

# Effects of modified risk tobacco product claims on consumer comprehension and risk perceptions of IQOS

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## ABSTRACT

**Introduction** Tobacco industry studies on consumers' perceptions of modified risk claims (MRCs) often had important omissions (eg, no control group, not investigating whether consumers understand what 'switching completely' means). This study examined the effects of IQOS MRCs on risk perceptions and behavioural intentions.

**Method** Based on tobacco companies' MRCs, we manipulated three MRC language features: explanation about 'switching completely' (absent vs present), number of diseases (single vs multiple) and language certainty (hypothetical vs certain). In an online experiment, we randomised 1523 US adult current smokers and 1391 young adult non-smokers to 1 of 9 conditions following a 2×2×2+1 control design. People reported their comprehension of 'switching completely', IQOS risk perceptions and behavioural intentions after message exposure.

**Results** More smokers exposed to MRCs that included an explanation about 'switching completely' (22.2%) (vs explanation absent (11.2%) and control (10.7%)) mentioned that 'switching completely' meant smoking 0 cigarettes. Compared with the control, several MRCs (eg, certain language) produced lower perceived risk of IQOS, including for diseases not mentioned in the MRCs. MRCs using certain and hypothetical language did not differ on any outcomes. MRCs highlighting reduced risk for a single disease and multiple diseases did not differ on any outcomes. MRCs did not influence behavioural intentions.

**Conclusion** The Food and Drug Administration should ensure that consumers understand what 'switching completely' means in an MRC and recognize that some language features may mislead consumers into believing that a product reduces the risk of diseases not mentioned in an MRC.

Communicating risks of tobacco products is increasingly complex as emerging products may present less harm than combusted cigarettes. In the USA, tobacco companies can submit modified risk tobacco product applications (MRTPAs) to use reduced or 'modified risk claims' (MRCs).<sup>1</sup> MRCs have two categories: (1) risk modification—claims that a product lowers risk of tobacco-related diseases and (2) exposure modification—claims that a product contains lower levels of harmful chemicals. By December 2020, the Food and Drug Administration (FDA) had issued a risk modification order for General Snus,<sup>2</sup> an exposure modification order for IQOS<sup>3</sup> and had three sets of MRTPAs under review.<sup>4</sup>

IQOS is a heated tobacco product developed by Philip Morris International (PMI), the manufacturer of Marlboro.<sup>5</sup> It was launched in the USA in 2019.<sup>6,7</sup> According to PMI, IQOS heats tobacco without producing harmful smoke.<sup>8</sup> Thus, PMI has claimed IQOS is less dangerous than cigarettes.<sup>9</sup> In 2016, PMI submitted an MRTPA for IQOS to FDA,<sup>10</sup> which proposed two MRCs and one modified exposure claim. Independent analyses of PMI's data suggested that modified exposure was possible, but modified risk was largely uncertain.<sup>11</sup> In July 2020, FDA issued an exposure modification order for IQOS and denied its risk modification order.<sup>3</sup> FDA emphasised the importance to study further the effects of IQOS MRCs. To date, all MRTPAs included studies about MRCs. However, these studies, such as those on IQOS, had many shortcomings, as detailed in comments to the FDA,<sup>12</sup> publications<sup>13,14</sup> and FDA's decision letters.<sup>15</sup> This paper aims to address some of these.

First, many MRC studies in the MRTPAs did not include a control group.<sup>14,16</sup> For example, the original MRTPA for IQOS tested MRCs with different combinations of warnings and 'disclaimers' without an MRC-absent control group. Lacking such information, we cannot know the effects of an MRC itself compared with advertisements without a claim.

Second, almost all MRTPAs included some language around 'switching completely', such as 'switching completely to this product from cigarettes reduces risk of lung cancer'.<sup>17</sup> However, MRTPAs lacked evidence about whether consumers understood what 'switching completely' means.<sup>14,18</sup> For smokers to realise the benefit from any potential MRTP, they need to quit combusted tobacco completely and only use the MRTP. Partial switch (ie, using an MRTP while continuing smoking) does not reduce disease risk.<sup>19–24</sup> However, communicating the need to switch completely is challenging. Some smokers considered reducing smoking equivalent to quitting,<sup>25</sup> and some misinterpreted 'switching completely' as compatible with continued smoking.<sup>26</sup> Consumer behaviour studies showed that complete switching is rare, but dual use is common.<sup>14</sup> Thus, it is important to explore how to communicate 'switching completely' so that consumers understand they need to stop smoking altogether.

Third, MRCs used both hypothetical and certain language (eg, 'switching completely from conventional cigarettes to the IQOS system *can* reduce the risks of tobacco-related diseases' vs 'switching completely to IQOS *presents* less risk of harm than



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continuing to smoke cigarettes<sup>10</sup>). Each may produce different responses.<sup>27 28</sup> First, messages using modal verbs such as *may* and *can* are forms of hedging claims.<sup>29</sup> Hedging and non-hedging claims could have different effects.<sup>29 30</sup> For example, cancer research news articles with versus without hedging claims about a cancer study's limitations produced lower levels of cancer fatalism.<sup>30</sup> Second, individuals can perceive an event at a far or close psychological distance, leading to different judgements.<sup>31</sup> When MRCs use hypothetical language, people may perceive reducing health risk at a far psychological distance and thus less possible. A recent study found that cigarette warnings using modal verbs *may* and *will* produced lower perceived risk of smoking than labels using certain language (ie, present tense) among male adult smokers.<sup>28</sup> Our study extended this and tested the impacts of certain and hypothetical MRCs.

Fourth, almost all MRCs highlighted reduced risk for some disease(s). However, the number of diseases varied (eg, four diseases (lung cancer, oral cancer, respiratory disease and heart disease) in Camel Snus' MRCs<sup>32</sup> and one disease (lung cancer) in Copenhagen's MRC<sup>33</sup>). When MRCs focus on reduced risk of multiple diseases, particularly presented as a long list, they may trigger halo effects. Halo effects are a form of heuristic processing where people use cognitive shortcuts to form global perceptions or infer other attributes absent from a claim about an object.<sup>34 35</sup> In General Snus MRTPA, the company found that their MRCs mentioning reduced risk of General Snus for six diseases reduced perceived risk of a seventh—gum disease—that was not in the MRCs.<sup>36</sup> Based on this evidence and halo effect theorising, featuring multiple diseases in MRCs may lead to at least two halo effects: (1) generalise lower risk perceptions to other diseases absent from the MRCs as shown in General Snus MRTPA and (2) lessen consumers' global risk perceptions about a product. Our study tested the impacts of multiple-disease versus single-disease MRCs.

