Public Submission #3

Bonnie Halpern-Felsher, PhD, FSAHM

Founder and Executive Director, Tobacco Prevention Toolkit and the Cannabis Awareness and Prevention Toolkit.

Hunter-Thomas, Serina

From: Dr. Bonnie Halpern-Felsher <bonnieh@stanford.edu>
Sent: Friday, February 7, 2020 9:08 AM
To: Hunter-Thomas, Serina; TPSAC
Cc: Bonnie Halpern-Felsher
Subject: New IQOS pub on MRTP claims, for TPSAC meeting on VLN MRTP application
Attachments: tobaccocontrol-2019-055318.full.pdf

Dear Ms. Hunter-Thomas and members of TPSAC,

Attached please find a paper just published in Tobacco for consideration at the February 14, 2020 TPSAC meeting concerning 22nd Century's MRTP applications for VLN King and VLN Menthol King.

This paper shows that when exposed to modified risk tobacco claims for IQOS product, youth misperceive the harms of the products. As such, there are concerns that they will then start using, as we have seen with other products.

I am submitting this as the same might apply for VLN products.

Please confirm receipt.

Thank you.
Bonnie

Bonnie Halpern-Felsher, PhD, FSAHM
Professor of Pediatrics
Professor (By courtesy), Health Research & Policy
Director of Fellows' Scholarship, Department of Pediatrics
Director of Research, Division of Adolescent Medicine
Associate Director, Adolescent Medicine Fellowship Program
Co-leader, Scholarly Concentrations, Pediatrics Residency Program

Founder and Executive Director, Tobacco Prevention Toolkit and the Cannabis Awareness and Prevention Toolkit.

Division of Adolescent Medicine
Department of Pediatrics
Stanford University
770 Welch Road, Suite 100
Palo Alto, CA 94304
bonnie.halpernfelsher@stanford.edu
650-724-1981 (W)
650-736-7706 (F)

PMI's heated tobacco products marketing claims of reduced risk and reduced exposure may entice youth to try and continue using these products

Karma McKelvey ,[1] Michael Baiocchi,[2] Bonnie Halpern-Felsher[1]

[1]Pediatrics/Adolescent Medicie, Stanford University School of Medicine, Stanford, California, USA
[2]Statistics, Stanford University Stanford Prevention Research Center, Stanford, California, USA

Correspondence to
Dr Bonnie Halpern-Felsher, Pediatrics/Adolescent Medicine, Stanford University School of Medicine, Stanford, CA 94304, USA; bonnieh@stanford.edu

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ABSTRACT

Importance Philip Morris International (PMI) is seeking Food and Drug Administration's (FDA) authorisation to market IQOS as a modified risk tobacco product and to make marketing claims of reduced risk and reduced exposure. Such claims may be misunderstood by youth, thereby increasing their risk for tobacco initiation.

Objective To assess youth (mean age 19.3, SD=1.7) understanding and perceptions of PMI's proposed consumer marketing claims of reduced risk and reduced exposure, we embedded a randomised controlled experiment into a survey of 450 California youth (April to August 2018). Participants were randomised to see 'reduced exposure', 'reduced risk' or neither claim. Perceptions of IQOS-related health risks and general harm and understanding of the term 'switching completely' as used in PMI's proposed claims were compared.

Results Mean expectancies to experience specific health risks did not differ by claim exposure. The reduced exposure group's perceptions of general harm did not differ from those of controls nor from the reduced risk group. The reduced risk group had the largest proportion who perceived IQOS as moderately/less harmful (n=78, 52%); controls the largest proportion perceiving IQOS as quite/extremely harmful (n=91, 63%). While 71% of the sample understood the term 'switch completely' correctly as used in the reduced risk (n=194, 71%) and reduced exposure (n=206, 72%) claims, more than 1 in 4 did not.

Conclusions FDA and other regulators must use caution when considering allowing claims of reduced risk or reduced exposure to appear on retail tobacco packaging. Youth misunderstand such claims, and misperceptions of harm are known to lead to tobacco-use initiation.

