Study Summary

Study THS-PBA-02-US

Study Title: Qualitative Study to Develop THS 2.2 Hypothetical Product Messages

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Study Summary

Philip Morris International Management S.A. conducted this study in the United States from October to December 2013. The protocol was approved by an Institutional Review Board (IRB) and the participants received complete information about the study and signed an informed consent form (ICF).

Study THS-PBA-02-US

This study summary contains key results.
The full results for the study are contained in the study report (PMI 2014).

Study Title:

Qualitative Study to Develop THS 2.2 Hypothetical Product Messages

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Background:

As part of the development program for a candidate Modified Risk Tobacco Product (MRTP), the Tobacco Heating System (THS) 2.2, PMI has undertaken a comprehensive program to study consumer perception and behavior that responds to the United States Food and Drug Administration's (US FDA's) recommendations outlined in the Draft Guidance for Modified Risk Tobacco Product (FDA 2012). Per the Draft Guidance, FDA recognizes that there can be "challenges to constructing appropriate claim language that conveys the potential benefits of the product to tobacco users…." (lines 1041 to 1043) (FDA 2012).

The THS 2.2 premarket consumer Perception and Behavior Assessment (PBA) program consists of 3 components: A - Scale Development, B - Development and Assessment of Label, Labeling, and Marketing Material, and C - Use Behavior. The goals of Component B are to develop label, labeling, and marketing materials for THS 2.2; to assess comprehension of various aspects of these materials; to assess risk perception based on these materials; and to confirm these label, labeling, and marketing materials generate low intent to use among those for whom THS 2.2 is not intended.. The studies of Component B are designed to provide science-based evidence that the THS 2.2 proposed label, labeling, and marketing materials enable the public to fully understand the information concerning modified risk and effectively communicate the risks associated with the product.

The current study, the first element of Component B, is a qualitative study that examined consumers' reactions to nine potential product messages for THS 2.2 through a combination of varying types and differing levels of specificity of the claims pertaining to the modified risk information (e.g., reduced exposure, reduced risk). The study's methods were consistent with the Draft Guidance recommendation

that "when assessing consumer perception of the product, labeling, and/or marketing…[the study should assess] several variations of the proposed claim(s) on labels and/or in advertisements (lines 1044 to 1046)" (FDA 2012).

Objectives:

The main objective of this two-phase qualitative study was to contribute to the development of THS 2.2 potential product messages that:

- Generate intent to use THS 2.2 among adult smokers of conventional cigarettes (CC);
- Generate low intent to use THS 2.2 among "special relevance populations" (adult never smokers, adult former smokers, and adult smokers motivated to quit); and
- Enable adult smokers and special relevance populations to comprehend THS 2.2 communicated claims and intended users.

Additionally, the study assessed risk perception for THS 2.2, CC, nicotine replacement therapies (NRTs), e-cigarettes, and cessation, and compare risk perception for these different categories.

Methodology:

Study Design:

This study was a two-phase, sequential, qualitative study conducted at research facilities in four US cities - Boston, MA; Chicago, IL; Charlotte, NC, and Phoenix, AZ - from October through December 2013. These cities were chosen as representatives of large metropolitan areas as well as medium-sized cities. Phase 1 - Product Message Development consisted of 21 focus group discussion (FGD) (1 pilot and 20 main study) to contribute to the development and refinement of the THS 2.2 product messages (Figure 1). In these FGDs, participants shared their opinions and reactions to a variety of discussion topics in an interactive group setting. Phase 2 - Product Message Understanding consisted of 38 individual interview (IDI) (1 pilot and 37 main study) that evaluated the clarity of the revised product messages resulting from Phase 1. These individual interviews were appropriate for identifying detailed perceptions, opinions, beliefs, and attitudes of participants. This study design followed the approach recommended by the Institute of Medicine [page 192] (IOM 2012).

