

IQOS reduced exposure claims mislead consumers to believe the product is less harmful:
Comments for the Tobacco Products Scientific Advisory Committee

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FDA has invited comments on the Philip Morris Products S.A (Philip Morris) modified risk tobacco product (MRTP) applications for the IQOS system and Heatsticks.¹ We submit this comment regarding the requested **exposure modification order** under FD&C §911(g)(2). Exposure modification orders allow companies to claim their products expose consumers to lower levels of a toxic substance. Philip Morris's requested reduced exposure claim is "Switching completely from cigarettes to the IQOS system significantly reduces your body's exposure to harmful and potentially harmful chemicals" (Claim 3 in application).¹

We have two points: I. The exposure modification order pathway is unlikely to be viable in general, and II. The specific reduced exposure claim by Phillip Morris misleads the public.

I. Generally, the exposure modification order pathway is unlikely to be viable

For a claim of reduced exposure to chemicals under section 911(g)(2), the applicant must provide evidence that "testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers **will not be misled** into believing that the product— (I) is or has been demonstrated to be less harmful; or (II) presents or has been demonstrated to present less of a risk of disease than 1 or more other commercially marketed tobacco products"² (emphasis added). Essentially, reduced exposure claims must not mislead consumers into thinking that the product is less harmful.

It is reasonable for consumers to infer that the rationale for providing information about reduced exposure to harmful chemicals is to convey that the product is less harmful. In conversations and other communication, people expect information provided to be relevant to them.^{3,4} Research from our group, and even research submitted by Philip Morris in the applications, shows that reduced exposure claims reduce people's perceived risk of the products. Below we present several relevant studies.

A. UNC MRTP study

Introduction. We sought to determine whether tobacco product claims about reduced exposure to toxic chemicals lowers perceived risk of health harm.⁵

Methods. We conducted a phone survey with a nationally-representative sample of 2,445 adult and 489 adolescent smokers and non-smokers from September 2015 to May 2016. The survey included an experiment that assessed perceptions of potential MRTPs. This between-subjects experiment randomly assigned participants to receive 1 of 3 claims: 90% less of the harmful

chemical in the MRTP relative to cigarettes, 20% less, or same amount (control). Because the pattern of findings was the same in various contexts, we present findings combined across experimental manipulations (3 MRTPs [IQOS, e-cigarette, and snus], 3 chemicals [arsenic, formaldehyde, and carbon monoxide]), and samples (adults and adolescents).

After introducing the MRTP and how it functions, the survey presented a scenario describing the amount of a chemical in the product. An example of a scenario for IQOS is: “I am going to describe a new type of cigarette called IQOS. It makes less smoke because it warms the tobacco without burning it. Suppose the FDA approves a label saying that IQOS exposes you to 90% less arsenic than cigarettes.” The survey then assessed perceived exposure, followed by perceived risk: “If you used IQOS regularly for the next 10 years, how likely do you think it is that you would eventually develop serious health problems?” (4 point response scale: “not at all likely” to “extremely likely”). This item follows good practices in risk communication questions⁶ and is readable at a 9th grade reading level.⁷ Finally, the survey assessed susceptibility to product use—whether the participant would try the product if it was offered by a friend (4 point scale: “definitely yes” to “definitely no.”) Survey items were adapted from previously validated items or cognitively tested if new. We report results of preliminary analyses.

Results. Claims of less exposure were associated with lower perceived risk. Claiming “20% less” chemicals led to lower perceived risk than claiming the “same amount” (mean [SD] = 3.08 [0.91] vs. 3.20 [0.85], $p < .05$). Claiming “90% less” also led to lower perceived risk than “same amount” (mean [SD] = 2.96 [0.91], $p < .05$).

Reduced exposure claims increased susceptibility through decreases in perceived risk, a finding consistent with mediation (Figure 1). The finding held for both claims of 90% and 20% reduced exposure (mediated effect_{90%} = 0.07, $p < .001$; mediated effect_{20%} = 0.04, $p = .006$).