INTRODUCTION

Globally, tobacco companies are marketing heated tobacco products (HTP), and their adoption has been steadily increasing since the 2014 introduction of Philip Morris International's (PMI) 'IQOS'.[1] Currently, IQOS is available in 48 countries, including Japan, Switzerland, Italy, Israel, Canada, South Korea, Great Britain and most recently the USA[2] (available at: https://www.pmi.com/media-center/news/fda-authorizes-sale-of-iqos-in-the-us accessed 7 October 2019). In December 2016, PMI submitted an application[3] (still under review as of 7 October 2019) seeking the US Food and Drug Administration's (FDA) authorisation to market IQOS in the USA as a modified risk tobacco product (MRTP). Manufacturers cannot market tobacco products with claims that they reduce harm or the risk of tobacco-related disease ('reduced risk' claims) or that they reduce consumers' exposure to harmful substances ('reduced exposure' claims) without first demonstrating to the FDA that these claims are supported by scientific evidence. PMI is seeking to make two reduced risk and one reduced exposure MRTP claims in consumer marketing, including the following: (1) '*Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system can reduce the risks of tobacco related-diseases*' (one of the two reduced risk claims) and (2) '*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*' (reduced exposure claim).[3]

When assessing how these claims of reduced risk and reduced exposure could impact consumers' and possible consumers' understanding and perceptions of IQOS, particular attention must be paid to the impact on youth as youth will likely not understand or will misinterpret these claims.[4–6] Further, applicable law mandates that any advertising or labelling concerning products marketed with reduced exposure claims does not mislead consumers.[7] For reduced exposure claims, the manufacturer must demonstrate that actual consumer perception tests show that consumers will not be misled into believing that the product is less harmful or presents less risk of disease than other commercially marketed tobacco products.[7] However, no study independent of the tobacco industry has empirically examined how these claims are interpreted by youth. In earlier work, the evidence PMI provided to support their claims that 'switching completely' would be understood by smokers, that smokers would in fact *switch completely* from cigarettes to IQOS and that the claims would not decrease smokers' intentions to quit was found to be deficient. Further, the studies and measurement tools used by PMI were found to be flawed and their reporting of findings misleading.[6] In other words, PMI did not meet its legal burden to demonstrate consumer understanding and cannot do so insofar as tobacco companies cannot and should not conduct studies among those not of legal age to purchase their products.

The packaging and marketing of IQOS in general may appeal to youth, so the addition of reduced risk and reduced exposure claims could make the products even more enticing.[8 9] In fact, a recently published report by Czoli and colleagues calls for research to examine whether youth view HTP as

harmful as these data will aid in understanding the potential harm these products may cause.[9] Data are needed to inform regulation of IQOS[6]; here, we investigate among youth (1) whether these claims result in misperceptions of the harms and specific risks of IQOS and (2) whether the term switching completely is fully understood. Correspondingly, we hypothesised (1) that reading any modified risk claim (ie, reduced risk claim or reduced exposure claim) would be associated with perceptions of less harm to health and lower risk of experiencing negative health effects and (2) not all youths understand that the term switching completely means only using IQOS and never using any other tobacco products, including e-cigarettes, again. Such data will inform FDA's decision on PMI's MRTP application and could influence its future consideration of HTP, of which IQOS is a representative product and an unofficial test case for the US market.

MATERIALS AND METHODS

Design and setting

Data derive from wave 6 of an ongoing prospective cohort study initated on 13 July 2014 among youth who were recruited from 10 California high schools with ethnically and socioeconomically diverse student populations. Rather than making population-level estimates, this cohort study was designed to examine changes in use and perceptions of tobacco products over time. A unique log-in was sent to participants inviting them to complete the online survey, administered by Qualtrics (Provo, UT). Data included in this study were collected 7 April through 17 August 2018. Additional details regarding study design, data collection and sampling are published elsewhere.[10 11] For completing the wave 6 survey, participants received a US$35 gift card. The survey and research protocol were approved by the Stanford IRB.