In sum, this study used a control condition and manipulated three language features of IQOS MRCs: explanation about 'switching completely' (absent vs present), language certainty (hypothetical vs certain) and number of diseases (single vs multiple). We aimed to compare two variations of a language feature with control messages and with each other on people's comprehension of 'switching completely', risk perceptions about IQOS and their behavioural intentions regarding IQOS. Given the novelty of our topic, our analyses are largely exploratory in nature. Nonetheless, based on prior review, at least three predictions can be made: (H1) MRCs including a switch explanation (vs excluding and control) will produce more correct understanding about 'switching completely'; (H2) MRCs using certain language (vs hypothetical and control) will produce lower IQOS risk perceptions; (H3) MRCs mentioning reduced risk for multiple diseases (vs single and control) will produce lower IQOS risk perception overall and for unmentioned diseases.

We examined message effects on adult smokers who can benefit from switching completely to non-combustible tobacco products—bringing a population-level benefit, and young adult non-smokers who might initiate tobacco use due to MRCs—producing a population-level harm. We only recruited young adult non-smokers because tobacco initiation rates are highest in this group and much lower for older non-smokers.<sup>24</sup>

## METHOD

### Participants

Participants were 1523 adult current smokers (18 years old or older, smoked 100 cigarettes in their life and are currently

smoking every day or some days) and 1391 young adult non-smokers (18–29 years, not smoked 100 cigarettes in their life). Participants were recruited through a commercial research company Toluna using multiple online recruitment channels (eg, web banners, website referrals, affiliate marketing, pay-per-click). Inclusion criteria were age and smoking behaviours specified above. Data were collected in August 2019. Participants received points for taking part in the study, redeemable for cash or vouchers for store credit.

### Design and procedure

This study followed a 2 (switch explanation: present vs absent) × 2 (language certainty: certain vs hypothetical) × 2 (number of diseases: single vs multiple) + 1 control design (see online supplemental appendix 1 for study diagram). Toluna implemented this study on its web portal. Participants first completed a consent form and reported their demographic information and prior experience with tobacco products. Then, participants were randomised to one of nine conditions stratified by smoking status. Each condition showed three IQOS ads one at a time in a fixed order. Following all messages, participants rated outcomes.

### Message stimuli

Existing MRTPAs informed message design. Messages explaining 'switching completely' told smokers: "Switching completely means not smoking any cigarettes, even taking one puff and using this product as a complete replacement of cigarettes. If you continue smoking while using this product, your risk of disease will increase". Messages using hypothetical language for instance mentioned: 'switching completely to this produce may reduce risk of lung cancer', whereas the certain language message used present tense.<sup>28</sup> The single-disease messages highlighted reduced risk of only lung cancer, whereas the multiple-disease messages highlighted reduced risk of lung cancer, emphysema, heart disease and stroke.

Each treatment condition had a MRC presented three times each in a different ad. All conditions used the same three ads. The control group saw only the three ads without any MRC (see online supplemental appendix 2 for detailed messages).

### Key measures

#### Comprehension of 'switching completely'

We asked: "If you switch completely to IQOS, how many cigarettes would you smoke per day?" Response categories included 0, 1–2, 3–9, 10–20, as many as you want and do not know. They were recoded into three categories: 0=0 cigarette; 1–2, 3–9, 10–20 and as many as you want=some cigarettes and do not know=do not know.

#### Perceived comparative risk of IQOS and cigarettes

We asked: 'Is using IQOS less harmful, about the same or more harmful than smoking regular cigarettes?' Choices included 'less harmful', 'about the same level of harm', 'more harmful' and 'I don't know'. Responses were recoded into three categories by combining 'about the same level of harm' and 'more harmful'.

#### Perceived general risk of IQOS

"In your opinion, how harmful is using IQOS to general health?" Answers were on a 0 (not at all) to 6 (extremely) plus "I don't know" scale.

### Perceived specific risk of IQOS

Participants were asked about their chances of having lung cancer, emphysema, heart disease, stroke, gum disease (unmentioned disease) and mouth disease (unmentioned disease) if they began using IQOS every day on a 0 (not at all) to 6 (extremely) plus “I don’t know” scale.<sup>37</sup>

### Smokers’ switch intentions

Current smokers were probed how likely they were to switch completely from using regular cigarettes to IQOS in the future on a 1 (not at all likely) to 9 (extremely likely) scale.<sup>38</sup>

### Non-smokers’ openness to IQOS

Non-smokers answered, “How open are you to trying IQOS in the future?” on a 1 (not at all open) to 9 (extremely open) scale.<sup>39</sup>

### Covariates

Included gender, age, race/ethnicity, education, ever use of heated tobacco products and past 30-day e-cigarette use.<sup>40</sup> Also, we measured smokers’ nicotine dependence through Heaviness of Smoking Index<sup>41,42</sup> and intentions to quit smoking.

### Analysis plan

Analyses were done separately for smokers and non-smokers. We ran two types of tests: (1) multinomial logistic regression for categorical outcomes, including comprehension of ‘switching completely’ (some cigarettes/do not know vs 0 cigarette) and perceived comparative risk of IQOS and cigarettes (more or equally harmful/do not know vs less harmful) and (2) univariate analyses of covariates (ANCOVAs) for continuous outcomes, including perceived general and specific risks of IQOS (“I don’t know” coded as missing), smokers’ switch intentions and non-smokers’ openness to IQOS.

In logistic regression and ANCOVAs, we first treated the three language features as key independent variables and examined

their interactions. There were one significant interaction among smokers and three significant interactions among non-smokers (online supplemental appendix 3). All had very small effect sizes. We thus reported only the main effect of each language feature. Specifically, we included the nine-category message condition variable as the key predictor, followed by nine comparisons using specified contrasts. Corresponding to the study aims, the contrasts compared two variations of each language feature with the control and with each other.

