The Consumer Advocates for Smoke-free Alternatives Association

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RE: Modified risk tobacco product applications (MRTPAs), submitted by Philip Morris Products S.A. for IQOS system with Marlboro Heatsticks, IQOS system with Marlboro Smooth Menthol Heatsticks, and IQOS system with Marlboro Fresh Menthol Heatsticks..

Introduction

The following comments are submitted on behalf of The Consumer Advocates for Smoke-free Alternatives Association (CASAA) in support of the scientific validity of the modified risk tobacco product applications ("MRTP applications") submitted by Philip Morris Products S.A. ("PMI") for the IQOS system with Marlboro Heatsticks, Marlboro Smooth Menthol Heatsticks, and Marlboro Fresh Menthol Heatsticks (collectively referred to as "IQOS"). CASAA is a 501(c)(4) nonprofit public health and education NGO and is the leading representative of consumers who use or might in the future use smoke-free tobacco and nicotine products. It is a U.S. membership organization with over 200,000 members. CASAA advocates on behalf of consumers and does not represent the interests of industry.

At the onset, we note the obvious, that not all tobacco products carry the same risks. Smoking cigarettes carries far greater risks than any other form of tobacco use. Generally, non-combustible tobacco products carry a much lower health risk than combustible tobacco products, and we note that consumers have a right to accurate and truthful information about these products to make informed decisions about their health and lifestyle choices. Previous TPSAC recommendations to the FDA have actively worked against this basic consumer right, contrary to sound scientific practices being the foundation of accurate and truthful risk communication. In the case of Swedish Match's MRTP application, TPSAC recommended against allowing required warning labels for Swedish Match's snus products to be restated much more in line with the best scientific evidence. As a result, millions of consumers will continue to be misled by these warning labels (e.g., "WARNING: This product is not a safe alternative to cigarettes."). While technically accurate, these kinds of warnings are highly unlikely to be interpreted literally by consumers, but, rather, as statements that the risks of smoking and using smokeless tobacco are wrongly similar.

CASAA has long been critical of FDA's actions and proposals in connection with low-risk products such as vapor products and smokeless tobacco. As expressed in several comments on government dockets[1], we believe that FDA's approach under the previous administration has worked against the interests of genuine public health by threatening consumer access to low-risk products and by misleading consumers about the relative risks of various tobacco products. While we have grave concerns about FDA's stated intention to explore reducing nicotine content in combusted cigarettes as part of a strategy to coerce smokers to choose safer nicotine and tobacco products, we are cautiously optimistic about FDA's statement that it is "committed to encouraging innovations that have the potential to make a notable public health difference and inform policies and efforts that will best protect young people and help smokers

[1] See, for example, the following comments filed by CASAA:
https://www.regulations.gov/document?D=FDA-2016-N-2527-7340;
https://www.regulations.gov/document?D=FDA-2014-N-1051-0828;
https://www.regulations.gov/document?D=FDA-2014-N-0189-78335;
https://www.regulations.gov/document?D=FDA-2015-N-2002-1904; and
https://www.regulations.gov/document?D=FDA-2014-N-0189-42893.

quit cigarettes."[2] We believe TPSAC has the duty to advise the FDA based on a dispassionate and unbiased interpretation of the existing science as a means to help the FDA fulfil their stated goals.

IQOS meets the standards for a modified risk order

The Family Smoking Prevention and Tobacco Control Act ("TCA") requires the MRTP application to demonstrate that "such 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 health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products."[3]

In its MRTP applications, PMI convincingly demonstrates that IQOS significantly reduces harm and risk of tobacco-related disease[4] to individuals. Simply stated, because IQOS heats, not burns, tobacco, and because exposure to harmful chemicals across the board is significantly reduced, there is no doubt that the health risks of using this technology are dramatically lower than smoking. We find the scientific data included by PMI in its MRTP applications, generally corroborated by independent research conducted by Dr. Konstantinos Farsalinos[5], compelling.