On the wave 6 survey, we embedded an experiment (see Consolidated Standards of Reporting Trials diagram, figure 1) wherein participants were randomised to one of three groups.

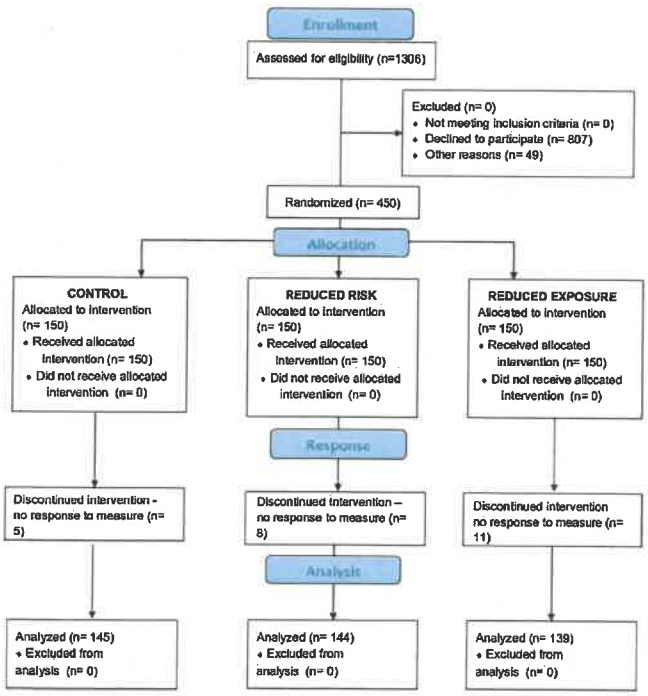

Figure 1 CONSORT diagram. CONSORT, Consolidated Standards of Reporting Trials.

Table 1 Randomised distribution of characteristics associated with tobacco-related risk perceptions among n=450 CA youth by exposure group

	Control (n=145)	Reduced Risk (n=142)	Reduced exposure (n=139)
Mean age	19.3 (1.7)	19.2 (1.7)	19.3 (1.7)
Male	57 (37%)*	38 (26%)*	50 (33%)
Heard of IQOS?	4	4	4
Used IQOS?	2	2	0
Ever use of…			
E-cigarette	48 (32%)	42 (29%)	45 (30%)
Cigarette	41 (27%)	27 (20%)	40 (28%)
Hookah	52 (34%)	35 (24%)	42 (28%)
Blunt	56 (37%)	49 (34%)	67 (45%)
None of these	70 (46%)	63 (43%)	59 (39%)
Two or more products	69 (45%)	69 (48%)	83 (55%)

*The only significant between-groups difference (p=0.0454) was that there were more males in the control group compared with the reduced risk group. However, our previously published work with this same cohort[10–12] has shown no differences between males and females in tobacco-related perceptions.
CA, California.

(See table 1 for participant characteristics by exposure group pursuant to randomisation.) One group was shown PMI's proposed reduced risk claim: '*Scientific studies have shown that switching completely from cigarettes to the IQOS system can reduce the risks of tobacco related-diseases*', one the proposed reduced exposure claim: '*Scientific studies have shown that switching completely from cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals*', and the other neither (control group members responded to the same queries, but without being asked to read a statement first). After responding to questions of perceived harm and perceived likelihood of experiencing negative health effects, participants' understanding of switching completely as used in PMI's claims, was examined, with equal numbers of control group members randomly assigned to both claim exposure groups.

Participants

The wave 6 sample (n=450; mean age=19.3, SD=1.7, range 16–23 mode 20 (n=122); 63% female (n=284), 33% male (n=145), 1% transgender (n=6) and 3% (n=15) did not provide a response) had fewer males and a higher percentage of Asian students than the schools from which they were recruited; nonetheless, participant demographics reflected the demographic make-up of the schools they attended. Self-reported race and ethnicity were 36.6% (n=163) white, 27.4% (n=122) Asian/Pacific Islander and 37.3% (n=166) Hispanic (28.8% (n=128) non-white Hispanic and 8.4% (n=38) white Hispanic). Project information sheets, assent forms and consent forms were taken home by students to review with their parents or guardians. Prospective participants provided signed parental informed consent and assent forms; students 18 years or older provided their own written informed consent.