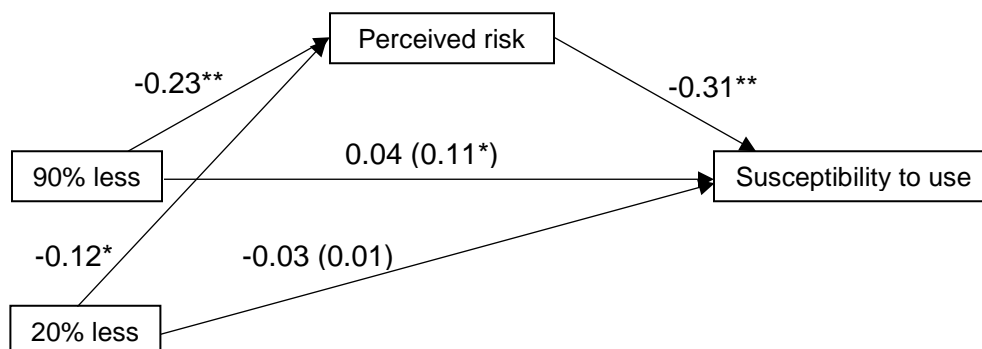


Figure 1. Perceived risk of harm mediated the association between reduced exposure claims and susceptibility to tobacco product use. Referent group for exposure was “same amount.” Numbers are standardized regression coefficients. Number in parenthesis is unadjusted pathway. Preliminary data. * $p < .01$; ** $p < .001$

Discussion. We found that claims of reduced exposure to the harmful chemicals in these products led to lower perceived risk. Reduced exposure claims also led to higher susceptibility to use the MRTP because of lower perceived risk. These results suggest that the exposure modification order pathway is not likely viable because reduced exposure claims may lower perceived risk and increase susceptibility to use.

B. UNC harmful chemicals study

Background. In another study we sought to identify effective ways to present information to the public about the harmful chemicals in cigarette smoke.⁸⁻¹⁰ Pertinent to MRTPs, the study assessed perceptions of cigarettes with lower levels of harmful chemicals than other cigarettes.

Methods. We conducted 4 surveys with US adults (smokers and nonsmokers), including a nationally-representative sample (Nat'l, $n=1,441$) and 3 convenience samples: S1 ($n=607$), S2 ($n=650$), S3 ($n=609$). Participants completed online surveys that assessed perceptions of cigarettes with lower levels of harmful chemicals.

Results. Many participants thought cigarettes with fewer harmful chemicals are safer than other cigarettes (Table 1). Across the 4 samples studies, 38% to 42% agree that “it is much safer to smoke cigarettes with fewer chemicals.” Participants were also inclined to switch to brands with fewer chemicals.

Table 1. Agreement with survey items about harmful chemicals in cigarette smoke

Survey item	Nat'l	S1	S2	S3
It's much safer to smoke cigarettes with fewer chemicals.	42%	38%	41%	42%
A cigarette is much safer to smoke if it has less arsenic than other cigarettes.	-	29%	29%	34%
If you learned that your cigarettes have 25% more of a dangerous chemical than other cigarettes, how likely, if at all, would you be to switch brands/styles?*	83%	-	-	-
If you learned that your cigarettes have a lot more of a dangerous chemical than other cigarettes, how likely, if at all, would you be to switch brands/styles?*	-	92%	-	-
If you learned that your cigarettes have a lot more of a dangerous chemical than other cigarettes, how likely, if at all, would you be to switch brands/styles?*	-	-	92%	89%

* Asked only of smokers. Responses “would definitely switch” and “might switch” coded as agreement. Nat'l data not weighted. Nat'l = national sample, S1-S3 = three convenience samples. Preliminary data.

Discussion. A substantial proportion of US adults interpret a reduction in harmful chemicals in a tobacco product as a reduction in harm. Although these studies were about combustible cigarettes, the findings indicate that information about reduced exposure to harmful chemicals is likely to mislead the public into thinking that a tobacco product poses less harm.