Moreover, there appears to be little doubt that this technology will benefit the health of the population as a whole. The barrier to entry for IQOS is high in terms of expense and training to use the device, which is highly suggestive it will have very little appeal to non-smokers. IQOS clearly appeals to a significant segment of the smoking population, as illustrated by the fact that more than 3 million smokers worldwide thus far have switched from smoking to the IQOS.[6] Moreover, the health benefits accrued by millions of smokers switching to this device is highly likely to overwhelm the health risks created by the near trivial number of new IQOS users who wouldn't otherwise use a tobacco product.

While there are some other low-risk alternatives to smoking currently available (e.g., vapor products and smokeless tobacco), not all smokers find them satisfying alternatives. Of course, many smokers have not made a serious attempt to make the switch to existing low-risk alternatives because they have been misinformed and wrongfully believe that such products are as dangerous as smoking. This problem is compounded by manufacturers being prohibited from truthfully informing the public that vapor products and smokeless tobacco are low risk compared

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[2] FDA News Release, "FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death," at https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm568923.htm

[3] Section 911(g)(1) of the TCA.

[4] We use the term "tobacco-related disease" reluctantly because that is the wording used in the TCA, but we feel it important to note our firm belief that the phrase is misleading given that virtually all of the significant harms associated with tobacco use come from smoking, not tobacco use generally.

[5] Konstantinos Farsalinos, "Toxicant exposure Heated tobacco products vs. e-cigarettes," presentation at Global Forum on Nicotine in Warsaw, Poland, June 16, 2017, at https://gfn.net.co/downloads/Presentations_2017_/Dr%20Konstantinos%20Farsalinos.pdf

[6] https://www.pmi.com/smoke-free-products/iqos-our-tobacco-heating-system

to smoking. But even among those who have tried existing low-risk products, there are some who find the current offering not acceptable for one reason or another. Smokers need more low-risk choices, and IQOS will appeal to many who do not find vapor products and smokeless tobacco effective alternatives.

We note that many of the factors that have made vapor products such an effective alternative to smoking also apply to IQOS. Like vapor products, IQOS mimics smoking in terms of nicotine delivery, visible vapor, and hand-to-mouth behavior. Although vapor products come in *tobacco flavors*, these flavors are a poor imitation of the tobacco smoke-like flavors offered by IQOS.

While the evidence supports the proposition that a significant number of smokers in the United States will find IQOS an acceptable alternative to smoking (and therefore reduce their health risks by making the switch), there is no evidence to suggest that IQOS will be particularly attractive to never smokers or nonsmokers.[7]

The modified risk claims for which approval is sought are appropriate

PMI seeks to make the following truthful claims:

- IQOS system heats tobacco but does not burn it, which significantly reduces the production of harmful and potentially harmful chemicals.
- Scientific studies have shown that switching completely from cigarettes to the IQOS system can reduce the risks of tobacco-related diseases[8].
- Switching completely to IQOS presents less risk of harm than continuing to smoke cigarettes.
- Switching completely from cigarettes to the IQOS system significantly reduces the body's exposure to harmful and potentially harmful chemicals.

All of these claims are accurate. However, we recognize that the TCA limits the types of claims that can be made, which, ironically, works against genuine public health goals and the rights of consumers to receive accurate and truthful information so that they can make informed choices.

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[7] "Overall, these studies [premarket Perception and Behavior Assessment studies] demonstrated that THS [IQOS] is not attractive to adult never smokers and it is minimally attractive to adult former smokers. Approximately 6% of adult former smokers and less than 1.2% never smokers expressed an intention to use THS." PMI THS 2.7 Executive Summary, p. 14 at https://www.fda.gov/downloads/TobaccoProducts/Labeling/MarketingandAdvertising/UCM560044.pdf

[8] But see Footnote 4 of this comment regarding our general objection to the phrase "tobacco-related diseases."

Ethical, economic, and behavioral considerations

According to John Stuart Mill[9],

> [T]he only purpose for which power can be rightfully exercised over any member of a civilised community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant.