Measures

First, participants were shown pictures of each product (see figure 2 for IQOS) asked about in the survey with accompanying text explaining how the product would be referred to throughout, for example: 'This is an IQOS, a type of device

Figure 2 Picture of IQOS shown to study participants.

known as a heated tobacco product'. As IQOS was newly added to wave 6, participants were also queried: 'Before today have you ever heard of an IQOS?'.

After reading their assigned claim statement (ie, reduced risk claim, reduced exposure claim, none/control), participants were asked a number of questions, as noted below. These questions were mirrored after other studies focusing on tobacco use and perceptions.[11 12] The flow of participants and questions is shown in detail in figure 3.

Perceptions of general harm

'Considering the statement above, imagine that you continue to use the IQOS system, a heated tobacco product, 2 to 3 times a day, every day for the rest of your life. How harmful would this be for your health?'. Participants in the control group were asked the same question minus the text, 'considering the statement above'. Response choices for all three groups were: not at all harmful, slightly harmful, moderately harmful, quite harmful or extremely harmful. Based on distribution of the data and to make more meaningful comparisons, the choices not at all harmful, slightly harmful and moderately harmful were collapsed into the category 'moderately/less harmful' and quite harmful and extremely harmful were combined into 'quite/extremely harmful'.

Perceived likelihood of experiencing specific health conditions

'Still considering the statement above, imagine now that you continue to use the IQOS system, a heated tobacco product, 2 to 3 times a day, every day for the rest of your life. What is the chance, from 0% to 100%, that...You'll get oral (mouth) cancer, You'll have a heart attack, You'll get lung cancer, You'll get another tobacco-related disease, You'll get addicted to the product, You'll get lung disease (COPD)'. Response choices for all three groups for the listed health conditions were 0%–100%. Participants in the control group were asked the same question minus the text: 'still considering the statement above'.

Understanding of 'switch completely' in proposed claims: after responding to the above questions, control group members were randomly assigned in equal number to see either the reduced risk claim or the reduced exposure claim. All participants were then shown either the reduced risk or the reduced exposure claim and were asked to choose the interpretation of the term switch completely that best fit their understanding after reading. Response choices were: 'Using only IQOS and never smoking cigarettes again, Using IQOS and other tobacco products but never smoking cigarettes again, Using IQOS or vapes but never smoking cigarettes again, Using IQOS and cutting way down on smoking cigarettes, Using only IQOS and never using vapes again, or Don't know'.

Study size and potential bias

The original sampling frame was all students in the 9th and 12th grades from the 10 participating high schools and there has been dropout across waves 1 through 6. The current analysis is constrained to wave 6, which was only a survey with items pertaining to PMI's proposed claims of reduced risk and reduced exposure. Data for this study included only participants who completed the wave 6 survey (450 (83.3%)). Although there were differences in sample proportions for race/ethnicity between wave 6 and wave 1, we did not make adjustments, as previous work with this cohort has revealed no association between race/ethnicity and outcomes of interest.[10–12] In accordance with the American Association for Public Opinion Research (AAPOR) reporting guideline for survey studies,[13] the participation rate for wave 6 was 43.0% (540 students who initiated the survey of 1257 viable email invitations containing survey links).

Statistical methods

Descriptive summaries include counts, means and percentages. 95% CIs were created using bootstrap estimates, which accounted for school clustering; no weighting scheme was deployed. Analyses were conducted using SPSS V.25.0.

