Effects of Modified Risk Tobacco Product Claims on Consumer Responses

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ABSTRACT

Background: US tobacco manufacturers can seek authorization from FDA to market products using modified risk tobacco product (MRTP) claims. To inform regulatory decisions, we examined the impact of MRTP claim specificity and content, including whether the claims produced halo effects (i.e., inferring health benefits beyond what is stated).

Methods: Participants were 3,161 US adult cigarette smokers. Using a 2 (general vs. specific) × 2 (risk vs. exposure) plus independent control design, we randomized participants to view one message from these conditions: general risk claim (e.g., "tobacco-related diseases"), general exposure claim (e.g., "harmful chemicals"), specific risk claim (e.g., "lung cancer"), specific exposure claim (e.g., "arsenic"), or control. Claims described benefits of completely switching from cigarettes to the heated tobacco product IQOS.

Results: MRTP claims of any sort elicited higher willingness to try IQOS relative to control (d=0.09, p=0.043). Claims also elicited lower perceived risk of disease and exposure to harmful chemicals for completely switching from cigarettes to IQOS (d=-0.32 and-0.31) and partially switching (d=-0.25 and=-0.26; all p<0.05). Relative to specific MRTP claims, general MRTP claims led to lower perceived risk and exposure for complete switching (d=-0.13 and d=-0.16) and partial switching (d=-0.14 and d=-0.12; all p<0.05). Risk and exposure MRTP claims had similar effects (all p>0.05).

Discussion: MRTP claims led to lower perceived risk and exposure, and higher willingness to try IQOS. General claims elicited larger effects than specific claims. MRTP claims also promoted unintended halo effects (e.g., lower perceived risk of disease and chemical exposure for partial switching).

Implications: We found evidence that MRTP claims promoted health halo effects. In light of these findings, FDA should require research on halo effects prior to authorization. Further, if an MRTP claim is authorized, FDA should require tobacco manufacturers to conduct post-market surveillance of how the claim affects consumer understanding, including partial switching perceived risk and exposure beliefs, as well as monitoring of dual-use behaviors.

INTRODUCTION

The 2009 Family Smoking Prevention and Tobacco Control Act (TCA) empowered the U.S. Food and Drug Administration (FDA) to regulate tobacco products.[1] FDA's regulatory authority includes oversight of advertising, marketing, and promotion of tobacco products, and public education about the harms of tobacco products.[2] Through these and other actions, the TCA aims to prevent youth tobacco initiation, encourage tobacco cessation, and decrease the harm and addictiveness of tobacco products.[2]

FDA has acknowledged that individual harm associated with tobacco product use exists along a continuum.[3] While combusted tobacco products are believed to be most detrimental to human health, non-combusted products (although still dangerous) are believed to cause comparatively less harm. Consequently, some have proposed tobacco harm reduction as a strategy to help smokers unable or unwilling to give up nicotine by encouraging the transition to a less harmful nicotine source.[4]

Tobacco companies have a well-documented history of using false and misleading claims in marketing campaigns, such as implying there are fewer health risks from certain tobacco products (e.g., "low-tar" or filtered cigarettes).[5,6] The TCA prohibits tobacco manufacturers from making any unauthorized implicit or explicit health claims about their products;[1] however, to help educate the public about tobacco product risks and encourage transitions away from combustible products, the TCA created a scientifically-grounded process for tobacco manufacturers to seek FDA authorization to make certain health claims. The TCA refers to potentially less harmful tobacco products as modified risk tobacco products (MRTP).[1]

The TCA describes two types of MRTP claims that can be authorized: 1) claims describing reduced disease risk (risk modification) and 2) claims describing reduced exposure to harmful substances (exposure modification).[1] In addition to *type* (i.e., risk vs. exposure),

MRTP claims can vary in their *specificity*.[7] For instance, claims may be general and broadly describe reduced disease risk or exposure (e.g., "tobacco-related diseases", "harmful chemicals"), or claims can be specific and identify precise disease risks and exposures that are reduced (e.g., "heart disease", "carbon monoxide"). Claim type and specificity are important messaging decisions that manufacturers will make in designing and proposing MRTP claims for FDA review. These message features may play an important role in attracting and persuading consumers, may affect consumer risk and exposure beliefs, as well as MRTP use behaviors.

Although MRTP claims have the potential to encourage smokers to transition to a less harmful tobacco product, such claims may also mislead consumers, which could result in unintended negative consequences. Of particular concern to FDA is whether MRTP claims will elicit "halo effects", leading consumers to infer health benefits beyond those in a stated claim.[8] For instance, a tobacco user may generalize claims describing reduced exposure to a harmful chemical (e.g., carbon monoxide) to mean that the product also conveys reduced *disease* risk (e.g., lung cancer).[9] According to both the TCA and industry guidance released by FDA, exposure claims should not to be interpreted as reduced risk claims.[1,10] Further, MRTP claims describing benefits (e.g., reduced disease risk) from *completely* switching from cigarettes to the MRTP may be generalized to mean that *partially* switching to the MRTP (i.e., using the MRTP and continuing to smoke) provides similar health benefits.[9] In some situations, these generalizations may be inaccurate. For instance, partial switching may do little to reduce disease risk, and could result in increased exposure to harmful chemicals compared to cigarette use alone.[11] Thus, if MRTP claims create halo effects, consumer decision making may be based on inaccurate risk beliefs, which could result in negative unintended consequences such as dual tobacco product use.[9]

Understanding how MRTP claims affect consumer responses may aid in the development of claims that are maximally effective at educating the public about tobacco product relative risk and exposure, while minimizing unintended consequences associated with misleading consumers. Moreover, such research is needed to guide FDA regulatory decisions for MRTP applications.