This statement encapsulates a basic principle of classical liberalism and the proper role of the government's relationship with the people in a free society. This view applies to consumer protection (i.e., the government has a proper role to protect the public from harms of others from which they are *unable* to protect themselves), but it also applies to consumer *access* to goods, which are freely chosen, that may contain some level of harm. IQOS is a relevant example. No one, including PMI, is arguing that use of IQOS is without potential harms, but, rather, that users of IQOS are exposed to significantly fewer harms than cigarette smoking. Moreover, as the evidence contained in the application makes clear, bystanders near IQOS users face virtually no health risks.

Therefore, smokers for whom IQOS is the only viable alternative to smoking should be free to assume this greatly lowered risk for their benefit. And the government lacks sufficient "warrant" to prohibit it on the basis that *some* harm may befall the user compared to using neither product. We understand that TPSAC does not write or set policy. But TPSAC does have the duty to report its findings on IQOS research to the FDA honestly and fairly. There is no need to cite any particular source on scientific ethics for this. If TPSAC has a role in policymaking, it is to provide the FDA with an accurate rendering of the IQOS science to help them craft the most reasonable policies possible. Recommending denial of PMI's MRTP application would be denying consumers truthful information about the relatively lower risks posed by IQOS use. This is tantamount to denying access to the product itself if smokers are misled into believing (by the suppression of this information) that using IQOS carries the same health risks as smoking.

Christopher Snowdon, of the Institute of Economic Affairs, writes[10]:

> Economics can be used to justify regulation of risky activities, up to and including prohibition, but not on the basis of paternalism. Like Mill, economists assume that individuals will use their freedom and resources to pursue the best life for themselves *as judged by themselves*. If we want to know people's preferences, we only have to observe what they do when they have the freedom to choose. If they are prevented from acting freely, they

[9] J.S. Mill (1987). *On Liberty.* London: Penguin.
[10] C. Snowden (2017). Killjoys: *A critique of paternalism.* London: Institute of Economic Affairs

> will be less able to maximise their utility and more likely to suffer a welfare loss. (emphasis in original)

We see evidence of *revealed preferences* throughout our database of over 11,000 narrative testimonials[11] from smokers who have used vapor products to quit smoking or significantly cut down on the number of cigarettes they smoke. Broadly defined, revealed preferences refers to the observation of what people *actually do* and is a far more reliable assessment of their preferences than what they *say* they want to do, and far more reliable still than what government officials or policymakers *assume* people's preferences are. A case in point is the often cited statistic that 70% of smokers say they want to quit smoking. Yet only a small fraction of these smokers actually *attempt* to quit in a given year. What the majority of these smokers are expressing is a *second order preference.*[12] They actually do want to smoke, because they continue to do so (their first preference), but also want to be a person who quits (their second preference).

However, it is well known that a small subset of smokers find it extremely difficult (some would say impossible) to quit. Buckner[13] argues

> . . . that second-order preferences have no role to play in the prescription or evaluation of actions aimed at ordinary ends. Instead, second-order preferences are relevant to prescribing or evaluating actions only insofar as those actions have a role in changing or maintaining first-order preferences.

Buckner is referring to something we see throughout our testimonials. Smokers unable to quit using traditional methods (e.g., nicotine replacement, cold turkey, etc.) often making multiple fruitless attempts and then find their second order preference realized (i.e., it becomes their first order preference) once they discover a viable substitute for smoking. In this case it was almost always the discovery of vapor products. We also see a consistent theme expressed by these now ex-smokers that, were it not for this discovery, they would still be smoking. This finding is a concise summary of why CASAA exists. Smokers who want to improve their health and often need multiple smoke-free options to discover and realize their now revealed preference of being a non-smoker. We believe, based on the scientific evidence, IQOS is such an option. For millions of smokers the IQOS may be the *only* option.

The psychology literature on the behavior of decision-making has pointed out several biases and faulty heuristics people commonly employ that lead to poor decision-making.[14] It would be

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[11] http://casaa.org/testimonials/

[12] D. W. Buckner (2011). Second-Order Preferences and Instrumental Rationality. *Acta Analytica*, Volume 26, Issue 4, pp 367–385.

[13] ibid.