RESULTS

Twelve participants (2.7% of the sample) had heard of IQOS before reading the survey, of which one participant reported having used IQOS with tobacco, three with marijuana and eight reported no use. Though findings did not reach statistical significance, we found exposure to either the reduced risk or reduced exposure claim was associated with lower point estimates of mean expectancies of experiencing specific health conditions compared with controls; exposure to the reduced risk claim was associated with the lowest point estimates of mean expectancies (table 2). Similarly, point estimates of perceptions of general harm varied by claim exposure (figure 4). Among participants who perceived IQOS as quite/extremely harmful to their health, the largest proportion was in the control group (n=91; 63%), with the next-largest proportion in the reduced exposure claim group (n=78; 56%); the reduced risk claim group had the smallest proportion (n=68; 48%). Within the control and reduced exposure groups, the proportion of participants choosing quite/extremely risk levels versus moderately/less risk were different ($p<0.001$ and $p=0.046$, respectively). However, within the reduced risk group, there was no difference between these proportions ($p=0.501$). There were between-group differences in the proportion of participants choosing quite/extremely and moderately/less for reduced risk versus control ($p=0.011$). A majority of participants (n=148; 72% of reduced exposure group and n=137; 71% of reduced risk group) understood the term switching completely in PMI's proposed MRTP marketing claims of reduced risk and reduced exposure. Post hoc analysis also revealed no difference by ever-use of any tobacco product.

DISCUSSION

This is the first study to examine youth perceptions of experiencing health conditions and of general harm associated with PMI's marketing of IQOS and the associated proposed claims of