In the current experiment, we evaluated the impact of potential MRTP claims about IQOS, a heated tobacco product sold by Philip Morris International.[12] Based on previous empirical results and theory,[13-17] we hypothesized that MRTP claims a) reduce perceived risk of disease, b) reduce perceived exposure to harmful chemicals, c) increase willingness to try IQOS, compared to control. We also hypothesized that specific MRTP claims a) reduce perceived risk of disease, b) reduce perceived exposure to harmful chemicals, c) increase willingness to try IQOS, compared to general MRTP claims. Finally, given previous research findings,[14] we hypothesized that MRTP claims describing reduced risk and reduced exposure have similar effects on a) perceived risk of disease, b) perceived exposure to harmful chemicals, c) willingness to try IQOS.

METHODS

Sample

Eligible participants were ≥18 years of age, US residents, and current combustible cigarette smokers (≥100 cigarettes in lifetime and currently smoking every day or some days). All were enrolled in August 2019. We initially recruited Amazon Mechanical Turk (MTurk) workers (n=1,116), limiting recruitment to those meeting the smoker premium qualification (self-reported current cigarette smokers) and those with an MTurk rating of ≥ 90%.[18] Due to slow enrollment (likely due to the premium qualification), we recruited additional participants with Prime Panels (n=2,045) using the same eligibility criteria.[19]

Procedures

Experimental Design. The between-subjects experiment used a 2 × 2 factorial design with an independent control (5 total conditions). The first experimental factor was MRTP *claim type*, which manipulated whether the claim described reduced risk (e.g., "lung cancer") or reduced exposure (e.g., "carbon monoxide) benefits of completely switching from cigarettes to IQOS. The second experimental factor was *claim specificity*, which manipulated whether the claim described reductions in specific (e.g., "carbon monoxide) or general (e.g., "smoking-caused diseases") exposures and risks. Control messages discouraged littering of IQOS waste. We chose this type of control message because it was relevant to IQOS but did not communicate any modified risk or exposure information.

The experiment was conducted online. Following consent and screening, eligible participants first viewed two webpages that contained information about and photographs of IQOS (Supplemental Figure 1). All participants could advance to the experiment after viewing each page for a minimum of ten seconds. These webpages explained what IQOS is, how IQOS is used, and how IQOS differs from e-cigarettes.

Next, participants were randomized to view one message, either an MRTP claim or control message. Above the message was the following instruction: "Please read the below message carefully and imagine you saw the message in an advertisement for IQOS." Participants then responded to a variety of outcome measures, followed by demographic and tobacco use questions. To allow for repeated exposure to the randomly assigned claim or control message, the claim/message appeared at the top of each page for all outcome measures. Participants were debriefed at the end of the study and informed that the information they saw was created by our research team, may not be true, and was used for

research purposes only. Participants also received website links to evidence-based quit smoking resources.

MTurk participants received $2.15 for completing the online questionnaire (median time: 8 minutes, 13 seconds). Prime Panel participants (median time: 9 minutes, 16 seconds) were compensated in the amount that they agreed to with the platform through which they entered this survey. This study was approved by the institutional review board at the University of North Carolina.

Stimuli. The experiment evaluated MRTP claims for IQOS. Because IQOS was not sold in the US at the time of data collection, we anticipated participants would be IQOS naïve and less likely to have existing attitudes or beliefs about IQOS; therefore, we anticipated that most responses would be fully shaped by the experimental stimuli. In 2017, only 5% of US adults were aware of heated tobacco products and fewer than 1% reported ever use.[20]

To increase generalizability of study findings, we created 3 messages per condition. Thus, we created 12 MRTP claims and 3 control messages. All MRTP claims had the same sentence structure to control for potential confounding by other claim features (e.g., framing, length). The sentence structure used was modeled off of MRTP claims included in the IQOS application submitted to FDA.[21] The following sentence structure was used for all experimental MRTP claims: "Switching completely from cigarettes to IQOS will reduce [exposure to/risk of] [exposure/risk].

In selecting the diseases and exposures for the MRTP claims, we developed claims that would discourage smoking and increase interest in IQOS, while also considering word length and readability. For the three specific exposure MRTP claims, we selected arsenic, carbon monoxide, and lead because these chemicals were among those that scored highest (out of 24 tested) for awareness and discouragement from smoking in research by Brewer *et al.*[22] Similarly, we selected lung cancer, permanent lung disease, and cardiovascular disease

because these outcomes were among those that scored highest on awareness and discouragement (out of 25 messages tested) in research by Kelley *et al*.[23]

In choosing content for the general MRTP claims we created claims with similar s and readability as the specific MRTP claims, while including broad language to describe relative risk and exposure modifications. General risk MRTP claims included the phrases "smoking-related diseases", "smoking-caused diseases", and "diseases caused by smoking". General exposure MRTP claims included the phrases "smoke chemicals," "chemicals in smoke," and "chemicals in cigarette smoke." We did not include words such as carcinogens or toxins in the general exposure claims because cognitive interviews revealed these terms are often interpreted as communicating reduced risk. The wording for all MRTP claims and control messages appear in Table 1. Mean s for each experimental condition and control were well matched, ranging from 11.2-13.0 words. Readability was also similar, with mean Flesch-Kincaid Grade Level below 12 for all groups (range: 11.0-11.8). Here forward we refer to general risk and general exposure claims as "general claims", and specific risk and specific exposure claims are referred to "specific claims."

