponsored social events, IQOS marketing at public events related to music and culture, and brand partnerships with fashion-related magazines. Since then, PMI has engaged in additional marketing activities that seek to broaden the appeal of IQOS as a fashion accessory for anyone interested in glamour and fun. Appendix A shows recent examples of social media posts by paid influencers; IQOS displays in non-tobacco locations such as gyms and barber shops; IQOS-sponsored bars, parties, and lounges at music festivals; partnerships with fashion stylists and magazines; collaborations with designers; and sports sponsorships. These images are utterly inconsistent with PMI’s claim that its marketing will avoid reaching “unintended” audiences like youth and will target only adult smokers. The pending applications offer little assurance that PMI will depart from its global marketing strategy and instead target only adult smokers in the U.S.

B. PMI’s use of social media marketing already reaches U.S. consumers, including youth, without a marketing order from FDA.

Although PMI did not mention social media as part of its plan to market IQOS in the U.S., PMI’s overseas influencer marketing – where the company pays and trains people with large numbers of followers on social media platforms such as Twitter and Instagram to post

⁴⁰ PMI Presentation to TPSAC, January 24, 2018, Transcript, <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM599234.pdf>.

⁴¹ Letter to CTP Director Zeller re Global Marketing of IQOS from Matthew Myers, Campaign for Tobacco-Free Kids, March 23, 2018.

content on their personal pages and use IQOS-related hashtags – is already reaching U.S. followers. Based on a report that Tobacco-Free Kids commissioned, the top 10 influencers (who have 50,000 or more followers) created posts that reached a potential 1.06 million Americans per post between 2016 and early 2018. Though they reach an American audience, these posts do not always use the “#ad” hashtag or similar to indicate to viewers that they are paid posts, as required by the U.S. Federal Trade Commission. American consumers, and especially youth who are highly attracted to social media, already have access to IQOS images from PMI that could undermine any potential benefit from the modified risk messages if youth find these products glamorous and attractive. In this regard, it is significant that a new study shows relatively high awareness of IQOS among U.S. youth, with the authors noting that “youth in the USA may be aware of these products via the internet, despite its absence on the US market.”⁴²

Tobacco-Free Kids submitted a letter about the findings of the report to the IQOS MRTP docket in August 2018. The examples included in the letter, like the other marketing examples in Appendix A, demonstrate how PMI has been framing IQOS as a lifestyle product in other countries. These marketing images and messages leaking into the U.S. from other countries certainly are already influencing American consumers. FDA needs to evaluate how these images and social media marketing reaching American audiences will impact behavior, particularly among youth, who are highly involved in and influenced by social media channels. The agency also should not grant the pending PMI applications without a full investigation into whether PMI’s social media activities amount to the illegal marketing of IQOS in the U.S. without the required PMTA and whether the company’s social media marketing contradicts the company’s representations to FDA concerning its planned U.S. marketing of IQOS.

C. Marlboro-branded HeatSticks may impact youth use.

The Truth Initiative submitted comments to TPSAC describing potential issues with marketing the IQOS HeatSticks using the Marlboro brand, and underscored the need for research on the impact of that branding on youth.⁴³ This is an important point because Marlboro cigarettes continue to be the most popular brand among 12- to 17-year olds.⁴⁴ Marketing HeatSticks with the Marlboro brand name could have the effect of enhancing the image of all Marlboro-branded products. Further, while PM USA claims that the IQOS device will be sold

⁴² Czoli, CD, et al., at 6.

⁴³ Truth Initiative, comments submitted to January 24-25, 2018 Tobacco Products Scientific Advisory Committee Meeting on IQOS MRTP application, January 4, 2018, tracking number 1k2-90qi-8lfd, <https://www.regulations.gov/document?D=FDA-2017-D-3001-0174>.

⁴⁴ SAMHSA’s public online data analysis system (PDAS), National Survey on Drug Use and Health, 2015. http://pdas.samhsa.gov/#/survey/NSDUH-2015-DS0001/crosstab/?row=CIG30BR2&column=CATAG2&weight=ANALWT_C&results_received=true. Another survey, the 2016 NYTS, found that 78.7% of high school students prefer these three brands. CDC, “Cigarette Brand Preference and Pro-Tobacco Advertising Among Middle and High School Students—United States, 2012-2016,” *MMWR*, 67(4): 119-124, February 2, 2018, <https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6704a3-H.pdf>.

exclusively in age-restricted “IQOS-branded stores,”⁴⁵ the HeatSticks will be sold in convenience stores and other retail stores, which means these products will be just as accessible to youth as Marlboro cigarettes. PMI needs to provide data showing how the Marlboro branding will impact the use of not only of IQOS and HeatSticks, but also Marlboro cigarettes, among youth, non-smokers, and smokers.

D. Additional shortfalls in PMI’s proposed marketing plan.

PMI’s marketing materials did not include information for consumers “about the health effects of partially switching from combusted cigarettes to IQOS, information that may affect how consumers use the product.”⁴⁶ This omission could lead consumers to believe that dual use would reduce their health risks, when that is not the case.

Moreover, PMI’s consumer perception studies using the menthol HeatSticks failed to use the actual packaging for its assessment. In a footnote in the Labels, Labeling and Advertising section of the application, PMI states, “In the PBA studies in which the HeatSticks packs were part of the tested materials (i.e., THS-PBA-05-RRC-US, THS-PBA-05-RRC2-US and THS-PBA-05-REC-US), the assessed Menthol HeatSticks pack was slightly different from the two Menthol HeatSticks packs included with this submission. Those differences were (1) the absence of the differentiators “Smooth” or “Fresh” on the tested HeatSticks pack; and (2) a different tone of green, the same used on the “Fresh Menthol” HeatSticks pack. The Menthol HeatSticks pack tested included the same “modified risk” claim and alternatively the “Important Warning” or the Surgeon General’s warning as the HeatSticks pack samples included with this submission.”⁴⁷ The descriptors “Smooth” and “Fresh” could have an impact on actual use, as consumers could misunderstand and think that these HeatSticks have less risk compared to other HeatSticks.

VI. THE APPLICATIONS SHOULD BE DENIED BECAUSE PMI DID NOT PROVIDE RESEARCH ON THE IMPACT OF MARKETING MENTHOL IQOS PRODUCTS WITH THE PROPOSED MODIFIED RISK CLAIMS ON THE AFRICAN-AMERICAN POPULATION AND YOUTH

PMI failed to submit adequate information on the impact of the marketing and use of Marlboro Smooth Menthol HeatSticks and Marlboro Fresh Menthol HeatSticks specifically on African Americans and youth, two populations that have been disproportionately affected by menthol cigarettes.

⁴⁵ PMI Presentation to TPSAC, January 24, 2018, Transcript, <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM599234.pdf>.

⁴⁶ FDA, FDA Briefing Document, January 24-25, 2018 Meeting of the Tobacco Products Scientific Advisory Committee (TPSAC), at 56 (FDA Briefing Document).

⁴⁷ PMI application, Module 4, Labels, Labeling and Advertising – Redacted, footnote 2 at 10.

FDA's briefing document describes how the menthol content in Marlboro Smooth Menthol HeatSticks and Marlboro Fresh Menthol HeatSticks are at the upper edge of or exceed the range of menthol contained in cigarettes, with Marlboro Fresh Menthol HeatSticks having 89 percent more menthol than the higher end of the cigarette menthol range.⁴⁸ PMI's studies submitted as part of its application to FDA identified more HPHCs in the aerosol from the use of Marlboro Smooth Menthol and Marlboro Fresh Menthol HeatSticks compared to the regular HeatSticks.⁴⁹

A. Tobacco companies have a history of targeting African American communities with menthol marketing.

The FDA and FDA's Tobacco Product Scientific Advisory Committee (TPSAC) concluded that African Americans are disproportionately burdened by the health harms of menthol cigarettes.⁵⁰ TPSAC, in its 2011 report to the FDA, estimated that by 2020, 4,700 excess deaths in the African American community will be attributable to menthol cigarettes, and over 460,000 African Americans will have started smoking because of menthol cigarettes.⁵¹

FDA's own study of the effect of the marketing of menthol cigarettes concluded that African-American smokers are much more likely to use menthol cigarettes than the general population of smokers.⁵² This is not surprising because tobacco companies have a long history of targeting and marketing flavored tobacco products to African Americans and youth, and that targeting continues today: neighborhoods with predominantly African-American residents have more tobacco retailers and lower prices for Newport cigarettes.⁵³ As a result of this targeting, 85 percent of African-American smokers smoke menthol cigarettes, compared to 29 percent of white smokers.⁵⁴ Moreover, as FDA noted in its previous report, menthol in cigarettes is likely

⁴⁸ FDA Briefing Document, at 8.

⁴⁹ FDA Briefing Document, at 12.

⁵⁰ TPSAC, FDA, *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations*, July 21, 2011,

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf> (TPSAC Menthol Review).

⁵¹ TPSAC Menthol Review.

⁵² FDA, *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes*, 2013 (FDA Menthol Report).

⁵³ See e.g., Rodriguez, D, et al., "Predictors of tobacco outlet density nationwide: a geographic analysis," *Tobacco Control* 22(5):349-55, 2013. Lee, JG, et al., "Inequalities in tobacco outlet density by race, ethnicity and socioeconomic status, 2012, USA: results from the ASPIRE Study," *Journal of Epidemiology and Community Health* 71(5):487-492, 2017. Henriksen, L, et al., "Targeted Advertising, Promotion, and Price for Menthol Cigarettes in California High School Neighborhoods," *Nicotine & Tobacco Research* 14(1):116-21, 2012. Moreland-Russell, S, et al., "Disparities and Menthol Marketing: Additional Evidence in Support of Point of Sale Policies," *International Journal of Environmental Research and Public Health*, 10:4571-4583, 2013.

⁵⁴ Villanti, A, et al., "Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004-2014," *Tobacco Control*, published online, October 20, 2016.

associated with reduced success in smoking cessation among African-American menthol smokers.⁵⁵ FDA now needs to consider those findings within the scope of menthol HeatSticks.

As discussed above, PMI failed to provide a detailed or complete marketing plan for IQOS. FDA cannot adequately evaluate the impact of IQOS marketing if it does not know where and how the Smooth Menthol and Fresh Menthol HeatSticks will be marketed, and if that marketing will be aimed at predominantly African-American communities or if the marketing will have a disproportionate impact on African Americans.

B. Extensive research shows that menthol tobacco products attract youth.

The fact that two of the three IQOS products PMI proposes to market are mentholated products enhances the importance of accurately assessing the effect of the proposed modified risk claims on adolescents, as mentioned in Section IV.B.⁵⁶ As described above, the levels of menthol content in the HeatSticks are relatively high compared to cigarettes⁵⁷ and could impact youth initiation.

Studies and the tobacco industry's internal documents show that menthol has been added to tobacco products to reduce the harshness and make them more appealing and tolerable for youth who are initiating tobacco use.⁵⁸ Menthol cools and numbs the throat, reducing the harshness of cigarette smoke, thereby making menthol cigarettes more appealing to youth who are initiating smoking.⁵⁹ In its report on menthol cigarettes, TPSAC has already concluded, "The evidence is sufficient to conclude that a relationship is more likely than not that the availability of menthol cigarettes increases the likelihood of addiction and the degree of addiction in youth smokers. (Above Equipose)."⁶⁰ FDA's own exhaustive analysis in 2013 of the effect of marketing menthol cigarettes demonstrated that newer smokers, and particularly adolescents, disproportionately use mentholated cigarettes and that menthol in cigarettes is likely associated with increased initiation and progression to regular cigarette smoking.⁶¹

More than half of youth smokers currently use menthol cigarettes, including seven out of ten African American youth smokers.⁶² There is a high likelihood that marketing "Fresh Menthol" and "Smooth Menthol" HeatSticks would also have a disproportionately large impact on adolescents. Indeed, a recent study showing high levels of current interest in, and susceptibility to, trying IQOS among U.S. youth, noted that it studied only an "unflavoured" version of IQOS, but the marketing of menthol versions as well may raise the levels of interest

⁵⁵ FDA Menthol Report, at 130.