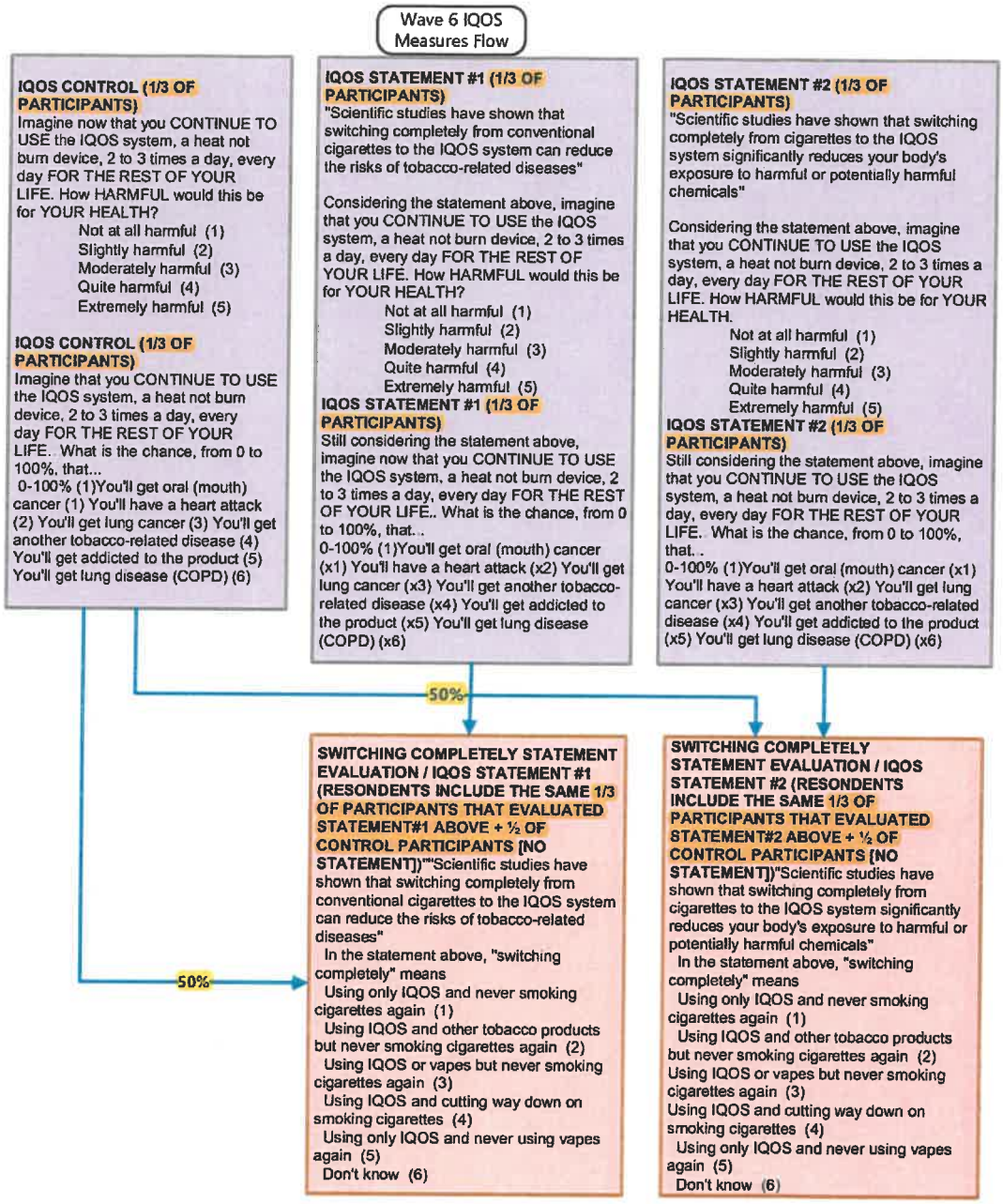

Figure 3 Study flowchart.

reduced risk and reduced exposure. We found no differences in perceived likelihood of experiencing specific health conditions, though the trend of point estimates shows less risk perceived by youth exposed to either marketing claim. General harm associated with use of IQOS was lower for youth exposed to PMI's reduced risk claim compared with no claim (control). For youth exposed to PMI's reduced exposure claim, general harm perceptions were not different from those exposed to the reduced risk claim or to no claim. Within the control group, more members perceived IQOS to be quite/extremely harmful to their health compared with moderately/less harmful; the opposite was true among reduced risk group members. While limited by sample size to detect differences, point estimates indicate if PMI were to mainly promote IQOS using the reduced risk claim, more youth would misperceive the associated dangers, which could lead to even greater numbers initiating tobacco use and result in a larger public health impact. While there is no direct evidence of which statement PMI will mainly promote, it is plausible that IQOS promotion will be mainly in the form of their reduced exposure claim. Our reasoning includes the fact that in the Tobacco Products Scientific Advisory Committee meeting last year, members voted that PMI met its burden of showing reduced exposure, but not reduced risk. Further, in its marketing order and Technical Project Lead discussion of that order for the IQOS Premarket Tobacco Application (issued in April this year), FDA stated repeatedly that one of the reasons it issued a marketing order was because IQOS exposed the user to fewer toxic chemicals than conventional cigarettes. Unfortunately, due to our small sample size, we cannot tease apart participant perceptions between reduced risk and reduced exposure claims.

Although this descriptive study was not powered for prospectively testing group differences, point estimates suggest that

Table 2 Perceived likelihood of experiencing health conditions from IQOS among n=450 youth* by exposure group: comparison of mean likelihood scores with control group

Claim exposure	None or control† (n=149)	Reduced exposure‡ (n=145)	Reduced risk§ (n=142)
Outcomes	**Mean (95% CI¶)**	**Mean (95% CI¶)**	**Mean (95% CI¶)**
Oral cancer	56.84 (52.59 to 61.14)	53.43 (48.95 to 58.04)	52.11 (47.11 to 57.21)
Heart attack	52.31 (48.16 to 56.43)	50.59 (46.15 to 55.08)	48.26 (43.67 to 52.99)
Lung cancer	59.04 (54.89 to 63.16)	58.03 (53.67 to 62.46)	56.10 (51.35 to 60.94)
Other tobacco-related disease	61.69 (57.41 to 65.88)	59.08 (54.67 to 63.48)	54.60 (49.68 to 59.57)
Addicted to the product	73.62 (69.55 to 77.51)	71.57 (67.26 to 75.86)	68.35 (63.61 to 73.13)
Lung disease (COPD)	59.53 (55.27 to 63.77)	58.79 (54.50 to 63.08)	55.11 (50.32 to 59.94)