Measures

The primary outcome was willingness to try IQOS, which was measured using four items adapted from measures used by Nodora *et al*[24] and Duke *et al*[25] (e.g., "willing to try…", "are you curious…" The 4-point response scale for the willingness items ranged from definitely yes (coded as 1) to definitely not (4). To create a willingness score, we reverse coded and averaged the items (α=0.93). Secondary outcomes included perceived risk and exposure from complete switching (from cigarettes to IQOS) and perceived risk and exposure from partial switching (from cigarettes to IQOS). Single items were used to measure perceived risk and exposure (for partially and completely switching from cigarettes to IQOS)

with a 5-point response scale ranging from much less (risk/exposure) to much more (risk/exposure). These items were accompanied by a figure depicting the type of switching assessed in the item (complete [100%] switching or partial [50%] switching). For instance, "20 cigarettes per day" → "10 cigarettes and 10 IQOS sticks per day", and with "Partial Switch" appearing above the arrow was used in the item measuring perceived risk and exposure from partial switching. A questionnaire coding error caused a typo in the instructions for perceived risk and exposure from partial switching items: "Imagine you smoke 20 cigarettes a day, and then partially switch from cigarettes to using 20 IQOS sticks a day." The instructions should have stated, "…switch to using 10 cigarettes and 10 IQOS sticks a day." However, the accompanying figure and item wording were correct (Supplemental Figure 2).

Additional secondary outcomes included message believability, ease of understanding, relevance, and perceived cognitive elaboration, all of which had 5-point response scales. The survey measured perceived cognitive elaboration using three items, which we averaged to create a scale (α=0.91). Single-item measures were used for believability, ease of understanding, and relevance (Supplemental Table 1).

The survey included three attention check items: 1) instructed participants to not respond to one item, 2) instructed participants to respond "no" to one item, regardless of their true answer, 3) asked participants about how much effort they gave in completing the questionnaire (responses of "somewhat" and "a lot" were deemed acceptable, while responses of "not at all" and "a little" were unacceptable). Missing responses for attention check items that required a response were deemed unacceptable. Three-quarters of participants (75.9%) answered all three attention check items acceptably, and 20.6% gave two acceptable answers. Only 3.3% and 0.25% of participants gave one and or no acceptable answers to the attention check items, respectively. To minimize demographic bias, we retained all respondents in our analyses and report results based on the full sample.

Sensitivity analyses excluding participants who gave unacceptable answers to two or more attention check items yielded the same pattern of results.

Statistical Analysis

We computed mean standardized differences (i.e., Cohen's *d*) comparing responses for 1) intervention (all MRTP claims) vs. control, 2) claim specificity (general vs. specific), and 3) claim type (risk vs. exposure). For all outcomes, we used linear regression models to 1) compare intervention (all MRTP claims) vs. control, 2) examine the main effects of claim specificity and type, 3) examine the interaction of specificity and type, for all primary and secondary outcomes. For any statistically significant interaction ($p<0.05$), we created interaction plots and calculated standardized mean differences between specific risk and specific exposure claims and between general risk and exposure claims. Given the experimental design, regression models did not control for any covariates. All tests were two-tailed with critical alpha of 0.05.

RESULTS

A total of 3,584 participants attempted to complete the questionnaire (Figure 1). Analyses excluded participants who were non-smokers (*n*=323), did not report smoking status (*n*=12), responded from a duplicate IP address (*n*=69), used an invalid MTurk ID (*n*=8), or had a duplicate MTurk ID (n=11). For participants with duplicate MTurk ID and IP address responses, we included data from the participants with the earliest questionnaire start time. Thus, analyses included data from a total of 3,161 eligible participants.

Overall, 63.9% of participants were female, participant mean age was 41.7 (sd=12.9) years, and 82.9% and 9.2% of the sample were White and Hispanic, respectively (Table 2). Awareness of IQOS was low among all participants (8.8%). Missingness across all primary and secondary outcomes was low, ranging from 0.13% to 0.70% per outcome. Analyses

comparing the five conditions did not identify differences with respect to recruitment source, demographic or tobacco use characteristics. Mean willingness to try IQOS (range: 1-4) across the five conditions were as follows: general risk: 3.36 (sd=0.74); general exposure: 3.40 (sd=0.70); specific risk: 3.40 (sd=0.70); specific exposure: 3.36 (sd=0.66); control: 3.32 (sd=0.73). Means for the other outcomes appear in Supplemental Table 2.

MRTP claims vs. Control

Participants viewing MRTP claims reported a slightly higher willingness to try IQOS (*d*=0.09), relative to control (litter message). Additionally, participants viewing any MRTP claim had lower scores for perceived risk (*d*=-0.32) and exposure from complete switching from cigarettes to IQOS (*d*=-0.31; Table 3). We also found evidence of the "exclusive-to-dual use halo effect,"[9] with MRTP claims resulting in lower scores for perceived risk (*d*=-0.25) and exposure from partial switching (*d*=-0.26;), compared to control. Thus, claims describing benefits of complete switching (exclusive IQOS use) were interpreted as also reducing risk and exposure when IQOS was used to partially replace cigarette use (dual-use).