Multiple comparisons employed Bonferroni-adjusted error rate. Analyses were done in Stata V.14. Results presented findings among smokers and then non-smokers. In each group, results of multinomial logistic regression in tables 1 and 2 were discussed first, followed by results of ANCOVAs from table 3 and online supplemental appendix 4. On each outcome, we first discussed a language variation versus the control and then two variations of a language feature.

## RESULTS

### Adult current smokers

#### Sample characteristics

Among 1523 adult smokers, 46.7% were male and 38.4% had high school or less education. The majority (62%) were non-Hispanic white and 26.7% indicated ever use of heated tobacco products (table 4).

#### Comprehension of ‘switching completely’

Greater proportion of participants seeing MRCs with a switch explanation correctly answered that switching completely meant smoking 0 cigarettes (22.2%) than in the control condition (10.7%). Still 57.4% in the explanation present condition reported some cigarette use and 20.4% did not know. Switch absent, certain or hypothetical language, single or multiple diseases conditions did not differ from the control. Regarding differences between two variations of a language feature, switch

**Table 1** Descriptive statistics of comprehension of ‘switching completely’ and perceived comparative risk of IQOS and cigarettes

| Condition                               | Comprehension of switching completely (%) |                 |             | Perceived comparative risk of IQOS and cigarettes (%) |                         |             |
|---|---|-----------------|-------------|---|-------------------------|-------------|
|   | 0 cigarette                               | Some cigarettes | Do not know | Less harmful  | More or equally harmful | Do not know |
| <b>Adult current smokers (n=1523)</b>   |   |                 |             |   |                         |             |
| Control                                 | 10.7                                      | 55.6            | 33.7        | 34.3  | 54.4                    | 11.2        |
| <b>Switch explanation</b>               |   |                 |             |   |                         |             |
| Present                                 | 22.2                                      | 57.4            | 20.4        | 43.8  | 47.0                    | 9.2         |
| Absent                                  | 11.2                                      | 60.0            | 28.8        | 41.7  | 46.8                    | 11.5        |
| <b>Language certainty</b>               |   |                 |             |   |                         |             |
| Hypothetical                            | 16.9                                      | 59.6            | 23.6        | 42.1  | 47.7                    | 10.2        |
| Certain                                 | 16.5                                      | 57.9            | 25.6        | 43.5  | 46.1                    | 10.5        |
| <b>Number of diseases</b>               |   |                 |             |   |                         |             |
| Single                                  | 16.7                                      | 57.1            | 26.2        | 42.2  | 47.6                    | 10.2        |
| Multiple                                | 16.7                                      | 60.3            | 23.0        | 43.4  | 46.2                    | 10.5        |
| <b>Young adult non-smokers (n=1391)</b> |   |                 |             |   |                         |             |
| Control                                 | 63.5                                      | 16.0            | 20.5        | 25.0  | 57.1                    | 18.0        |
| <b>Switch explanation</b>               |   |                 |             |   |                         |             |
| Present                                 | 68.0                                      | 16.0            | 16.0        | 38.4  | 46.8                    | 14.9        |
| Absent                                  | 63.9                                      | 16.4            | 19.8        | 38.1  | 44.7                    | 17.2        |
| <b>Language certainty</b>               |   |                 |             |   |                         |             |
| Hypothetical                            | 66.3                                      | 15.6            | 18.0        | 39.0  | 45.3                    | 15.8        |
| Certain                                 | 65.5                                      | 16.8            | 17.8        | 37.5  | 46.3                    | 16.3        |
| <b>Number of diseases</b>               |   |                 |             |   |                         |             |
| Single                                  | 63.5                                      | 17.0            | 19.5        | 36.0  | 48.3                    | 15.7        |
| Multiple                                | 68.3                                      | 15.4            | 16.3        | 40.5  | 43.2                    | 16.3        |

**Table 2** Multiple comparisons of two variations of a language feature with the control and with each other on comprehension of 'switching completely' and perceived comparative risk of IQOS and cigarettes