*Mean age=19.3 (SD=1.68).
†No claim.
‡Scientific studies have shown that switching completely from cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals.
§Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system can reduce the risks of tobacco-related diseases.
¶95% CIs created with bootstrap estimates stratified by school and using 10 000 replicate samples.
COPD, Chronic Obstructive Pulmonary Disease.

compared with controls, youth exposed to either PMI's reduced risk or reduced exposure claim believe that IQOS is a less harmful product in general, and that using IQOS will result in less risk of experiencing associated specific health conditions. It could also be true that all participants (including control group members) perceived IQOS as less harmful *simply because the products are referred to as 'heated' or 'heat not burn' (vs 'combustible') products,* underscoring the conservative nature of these findings. These findings suggest youth interpreted PMI's reduced exposure claim similar to how they interpreted the reduced risk claim: that IQOS is less harmful or risky than other tobacco products. These findings align with earlier reports[4] showing conflation of reduced exposure claims and claims of reduced risk. It is important to also note that earlier work has shown even PMI's own studies failed to provide evidence that youth, including non-smokers and former smokers, will not misperceive their proposed claims of reduced exposure and reduced risk.[14] Taken together, these points illustrate that the reduced exposure claims as well as reduced risk claims on PMI's IQOS product packaging are likely to mislead consumers, especially youth, and thereby endanger public health.

The basis for the MRTP laws is essentially to *make companies prove that their products are actually less harmful* if they want to make claims that they are less harmful. For example, one of the main reasons the MRTP laws were created was because companies were making deceptive claims about some cigarettes being less harmful than others because they were marketed with claims that they were 'light' or 'mild'; hence, the requirement that manufacturers must demonstrate that consumers are not misled to believe that claims of reduced exposure are claims of reduced risk:

> To issue an order [for a reduced exposure claim] the Secretary must also find that the applicant has demonstrated that—
> (iii) testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product—
> (I) is or has been demonstrated to be less harmful; or
> (II) presents or has been demonstrated to present less of a risk of disease than 1 or more other commercially marketed tobacco products…[15]

Manufacturers of HTP who wish to make MRTP claims must demonstrate that youth, as well as other consumers, do not misinterpret reduced exposure claims to suggest that the product poses less risk than other tobacco products on the market. The impact of novel products being introduced on the tobacco/nicotine market can not be understated, especially in light of the recent reports of lung ailments and deaths associated with e-cigarettess, and the fact that cites and states are prohibiting sales of e-cigarettes. In fact, Campaign for Tobacco Free Kids and others have issued reports showing how PMI is using young influencers on social media to promote IQOS, and is using many other classic Big Tobacco approaches to marketing IQOS to teens, increasing the chances youth will, in fact, turn to IQOS.[9 16]

Misperceptions of low-harm or no-harm can negatively impact public health on a grand scale. Take the case of e-cigarettes and youth,[17] especially the recent example of JUUL,[8 18–20] where misperceptions of harm have been cited as leading reasons behind the still burgeoning rates of initiation and continued use especially among youth.[11 21–25] Public health researchers are concerned that as with e-cigarettes, youth who would otherwise have remained nicotine-naïve could initiate tobacco using IQOS,[14] use IQOS along with other tobacco products (as shown by reports of the IQOS experiences in Japan,[26] Korea,[27] Italy[28] and Great Britain)[29] and progress to cigarette smoking.[30 31] Finally, the novel device technology may entice youth to use IQOS, as it has with e-cigarettes[32–35]; exacerbating this concern

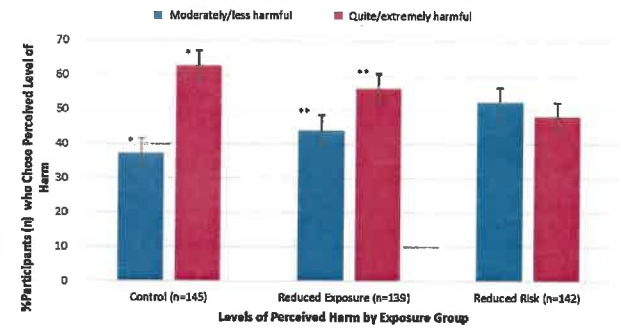

Figure 4

* Significant difference in proportion of participants choosing moderately/less and quite/extremely harmful (p<.001)