Participants found MRTP claims to be more personally relevant (d=0.32) and MRTP claims led to greater cognitive elaboration (d=0.66), compared to control messages. In contrast, MRTP claims were less believable (*d*=-0.37) and less easy to understand (*d*=-0.13), compared to control messages.

Claim Specificity

When examining the effect of claim specificity on responses (i.e., examining responses from general claims group vs. specific claims group), specificity had no effect on willingness to try IQOS (*d*=0.00). In contrast, general claims led to lower perceived risk (*d*=-0.13) and exposure (*d*=-0.16) from complete switching, as compared to specific claims. Similarly, general claims resulted in lower

perceived risk (*d*=-0.14) and exposure (*d*=-0.12) from partial switching, compared to specific claims. General MRTP claims were perceived as more personally relevant, compared to specific MRTP claims (*d*=0.11). Specificity did not influence claim believability (*d*=-0.00), ease of understanding (*d*=0.05), or elaboration (*d*=0.03).

Claim Type

Claim type was not associated with willingness to try IQOS (*d*=0.00), perceived risk (*d*=0.05) or exposure (*d*=-0.07) from complete switching, or perceived risk (*d*=0.05) or exposure (*d*=-0.07) from partial switching. However, exposure MRTP claims were rated as more believable than risk MRTP claims (*d*=0.15). Claim type did not influence relevance (*d*=-0.03), ease of understanding (*d*=-0.03), or perceived cognitive elaboration (*d*=-0.01).

Claim Specificity × Type Interaction

The interaction of specificity and type was present for message relevance (*p*=0.019). Post-hoc analyses showed that the difference between specific risk and specific exposure claims (*d*=0.12; p=0.028) was greater than the difference between general risk and general exposure claims (*d*=0.07; p=0.223). None of the eight other interactions tested were statistically significant. Given the number of tests conducted for the interaction testing and small effects observed, these findings should be interpreted with caution.

DISCUSSION

MRTP claims are intended to communicate relative risk and exposure information to consumers, but must not be misleading and encourage unsafe use. We observed that MRTP claims for IQOS led to lower perceived risk and exposure from complete switching from cigarettes to IQOS,

and higher willingness to try IQOS, compared to control messages about littering. Viewing MRTP claims also reduced perceived risk and exposure from partial switching from cigarettes to IQOS, a potentially problematic halo effect. We found that general MRTP claims reduced perceived risk and exposure more than specific claims, though specificity was not associated with willingness to try IQOS. There was no association between claim type with perceived risk and exposure, or willingness to try IQOS, suggesting that risk and exposure claims are interpreted similarly.

Our experiment found that MRTP claims reduced perceived risk and exposure from complete switching, suggesting MRTP claims may help correct tobacco product relative-risk misperceptions that have been previously identified. For instance, Fong *et al.* analyzed data from the Population Assessment of Tobacco and Health Study and found that a majority of adult Americans perceived e-cigarettes and smokeless tobacco products as being more harmful or about the same harmfulness as cigarettes.[26] Similarly, Kiviniemi and Kozlowski analyzed data from the Health Information National Trends Survey and found that <10% of adult Americans correctly believed smokeless tobacco products to be less harmful than cigarettes.[27] Using the same data source, researchers found an increase between 2019 and 2020 in the percentage of US adults believing that e-cigarettes are *more* harmful than cigarettes.[28]

Previous research has reported mixed results on how MRTP claims affect perceived risk. For instance, studies by Callery *et al.* (smokeless tobacco)[29] and Katz *et al.* (e-cigarettes)[30] found that MRTP claims reduced perceived risk, whereas research by Wackowski *et al.* (e-cigarettes)[31] and Mumford *et al.* (e-cigarettes)[32] observed no association between viewing a claim and perceived risk. Because perceived risk has been found to be an important theoretical antecedent to behavior change,[13,17] it is possible that by reducing perceived risk (and likely perceived exposure as well), MRTP claims could increase MRTP initiation rates. Further research is needed to understand these mixed findings and elucidate how MRTP claims affect product use.

The finding that MRTP claims reduced perceived risk and exposure from partial switching underscores how MRTP claims could potentially mislead consumers. Moreover, the magnitude of these effects were only slightly smaller than the effect sizes for perceived risk and exposure from complete switching. Thus, the effect size for the intended effect of MRTP claims (reducing perceived risk/exposure from complete switching) was similar to the effect size of unintended effects (reducing perceived risk/exposure from partial switching).

Additional research is needed to explore whether perceived risk and exposure from partial switching are important predictors of dual use behaviors, and if these beliefs are a barrier to complete switching or quitting tobacco use entirely. Further research is also needed to develop and test MRTP claims designed to minimize halo effects and misperceptions about partial switching. For instance, MRTP claims could include language to explicitly communicate that partial switching does not reduce risk/exposure. In light of these findings, if FDA authorizes an MRTP claim, it should require tobacco manufacturers to conduct post-market surveillance of how the claim affects partial switching risk and exposure beliefs, as well as dual use behaviors. Research may also be needed to develop and evaluate new measures of perceptions related to complete vs. partial switching.