| Comparison of conditions                | Comprehension of switching completely                  |  | Perceived comparative risk of IQOS and cigarettes               |   |
|---|--|--|---|---|
|   | Some cigarettes (vs 0 cigarette) RRR (95% CI), p value | Do not know (vs 0 cigarette) RRR (95% CI), p value | More or equally harmful (vs less harmful) RRR (95% CI), p value | Do not know (vs less harmful) RRR (95% CI), p value |
| <b>Adult current smokers (n=1523)</b>   |  |  |   |   |
| <b>Switch explanation</b>               |  |  |   |   |
| Present versus control                  | <b>0.04 (0.00 to 0.90), 0.04</b>                       | <b>0.01 (0.00 to 0.20), &lt;0.001</b>              | 0.18 (0.02 to 1.48), 0.21                                       | 0.19 (0.01 to 5.66), 1.00                           |
| Absent versus control                   | 0.86 (0.03 to 22.67), 1.00                             | 0.41 (0.01 to 12.66), 1.00                         | 0.21 (0.02 to 1.74), 0.37                                       | 0.51 (0.02 to 14.03), 1.00                          |
| Present versus absent                   | <b>0.04 (0.01 to 0.28), &lt;0.001</b>                  | <b>0.02 (0.00 to 0.13), &lt;0.001</b>              | 0.85 (0.23 to 3.16), 1.00                                       | 0.38 (0.04 to 3.25), 1.00                           |
| <b>Language certainty</b>               |  |  |   |   |
| Hypothetical versus control             | 0.19 (0.01 to 4.84), 1.00                              | 0.04 (0.00 to 1.25), 0.09                          | 0.21 (0.03 to 1.77), 0.38                                       | 0.29 (0.01 to 8.43), 1.00                           |
| Certain versus control                  | 0.17 (0.01 to 4.23), 1.00                              | 0.07 (0.00 to 2.00), 0.25                          | 0.18 (0.02 to 1.46), 0.20                                       | 0.34 (0.01 to 9.43), 1.00                           |
| Hypothetical versus certain             | 1.15 (0.19 to 7.11), 1.00                              | 0.62 (0.08 to 4.86), 1.00                          | 1.21 (0.33 to 4.47), 1.00                                       | 0.88 (0.10 to 7.52), 1.00                           |
| <b>Number of diseases</b>               |  |  |   |   |
| Single versus control                   | 0.17 (0.01 to 4.16), 1.00                              | 0.07 (0.00 to 2.00), 0.25                          | 0.22 (0.03 to 1.82), 0.42                                       | 0.32 (0.01 to 8.97), 1.00                           |
| Multiple versus control                 | 0.20 (0.01 to 4.91), 1.00                              | 0.04 (0.00 to 1.25), 0.09                          | 0.17 (0.02 to 1.42), 0.18                                       | 0.31 (0.01 to 8.86), 1.00                           |
| Single versus multiple                  | 0.85 (0.14 to 5.27), 1.00                              | 1.65 (0.21 to 12.82), 1.00                         | 1.29 (0.35 to 4.77), 1.00                                       | 1.02 (0.12 to 8.73), 1.00                           |
| <b>Young adult non-smokers (n=1391)</b> |  |  |   |   |
| <b>Switch explanation</b>               |  |  |   |   |
| Present versus control                  | 0.70 (0.03 to 14.06), 1.00                             | 0.26 (0.02 to 3.52), 1.00                          | <b>0.07 (0.01 to 0.79), 0.02</b>                                | 0.07 (0.00 to 1.65), 0.18                           |
| Absent versus control                   | 1.15 (0.06 to 23.15), 1.00                             | 0.83 (0.06 to 10.55), 1.00                         | <b>0.07 (0.01 to 0.70), 0.01</b>                                | 0.14 (0.01 to 3.00), 0.67                           |
| Present versus absent                   | 0.61 (0.09 to 4.09), 1.00                              | 0.32 (0.06 to 1.77), 0.58                          | 1.14 (0.28 to 4.63), 1.00                                       | 0.54 (0.08 to 3.61), 1.00                           |
| <b>Language certainty</b>               |  |  |   |   |
| Hypothetical versus control             | 0.84 (0.04 to 16.87), 1.00                             | 0.51 (0.04 to 6.54), 1.00                          | <b>0.06 (0.01 to 0.68), 0.01</b>                                | 0.09 (0.00 to 1.86), 0.24                           |
| Certain versus control                  | 0.97 (0.05 to 19.27), 1.00                             | 0.43 (0.03 to 5.69), 1.00                          | <b>0.08 (0.01 to 0.82), 0.02</b>                                | 0.12 (0.01 to 2.66), 0.53                           |
| Hypothetical versus certain             | 0.86 (0.13 to 5.79), 1.00                              | 1.18 (0.21 to 6.52), 1.00                          | 0.83 (0.21 to 3.39), 1.00                                       | 0.70 (0.10 to 4.71), 1.00                           |
| <b>Number of diseases</b>               |  |  |   |   |
| Single versus control                   | 1.28 (0.06 to 25.51), 1.00                             | 0.79 (0.06 to 10.04), 1.00                         | 0.11 (0.01 to 1.18), 0.09                                       | 0.12 (0.01 to 2.72), 0.55                           |
| Multiple versus control                 | 0.63 (0.03 to 12.75), 1.00                             | 0.28 (0.02 to 3.70), 1.00                          | <b>0.04 (0.00 to 0.47), 0.002</b>                               | 0.08 (0.00 to 1.82), 0.23                           |
| Single versus multiple                  | 2.04 (0.30 to 13.70), 1.00                             | 2.83 (0.51 to 15.66), 0.83                         | 2.51 (0.62 to 10.18), 0.62                                      | 1.48 (0.22 to 9.92), 1.00                           |

Results of multinomial logistic regression with specified contrasts. Bold numbers indicate difference at  $p < 0.05$ . Error was adjusted through Bonferroni procedure. Covariates included gender, age, race (non-Hispanic black, non-Hispanic other, Hispanic vs non-Hispanic white), education (high school or below vs others), past 30-day e-cigarette use and ever use of heated tobacco products. Models for smokers also controlled for heaviness of smoking and pre-exposure quit intentions. RRR, relative risk ratio.

explanation present condition produced more mentions of consuming 0 cigarettes (22.2% vs absent (11.2%)). Two variations of either language certainty or number of diseases did not differ (tables 1 and 2).

#### Perceived comparative risk of IQOS and cigarettes

The control did not differ from any variation of a language feature. Two variations of any one language feature did not differ (tables 1 and 2).

#### Perceived general risk of IQOS

Compared with the control ( $M = 3.45$ ,  $SD = 1.61$ ), participants in the conditions with a switch explanation ( $M = 2.96$ ,  $SD = 1.65$ ), certain language ( $M = 2.98$ ,  $SD = 1.72$ ) or single disease ( $M = 3.02$ ,  $SD = 1.66$ ) reported significantly lower perceived general risk of IQOS. Two variations of any one feature did not differ (table 3 and online supplemental appendix 4).

#### Perceived specific risk of IQOS

Compared with the control, all types of MRCs reduced perceived risk of IQOS for *lung cancer*. Three types of MRCs (switch explanation present, certain language and multiple diseases) reduced perceived risk for *emphysema*. Switch explanation present MRCs reduced perceived risk for *heart disease*. Switch explanation absent MRCs reduced perceived risk for *gum disease*, a disease not mentioned in any MRCs. Messages with a switch explanation and certain language reduced perceived risk

for *mouth cancer*, another unmentioned disease. Two variations of any one feature did not differ (table 3 and online supplemental appendix 4).

#### Behavioural intentions

The control did not differ from any variation of a language feature. Two variations of any one language feature did not differ (table 3 and online supplemental appendix 4).

#### Young adult non-smokers

##### Sample characteristics

Among 1391 young adult non-smokers, 48.2% were male, 47.7% were non-Hispanic white and 33.4% had high school or less education. Few (8.9%) indicated ever use of heated tobacco products (table 5).

##### Comprehension of 'switching completely'

The control did not differ from any variation of a language feature. For any language feature, two variations did not differ (tables 1 and 2).