⁵⁶ PMI Executive Summary, at 20.

⁵⁷ FDA Briefing Document, at 8.

⁵⁸ 2012 Surgeon General's Report. FDA Menthol Report.

⁵⁹ FDA Menthol Report.

⁶⁰ TPSAC Menthol Review.

⁶¹ FDA Menthol Report, at 5.

⁶² Villanti, A., et al., "Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004–2014," *Tobacco Control*, published online October 20, 2016.

and susceptibility among youth because menthol products “are associated with greater appeal among youth and young adults.”⁶³ PMI submitted no analysis of this impact.

VII. THE APPLICATIONS SHOULD BE DENIED BECAUSE THE EVIDENCE INDICATES THAT THE MARKETING OF IQOS WITH MODIFIED RISK CLAIMS WILL LEAD TO GREATER DUAL USE WITH CIGARETTES INSTEAD OF LEADING SUBSTANTIAL NUMBERS OF SMOKERS TO SWITCH COMPLETELY TO IQOS

The Tobacco Control Act requires that FDA’s evaluation both of the risk to the individual and the risk to the population as a whole must take account of the way the product is “actually used by consumers.” PMI’s application documents raise serious concerns regarding how the product will be used by consumers, particularly the high rates of dual use of IQOS and conventional cigarettes (even in individuals PMI considers to be “predominant” users of the tobacco heating system).

A substantial body of evidence supports the proposition that health benefits to an individual from quitting smoking occur only if the individual completely quits smoking. Merely reducing the level of smoking or smoking cigarettes and using other tobacco products concurrently does not eliminate the health risk.⁶⁴ Several U.S. Surgeon General’s Reports and studies have indicated that the risk of cardiovascular disease and other smoking-related diseases depends largely on the length of time a person smokes, not the number of cigarettes smoked.⁶⁵ According to the CDC, “If you only cut down the number of cigarettes you smoke by adding another tobacco product...you still face serious health risks. Smokers must quit smoking completely to fully protect their health – even a few cigarettes a day are dangerous.”⁶⁶

Thus, even if IQOS might “significantly reduce harm and the risk of tobacco-related disease” if an individual quits smoking altogether and takes up IQOS instead, it might not do so for an individual who continues to smoke at the same time as he or she takes up IQOS.

⁶³ Czoli, CD, et al., at 6.

⁶⁴ U.S. Department of Health and Human Services (HHS), *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General*, U.S. Centers for Disease Control and Prevention (CDC), Office of Smoking and Health (OSH), 2010, at 9 (2010 Surgeon General’s Report). 2012 Surgeon General’s Report, at 22.

⁶⁵ 2010 Surgeon General’s Report, at 22. Schane, RE, Ling, PM, & Glantz, SA, “Health Effects of Light and Intermittent Smoking: A Review,” *Circulation* 121(3):1518-1522, 2010. Tverdal, A & Bjartveit, K, “Health Consequences of Smoking 1-4 Cigarettes per Day,” *Tobacco Control* 14(5), 2005. Hackshaw, A, et al., “Low cigarette consumption and risk of coronary heart disease and stroke: meta-analysis of 141 cohort studies in 55 study reports,” *BMJ* 360:j5855, <http://doi.org/10.1136/bmj.j5855>, 2018.

⁶⁶ CDC, “Powerful new Tips from Former Smokers” ads focus on living with vision loss and colorectal cancer,” CDC Press Release, March 26, 2015, <http://www.cdc.gov/media/releases/2015/p0326-tips.html>. See also: CDC, “Dual Use of Tobacco Products,” <http://www.cdc.gov/tobacco/campaign/tips/diseases/dual-tobacco-use.html>.

The question of whether smokers who take up IQOS switch completely and abstain from smoking entirely or whether they use both products concurrently has extremely important health consequences. This question is critical in evaluating any potential benefit to health that might result from approval of this application. Indeed, the modified risk claims PMI seeks to make in these applications are based on the assumption that IQOS users will switch completely away from cigarette smoking.

- A. PMI's own evidence indicates a greater likelihood of dual use than complete switching.

The evidence presented in PMI's applications, in particular the studies conducted in the U.S., raises concern that smokers would not switch to exclusive IQOS use (i.e., the evidence does not demonstrate that smokers who take up IQOS would abstain from smoking cigarettes). In fact, the evidence suggests that a significant number of smokers in the U.S. who would use IQOS products would do so in conjunction with smoking, rather than switching entirely.

Information in the application indicates that, in the populations studied, dual users outnumber those who completely or near-completely switch to IQOS. Studies from the United States demonstrate this result. As shown in the table below, one PMI study of U.S. smokers (THS-PBA-07-US) found that the vast majority of smokers in the study (more than 92%) still used conventional cigarettes at the conclusion of the six-week study period, with a significant number combining cigarette use with some IQOS use. The study found that, at the end of six weeks, only 7.5 percent of U.S. smokers in the study transitioned to "exclusive" IQOS use (defined as use of IQOS/HeatSticks 95-100% of the time).⁶⁷ The U.S. study participants received the IQOS device and HeatSticks at no cost during the study, and few indicated that they would purchase and use the product outside of the study environment. When asked if they would purchase the system if it were available, just six percent of participants overall said they would definitely buy it and 16 percent said they would probably buy it. Among those with predominant or exclusive IQOS use at the end of the study, 16 percent said they would definitely buy the system and 31 percent said they would probably buy it.⁶⁸

The study did not detail any patterns of IQOS use beyond the six-week period. A follow-up interview of 344 study participants, conducted after they no longer had access to IQOS, found that 92 percent remained daily smokers of conventional cigarettes, six percent were occasional smokers and two percent stopped smoking.⁶⁹

⁶⁷ PMI, Section 6.2.2, at 99.

⁶⁸ PMI, THS-PBA-07-US Study Report, at 117.

⁶⁹ PMI, Amendments, THS-PBA-07-US 30-Day Follow-up Interview, at 38.

**Percent Use By Usage Category - Study Week 6
FAS Population (THS-PBA-07-US)**

<i>Usage Categories For Study Week 6</i>	United States
Exclusive IQOS HeatStick (HS) Use 95-100% HS	7.5%
Predominant IQOS HeatStick (HS) Use 70-95% HS	7.0%
Combined mostly IQOS HeatStick (HS) Use 30-70% HS	22.4%
Predominant Conventional Cigarette (CC) Use 5-30% HS	28.2%
Exclusive Conventional Cigarette (CC) Use 0-5% HS	34.5%
Zero IQOS HeatStick and CC Use	0.3%
FAS (N=)	968

Studies provided by PMI also show large rates of dual use in other countries, even though smokers in other countries appear to more readily adopt at least some IQOS use than smokers in the U.S. As discussed below, at the conclusion of the 4-week study period in the multi-country Whole Offer Test (“WOT”), in every one of the countries studied a majority of IQOS users were dual users rather than exclusive users.

At the conclusion of the multi-country WOT, exclusive IQOS use (use of IQOS HeatSticks 95-100% of the time) was highest in South Korea (15.7%) and Japan (13.6%) and below ten percent in the remaining countries, with exclusive use at 8.5 percent in Germany, 5.2 percent in Italy, and 4.3 percent in Switzerland.⁷⁰

Given the significant variation in use patterns among countries in the WOT, the likelihood of dual use versus exclusive use in the United States cannot be reliably extrapolated from studies in other countries, particularly without understanding why the numbers vary so greatly from country to country. In its application, PMI noted differences across countries in multiple studies, “with differences between Japan and the U.S. populations consistently observed, regardless of the type of studies.”⁷¹ PMI named a number of possible explanations, including cultural differences in taste preferences and interest in trying new products. It also noted that, “These cultural differences may also explain why complete switch was higher in

⁷⁰ PMI, Section 7.3.3, Data calculation from tables in the Analysis of Whole Offer Test Data, Summary Report.

⁷¹ PMI, Sec. 2.7, at 160.

some countries while combined/dual use of THS [tobacco heating system] and cigarettes was the predominant pattern in other countries in observational studies.”⁷²

Note that for the multi-country WOT, PMI does not report the breakdown of usage categories for the Full Analysis Set (FAS) in its Full Summary Report or the accompanying Appendices. The table below presents usage categories for the entire FAS, which were determined by calculating the data presented for the “Usage Categories for Continued Use of *Heat Sticks*” and “Usage Categories for Early Stages of Using *Heat Sticks*” to yield data for the FAS.

**Whole Offer Test (WOT) Percent Use By Usage Category of Participants - Study Week 4 -
Calculated for Full Analysis Set (FAS) Population**

<i>Usage Categories For Study Week 4</i>	Japan	Italy	Germany	Switzerland	South Korea
Exclusive IQOS HeatStick (HS) Use 95-100% HS	13.6%	5.2%	8.5%	4.3%	15.7%
Predominant IQOS HeatStick Use 70-95% HS	16.1%	6.9%	11.4%	5.5%	21.5%
Combined mostly IQOS HeatStick Use 60-70% HS	7.7%	4.3%	5.6%	5.3%	8.5%
Combined balanced Use 40-60% HS	16.3%	19.3%	15.4%	23.8%	18.3%
Combined mostly Conventional Cigarette (“CC”) Use 30-40% HS	8.3%	14.4%	6.4%	10.3%	9.5%
Predominant CC Use 5-30% HS	27.7%	39.3%	24.7%	30.5%	17.3%
Exclusive CC Use 0-5% HS	10.0%	10.7%	26.5%	20.0%	8.5%
Zero HeatStick and CC Use	0.2%	0.0%	1.6%	0.2%	0.7%
FAS (N=)	638	535	377	416	843

Source: PMI, Section 7.3.3, Data calculation from tables in the Analysis of Whole Offer Test Data, Summary Report.

See also 2.7 Executive Summary, Figure 36, p. 149

⁷² PMI, Sec. 2.7, at 160.

The results of PMI’s multi-country WOT, while instructive, should not be extrapolated to the entire universe of smokers. In order to qualify for the study, participants had to express at least some interest in purchasing the product (those not interested in purchasing IQOS were excluded) and the participants were provided the IQOS device and HeatSticks free of charge for the duration of the study (while they had to purchase conventional cigarettes at their own expense). Therefore, the level of adoption among smokers in the WOT may well be higher than it would be in the general population, and certainly may not apply to smokers in the U.S.

Because of the likely difference in health outcomes for those who completely quit smoking conventional cigarettes when they take up IQOS and those who use cigarettes and IQOS concurrently, it is essential that any modified risk claims for IQOS include clear and understandable statements to consumers advising them that any health benefits depend upon their switching entirely away from cigarettes. While the modified risk messages proposed by PMI do include language about “switching completely” as part of their overall message of reduced risk or reduced exposure, it is questionable whether consumers fully comprehend that “switching completely” means no use of cigarettes at all, or that consumers comprehend that the reduced risk and exposure outcomes only occur when one fully quits smoking conventional cigarettes.

With the high levels of dual use present in both the research studies and the real world experience, it is critical to understand whether consumers mistakenly believe that dual use of IQOS and other tobacco products would confer a health benefit when in fact it would not. It is also important to assess exposure to toxicants, including harmful or potentially harmful constituents (HPHCs), during periods of dual use of IQOS and conventional cigarettes, an issue not clearly addressed in the application.⁷³

B. TPSAC’s conclusions support a greater likelihood of dual use than complete switching

TPSAC’s findings from its January 2017 meeting suggest that IQOS would provide little beneficial population-wide impact on the public health.

First, TPSAC members did not think it likely that U.S. smokers would switch completely to IQOS. On the question of “the likelihood that U.S. smokers would completely switch to use of the IQOS system,” seven TPSAC members voted “low,” two voted “medium” and none voted “high.” The importance of this finding is underscored by the fact that the claims PMI wishes to make for IQOS assert only that switching **completely** from cigarettes to IQOS has health benefits.