To our knowledge, this is the first study to examine how MRTP claim specificity affects consumer responses. While claim specificity was not associated with willingness to try IQOS, we found general claims produced lower perceived risk and exposure, compared to specific claims. Such findings are inconsistent with previous research from other domains and theory. For instance, the advertising literature suggests that specific messages are more accepted and produce fewer counterarguments compared to general messages.[33] Additionally, specific advertising messages are more credible and attract greater attention, compared to more abstract messages.[34,35] Previous research has also found that specific messages are perceived as being more persuasive, compared to general messages.[36,37] However, our current study found no significant difference in believability

between general and specific claims. Further research is needed to identify putative factors driving these unexplained null effects.

We found that consumer responses to risk vs. exposure claims were similar (e.g., no main effect of claim type on perceived risk and exposure). These findings are consistent with a previous experiment by El-Toukhy and colleagues,[14] who found that risk and exposure claims reduced both perceived risk and exposure. Additionally, qualitative research by Wackowski et al. found that MRTP claims describing reduced exposure were interpreted as reducing disease risk.[38] Fearing consumer misunderstanding, the TCA explicitly states that exposure modifications must not be interpreted as risk modifications.[1] Given this mandated provision, some researchers have argued that the exposure modification pathway is not legally viable for MRTP claims.[14] The findings reported here provide additional evidence that exposure MRTP claims reduce perceived risk. However, after FDA authorized an exposure MRTP claim for IQOS (e.g., "Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals") the agency acknowledged that an exposure claim can be authorized even if the claim reduces perceived risk. In a Technical Project Lead document, FDA expounded, "…the totality of the evidence supports that risk reduction is reasonably likely to be demonstrated in subsequent studies" and therefore, "…consumer understanding is in line with the relative health risks of the product that are reasonably likely."[39] It is unclear how future research in this domain will inform tobacco regulatory science; this example highlights the complexities involved with integrating scientific knowledge with regulatory concerns.

Study strengths include the use of a large sample of smokers, testing of two important MRTP design features (while controlling for other features), testing multiple claims per condition, and the experimental design. Participants were also repeatedly exposed to claim and control messages, maximizing exposure to the stimuli.

The study's major limitations include the absence of behavioral outcomes (e.g., IQOS use, dual use with cigarettes) and use of a convenience sample. However, at the time of data collection, IQOS was not available for sale in the US and assessment of IQOS use post message exposure was not possible. Although large and diverse, the study sample was non-probability based. Research by Jeong et al. found that using convenience samples for online tobacco product perception experiments consistently yield similar results as national probability samples.[40] Furthermore, MRTP claims were presented to participants as text only to maximize claim visibility. However, such claims in the real world typically appear in marketing materials with color images. This study also assessed responses to MRTP claims for a single product; therefore, findings may not generalize to other potential MRTPs. Additionally, as previously described, incorrect instructions were displayed for the perceived risk and exposure from partial switching items due to a coding error. It is unknown whether this typo affected responses; however, our sample size was large and the accompanying figure and item wording were correct. We therefore speculate that the typo likely added some modest noise to the results but did not qualitatively affect the overall size or direction of the effect. Finally, contemporaneous to data collection (August of 2019), an outbreak of severe lung injury associated with e-cigarette use in the US occurred and was widely reported in the media (E-cigarette, or Vaping Product, Use Associated Lung Injury; EVALI), which could have affect perceived risk of IQOS use.[41] However, we believe that the use of informative text and pictures describing IQOS at the start of the experiment, which included text stating that IQOS was not an e-cigarette product, mitigated potential confusion on this point.

CONCLUSIONS

MRTPs represent an important harm reduction strategy for FDA's regulatory framework. Research evaluating MRTP claims are critical to elucidating the potential public health impact of authorizing MRTP claims and informing FDA regulatory decisions. We

experimentally tested how MRTP claims and claim features affect consumer responses. As hypothesized, risk claims reduced perceived risk from complete switching and exposure claims reduced perceived exposure from complete switching. Such findings suggest that MRTP claims may be effective at educating consumers about tobacco product relative risk. Additionally, we found that viewing an MRTP claim reduced perceived risk and exposure from partial switching. Such unintended misperceptions could promote dual use behaviors and potentially weaken the harm reduction potential of MRTPs. These findings suggest that consumers may be inferring health benefits beyond what is stated in a MRTP claim. Additional research is needed to understand how to reduce these generalizations in response to MRTP claims and how MRTP claims affect tobacco use behaviors.

DATA AVAILABILITY

The data underlying this article will be shared on reasonable request to the corresponding author.