##### Perceived comparative risk of IQOS and cigarettes

Participants in all conditions except single disease were more likely to report lower perceived comparative risk of IQOS (37.5%–40.5%) than in the control condition (25%). Two variations of a language feature did not differ (tables 1 and 2).



**Table 3** Means and SD of two variations of a language feature and control condition on perceived risk of IQOS and behavioural intentions

|                         |              | Specific risk |             |               |             |                                   |                                    |                        |
|-------------------------|--------------|---------------|-------------|---------------|-------------|-----------------------------------|------------------------------------|------------------------|
| Conditions              | General risk | Lung cancer   | Emphysema   | Heart disease | Stroke      | Gum disease (unmentioned disease) | Mouth cancer (unmentioned disease) | Behavioural intentions |
| Adult current smokers   |              |               |             |               |             |                                   |                                    |                        |
|                         | n=1363       | n=1363        | n=1322      | n=1345        | n=1324      | n=1323                            | n=1325                             | n=1523                 |
| Control                 | 3.45 (1.61)  | 4.10 (1.57)   | 3.90 (1.68) | 3.87 (1.59)   | 3.75 (1.66) | 3.76 (1.68)                       | 3.77 (1.70)                        | 4.29 (2.49)            |
| Switch explanation      |              |               |             |               |             |                                   |                                    |                        |
| Present                 | 2.96 (1.65)  | 3.54 (1.81)   | 3.40 (1.81) | 3.42 (1.86)   | 3.30 (1.79) | 3.34 (1.84)                       | 3.29 (1.85)                        | 4.58 (2.51)            |
| Absent                  | 3.14 (1.73)  | 3.59 (1.79)   | 3.53 (1.83) | 3.55 (1.78)   | 3.48 (1.81) | 3.32 (1.86)                       | 3.47 (1.82)                        | 4.52 (2.49)            |
| Language certainty      |              |               |             |               |             |                                   |                                    |                        |
| Hypothetical            | 3.12 (1.67)  | 3.57 (1.83)   | 3.51 (1.81) | 3.49 (1.81)   | 3.38 (1.81) | 3.33 (1.84)                       | 3.41 (1.82)                        | 4.49 (2.49)            |
| Certain                 | 2.98 (1.72)  | 3.56 (1.77)   | 3.42 (1.83) | 3.48 (1.83)   | 3.41 (1.79) | 3.33 (1.86)                       | 3.35 (1.86)                        | 4.61 (2.51)            |
| Number of diseases      |              |               |             |               |             |                                   |                                    |                        |
| Single                  | 3.02 (1.66)  | 3.58 (1.82)   | 3.52 (1.84) | 3.51 (1.84)   | 3.34 (1.81) | 3.32 (1.85)                       | 3.38 (1.84)                        | 4.50 (2.51)            |
| Multiple                | 3.08 (1.73)  | 3.56 (1.78)   | 3.42 (1.80) | 3.46 (1.81)   | 3.44 (1.79) | 3.34 (1.85)                       | 3.38 (1.84)                        | 4.60 (2.50)            |
| Young adult non-smokers |              |               |             |               |             |                                   |                                    |                        |
|                         | n=1281       | n=1251        | n=1132      | n=1237        | n=1207      | n=1233                            | n=1225                             | n=1391                 |
| Control                 | 4.01 (1.83)  | 4.56 (1.76)   | 4.05 (1.99) | 4.28 (1.74)   | 4.19 (1.89) | 4.39 (1.75)                       | 4.40 (1.74)                        | 2.23 (2.10)            |
| Switch explanation      |              |               |             |               |             |                                   |                                    |                        |
| Present                 | 3.59 (1.72)  | 4.06 (1.92)   | 3.74 (1.94) | 3.70 (1.90)   | 3.63 (1.94) | 3.87 (1.93)                       | 3.81 (1.96)                        | 2.22 (1.96)            |
| Absent                  | 3.79 (1.76)  | 4.20 (1.82)   | 3.84 (1.89) | 3.98 (1.86)   | 3.86 (1.88) | 4.02 (1.82)                       | 4.01 (1.86)                        | 2.23 (1.95)            |
| Language certainty      |              |               |             |               |             |                                   |                                    |                        |
| Hypothetical            | 3.68 (1.73)  | 4.16 (1.85)   | 3.73 (1.91) | 3.89 (1.86)   | 3.75 (1.90) | 3.92 (1.89)                       | 3.96 (1.86)                        | 2.22 (1.97)            |
| Certain                 | 3.70 (1.76)  | 4.10 (1.89)   | 3.85 (1.92) | 3.80 (1.91)   | 3.74 (1.92) | 3.97 (1.87)                       | 3.86 (1.96)                        | 2.24 (1.94)            |
| Number of diseases      |              |               |             |               |             |                                   |                                    |                        |
| Single                  | 3.71 (1.73)  | 4.26 (1.79)   | 3.86 (1.89) | 3.95 (1.86)   | 3.78 (1.89) | 3.98 (1.88)                       | 4.01 (1.86)                        | 2.25 (1.94)            |
| Multiple                | 3.67 (1.76)  | 4.00 (1.93)   | 3.72 (1.94) | 3.74 (1.90)   | 3.71 (1.93) | 3.91 (1.88)                       | 3.82 (1.95)                        | 2.20 (1.97)            |

Results of ANCOVA with specified contrasts comparing two variations of each variable with each other and with the control. Bold numbers indicate differences between control and a specific language feature at  $p < 0.05$ . There were no significant differences between two variations of each language feature for any outcomes (eg, for perceived general risk, there was no significant difference between hypothetical and certain language; but the difference between certain language and control was significant, as indicated by the bold font). Error was adjusted through Bonferroni procedure. Covariates included gender, age, race (non-Hispanic black, non-Hispanic other, Hispanic vs non-Hispanic white), education (high school or below vs others), past 30-day e-cigarette use and ever use of heated tobacco products. Models for smokers also controlled for heaviness of smoking and pre-exposure quit intentions. Perceived risk items were measured on a 0 (not at all) to 6 (extremely) plus I don't know scale. Behavioural intentions were measured on a 1 (not at all likely/open) to 9 (extremely likely/open) scale. Each outcome has different n because of missing values (ie, I don't know) for risk perception variables. Behavioural intentions (ie, switch and openness intentions) did not have I don't know option and thus did not have any missing values.