[14] D. Kahneman, P. Slovic, & A. Tversky (1982). *Judgment under uncertainty: Heuristics and Biases.* Cambridge: Cambridge University Press

foolish, therefore, to believe that people always make good decisions regarding many aspects of their lives. However, this does not support the use of government intervention as a means for mitigating the poor decision-making of the populace. As Snowdon points out[15]

> There is no assumption in economics that people will make the 'best' choices according to some objective standard. The real question is whether somebody else – in practice, a politician – would make better choices for them. It is doubtful that he would.

The government is charged with helping people make the best decisions possible as often as possible. A foundation of this goal is the provision of truthful information about products that the citizen is unaware of. Kahneman and co-authors easily demonstrated the errors people tend to make in certain situations. But what is notable about this is that in these experiments the participants are given *perfectly accurate information*, but still commit the errors. It is obvious to see that even greater errors will occur more often if people are given ambiguous or misleading information.

The work of Rapp[16] and Marsh[17] illustrate how pernicious providing *false* information is to people's decision making. Rapp states

> . . . studies have consistently shown that even when people possess relevant prior knowledge, they may encode and rely upon obviously inaccurate information that they should know is patently wrong.

Based on this research, it takes little imagination to see how TPSAC's previously endorsed snus warning labels like "WARNING: This product is not a safe alternative to cigarettes" and "WARNING: This product *can* cause mouth cancer" (emphasis added) are open to broad interpretation, but mostly in the direction of exaggerated harm. This has the unconscionable result of misinforming people and surely contributes to more poor decision-making. These labels exist as a means of influencing the behavior of consumers considering using these products, not as a means of providing clear and accurate information. We submit that it is not TPSAC's role to be a party in attempts to control consumer behavior one way or another. TPSAC's role is to dispassionately summarize the science for the FDA. What the FDA does with TPSAC's recommendations should not be TPSAC's concern.

The FDA may hold the position that providing as accurate and truthful information as possible about alternative low-risk products will inevitably lead people to make poor decisions with vastly

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[15] ibid.
[16] D. N. Rapp (2016). The Consequences of Reading Inaccurate Information. *Current Directions in Psychological Science,* Vol. 25(4) 281–285.
[17] E. J. Marsh (2004). Story stimuli for creating false beliefs about the world. *Behavior Research Methods, Instruments & Computers*, 36, 650–655.

negative public health outcomes. TPSAC should strenuously avoid endorsing this specious line of reasoning when it comes to recommendations regarding the IQOS application. A case in point is the current warning labels on cigarettes. These have been accurate and clear for decades, and as a result, they have arguably been the most effective tool for reducing smoking to the rates we see today. We believe this trend will continue, and may even accelerate, if IQOS is approved as a reduced risk tobacco product, for much the same reasons. People make the best choices when they are provided with the unvarnished facts.

Conclusion

While we appreciate the government's desire to protect consumers against false and misleading advertising and marketing claims, we firmly reject the *status quo* whereby companies are prohibited from truthfully informing smokers that their smoke-free products pose a much lower risk of disease and premature death than smoking. At present, the only way for a company to communicate the lower risk of its product is to obtain a modified risk order, and even then, the claims being made are artificially limited in a manner that we believe does a disservice to consumers by overstating the risks.

If FDA is truly committed to reducing the health burden associated with tobacco use (virtually all of which comes from combustible tobacco products), the single-best thing it could do would be to accurately inform consumers that use of non-combustible tobacco products poses much lower health risks as compared to smoking. TPSAC should support this ideal. When consumers are misled into believing that all tobacco products carry similar and significant health risks, the result is that many people will continue to smoke rather than switch to a lower-risk product. Accurately communicating the much lower-risk nature of non-combustible tobacco products such as IQOS would have a tremendously positive impact on the public's health and well-being by encouraging smokers to make the switch to lower risk products.

For the foregoing reasons, along with the ethical, economic, and behavioral evidence provided, we respectfully encourage TPSAC favorably recommend FDA approval of PMI's MRTP applications for IQOS as an important step in truthfully communicating risks to consumers that will lead to fewer smoking-related illnesses and early death.