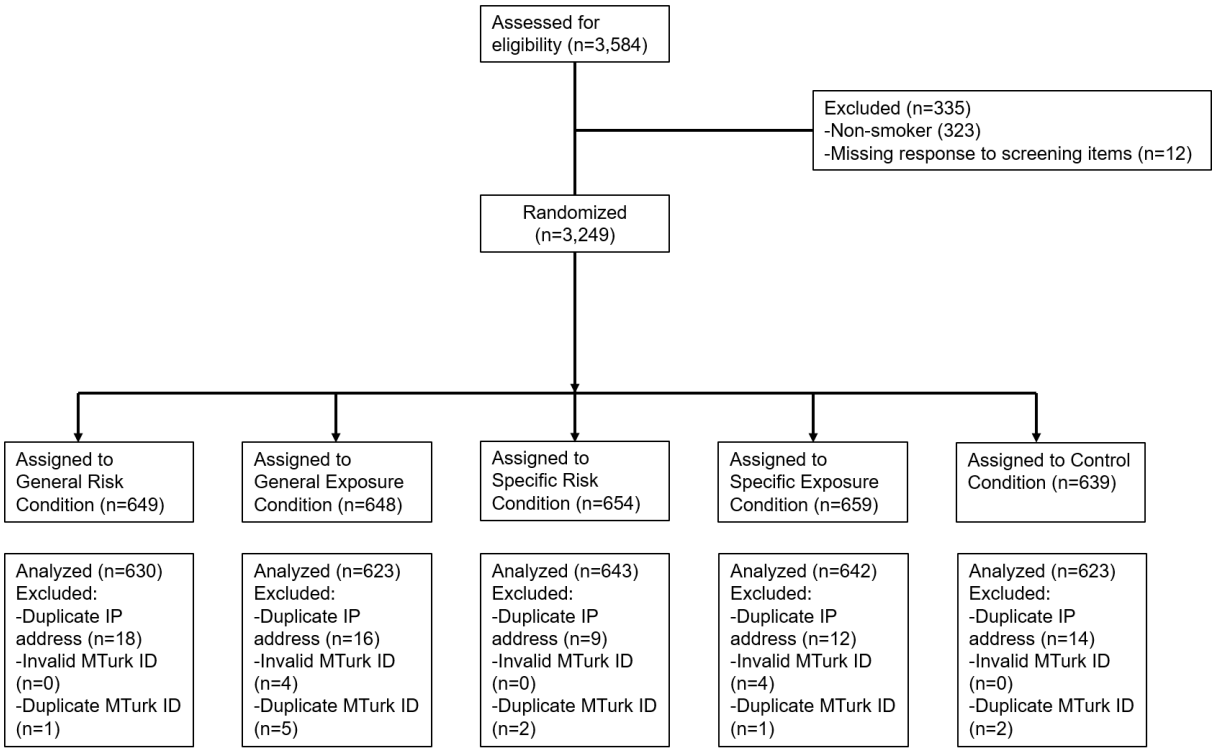

Figure 1. CONSORT flow diagram.

Table 1. Experimental Claims and Control Messages

General Exposure (Mean: 13.0 words; 11.8 Flesch-Kincaid Grade Level)

Switching completely from cigarettes to IQOS will reduce exposure to smoke chemicals.

Switching completely from cigarettes to IQOS will reduce exposure to chemicals in smoke.

Switching completely from cigarettes to IQOS will reduce exposure to chemicals in cigarette smoke.

Specific Exposure (Mean: 11.3 words; 11.7 Flesch-Kincaid Grade Level)

Switching completely from cigarettes to IQOS will reduce exposure to arsenic.

Switching completely from cigarettes to IQOS will reduce exposure to lead.

Switching completely from cigarettes to IQOS will reduce exposure to carbon monoxide.

General Risk (Mean: 12.7 words; 11.8 Flesch-Kincaid Grade Level)

Switching completely from cigarettes to IQOS will reduce risk of smoking-related diseases.

Switching completely from cigarettes to IQOS will reduce risk of smoking-caused diseases.

Switching completely from cigarettes to IQOS will reduce risk of diseases caused by smoking.

Specific Risk (Mean: 11.7 words; 11.2 Flesch-Kincaid Grade Level)

Switching completely from cigarettes to IQOS will reduce risk of lung cancer.

Switching completely from cigarettes to IQOS will reduce risk of cardiovascular disease.

Switching completely from cigarettes to IQOS will reduce risk of emphysema.

Control (Mean: 12.7 words; 11.0 Flesch-Kincaid Grade Level)

Protect the environment by discarding used IQOS tobacco sticks in a trash receptacle.

Protect the environment by discarding used IQOS tobacco sticks in a trashcan.

Protect the environment by discarding used IQOS tobacco sticks in a garbage can.

Table 2. Demographic characteristics and tobacco use behaviors among 3,161 smokers randomized to condition (%, unless indicated).

	General claim		Specific claim			
	Risk	Exposure	Risk	Exposure	Control	p
Total, n	630	623	643	642	623	-
MTurk, n	229	223	220	217	227	0.79
Prime Panel, n	401	400	423	425	396	
Sex						
Male	35.4	38.5	33.4	35.8	37.6	0.36
Age, mean (sd)	42.2 (13.1)	41.5 (12.7)	41.5 (13.2)	42.1 (12.7)	41.3 (12.7)	0.69
Hispanic	7.7	9.1	10.9	9.5	8.7	0.41
Race						
Am Indian/Alaska Native	1.0	1.8	1.3	0.8	1.0	
Asian	1.8	3.2	2.1	2.8	1.9	
Black/African American	9.2	8.3	9.8	9.5	8.6	
Native Hawaiian/Pacific Islander	0.2	0.0	0.3	0.6	0.2	0.65
White	83.2	83.0	82.3	81.1	84.7	
Other/multiracial	4.7	3.7	4.3	5.2	3.7	
Sexual Orientation						
Heterosexual	86.2	88.7	85.5	87.3	89.0	
Gay or Lesbian	4.2	3.2	3.5	4.4	3.2	0.44
Bisexual	9.7	8.1	11.0	8.3	7.7	
Education						
HS Graduate or Less	27.4	24.6	27.4	26.9	27.1	
Some College/Assoc Deg	44.9	45.8	42.1	41.6	40.3	0.47
Bachelor's Deg	18.0	19.1	20.6	21.7	19.5	