⁷³ Comments by St. Helen, G, et al., “Because PMI application did not report the full range of HPHCs in IQOS aerosol, characterize HPHCs in sidestream emissions, include a non-targeted analysis of chemicals in emissions, or conduct clinical studies to describe exposure to toxicants during dual use with other tobacco products, FDA must deny PMI’s application,” tracking number 1k1-902j-m8kv, November 29, 2017, at 9. Available at https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/u9/Gideon-ClinPharm_Comments%20on%20aerosol%20and%20exposure_IQOS_11292017-FINAL.pdf.

Second, TPSAC found dual use more likely than complete switching. On the likelihood that “U.S. smokers would become long-term dual users of IQOS and combusted cigarettes,” three TPSAC members voted “high,” five voted “medium,” and only one voted “low.” Given that even PMI appears to concede that any individual health benefits from IQOS would be realized only through complete switching from combusted cigarettes and that dual use may serve to simply perpetuate smoking among those who otherwise may have quit cigarettes entirely, these TPSAC votes demonstrate that the Committee thought it unlikely that IQOS would yield a population-wide health benefit and instead that it might well have an adverse net effect on public health.

TPSAC’s conclusions, supported by the available evidence, do not support a population-wide public health benefit from the marketing of IQOS with modified risk claims.

VIII. THE APPLICATION SHOULD BE DENIED BECAUSE THERE EXISTS CONSIDERABLE DOUBT ABOUT THE EXTENT OF INDIVIDUAL HEALTH BENEFITS FROM COMPLETE SWITCHING FROM CIGARETTES TO IQOS

- A. Preliminary analysis by FDA, independent research, and other filed comments raise doubts about the extent of individual health benefits from completely switching to IQOS.

As noted above, Section 911 requires FDA to evaluate whether the product “as it is actually used by consumers will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users.” This standard requires an evaluation of “the relative health risks to individuals of the tobacco product that is the subject of the application.” FDA’s own analysis, independent studies, and comments from others filed in this Docket further indicate that PMI’s studies and findings deserve serious scrutiny by FDA.

FDA’s briefing document to TPSAC described data submitted by PMI and from separate analysis by an FDA lab showing differences in some harmful and potentially harmful constituent (HPHCs) levels from HeatStick aerosol compared to reference cigarette (3R4F) smoke.⁷⁴ While the degree to which the levels of HPHCs are lower in HeatStick aerosol vary by compound, the health impact of having less of a reduction in a particular compound is unclear. For instance, FDA must determine how a 66 to 91 percent reduction in formaldehyde, as reported in the FDA’s briefing document,⁷⁵ might or might not change the health risk for an adult smoker who switches to IQOS.

In considering how the products will be actually used, FDA also must consider how repeated exposure to those HPHCs – even if measured at lower levels in lab testing – may impact

⁷⁴ FDA Briefing Document, at 8-13.

⁷⁵ FDA Briefing Document, at 11.

health risks. This idea was raised in the FDA briefing document: “based on the results, consuming 10 HeatSticks exposes users to levels of acetaldehyde, acetamide, acrylamide, ammonia, butyraldehyde, catechol, formaldehyde, mercury, propylene oxide, and pyridine that are comparable to smoking 1-3 cigarettes... For carcinogens that are mutagenic, such as the HPHCs listed above, the cancer potency is assessed using a linear extrapolation from the low-dose region of the dose-response model. Using this model, any increased exposure increases cancer risk.”⁷⁶ FDA questioned PMI’s studies on cellular reactions to HeatStick aerosol, noting that PMI data showed “evidence of recovery after acute exposure to IQOS aerosol, but the relevance of these data is unclear since consumers are anticipated to use the product on an ongoing basis.”⁷⁷ In addition, lower levels of certain HPHCs in IQOS may not confer a health benefit on consumers who are dual using and continuing to expose themselves to the higher levels of HPHCs from cigarettes.

A 2018 systematic review of research on various heated tobacco products published by November 2017 evaluated both studies conducted by manufacturers (the majority of studies available) and by independent researchers. The authors found that the few independent studies on the issue showed less beneficial or contradictory findings compared to the manufacturers’ research. For instance, manufacturers’ studies reported lower levels of tobacco-specific nitrosamines (TSNAs) in mainstream smoke from IQOS compared to independent studies. The authors also found that manufacturers tended to have “over-stated conclusions,” stating, “manufacturer-funded studies concluded that HnB [heat-not-burn] use impact on indoor air quality was negligible or that HnB emissions were less harmful than cigarette smoke, while an independent study concluded that despite lower emissions, HnB still pose evident risks through secondhand emissions.”⁷⁸

More than 50 compounds in each of the HeatStick varieties were higher in the HeatStick aerosol compared to reference cigarettes (3R4F).⁷⁹ FDA stated, “The quantity of glycidol, acetol, propylene glycol are higher by 108 – 224%, 35 – 67%, and 383 – 638%, respectively, in the aerosol of the HeatSticks compared to the smoke of the 3R4F.”⁸⁰ In fact, FDA described these as “compounds of toxicological concern.”⁸¹ The health impact of those higher rates must be evaluated by FDA, even if levels of other HPHCs are lower in IQOS compared to cigarettes.

Because HeatSticks are composed and used differently than cigarettes, other chemicals not on FDA’s HPHC list may be released by IQOS and need to be evaluated for potential harm

⁷⁶ FDA Briefing Document, at 15.

⁷⁷ FDA Briefing Document, at 16.

⁷⁸ Simonavicius, E, et al., “Heat-not-burn tobacco products: a systematic literature review,” *Tobacco Control* [Epub ahead of print], pii: tobaccocontrol-2018-054419, 2018.

⁷⁹ St. Helen, G, et al., “IQOS: examination of Philip Morris International’s claim of reduced exposure,” *Tobacco Control* 27:s30–s36, 2018.

⁸⁰ Errata to FDA Briefing Document, at 1.

⁸¹ FDA Briefing Document, at 15.

to users and bystanders.⁸² For instance, FDA’s briefing document described a study that found 82 compounds from Heatstick aerosol that have not been previously reported in cigarette smoke.⁸³ A recent study analyzing used HeatSticks and devices found evidence that the tobacco plug in the HeatSticks chars (an indication of pyrolysis) during use despite PMI’s claims and, even more troublesome, that the filters in the HeatSticks melt from the heat and release formaldehyde cyanohydrin, a highly toxic chemical. Though this toxicant is not on FDA’s HPHC list for cigarettes, one of its byproducts of metabolism in the body, formaldehyde, is.⁸⁴ FDA needs to consider the health risks of exposure to those substances from using IQOS independently from cigarette smoking and cigarette smoke exposure.

PMI recommends that the device be cleaned after each use, but even doing so still leaves “deposits of hardened dark debris” on the heating element of the device. In a tested device that wasn’t cleaned after each use, researchers found “brown liquid and particulates covered the base, walls and heater,” which increased with continued use without cleaning. HeatSticks used in the device that was not cleaned between uses showed even more char in the tobacco plug than HeatSticks used in cleaned devices. Again, to consider how the products are *actually* used by consumers, it seems unrealistic to assume that all IQOS users will clean their device after each and every use, so FDA needs to evaluate the consequences of using uncleaned devices.

In comments filed in this docket, other researchers indicated that the in vitro and animal toxicology studies provided by PMI do signal lower levels of adverse biological effects. However, these same comments raise concerns about whether the studies support the claims of reduced risk, noting that the “human studies do not show statistically significant differences between iQOS and conventional cigarettes for most of the biomarkers of potential harm.”^{85,86} Additional comments raise concerns about IQOS emissions posing a risk for pulmonary toxicity,⁸⁷ and the lack of adequate information regarding the potentially unique toxicities of IQOS.⁸⁸

⁸² See also, comments by St. Helen, G, et al., Docket No. FDA-2017-D-3001, tracking number 1k1-902j-m8kv, at 9.

⁸³ FDA Briefing Document, at 14.

⁸⁴ Davis, B, Williams, M, & Talbot, P, “iQOS: evidence of pyrolysis and release of a toxicant from plastic,” *Tobacco Control* 28:34–41, 2019.

⁸⁵ Comments by Glantz, S & Lempert, L, Docket No. FDA-2017-D-3001, “Detailed analysis of the Executive Summary (Section 2.7) submitted by Philip Morris International in support of its MRTP application for IQOS,” December 9, 2017. Available at

<https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/u9/Comments%20on%20Exec%20Summary%20-%20final.pdf>

⁸⁶ Comments by Glantz, S, Docket No. FDA-2017-D-3001, tracking number 1k1-8zrx-juh9. “PMI’s Own Data on Biomarkers of Potential Harm in Americans Show that IQOS is Not Detectably Different from Conventional Cigarettes, so FDA Must Deny PMI’s Modified Risk Claims,” November 13, 2017. Available at

<https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/u9/Clinical%20studies%20do%20not%20show%20significant%20reduction%20in%20harm-1k1-8zrx-juh9.pdf>

⁸⁷ Comments by St. Helen, G, et al., Docket No. FDA-2017-D-3001, tracking number 1k1-902j-m8kv.

⁸⁸ Comments by Chun, L, et al., Docket No. FDA-2017-D-3001, tracking number 1k1-903a-mnpl. “IQOS emissions create risks of immunosuppression and pulmonary toxicity, so FDA should 1 not issue an order permitting IQOS to be labeled or marketed with reduced risk claims,” November 30, 2017. Available at

https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/u9/FINAL%20MRTP%20Comment%20Pulm%20and%20Immuno_Calfee%20Group.pdf

Separate comments and FDA’s analysis also found some methodological issues that could raise doubts about PMI’s findings. One comment questioned whether noncompliance during some of the key studies “reduces the validity of conclusions made regarding reduced toxicant exposure from IQOS.”⁸⁹ These studies compared the level of reduction in biomarkers of HPHCs after use of IQOS with cessation (smoking abstinence) and with continued use of combustible cigarettes. However, the comparison is valid only if the study participants fully complied with their assigned criteria (particularly the smoking abstinence arm of the study). As the authors of the comment explain, if participants in the smoking abstinence group actually smoked cigarettes, then the study would be more likely to show comparable reductions in HPHC exposure with IQOS and “abstinence.” Across the studies, compliance varied, and PMI noted that due to increased variability the results should be interpreted with caution.

FDA’s briefing document also raised an issue about lack of research on light smokers (those who do not smoke frequently).⁹⁰ PMI did not submit data on the health impact of IQOS use among those smokers and so it is difficult to know the risk level from IQOS use for this population.

A Reuters investigation published in December 2017⁹¹ provides reason for further caution. The article details how former PMI employees and contractors described “a number of irregularities involving clinical trials” for IQOS and that one employee responsible for helping coordinate the clinical trials, “questioned the quality of some of the researchers and sites contracted to carry out those experiments.” Among the concerns were the qualifications and training of the Principal Investigators of certain studies, as well as the rigor of the screening process assuring that the study participants met the criteria for inclusion in a particular study.

Reuters outlined its findings about the IQOS trials to FDA, and the agency must carefully examine the information to determine whether audits of the facilities in question are necessary, and whether all of the studies adhered to standards for Good Clinical Practice.

Each of these issues is relevant to the statutory criterion FDA must apply: whether IQOS, as actually used by consumers, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users. The data submitted by PMI by the time of the TPSAC meeting, in January 2018, had not convinced FDA researchers, who wrote in the briefing document: “Based on the studies submitted, it is unclear how the effects observed in treatment groups exposed to IQOS aerosols translate to a potential risk reduction for noncancer-related effects when chronically used by humans.”⁹²

⁸⁹ Comments by St. Helen, G, et al., Docket No. FDA-2017-D-3001, tracking number 1k1-902j-m8kv.

⁹⁰ FDA Briefing Document, at 27, 35.

⁹¹ Lasseter, T, et al., “Scientists Describe Problems in Philip Morris E-Cigarette Experiments,” *Reuters*, December 20, 2017, <https://www.reuters.com/investigates/special-report/tobacco-iqos-science/>.

⁹² FDA Briefing Document, at 21.