ANCOVA, analysis of covariance.

### Perceived general risk of IQOS

The control did not differ from each variation of switch explanation, language certainty or number of diseases. Two variations of any one of the three features did not differ (table 3 and online supplemental appendix 4).

### Perceived specific risk of IQOS

Compared with the control, two types of MRCs (switch explanation present and multiple diseases) reduced perceived risk of IQOS for *lung cancer*, *heart disease* and *stroke*. Three types of MRCs (switch explanation present, hypothetical language and multiple diseases) reduced perceived risk of IQOS for *gum disease*, an unmentioned disease. Three types of MRCs (switch explanation present, certain language, multiple diseases) reduced perceived risk for *mouth cancer*, an unmentioned disease. Two variations of any one feature did not differ (table 3 and online supplemental appendix 4).

### Behavioural intentions

The control did not differ from any variation of a language feature. For any language feature, two variations did not differ (table 3 and online supplemental appendix 4).

## DISCUSSION

MRCs with different language features had some effects on comprehension and risk perceptions, but not on behavioural intentions. The effects varied by different features and for

current smokers and non-smokers. We discuss these findings and their implications for regulation and communication.

An explanation of 'switching completely' increased correct perceptions among smokers that 'switching completely' means smoking 0 cigarettes; however, it only increased to 22.2%. The default understanding among smokers seems to be that they can switch completely, but still smoke multiple cigarettes a day. Across all conditions, 55%–60% of smokers believed that, and an additional 20%–33% did not know. The findings indicate that adult smokers may have prevalent and entrenched misperceptions about what 'switching completely' means, at least for IQOS. Changing those misperceptions may require more than just a brief exposure to a short explanatory message. Our finding extends previous qualitative research demonstrating that some smokers interpreted 'completely switching' as compatible with continued use of cigarettes<sup>26</sup> and perceived it as giving them more choice than the more overt 'completely replacing'.<sup>43</sup>

All MRCs using the phrase 'switching completely' to date have not had an explanation about the phrase, including PMI's IQOS MRCs. According to our findings, such claims are likely to fail the FDA's requirement that consumers should correctly understand tobacco companies' MRCs.<sup>1</sup> In our study, adding an explanation about 'switching completely' enhanced consumers' understanding of the phrase. Nonetheless, more research is needed on how to better explain 'switching completely', given that our explanatory message seemed to unintentionally reduce the perceived risk of unmentioned diseases in MRCs.

**Table 4** Adult current smoker ( $\geq 18$  years) sample characteristics overall and by condition

|   | Overall<br>(n=1523)<br>Unweighted% | Treatment                   |                             |                             |                             |                             |                             |                             |                             | Control<br>(n=169)<br>Unweighted% |
|---|------------------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------------|
|   |                                    | 1<br>(n=170)<br>Unweighted% | 2<br>(n=167)<br>Unweighted% | 3<br>(n=167)<br>Unweighted% | 4<br>(n=172)<br>Unweighted% | 5<br>(n=169)<br>Unweighted% | 6<br>(n=169)<br>Unweighted% | 7<br>(n=170)<br>Unweighted% | 8<br>(n=170)<br>Unweighted% |                                   |
| Gender  |                                    |                             |                             |                             |                             |                             |                             |                             |                             |                                   |
| Male  | 46.7                               | 48.2                        | 46.7                        | 44.3                        | 48.8                        | 45.0                        | 46.2                        | 48.2                        | 44.1                        | 49.1                              |
| Female  | 52.7                               | 51.2                        | 53.3                        | 55.1                        | 50.0                        | 53.8                        | 53.3                        | 51.2                        | 55.3                        | 50.9                              |
| Transgender   | 0.5                                | 0.6                         | 0.0                         | 0.0                         | 1.2                         | 1.2                         | 0.6                         | 0.0                         | 0.6                         | 0.0                               |
| Other   | 0.1                                | 0.0                         | 0.0                         | 0.6                         | 0.0                         | 0.0                         | 0.0                         | 0.6                         | 0.0                         | 0.0                               |
| Age (years)   |                                    |                             |                             |                             |                             |                             |                             |                             |                             |                                   |
| 18–29   | 33.7                               | 38.2                        | 37.7                        | 38.9                        | 25.6                        | 28.4                        | 32.0                        | 34.1                        | 35.9                        | 32.5                              |
| 30–44   | 25.6                               | 24.7                        | 22.8                        | 24.0                        | 29.7                        | 30.8                        | 30.8                        | 25.9                        | 19.4                        | 22.5                              |
| 45–59   | 22.7                               | 20.6                        | 18.6                        | 19.8                        | 22.1                        | 24.3                        | 22.5                        | 24.7                        | 27.6                        | 24.3                              |
| 60+   | 18.0                               | 16.5                        | 21.0                        | 17.4                        | 22.7                        | 16.6                        | 14.8                        | 15.3                        | 17.1                        | 20.7                              |
| Race/Ethnicity  |                                    |                             |                             |                             |                             |                             |                             |                             |                             |                                   |
| White, NH   | 62.0                               | 62.4                        | 64.7                        | 62.3                        | 66.3                        | 65.1                        | 60.4                        | 59.4                        | 50.0                        | 67.5                              |
| Black, NH   | 14.8                               | 15.3                        | 12.6                        | 15                          | 11.6                        | 13.6                        | 13.6                        | 14.1                        | 22.4                        | 15.4                              |
| Hispanic  | 17.6                               | 17.6                        | 18.0                        | 18.6                        | 14.0                        | 16.6                        | 18.9                        | 19.4                        | 20.6                        | 14.8                              |
| Other, NH   | 5.6                                | 4.7                         | 4.8                         | 4.2                         | 8.1                         | 4.7                         | 7.1                         | 7.1                         | 7.1                         | 2.4                               |
| Education   |                                    |                             |                             |                             |                             |                             |                             |                             |                             |                                   |
| Less than high school   | 10.7                               | 14.7                        | 7.2                         | 10.8                        | 11.0                        | 11.8                        | 10.1                        | 12.4                        | 10.0                        | 8.3                               |
| High school   | 27.7                               | 28.8                        | 29.9                        | 22.2                        | 27.3                        | 27.2                        | 29.0                        | 25.9                        | 27.1                        | 32.0                              |
| Some college  | 35.4                               | 33.5                        | 31.7                        | 38.3                        | 36.6                        | 33.7                        | 37.3                        | 38.8                        | 30.6                        | 37.9                              |
| Bachelor or higher degree   | 26.2                               | 22.9                        | 31.1                        | 28.7                        | 25.0                        | 27.2                        | 23.7                        | 22.9                        | 32.4                        | 21.9                              |
| E-cigarette use   |                                    |                             |                             |                             |                             |                             |                             |                             |                             |                                   |
| Past 30 days  | 53.3                               | 54.1                        | 47.9                        | 57.5                        | 48.3                        | 53.3                        | 55                          | 58.2                        | 56.5                        | 48.5                              |
| Heat-not-burn tobacco product use   |                                    |                             |                             |                             |                             |                             |                             |                             |                             |                                   |
| Ever  | 26.7                               | 28.8                        | 26.3                        | 31.1                        | 24.4                        | 30.2                        | 26.6                        | 22.9                        | 29.4                        | 20.7                              |
| Past 30 days  | 21.4                               | 22.9                        | 20.4                        | 22.8                        | 20.9                        | 27.2                        | 20.7                        | 15.3                        | 24.7                        | 17.8                              |
| There were no significant differences between conditions on sample characteristics. 1=switch explanation present+hypothetical+single disease; 2=switch explanation absent+hypothetical+single disease; 3=switch explanation present+certain+multiple diseases; 4=switch explanation absent+certain+single disease; 5=switch explanation present+hypothetical+multiple diseases; 6=switch explanation absent+hypothetical+multiple diseases; 7=switch explanation present+certain+multiple diseases; 8=switch explanation absent+certain+multiple diseases.<br>NH, non-Hispanic. |                                    |                             |                             |                             |                             |                             |                             |                             |                             |                                   |