** Significant difference in proportion of participants choosing moderately/less and quite/extremely harmful (p=.046).

is the fact that IQOS are sold in youth-appealing Apple-like 'boutiques',[36 37] where packaging for the charging and heating units do not have explicit warning labels as these components (compared with the tobacco sticks used with the devices) do not contain nicotine. Still, it is encouraging that given the limited knowledge study participants likely had about health conditions and toxicant exposures associated with IQOS, very few participants rated iQOS as having no or even slight risks to health over time.

While 71% correctly understood the term switching completely to mean exclusive use of IQOS and never smoking cigarettes again, that leaves more than one in four, regardless of which claim they were exposed to, who misunderstood. Since misunderstanding switching completely also did not differ by ever-use status, it is reasonable to assume that understanding this statement may have less to do with tobacco-related perceptions and behaviour and more to do with the overall clarity of the statement as written; perhaps PMI could proffer an alternative statement using clearer language more accessible and readily understood by all, including youth. Otherwise, those who misunderstand the meaning and believe it to mean use of e-cigarettes and other tobacco products is allowed could be at increased risk for polytobacco use and nicotine dependence.

Limitations

This study has some limitations, though none that would likely change interpretation nor import of findings. First, the survey draws from schools in California; as diffusion of newer tobacco products likely differs across states, generalisation of use perceptions is not warranted. Second, IQOS survey queries were not designed to assess all perceptions that could be affected by exposure to PMI's claims and we suspect some differences in perceptions of harm and experiencing specific health conditions may have been masked due to social acceptability bias; still, many published studies have shown these measures among this cohort to be meaningful.

What this paper adds

What is already known on this subject

- Consumers misunderstand tobacco-industry marketing claims such as 'low tar' to mean the products bearing such claim is reduced or low risk.
- Misperceptions of harm lead to tobacco-use initiation, especially among youth.

What important gaps in knowledge exist on this topic

- How youth interpret the claims of reduced risk and reduced exposure proposed by Philip Morris International (PMI) to appear on consumer packaging for their new heated tobacco product, 'IQOS', is unknown.

What this study adds

- Compared to controls, fewer of those exposed to the reduced risk claim perceived IQOS as 'quite' or 'extremely' harmful.
- Regardless of which PMI claim participants read, 71% correctly understood 'switching completely' to mean exclusive use of IQOS, leaving more than one in four with the understanding that using tobacco products other than cigarettes with IQOS was allowable.

CONCLUSIONS

Results from this study and many other existing studies[4 6 14 38 39] clearly show that adolescents and young adults misunderstand reduced risk and reduced exposure claims. Existing law[40] states that a tobacco product shall be deemed to be misbranded if its labelling or advertising is false or misleading in any particular way. The FDA therefore should take great caution when considering MRTP claims on any tobacco product packaging or in marketing campaigns, and should deny MRTP authorisation unless the manufacturer wishing to make such claims demonstrates that they are not misunderstood by adolescents and young adults. Additionally, public health professionals, tobacco control advocates, healthcare providers and concerned citizens alike can advocate for the recall of such misbranded products. Given the body of research showing how misperceptions of associated harm lead to tobacco-use initiation for this age group, the negative impact on public health could be great.

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Contributors All four authors are responsible for the information in this manuscript; and have participated in the concept, design and drafting of the submitted manuscript.

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Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Due to legal restrictions on grant-funded research, and the fact that this is an ongoing longitudinal study asking youth below age 18 about illegal activity (tobacco and marijuana use) relevant data may be shared with a signed data use agreement through Dr. Bonnie Halpern-Felsher, at bonnie.halpernfelsher@stanford.edu.

ORCID iD

Karma McKelvey http://orcid.org/0000-0003-4047-3120

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