- B. TPSAC’s conclusions indicate PMI has not met its burden to demonstrate an individual health benefit from complete switching to IQOS.

TPSAC’s conclusions at its January 2018 meeting to consider the modified risk application for IQOS provided FDA cast substantial doubt on the degree to which an individual health benefit would be conferred on smokers, even if they completely switch to IQOS. On the question of whether “scientific studies have shown that switching completely from cigarettes to the IQOS system can reduce the risks of tobacco-related diseases,” TPSAC voted “no” by 8-0, with one abstention. Moreover, on the question whether the applicant demonstrated that “[s]witching completely to IQOS presents less risk of harm than continuing to smoke cigarettes,” TPSAC was sharply divided, voting “no” 5-4. Thus, on the fundamental question of the health impact of IQOS on smokers who switch completely to the product, TPSAC reached no consensus that IQOS would be less hazardous than continued smoking.

Although TPSAC voted 8-1 that switching completely from cigarettes to IQOS “significantly reduces your body’s exposure to harmful or potentially harmful chemicals” (HPHC), the Committee, by a vote of 5-2, with one abstention, determined that PMI had not shown that this reduction in exposure to HPHCs was “reasonably likely to translate to a measurable and substantial reduction in morbidity and/or mortality.” Thus, again, TPSAC was not persuaded that switching completely from cigarettes to IQOS would yield significant health gains for individual smokers. Based on the available data, TPSAC clearly differentiated between reduced *exposure* and reduced *risk*.

- C. Studies, including those from PMI, show that people misinterpret reduced *exposure* messages as reduced *risk*.

FDA must also examine consumer comprehension of the proposed reduced risk and reduced exposure messages. In particular, FDA needs to assess whether there is sufficient evidence that consumers can accurately comprehend the proposed reduced-exposure message. According to FDA, “applicants seeking an exposure modification order must demonstrate through testing of actual consumer perception that the proposed labeling and marketing of the product does not mislead consumers into believing that the product is or has been demonstrated to be less harmful, or mislead consumers into believing that the product presents less of a risk of disease than one or more other commercially marketed tobacco products.”⁹³

In its application materials, PMI acknowledges that “a substantial portion of subjects in the reduced exposure claim study incorrectly stated that switching to THS would reduce the risk

⁹³ FDA 2012 Draft Guidance.

of developing tobacco-related diseases.”⁹⁴ PMI’s qualitative (focus group) and quantitative research, reinforce that finding.⁹⁵

FDA’s briefing document also mentioned consumers’ potential confusion between reduced exposure and reduced risk. In analyzing PMI’s study on the marketing materials with the proposed reduced exposure claim, FDA stated, “Although viewing PMI Important Warnings increased correct responding, approximately one quarter of participants who viewed PMI Important Warnings still incorrectly responded that IQOS reduces one’s *risk*. These results reflect the difficulty of conveying the message that IQOS reduces exposure to harmful or potentially harmful chemicals but has not been shown to be less harmful or present less risk of disease. Moreover, as mentioned above, smokers who viewed LLA materials with the reduced exposure claim tended to rate IQOS as lower in health *risks* (on average) than combusted cigarettes, regardless of whether the LLA materials contained PMI Important Warnings or SG Warnings” (emphasis added).⁹⁶

Other published literature also reinforces how consumers fail to distinguish between reduced exposure and reduced risk. This holds true for lower exposure claims for snus and e-cigarettes, where adults and adolescents lowered their perceptions of risks because of the claims and in communications about levels of harmful chemicals in cigarettes, where consumers consistently believed quantity translated into level of risk (i.e., lower quantity equaled lower risk).⁹⁷

While it may be true that IQOS presents lower exposure to chemical constituents, consumer misinterpretation of that claim as a reduced risk statement will have important implications for public health. For instance, when the tobacco industry listed tar levels of cigarettes on packs and in advertisements to make claims about low-tar levels, smokers believed that lower tar numbers meant less health risks, and as research has shown, were less likely to quit. A consumer study conducted for Philip Morris stated, “The low tar brands have cornered the opinion that to the extent that any brands are better for your health, they are. . . . Furthermore, it is the lower tar content of these brands that make people say they are better for health. When asked why the brands they named were better for your health, answers overwhelmingly were concerned with lower tar content.”⁹⁸ There is a very strong chance that the lower exposure message proposed by PMI could lead to similar misunderstanding.

⁹⁴ PMI, Sec. 2.7, at 189.

⁹⁵ Popova, L, Lempert, LK, & Glantz, SA, “Light and mild redux: heated tobacco products’ reduced exposure claims are likely to be misunderstood as reduced risk claims,” *Tobacco Control* 27:s87–s95, 2018.

⁹⁶ FDA Briefing Document, at 54.

⁹⁷ Popova, L, Lempert, LK, & Glantz, SA, “Light and mild redux: heated tobacco products’ reduced exposure claims are likely to be misunderstood as reduced risk claims,” *Tobacco Control* 27:s87–s95, 2018.

⁹⁸ The Roper Organization, Inc., “A study of smokers’ habits and attitudes with special emphasis on low tar cigarettes. Prepared for Philip Morris USA,” May 1986, Bates No. 3990669768-3990670067, <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/fmbk0191>.

CONCLUSION

For these reasons, the undersigned public health organizations urge FDA to deny the PMI modified risk applications for IQOS.

Respectfully submitted,

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Truth Initiative

Appendix A

Examples of PMI's Marketing of IQOS

IQOS Retail Stores

IQOS stores are highly stylized and sleek. The image of the store in Japan shows a Café IQOSignature.



IQOS store in Tokyo, Japan, with cafe.

<https://jp.iqos.com/iqos-store>

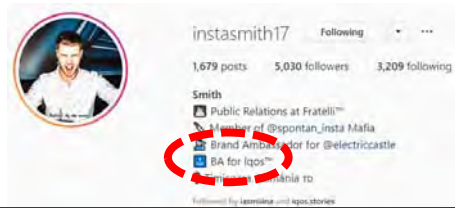
IQOS store in Moscow, Russia.

<https://www.vapingpost.com/2016/09/26/switzerland-philip-morris-flagship-store-to-open-in-lausanne-for-iqos-products/>



Social Media Posts by Brand Ambassadors

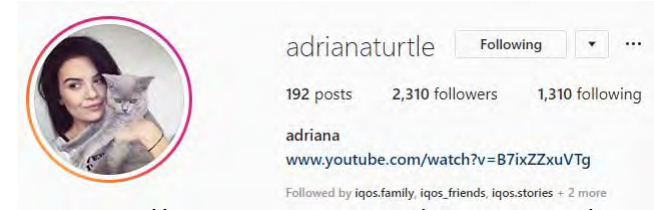
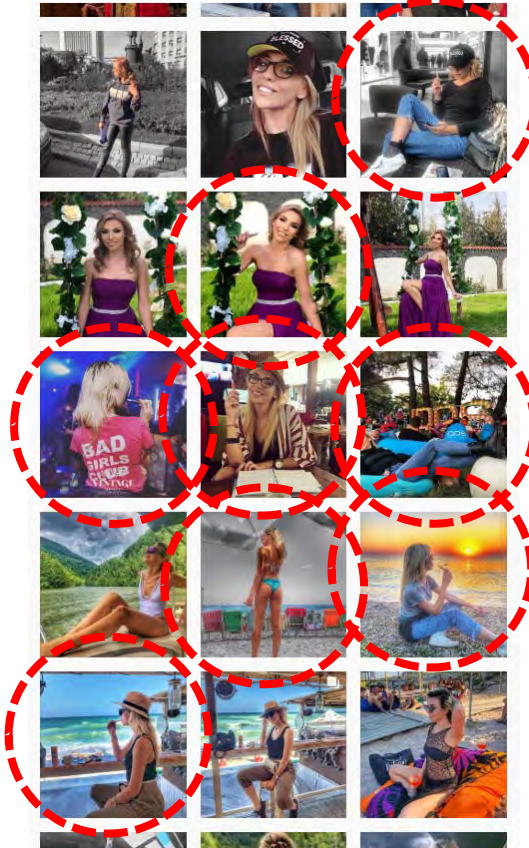
These are only a few examples of Instagram posts and accounts by paid brand ambassadors for IQOS. These types of images do not at all portray adult smokers trying to quit, but rather present a glamorous lifestyle for IQOS users.



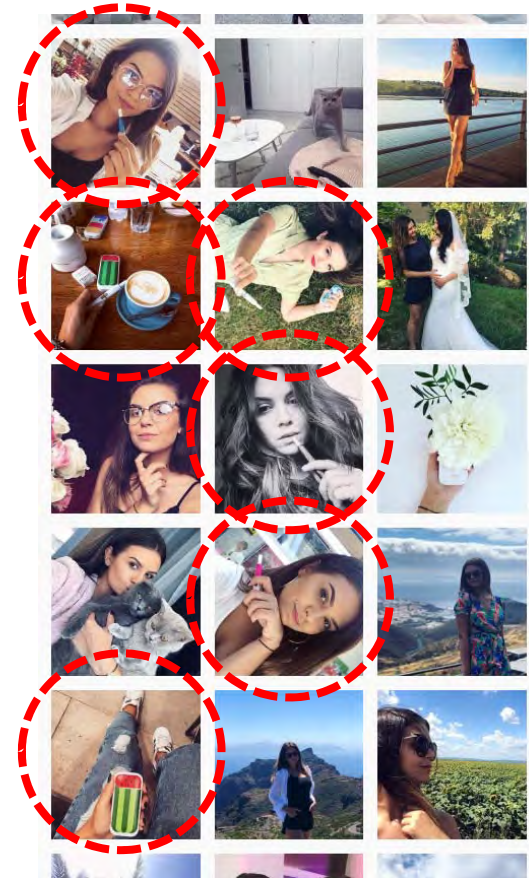
Instagram post, January 18, 2019,
<https://www.instagram.com/p/BsvePcoBbjS/>



<https://www.instagram.com/iasmiina/>



<https://www.instagram.com/adrianaturtle/>



Additional Examples of Social Media Posts by Brand Ambassadors



Instagram post, December 16, 2018,
<https://www.instagram.com/p/BrcU66gAegu/>



Instagram post, August 21, 2018,
<https://www.instagram.com/p/BmwFT8VhN4C/>



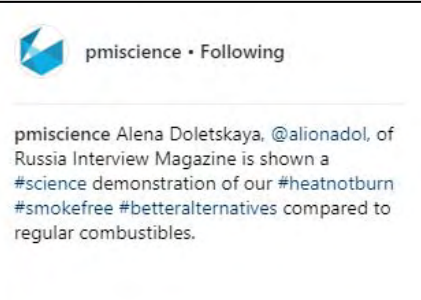
Instagram post, December 22, 2018, <https://www.instagram.com/p/Brr0AjSFyrl/>



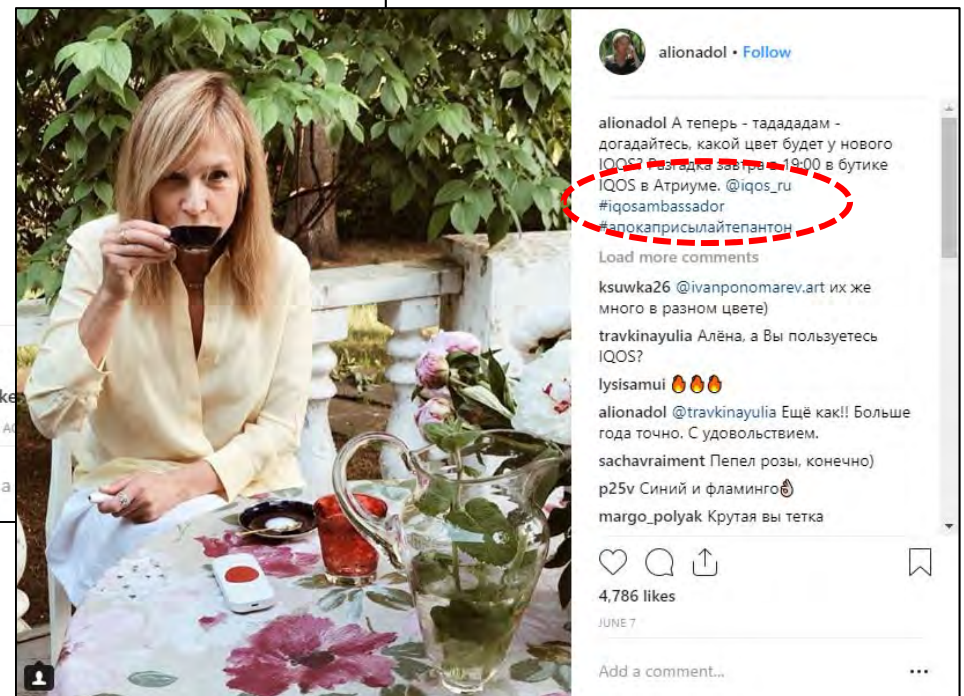
Instagram post, June 29, 2018,
<https://www.instagram.com/p/BkmkY8MI0oc/>

PMI Science with Russia Interview Magazine

PMI Science posted on its Instagram account about the Russia Interview Magazine editor in chief learning about IQOS, but failed to mention she identifies herself as an IQOS Ambassador (note hashtag in her personal post).