There were no significant differences between conditions on sample characteristics. 1=switch explanation present+single disease; 2=switch explanation present+certain+single disease; 3=switch explanation present+certain+multiple diseases; 4=switch explanation absent+certain+single disease; 5=switch explanation present+certain+multiple diseases; 6=switch explanation present+certain+multiple diseases; 7=switch explanation present+certain+multiple diseases; 8=switch explanation absent+certain+multiple diseases. NH=non-Hispanic.

**Table 5** Young adult non-smoker (18–29 years) sample characteristics overall and by condition

|  | Overall<br>(n=1391)<br>Unweighted% | Treatment                   |                             |                             |                             |                             |                             |                             |                             | Control<br>(n=156)<br>Unweighted% |
|--|------------------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------------|
|  |                                    | 1<br>(n=154)<br>Unweighted% | 2<br>(n=157)<br>Unweighted% | 3<br>(n=153)<br>Unweighted% | 4<br>(n=153)<br>Unweighted% | 5<br>(n=155)<br>Unweighted% | 6<br>(n=155)<br>Unweighted% | 7<br>(n=156)<br>Unweighted% | 8<br>(n=152)<br>Unweighted% |                                   |
| <b>Gender</b>                            |                                    |                             |                             |                             |                             |                             |                             |                             |                             |                                   |
| Male                                     | 48.2                               | 50.6                        | 49.7                        | 46.4                        | 44.4                        | 45.2                        | 54.2                        | 48.7                        | 50.7                        | 44.2                              |
| Female                                   | 49.4                               | 46.8                        | 48.4                        | 51.0                        | 53.6                        | 52.9                        | 42.6                        | 48.7                        | 47.4                        | 53.2                              |
| Transgender                              | 1.6                                | 1.9                         | 1.3                         | 1.3                         | 2.0                         | 1.9                         | 1.9                         | 1.9                         | 1.3                         | 0.6                               |
| Other                                    | 0.8                                | 0.6                         | 0.6                         | 1.3                         | 0.0                         | 0.0                         | 1.3                         | 0.6                         | 0.7                         | 1.9                               |
| <b>Race/Ethnicity</b>                    |                                    |                             |                             |                             |                             |                             |                             |                             |                             |                                   |
| White, NH                                | 47.7                               | 51.9                        | 45.9                        | 46.4                        | 49.0                        | 43.9                        | 54.8                        | 41.7                        | 47.4                        | 48.1                              |
| Black, NH                                | 19.7                               | 20.8                        | 21.0                        | 18.3                        | 19.0                        | 17.4                        | 18.7                        | 22.4                        | 17.1                        | 22.4                              |
| Hispanic                                 | 21.4                               | 16.9                        | 21.7                        | 22.2                        | 20.3                        | 23.9                        | 15.5                        | 22.4                        | 27.0                        | 22.4                              |
| Other, NH                                | 11.3                               | 10.4                        | 11.5                        | 13.1                        | 11.8                        | 14.8                        | 11.0                        | 13.5                        | 8.6                         | 7.1                               |
| <b>Education</b>                         |                                    |                             |                             |                             |                             |                             |                             |                             |                             |                                   |
| Less than high school                    | 3.5                                | 1.3                         | 3.8                         | 0.7                         | 3.9                         | 1.3                         | 5.8                         | 5.1                         | 4.6                         | 4.5                               |
| High school                              | 29.9                               | 32.5                        | 28.0                        | 26.1                        | 32.7                        | 30.3                        | 36.1                        | 28.8                        | 25.7                        | 28.8                              |
| Some college                             | 36.0                               | 35.7                        | 33.8                        | 42.5                        | 31.4                        | 37.4                        | 32.3                        | 37.8                        | 35.5                        | 37.8                              |
| Bachelor or higher degree                | 30.6                               | 30.5                        | 34.4                        | 30.7                        | 32.0                        | 31.0                        | 25.8                        | 28.2                        | 34.2                        | 28.8                              |
| <b>E-cigarette use</b>                   |                                    |                             |                             |                             |                             |                             |                             |                             |                             |                                   |
| Past 30 days                             | 18.7                               | 18.8                        | 15.9                        | 20.3                        | 18.1                        | 16.8                        | 17.4                        | 19.9                        | 20.4                        | 20.5                              |
| <b>Heat-not-burn tobacco product use</b> |                                    |                             |                             |                             |                             |                             |                             |                             |                             |                                   |
| Ever                                     | 8.9                                | 10.4                        | 8.9                         | 8.5                         | 10.5                        | 6.5                         | 8.4                         | 10.3                        | 8.6                         | 8.3                               |
| Past 30 days                             | 4.7                                | 5.8                         | 4.5                         | 4.6                         | 5.9                         | 2.6                         | 3.2                         | 6.4                         | 5.3                         | 4.5                               |