II. Philip Morris's own application clearly shows that their reduced exposure claim misleads the public

Philip Morris's claim is misleading

For an exposure modification order, an applicant must demonstrate that consumers “will not be misled” into believing the product is less harmful than another product. The study in the application by Philip Morris (THS-PBA-05-REC-US) instead shows that consumers were misled into believing IQOS is less harmful than cigarettes. Philip Morris attempted to remedy this with a disclaimer (“PMI Warning”), yet **even with the disclaimer, a substantial proportion of participants were misled.**

Philip Morris surveyed a convenience sample of 2,272 US adults in 2015. Philip Morris randomly assigned participants to 1 of 5 study arms defined by the marketing material participants were shown: IQOS brochure, IQOS brochure with disclaimer, Heatsticks package, Heatsticks package with disclaimer, and IQOS direct mail with disclaimer. The survey assessed harm reduction beliefs using the following “Global Comprehension” item: “Next, thinking about all of the information on the IQOS material, switching completely from conventional cigarettes to

IQOS: Has a greater risk of tobacco-related diseases; Reduces the risk of tobacco-related diseases; Has not been demonstrated to reduce the risk of tobacco-related diseases [correct]; Eliminates the risk of tobacco-related diseases; Don't know." Note that the item is problematic in many ways, including requiring an advanced college degree to understand (mean reading level of the item: grade level 18.5).⁷

Per the results of the "Global Comprehension" survey question that was used by Philip Morris, **even with the disclaimer, 26% of participants were misled by the brochure, believing that IQOS "eliminates" or "reduces" the risk of tobacco related disease.** Similarly, 31% were misled by the Heatsticks package with disclaimer and 28% were misled by the direct mail piece with disclaimer. **Additionally, on the Philip Morris "Perceived Health Risk" score, even with the disclaimers, participants believed IQOS to be lower risk than conventional cigarettes.**¹¹ Stronger disclaimers would only put more burden on the consumer; it is more effective and more appropriate to not make the reduced exposure claim at all.

Misleading 26% of the 36 million smokers in the US means misleading millions of people. These messages could also mislead millions of susceptible nonsmokers, including adolescents. **Clearly, Philip Morris has not met the requirements for an exposure modification order.**

It is unsurprising that the Phillip Morris disclaimer did not remedy misperceptions. **Disclaimers do not and will not fully remedy misleading marketing claims.** Decades of research across an array of products and legal corrections have shown that disclaimers do not fully negate a marketing claim, especially in the real world.¹²⁻¹⁹ The problem is exacerbated when claims appear in bold type at the top of advertising and disclaimers appear buried in small font in the footer of ads.²⁰ Disclaimers may be especially ineffective when they rely on brief negation words like "not," which is the type of disclaimer Philip Morris is proposing.¹²

Claims and disclaimers for tobacco products: Natural American Spirit

In 2000, the US Federal Trade Commission (FTC) filed a complaint against Santa Fe Tobacco Company that their "no additives" advertising for American Spirit cigarettes implied a less hazardous cigarette. The company settled, agreeing to disclose in advertisements and on cigarette packs that "No additives in our tobacco does NOT mean a safer cigarette."²¹ In 2010 the company agreed to add a similar disclaimer regarding "organic" tobacco.²² Studies of perceptions of American Spirit cigarettes have **consistently shown that even after a decade of the use of the "natural" disclaimer, the public still perceives these cigarettes as less harmful than other cigarettes.**^{15,20,23-26} In one of these studies, our research group convened 9 focus groups ($n=59$) stratified by age and cigarette smoking status, and asked about an example American Spirit ad that included the claims and disclaimers. We found that the disclaimers were ignored, questioned, distrusted, misinterpreted, or simply not noticed.²⁰ In another study, we conducted a randomized experiment with digitally-manipulated American Spirit ads with US adults ($n=1,114$). We found that ads with "natural," "organic," and "additive-free" claims elicited lower perceptions of harm than claims of "light" or "regular" (Cohen's $d = 0.87$ [0.47-1.29]).²⁵ Of critical importance, adding a disclaimer did not substantially offset the misleadingness of these terms (Cohen's $d = 0.25$ [0.08-0.41]).

Conclusion

Philip Morris' claims of reduced exposure will mislead the public to think the product is safer. Disclaimers, such as those proposed by Philip Morris, are an inadequate solution to the problem of misleading the public created by the proposed claim of reduced exposure to toxic chemicals. **Philip Morris has not met the requirements for an exposure modification order.**

Disclosures

Dr. Brewer and Dr. Ribisl have served as expert consultants in lawsuits pertaining to tobacco products. Both have also received research funding from the NIH/FDA.

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