Instagram post, August 31, 2018,
<https://www.instagram.com/p/BnHDcdClcOJ/?taken-by=pmiscience>



Instagram post, June 7, 2017,
<https://www.instagram.com/p/BjuA8sFHajb/?taken-by=alionadol>

IQOS Hashtags for Social Media

A few examples of common hashtags used in social media posts related to IQOS.



<https://www.instagram.com/p/BnbtVfSn6b7/>



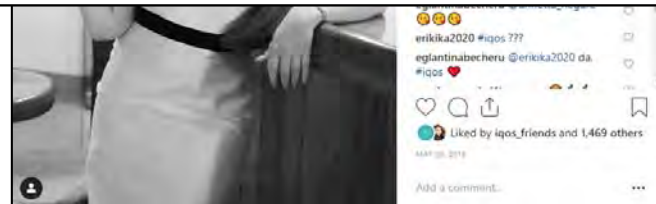
<https://www.instagram.com/p/Bn6Fx8KBqqu/>



<https://www.instagram.com/p/Bna0ZZ8hEE2/>



#challengeyourimagination



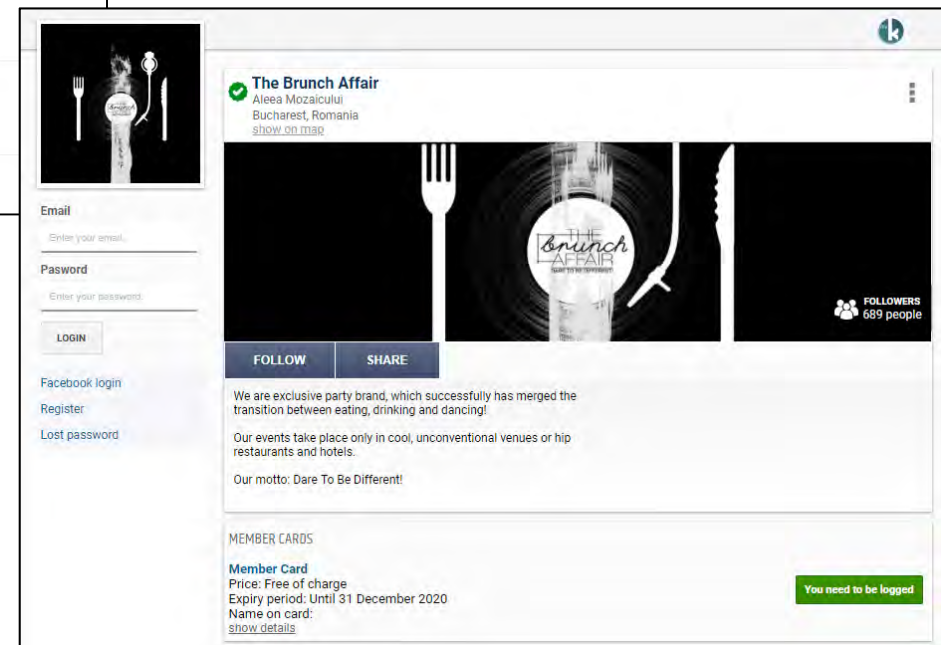
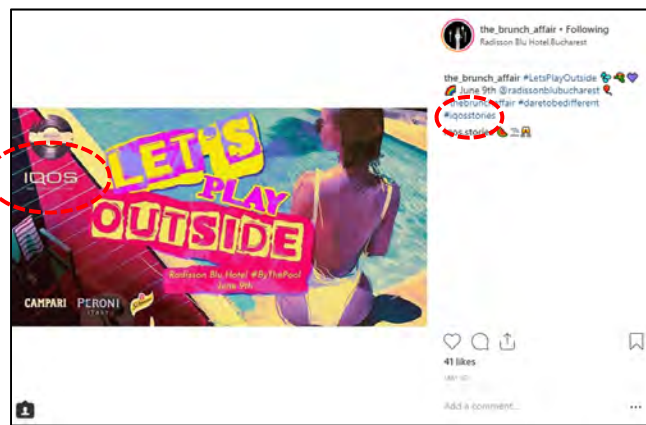
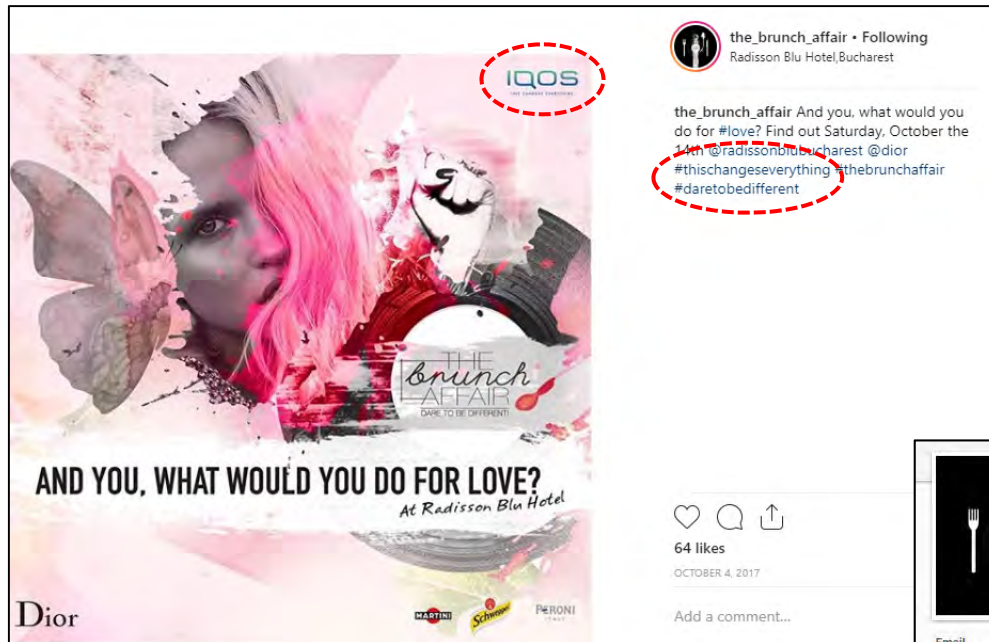
<https://www.instagram.com/p/BjW-Yq2F5tu/>



<https://www.instagram.com/p/BIJvMYOgNBV/>

IQOS Sponsoring Party Series

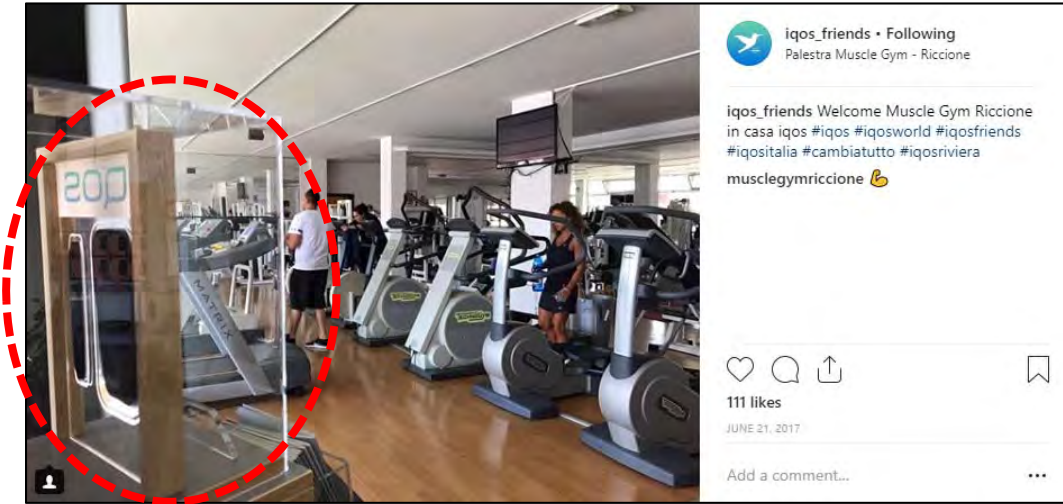
These examples of IQOS sponsoring a series of parties is from across Romania. The Brunch Affair hosts members-only themed parties and then posts about them on social media using IQOS-related hashtags including #thischangeseverything and #daretobedifferent. Social media advertisements for these parties clearly identify IQOS as the sponsor.



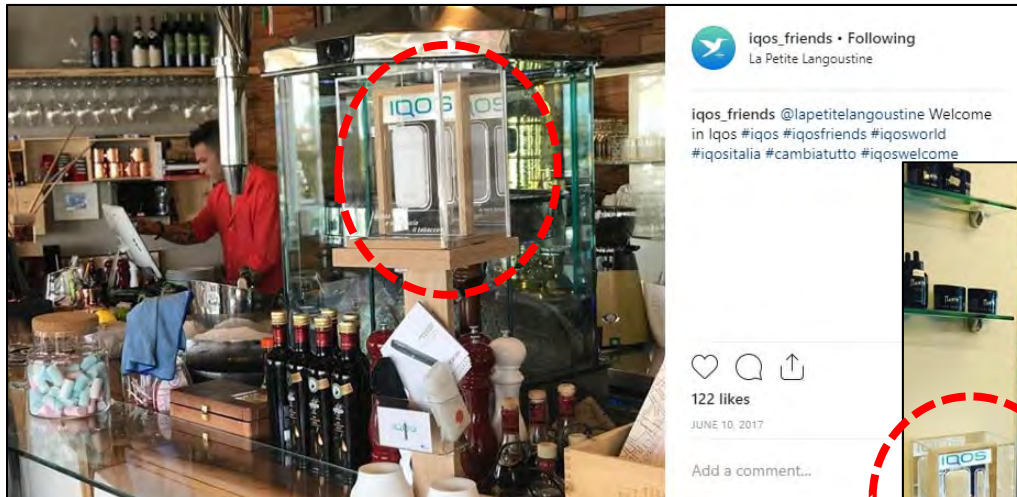
https://www.instagram.com/p/BZ0sf3OFtXI/?taken-by=the_brunch_affair; https://www.instagram.com/p/BjaJB-1IRXB/?taken-by=the_brunch_affair; <https://www.myk.ro/thebrunchaffair>

IQOS Displays in Non-Tobacco Related Places – Examples from Italy

These displays clearly do not adhere with PMI's claim that it intends to introduce adult smokers to these products in adult-only device stores. By placing these displays in everyday venues, such as workout gyms, cafes, and barber shops, these products are being linked to an everyday lifestyle.