There were no significant differences between conditions on sample characteristics. 1=switch explanation present+hypothetical+single disease; 2=switch explanation absent+hypothetical+single disease; 3=switch explanation present+certain+single disease; 4=switch explanation absent+certain+single disease; 5=switch explanation present+hypothetical+multiple diseases; 6=switch explanation absent+hypothetical+multiple diseases; 7=switch explanation present+certain+multiple diseases; 8=switch explanation absent+certain+multiple diseases.

NH, non-Hispanic.

Compared with adult current smokers, young adult non-smokers reported a better understanding of 'switching completely' (>60%). However, including an explanation about 'switching completely' in MRCs did not produce more correct beliefs.

MRCs with hypothetical and certain language both reduced perceived risk of IQOS for lung cancer, and only MRCs using certain language reduced perceived general risk and risk of IQOS for emphysema among current smokers and for mouth cancer among both current smokers and young adult non-smokers. Thus, it appears that the certain language had a greater effect on risk perceptions, indicating if sufficient evidence of reduced risk based on long-term population-level studies becomes available, it may be communicated to the consumers using certain language.

We did not find evidence of a halo effect (mentions of multiple diseases having greater effects) among adult current smokers. However, among young adult non-smokers, MRCs with multiple diseases reduced perceived risk of IQOS for two unmentioned diseases in the study, suggesting a halo effect. This is consistent with the elaboration likelihood model,<sup>44</sup> which suggests that participants with low involvement in a message are more likely to use heuristics (ie, number of diseases in this study) to guide their responses to a message. This finding is similar to what Swedish Match found in its studies: an MRC for General Snus listed six diseases, but it also reduced perceived risk of the unmentioned gum disease.<sup>45</sup> This indicates that MRCs listing multiple diseases might mislead people, particularly non-smokers, to believe that MRTPs reduce the risks of other diseases.

IQOS MRCs with all language variations (except single disease) increased the proportion of young adult non-smokers who thought that IQOS is less harmful than cigarettes. By contrast, MRCs did not change the proportion of current smokers who held that belief. This could be due to non-smokers having more room to change their beliefs about the relative risk of IQOS and cigarettes compared with smokers.

We did not find that IQOS MRCs with any language variation influenced behavioural intentions, similar to other studies,<sup>46 47</sup> where a single exposure to an MRC is typically insufficient to change behavioural intentions. More independent research should examine how IQOS MRCs influence behavioural intention and behaviour.

This study's limitations include the use of convenience sample, lack of behavioural outcome, not controlling for flavoured tobacco use, showing three ads in a fixed order and using only 'may' for hypothetical language. The study was conducted several months after the FDA's approval of IQOS's premarket application, which might have affected the results. Many participants reported ever use of heated tobacco products (26.7% among smokers, 8.9% among non-smokers). It is likely that some of these who reported using heated products actually used cannabis or confused heated tobacco products with e-cigarettes.

Our findings have implications for FDA's decision-making on current and future MRTPAs. FDA's recent exposure marketing order for IQOS emphasised the lack of information on smokers' understanding of 'switching completely' and the need for continuous monitoring.<sup>18</sup> We found that smokers largely misunderstand what 'switching completely' means, and while corrective explanation increased the understanding, the majority of smokers still held incorrect beliefs. FDA should require PMI to demonstrate efforts to bring smokers' understanding of 'switching completely' closer to non-smokers' and to develop communications (included in product promotions, website marketing and 'personal experience'<sup>6</sup>) that directly address that. Similarly,

postmarket surveillance studies for General Snus should evaluate how their authorised MRC ('using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema and chronic bronchitis') influences the understanding of the need to switch completely. We recommend that the FDA make postmarket surveillance studies submitted by tobacco companies public so the research community can provide input on them.

## CONCLUSION

MRCs with varied language features reduced some misperceptions but created others and had different impacts on smokers and non-smokers in the IQOS context. Future MRCs may use an explanation of 'switching completely'. Certain (vs hypothetical) language had a greater effect on reducing risk perceptions and may be used in MRCs when evidence allows. Several MRCs seemed to have a halo effect, where participants reported reduced perceived risk for diseases not mentioned in the claims. Future studies should evaluate strategies to reduce these misperceptions.

## What this paper adds

- Tobacco industry studies on consumers' perceptions of modified risk claims (MRCs) were frequently methodologically flawed.
- This study provides an independent assessment of the effects of MRCs in the USA.
- Based on a review of MRCs developed by tobacco companies and our knowledge about communication science, we manipulated three language features of MRCs: explanation about 'switching completely' (absent vs present), number of diseases (single vs multiple) and language certainty (hypothetical vs certain).
- We tested the effects of these features on US adult current smokers' and young adult non-smokers' understanding of the phrase 'switching completely', risk perceptions and behavioural intentions about IQOS.
- Findings revealed a widespread misperception about what 'switching completely' means among adult smokers—explaining the phrase in MRCs slightly reduced such misperception.
- IQOS MRCs using certain (vs hypothetical) language appeared more likely to change risk perceptions about IQOS, indicating if sufficient evidence of reduced risk based on long-term population-level studies becomes available, MRCs may use certain language.
- IQOS MRCs describing reduced risk of multiple diseases might evoke halo effect (eg, reduce perceived risk for diseases not mentioned in an MRC) among young adult non-smokers.

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