Graduate or Prof Deg	9.7	10.5	9.9	9.8	13.1	
Smoking Frequency						
Everyday	83.3	81.5	82.7	83.3	84.8	0.66
Some Days	16.7	18.5	17.3	16.7	15.3	
Current E-cig Use						
Yes	37.8	42.3	41.7	40.2	43.9	0.24
Want to Quit Smoking w/in 6 Months						
Yes	66.8	65.9	69.7	66.4	66.3	0.62
IQOS Awareness						
Yes	7.6	8.9	6.5	8.9	8.7	0.41
First Cigarette after Waking						
Within 5 Minutes	30.7	30.1	32.4	31.3	33.2	0.19
6-30 Minutes	40.1	43.2	38.4	43.4	36.8	
31-60 Minutes	14.9	11.3	15.7	12.0	13.6	
After 60 Minutes	14.3	15.4	13.5	13.3	16.5	

Note. HS=high school; Deg=degree; Prof=Professional

Table 3. Mean standardized differences (Cohen's d) comparing all MRTP claims vs. control, general claims vs. specific claims, risk claims vs exposure claims.

			EXPERIMENTAL CONDITIONS				
	All MRTP Claims vs. Control		Specificity		Type		Type x Specificity
OUTCOMES	*d*	*p*	*d*	*p*	*d*	*p*	*p*
Complete Switching Perceived Risk	-0.32	<0.001	-0.13	0.001	0.05	0.235	0.961
Complete Switching Perceived Exposure	-0.31	<0.001	-0.16	<0.001	-0.07	0.073	0.972
Partial Switching Perceived Risk	-0.25	<0.001	-0.14	<0.001	0.05	0.186	0.542
Partial Switching Perceived Exposure	-0.26	<0.001	-0.12	0.003	-0.07	0.095	0.368
Willingness to Try	0.09	0.043	0.00	0.972	0.00	0.891	0.174
Believability	-0.37	<0.001	-0.00	0.929	0.15	<0.001	0.305
Relevance	0.32	<0.001	0.11	0.008	-0.03	0.479	0.019
Ease of Understanding	-0.13	0.003	0.05	0.193	-0.03	0.412	0.995
Elaboration	0.66	<0.001	0.03	0.400	-0.01	0.919	0.127

Note. Positive effect size *d* indicates higher scores for intervention compared to control, higher scores for specific claims compared to general claims, and higher scores for risk claims compared to exposure claims.

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DECLARATION OF INTERESTS

The authors declare no conflict of interest

REFERENCES

1. Family Smoking Prevention and Tobacco Control Act, H.R. 1256, PUB. L. No. 111-31, 123, 1776 STAT. (June 22, 2009).
2. Husten CG, Deyton LR. Understanding the Tobacco Control Act: efforts by the US Food and Drug Administration to make tobacco-related morbidity and mortality part of the USA's past, not its future. *Lancet.* 2013;381(9877):1570-1580.
3. U.S. Food & Drug Administration. FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death. https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death. Accessed January 30, 2023.
4. Warner KE. Tobacco harm reduction: promise and perils. *Nicotine Tob Res.* 2002;4 Suppl 2:S61-71.
5. Paek HJ, Reid LN, Choi H, Jeong HJ. Promoting health (implicitly)? A longitudinal content analysis of implicit health information in cigarette advertising, 1954-2003. *J Health Commun.* 2010;15(7):769-787.
6. Campaign for Tobacco-free Kids. U.S. district judge Gladys Kessler's final opinion: Summary of findings against the tobacco industry. https://www.tobaccofreekids.org/assets/content/what_we_do/industry_watch/doj/FinalOpinionSummary.pdf. Accessed January 30, 2023.
7. US Food and Drug Administration. Letter to Swedish Match North America, Inc,. https://www.fda.gov/media/102011/download. Accessed January 31, 2023.
8. JAMA Netw OpenAndrews JC, Choiniere CJ, Portnoy DB. Opportunities for consumer research from the Food and Drug Administration's Center for Tobacco Products. *J Public Policy Mark.* 2015;34(1):119-130.
9. Seidenberg AB, Popova L, Ashley DL, Wackowski OA. Inferences beyond a claim: a typology of potential halo effects related to modified risk tobacco product claims. *Tob Control.* 2020.
10. US Department of Health Human Services. Draft guidance for industry: modified risk tobacco product applications. https://www.fda.gov/media/83300/download. Accessed January 30, 2023.
11. Goniewicz ML, Smith DM, Edwards KC, et al. Comparison of nicotine and toxicant exposure in users of electronic cigarettes and combustible cigarettes. *JAMA network open.* 2018;1(8):e185937-e185937.
12. Philip Morris International. Heated tobacco products. https://www.pmi.com/smoke-free-products/iqos-our-tobacco-heating-system. Accessed January 31, 2023.
13. Rosenstock IM. The health belief model and preventive health behavior. *Health Educ Monogr.* 1974;2(4):354-386.
14. El-Toukhy S, Baig SA, Jeong M, Byron MJ, Ribisl KM, Brewer NT. Impact of modified risk tobacco product claims on beliefs of US adults and adolescents. *Tob Control.* 2018;27(Suppl 1):s62-s69.
15. Chen-Sankey JC, Kechter A, Barrington-Trimis J, et al. Effect of a hypothetical modified risk tobacco product claim on heated tobacco product use intention and perceptions in young adults. *Tob Control.* 2023;32(1):42-50.
16. Berg CJ, Duan Z, Wang Y, et al. Impact of FDA endorsement and modified risk versus exposure messaging in IQOS ads: a randomised factorial experiment among US and Israeli adults. *Tob Control.* 2022.