Instagram post from June 21, 2017,
https://www.instagram.com/p/BVm612BDnwb/?taken-by=iqos_friends



Instagram post from June 10, 2017,
https://www.instagram.com/p/BVKXj7ejTa0/?taken-by=iqos_friends

Instagram post from June 13, 2017,
https://www.instagram.com/p/BVRpZvvjhd0/?taken-by=iqos_friends



IQOS Advertisements and Displays in Shopping Malls

While PMI claims sales of IQOS devices will be limited to IQOS stores, it is clear that the marketing could be much more ubiquitous and visible, if not attractive, to youth. The images below show IQOS branding and associated imagery plastered in the general area of a mall, and a holographic display capturing the interest of a child.



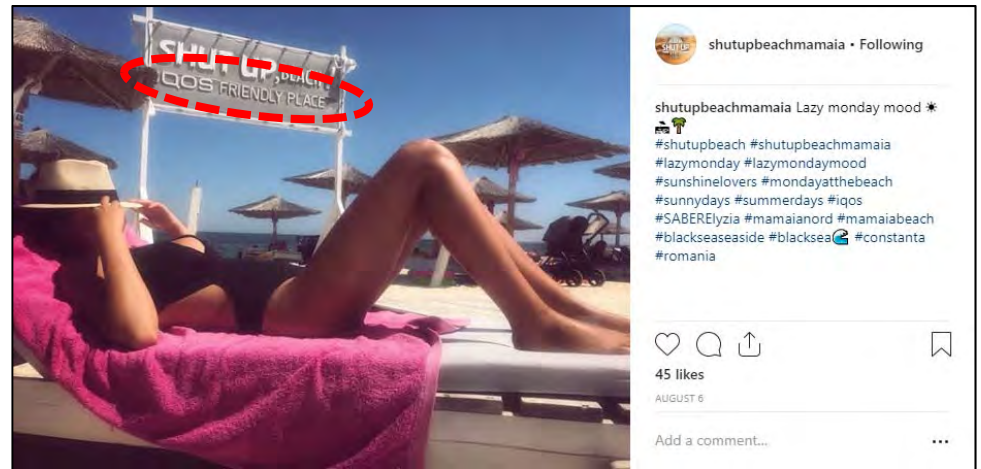
Mall in Sofia, Bulgaria. Image taken April 19, 2018.



Mall in Bulgaria. Image taken June 2018.

IQOS-Sponsored Beach Bar: Shut Up, Beach!, Romania

Similarly to the images on the previous slide, this is an IQOS-sponsored beach bar, where IQOS branding is ubiquitous. These types of sponsorships and “IQOS-Friendly Place” messages are beyond PMI’s claimed focus on adult smokers, but rather normalizes use of the product and links it to everyday activities.



<https://www.instagram.com/shutupbeachmamaia/>

“IQOS Zone” at 2017 Belgrade Beer Fest

IQOS sponsored a stage and lounge area at the Belgrade Beer Fest, extending its brand recognition beyond adult smokers.



Image by Goran Srdanov, at <http://www.telegraf.rs/vesti/beograd/2889153-nastup-grupe-sars-kao-kruna-jubilarnog-beer-festa-foto>

IQOS Area at Oktoberfest Romania

An example of an IQOS-sponsored lounge area at a music festival in Romania.



Instagram post by IQOS team member, September 8, 2018,
<https://www.instagram.com/p/BneIUqKFwDU/?taken-by=iasmiina>

Instagram post, September 9, 2018,
<https://www.instagram.com/p/BnhDCxIAh6R/?taken-at=391214416>



IQOS Lounges at Music Festivals in Portugal, Summer 2018

These IQOS-sponsored lounges included Instagram-ready photo opportunities, which attendees could then share on their personal Instagram accounts. This extends the IQOS-related marketing beyond the companies' reach to the followers of the individuals who post these images.



NOS Summer Opening Music Festival, Instagram post, July 21, 2018,
<https://www.instagram.com/p/BlgPLb2laA9/?tagged=mundosemfumo>



MEO Sudoeste, Instagram Post, August 13, 2018,
<https://www.instagram.com/p/BmbD8HTHLWA/?tagged=mundosemfumo>



MEO Sons de Mar, Instagram post, September 1, 2018,
<https://www.instagram.com/p/BnMb1XnnQfS/?tagged=mundosemfumo>

IQOS Party Invitations to Non-Smokers

This Instagram post, from a blogger in Bulgaria with over 23,000 followers, shows that non-smokers were invited to and attended a sponsored event featuring the new IQOS 3 product. This contradicts PMI's claims that its sponsored events are for smokers only.

fbasheva #PhilipMorris Thanks for the invitation. ☺ I do not smoke, but I was extremely impressed with the performance of #iqos3 and the party as a whole. 🌟🌟👍 #innovation #galaevent #iqos3bg

(Translation by Google Translate)



Instagram post, December 7, 2018, <https://www.instagram.com/p/BrGXPBjg6ye/>

IQOS Collaboration with Designer Karim Rashid

PMI has recruited fashion and lifestyle designers to create limited edition “sleeves” for IQOS devices. These images were posted on the designer’s Instagram account, which means people who follow him for his designs and who are not necessarily tobacco users are exposed to these brand-positive images.



September 3, 2018, https://www.instagram.com/karim_rashid_official/



September 3, 2018, https://www.instagram.com/p/BnO67Eth-3N/?taken-by=karim_rashid_official

IQOS at Mercedes-Benz Fashion Days, Kiev, Ukraine, September 3, 2016

IQOS sponsored an area at the Mercedes-Benz Fashion Days event in Ukraine, where it linked the brand with fashion, created an interactive display for people to take pictures and share, and, as seen in the top image, also exposed children to its brand and product. The “95% less don’t’s” message could be a tongue-in-cheek reduced risk claim.



Qreator by IQOS Branded Items

Qreator by IQOS is a building in Romania that PMI has turned into an event and community space where it also hosts designers who have created a variety of branded items for sale. Note the Q symbol on each product reminiscent of the symbol for the venue and IQOS product.



July 12, 2018,
<https://www.instagram.com/p/BIJETcRB74N/?tagged=collection>



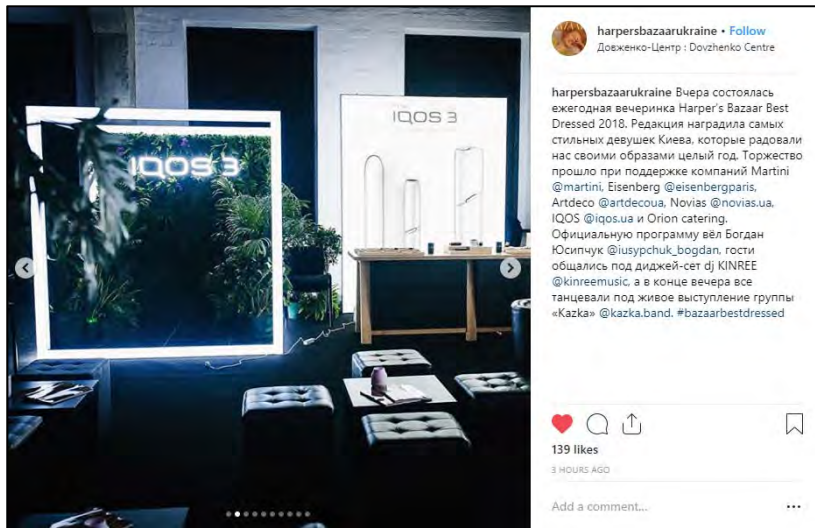
July 16, 2018,
<https://www.instagram.com/p/BIS65vBBnxI/?tagged=collection>



August 29, 2018, https://www.instagram.com/p/BnBwZiPAmMU/?taken-by=qreator_by_iqos

IQOS Sponsorship of Harper's Bazaar Ukraine Magazine's Best Dressed Event

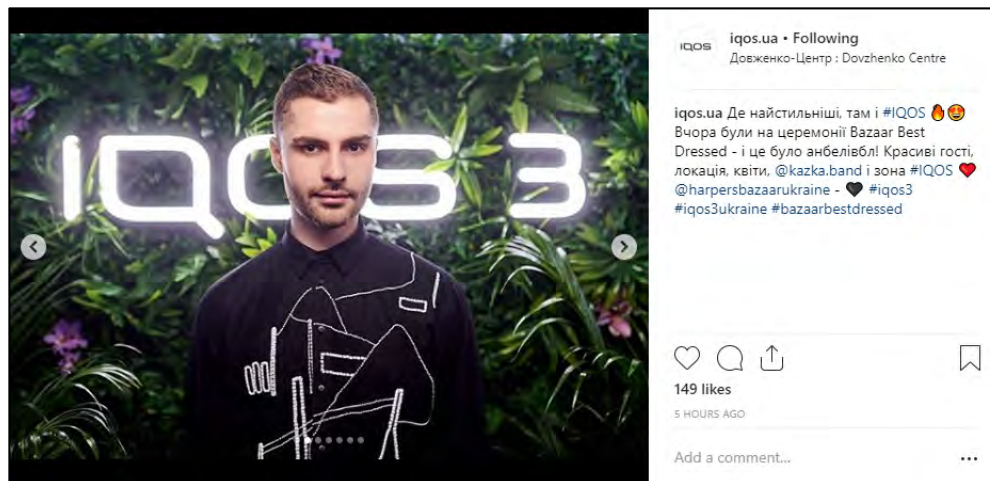
Another example of IQOS sponsoring a fashion event in Ukraine where, again, attendees can take pictures of themselves and share on their personal account. Note the young girl in the post on the top right.



December 5, 2018, <https://www.instagram.com/p/BrAp-hyBAy5/>



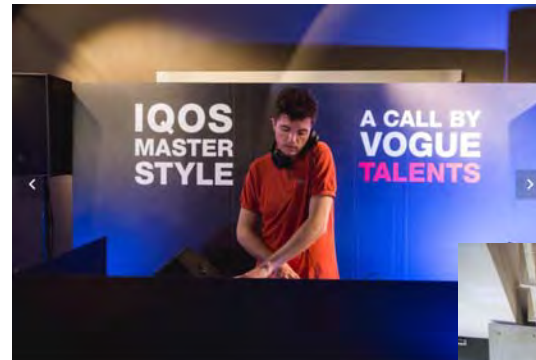
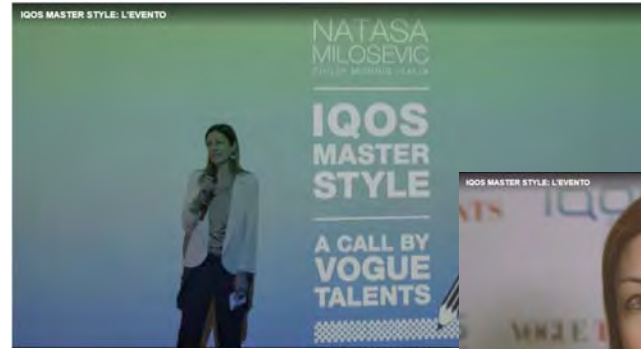
December 4, 2018, <https://www.instagram.com/p/Bq-xaxjhXdN/>



December 5, 2018,
<https://www.instagram.com/p/BrAesPKHv6l/>


IQOS Master Style: Collaboration with Vogue Talents (Italy), June 2017 Event

PMI sponsored the IQOS Master Style event with Vogue Talents in Italy to mentor young fashion designers. PMI executives participated and spoke to attendees.



https://www.vogue.it/en/vogue-talents/contest-opportunities/2017/06/27/iqos-master-style-event-philip-morris-call-for-action/?refresh_ce=
<https://www.vanityfair.it/fashion/red-carpet/2017/06/28/iqos-master-style-vogue-talents>

IQOS-Sponsored London Fashion Week Blog Post



Toula Rose



MARCH 5, 2018

LONDON FASHION WEEK X IQOS AT THE ROSEWOOD HOTEL

London Fashion Week: My stay at the Rosewood hotel in collaboration with [IQOS](#)

So usually I would be absolutely dreading the stress of fashion week, the trawling around London and the early and late commute home – but this LFW I absolutely did it the way you should thanks to [IQOS](#) (heated tobacco technology)

[IQOS](#) provided me the most beautiful room at the [Rosewood Hotel](#) (I had literally wanted to stay here for years since I first visited it!) during London Fashion Week which was walking distance to all the shows so perfect location and just the best place ever!



Toula Rose. London based fashion & lifestyle blogger. Affordable Style.

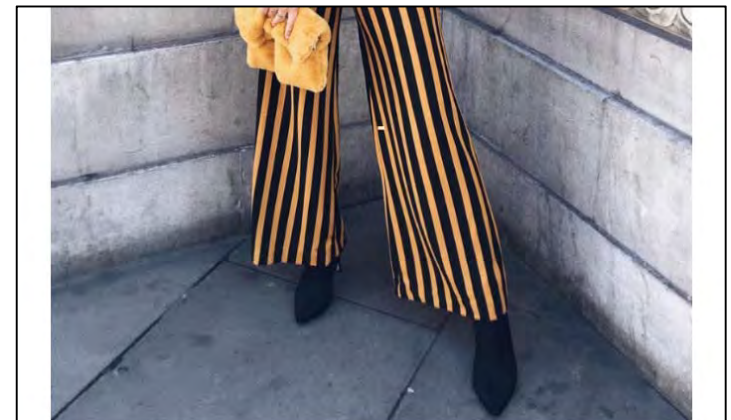
[The rooms were IQOS friendly. If you guys smoke but don't know about IQOS then you'll be glad you've read this post.](#)

It uses heat technology rather than burning tobacco, which gives you the true taste of tobacco with no smoke, no ash and a lot less smell. One of the things that I hated about normal smoking was the smell that can get left on you, whereas with IQOS your hair or clothes don't smell of smoke at all afterwards! So I was fashion week ready! The device is super sleek and comes in a variety of colours.



Shop IQOS [here](#)

See what I wore on the first day of fashion week below:



[Be sure to check out IQOS for a way better alternative to normal cigarettes > here](#)

Thanks to IQOS + The Rosewood Hotel for a fantastic fashion week experience!

March 2018, <https://www.toularose.com/2018/03/05/london-fashion-week-x-iqos-rosewood-hotel/>

IQOS-Sponsored Magazine Articles

In addition to sponsoring fashion and style events, PMI has sponsored “lifestyle” articles in fashion magazines touting IQOS.

COSMOPOLITAN

Home » Lifestyle » 5 lucruri care merită un loc pe lista ta de schimbări pentru noul an

5 lucruri care merită un loc pe lista ta de schimbări pentru noul an

By [Alina Neamtu](#) | 22 decembrie 2017

(...)

- **Modificarea unui tabiet**

Putem adopta un obicei nou în doar 21 de zile, scrie Maxwell Maltz în cartea sa **Psycho-Cybernetic**, iar dacă nu vrei decât să îl modifici, îți va lua și mai puțin timp. O mulțime de alte tabieturi pot fi modificate: ceai în loc de cafea, citit înainte de culcare în loc de televizor, mersul pe jos în locul mașinii sau al taxiului.

Totodată, un tabiet al multora dintre noi este să ne însoțim cafeaua de dimineață cu o țigară, însă anul următor ai putea să înlocuiești țigara cu un **IQOS**, un dispozitiv care nu mai lasă în urmă acel miros neplăcut de fum.

(...)

(P) Articol realizat împreună cu IQOS

Home » Lifestyle » 5 things that deserve a place on your list of changes for the new year

5 things that deserve a place on your list of changes for the new year

“At the same time, it is a taboo for many of us to accompany our morning coffee with a cigarette, but the following year you could replace the cigarette with an **IQOS**, a device that does not leave behind that unpleasant smell of smoke.”

(P) Article made with IQOS

(Translated by Google Translate)

Cosmopolitan Romania, December 22, 2017, <https://www.cosmopolitan.ro/cosmo-fun/5-lucruri-care-merita-un-loc-pe-lista-ta-de-schimbari-pentru-noul>

Fashion Magazine Articles

While some articles are explicitly identified as sponsored by IQOS, others highlight the product but do not include sponsoring information. This article featured high-quality images of the product and had the two subjects mention how IQOS is part of their winter plans.

VOGUE

Мой идеальный зимний вечер: рассказывают Ульяна Нешева и Тимур Мирошниченко

28 ЯНВАРЯ 2019

Зима – идеальное время года, когда можно хоть ненадолго замедлить темп, посвящать больше времени себе и собственным хобби: наслаждаться искусством, кататься на лыжах, читать книги в компании IQOS, играть с друзьями в настольные игры. В нашем новом материале тату-мастер Ульяна Нешева и телеведущий Тимур Мирошниченко рассказывают о том, что такое для них идеальный зимний вечер и без чего они не представляют свою зиму.

(Translated by Google Translate)

My perfect winter evening: tell Uliana Nesheva and Timur Miroshnichenko

JANUARY 28, 2019



Winter is the ideal time of the year when you can slow down the pace, spend more time for yourself and your own hobbies: enjoy art, ski, read books at IQOS, play board games with friends. In our new material, tattoo artist Uliana Nesheva and TV presenter Timur Miroshnichenko talk about what an ideal winter evening is for them and without which they cannot imagine their winter.

Зима у меня ассоциируется с лыжным костюмом, а настоящим спасением в это время года становится IQOS. Теперь мне не нужно выходить на холодный балкон зимой и даже открывать окна в машине. Device абсолютно не дышит и не производит характерных для курительных запалов. И как мои прошлые зимы проходили без него?



My winter is associated with a ski suit, and [IQOS](#) becomes a real salvation at this time of the year. Now I don't need to go out to a cold balcony in winter and even open windows in the car. The device does not smoke at all and does not produce smells characteristic of smokers. And how did my last winters go without him?

(Translated by Google Translate)

Vogue Ukraine, January 28, 2019,
<https://vogue.ua/article/culture/lifestyle/moy-idealnyy-zimniy-vecher-rasskazyvayut-ulyana-nesheva-i-timur-miroshnichenko.html>

PMI-Ferrari Sponsorship

PMI announced its renewal of its Ferrari sponsorship in early 2018. Sports sponsorships, and particularly Marlboro's sponsorship of Formula 1 racing has long been recognized as a successful way to present its brand to millions of viewers and elevate its image as a "winning" product.¹

February 20, 2018

Philip Morris International and Scuderia Ferrari Partner Together to Advance the Vision of a World Free of Tobacco Smoke

LAUSANNE, Switzerland--(BUSINESS WIRE)--Feb. 20, 2018-- Philip Morris International Inc. (NYSE/Euronext Paris: PMI) and Scuderia Ferrari have extended their partnership until 2021. Their successful collaboration spans more than 40 years. As of today, the partnership will be exclusively focused on advancing the cause of a smoke-free world – a world in which all people who would otherwise continue smoking switch from the most harmful form of nicotine consumption – cigarettes – to scientifically substantiated less harmful alternatives that are smoke-free.

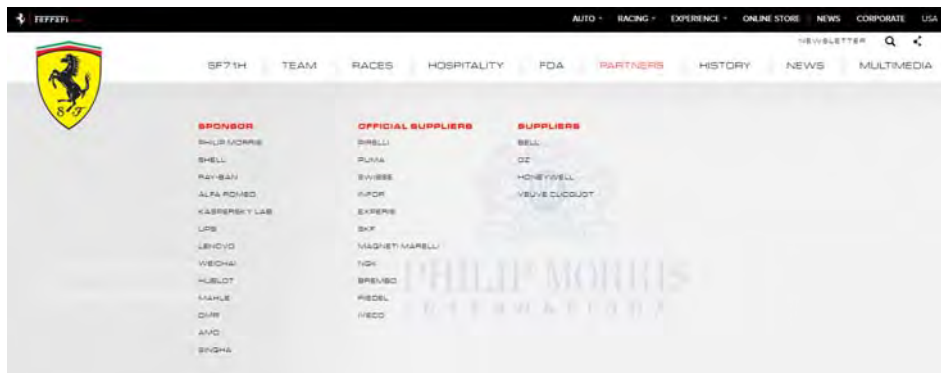
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PMI Operations Center Media Office

+41 (0)58 242 4500

Media@pmi.com

<https://www.pmi.com/media-center/press-releases/press-release-details?newsId=2333298>



<http://formula1.ferrari.com/en/partners/philip-morris-international/>



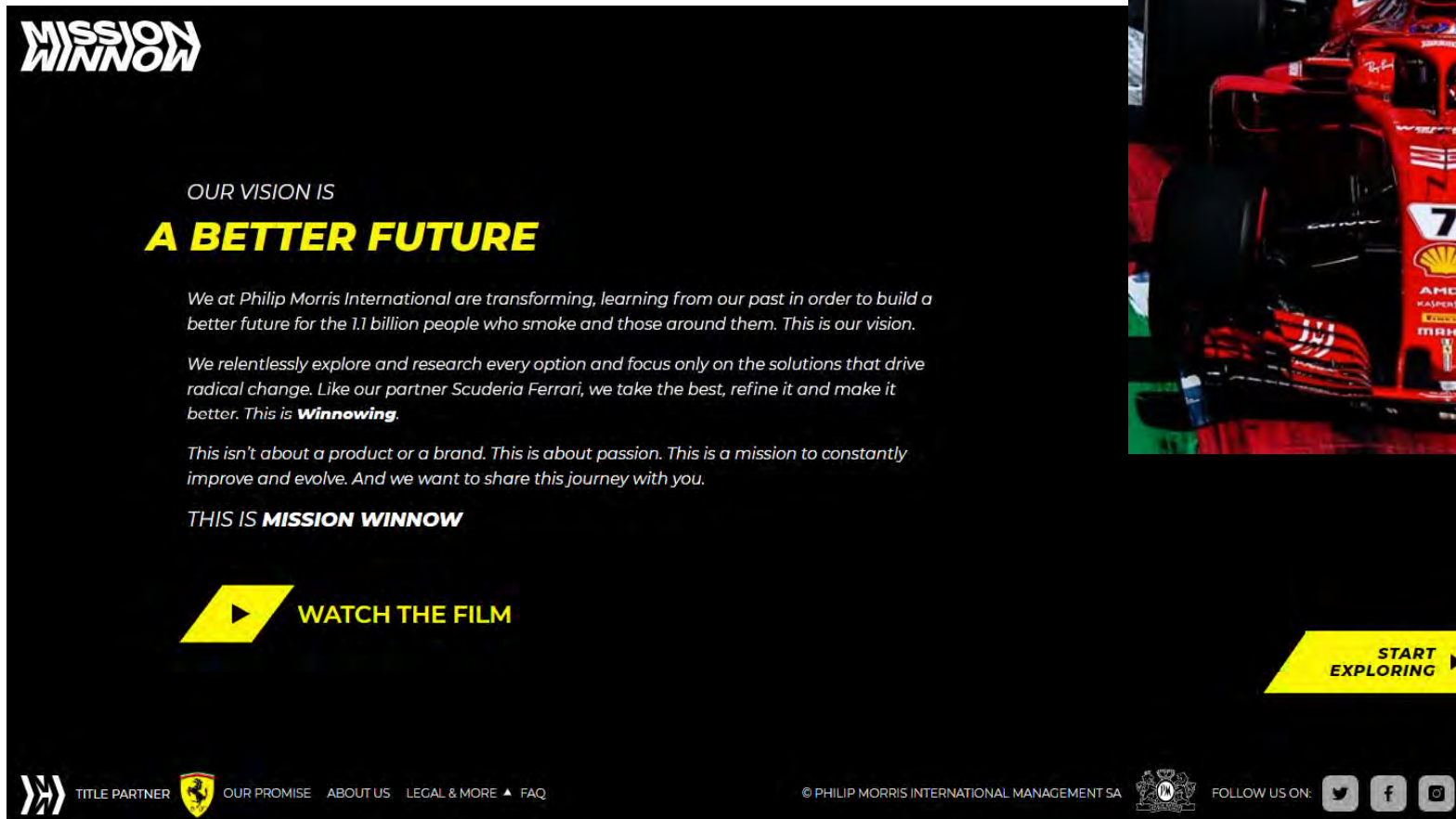
Blog post, October 7, 2017, <http://sebastian-vettel-fans.blog.cz/1710/videos-photos-seb-kimi-and-maurizio-at-the-iqos-event-today>

¹ National Cancer Institute, *The Role of the Media in Promoting and Reducing Tobacco Use, Smoking and Tobacco Control Monograph No. 19*, NIH Pub. No. 07-6242, June 2008, http://cancercontrol.cancer.gov/tcrb/monographs/19/m19_complete.pdf, at 65, 68-69.