17. Witte K. Putting the fear back into fear appeals: The extended parallel process model. *Commun Monogr.* 1992;59(4):329-349.
18. Litman L, Robinson J, Abberbock T. TurkPrime.com: A versatile crowdsourcing data acquisition platform for the behavioral sciences. *Behav Res Methods.* 2017;49(2):433-442.
19. Cloud Research. Recruit Your Perfect Online Research Panel. https://www.cloudresearch.com/products/prime-panels/. Accessed January 31, 2023.
20. Marynak KL, Wang TW, King BA, Agaku IT, Reimels EA, Graffunder CM. Awareness and Ever Use of "Heat-Not-Burn" Tobacco Products Among U.S. Adults, 2017. *Am J Prev Med.* 2018;55(4):551-554.
21. U.S. Food and Drug Administration. Philip Morris Products S.A. modified risk tobacco product (MRTP) applications. https://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm546281.htm. Accessed January 31, 2023.
22. Brewer NT, Morgan JC, Baig SA, et al. Public understanding of cigarette smoke constituents: three US surveys. *Tob Control.* 2016;26(5):592-599.
23. Kelley DE, Boynton MH, Noar SM, et al. Effective Message Elements for Disclosures About Chemicals in Cigarette Smoke. *Nicotine Tob Res.* 2018;20(9):1047-1054.
24. Nodora J, Hartman SJ, Strong DR, et al. Curiosity predicts smoking experimentation independent of susceptibility in a US national sample. *Addict Behav.* 2014;39(12):1695-1700.
25. Duke JC, Alexander TN, Zhao X, et al. Youth's Awareness of and Reactions to The Real Cost National Tobacco Public Education Campaign. *PLoS One.* 2015;10(12):e0144827.
26. Fong GT, Elton-Marshall T, Driezen P, et al. U.S. adult perceptions of the harmfulness of tobacco products: descriptive findings from the 2013-14 baseline wave 1 of the path study. *Addict Behav.* 2019;91:180-187.
27. Kiviniemi MT, Kozlowski LT. Deficiencies in public understanding about tobacco harm reduction: results from a United States national survey. *Harm Reduct J.* 2015;12:21.
28. Bandi P, Asare S, Majmundar A, Nargis N, Jemal A, Fedewa SA. Relative Harm Perceptions of E-Cigarettes Versus Cigarettes, U.S. Adults, 2018-2020. *Am J Prev Med.* 2022;63(2):186-194.
29. Callery WE, Hammond D, O'Connor RJ, Fong GT. The appeal of smokeless tobacco products among young Canadian smokers: the impact of pictorial health warnings and relative risk messages. *Nicotine Tob Res.* 2011;13(5):373-383.
30. Katz SJ, Erkkinen M, Lindgren B, Hatsukami D. Assessing the Impact of Conflicting Health Warning Information on Intentions to Use E-Cigarettes -An Application of the Heuristic-Systematic Model. *J Health Commun.* 2018;23(10-11):874-885.
31. Wackowski OA, Sontag JM, Hammond D, et al. The Impact of E-Cigarette Warnings, Warning Themes and Inclusion of Relative Harm Statements on Young Adults' E-Cigarette Perceptions and Use Intentions. *Int J Environ Res Public Health.* 2019;16(2):184.
32. Mumford EA, Pearson JL, Villanti AC, Evans DW. E-cigarette Beliefs: Testing a Relative Risk Message in a Representative US Sample. *Tob Reg Sci.* 2019;5(2):115-123.
33. Macklin MC, Bruvold NT, Shea CL. Is it always as simple as “keep it simple!”? *Journal of Advertising.* 1985;14(4):28-35.

34. MacKenzie SB. The role of attention in mediating the effect of advertising on attribute importance. *J Consum Res.* 1986;13(2):174-195.
35. Aguirre-Rodriguez A. The effect of consumer persuasion knowledge on scarcity appeal persuasiveness. *J Advert.* 2013;42(4):371-379.
36. O'keefe DJ. *Persuasion: Theory and research.* Vol 2: Sage; 2002.
37. O'Keefe DJ. The relative persuasiveness of different message types does not vary as a function of the persuasive outcome assessed: Evidence from 29 meta-analyses of 2,062 effect sizes for 13 message variations. *Ann Int Comm.* 2013;37(1):221-249.
38. Wackowski OA, Rashid M, Greene KL, Lewis MJ, O'Connor RJ. Smokers' and Young Adult Non-Smokers' Perceptions and Perceived Impact of Snus and E-Cigarette Modified Risk Messages. *Int J Environ Res Public Health.* 2020;17(18).
39. U.S. Food and Drug Administration. Scientific Review of Modified Risk Tobacco Product Application (MRTPA) Under Section 911(d) of the FD&C Act - Technical Lead Project. https://www.fda.gov/media/139796/download. Accessed January 31, 2023.
40. Jeong M, Zhang D, Morgan JC, et al. Similarities and Differences in Tobacco Control Research Findings From Convenience and Probability Samples. *Ann Behav Med.* 2019;53(5):476-485.
41. Centers for Disease Control and Prevention. Outbreak of lung injury associated with e-cigarette use, or vaping. https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html. Accessed January 31, 2023.