PMI's "Mission Winnow"

As a way to sponsor Ferrari while staying within the parameters of the EU Tobacco Advertising Directive, PMI has come up with the "Mission Winnow" logo and concept. This strategy allows them to highlight its technology and forward-thinking advances with analogies to racing and advancing towards a finish line. This is not the first time that PMI has attempted to skirt the advertising law.²

October 30, 2018, <https://www.instagram.com/p/BphQaoSFGvG/>



MISSION WINNOW

OUR VISION IS
A BETTER FUTURE

We at Philip Morris International are transforming, learning from our past in order to build a better future for the 1.1 billion people who smoke and those around them. This is our vision.


We relentlessly explore and research every option and focus only on the solutions that drive radical change. Like our partner Scuderia Ferrari, we take the best, refine it and make it better. This is **Winnowing**.





This isn't about a product or a brand. This is about passion. This is a mission to constantly improve and evolve. And we want to share this journey with you.

THIS IS **MISSION WINNOW**

WATCH THE FILM

START EXPLORING

TITLE PARTNER  OUR PROMISE ABOUT US LEGAL & MORE ▲ FAQ

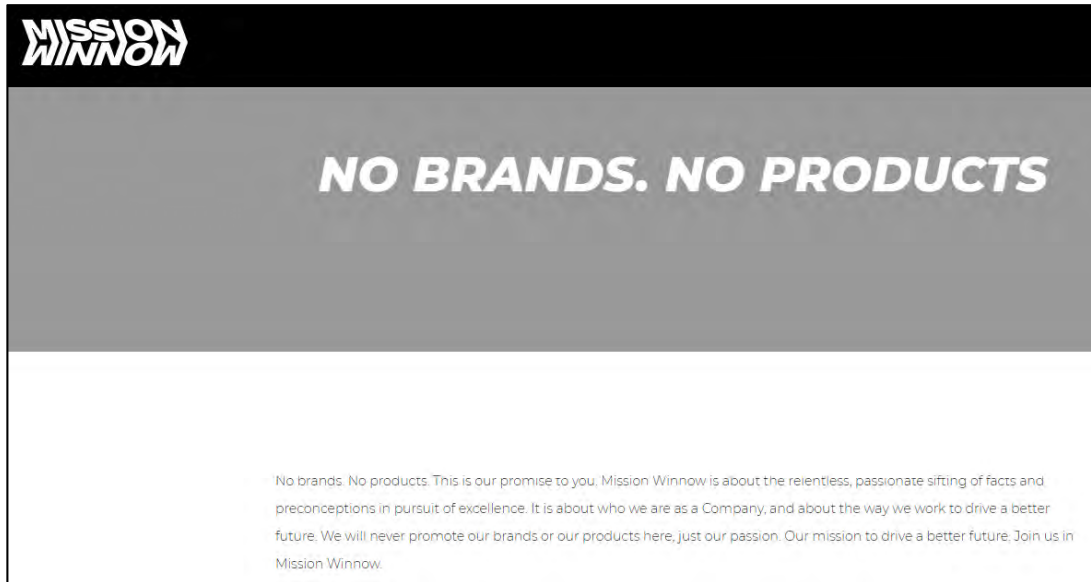
© PHILIP MORRIS INTERNATIONAL MANAGEMENT SA  FOLLOW US ON:   



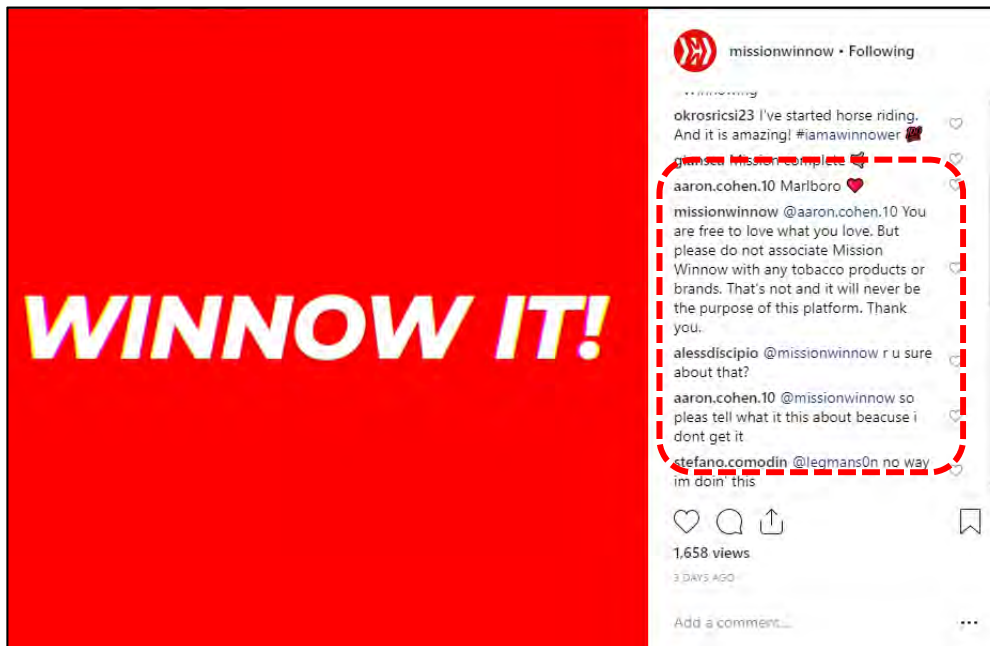
Screenshot taken November 5, 2018, <https://www.missionwinnow.com/>

² Grant-Braham, B & Britton, J, "Motor racing, tobacco company sponsorship, barcodes and alibi marketing," *Tobacco Control* 21(6):529-535, 2012.

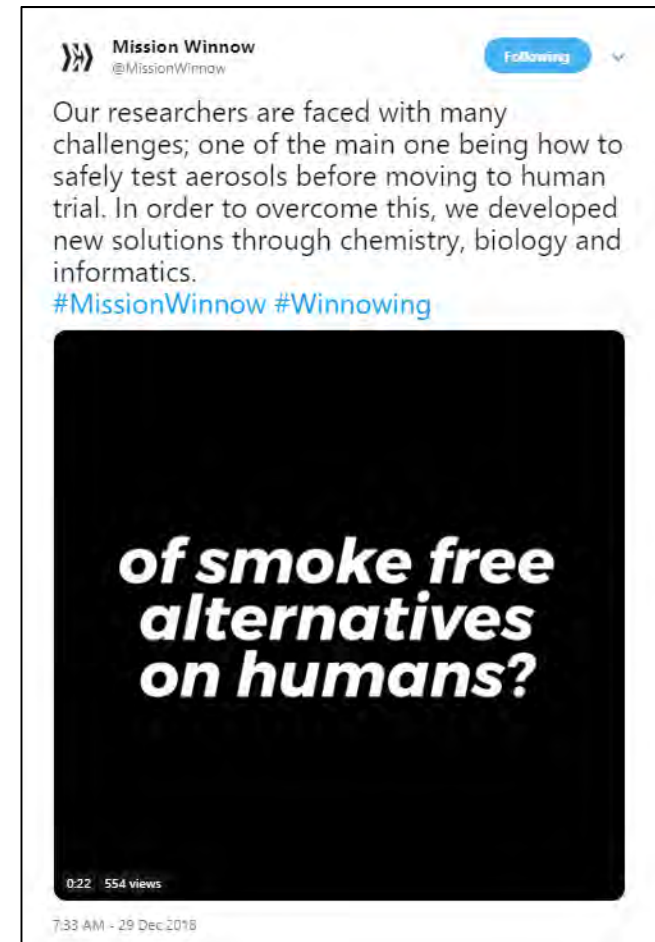
Mission Winnow – Not Associated with Tobacco Products or Brands...Yet Tweets about Smoke-Free Alternatives



Screenshot taken November 5, 2018,
<https://www.missionwinnow.com/no-brands-no-products>



November 2, 2018, <https://www.instagram.com/p/BprftHnI9at/>



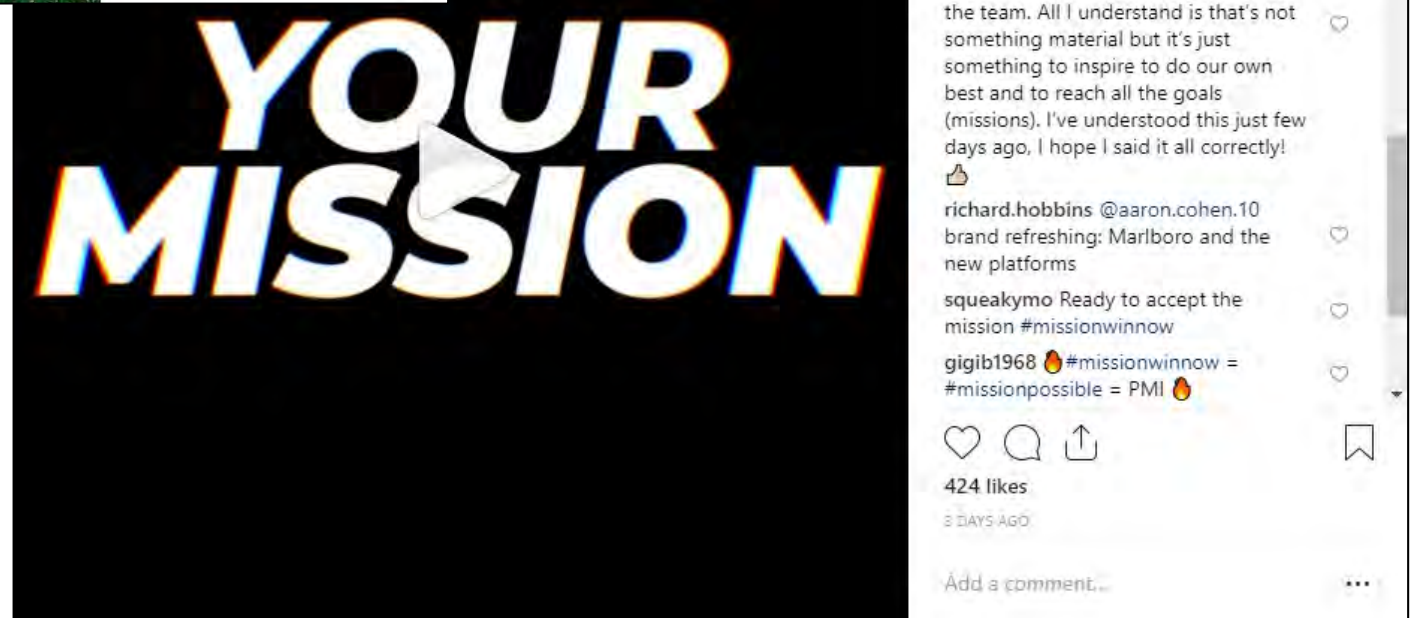
December 29, 2018,
<https://twitter.com/MissionWinnow/status/1079037622163525634>

Mission Winnow – Young Followers

An example of the young followers of Mission Winnow. Note also the acceptance that the campaign is linked to PMI.



May 26, 2018, <https://www.instagram.com/p/BjPekxEILmN/>



November 2, 2018,
<https://www.instagram.com/p/BprftHnI9at/>

PMI's Mission Winnow and Ducati Corse Racing Team

PMI has recently extended its sponsorship to the Ducati Course Racing Team.



Instagram post, January 18, 2019, <https://www.instagram.com/p/BsyRCKenLbM/>

Instagram story from Mission Winnow, January 18, 2019, <https://www.instagram.com/missionwinnow/>