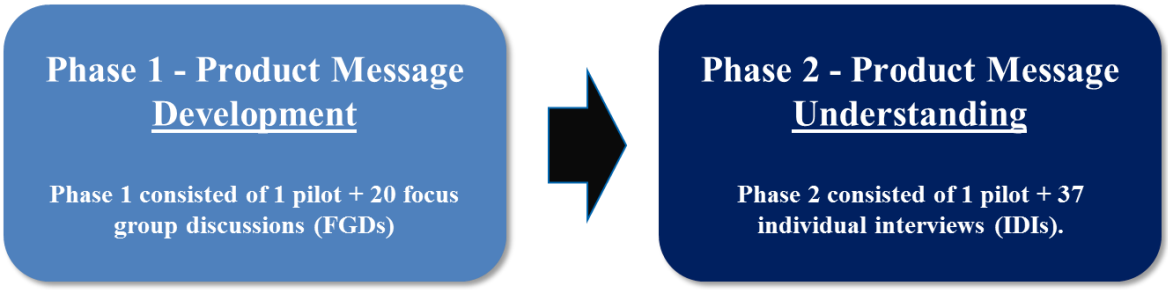

Figure 1. Study Design

Study Methods:

For both study phases, participants were recruited via telephone by local market research agencies using recruitment lists and databases. Participants who met the eligibility criteria were categorized based on:

- Smoking status based on self-reporting and defined in accordance with guidelines established by the World Health Organization (WHO 1998). In addition to the WHO guidelines, adult smokers were also divided into those with no intention to quit and those motivated to quit in accordance with Prochaska and DiClemente's Stages of Change model (Prochaska 1982).
  - adult smokers with no intention to quit
  - adult smokers motivated to quit
  - adult former smokers
  - adult never smokers (Phase 2 only)[1]
- Gender
- Age (21 to 35 years old; 36 to 50 years old; 51+ years old)
- CC taste most often consumed (full flavor taste; lighter taste) – for adult smokers only
- Type of CC most often consumed (menthol [mCC] or non-menthol [regular CC]) – for adult smokers only
- Literacy level based on REALM (Score < 61 or ≥ 61) – for Phase 2 only

Experienced moderators (≥ 5 years) were utilized to conduct the FGDs or IDIs. A discussion guide was employed in each FGD or IDI in order to elicit participant feedback in a consistent manner across the various FGDs and IDIs. Visual aids were used as the basis for the discussion of risk perception and intent to use (example shown in Figure 2, for intent to use).

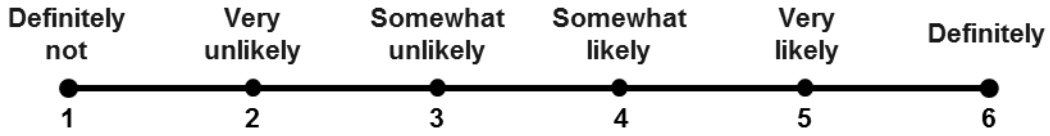

Figure 2. Visual Aid for Intent to Use

In both the FGDs and IDIs, the discussion topics consisted of:

(1) Introduction and discussion of tobacco-related product categories (i.e., CCs, NRTs, e-cigarettes, and cessation)
(2) Positioning of product categories on visual aids (risk of exposure to harmful compounds; risk of developing tobacco-related diseases; intent to use)
(3) Exposure to written and visual description of THS 2.2
(4) Introduction and sorting of THS 2.2 product messages in terms of intent to use

[1] Developmental work should be conducted on participants who either had knowledge about the topic of interest or have interest in the development work. This is generally not the case for adult never smokers when it comes to tobacco products. Thus, this group was not included in Phase 1 and only included in Phase 2 of the study.

Study Methods (continued):

(5) Introduction and discussion about product message understanding and comprehension and positioning of selected THS 2.2 product messages on visual aids

(6) Debriefing of participants to ensure that participants had not acquired any false or unintended beliefs about THS 2.2

Participants were interviewed for ~2.5 hours in a FGD and for ~90 minutes in an IDI. Participants were compensated for their participation in the study with US$125. All FGDs and IDIs were audio-recorded and transcribed to ensure accurate records of the discussions as well as to permit qualitative analyses of the verbal materials.

An example of a potential product message is shown in Figure 3. The elements in the left panel were constant across all the potential product messages while the elements in the right panel varied, depending on the product message assessed.

What is THS 2.2? THS 2.2 is a specially designed, innovative product. With this product, you still get the flavor and taste satisfaction you expect from smoking. Each tobacco stick lasts approximately as long as a regular cigarette. **How does it work?** THS 2.2 tobacco stick is inserted into a holder which heats the specially blended tobacco to a precisely controlled temperature to release its flavor. **Who is this THS 2.2 for?** ✓ It's for smokers who want to continue using tobacco. **Who is it <u>not</u> for?** ✘ It's not for smokers who want to quit. ✘ It's not for ex-smokers. ✘ It's not for non-smokers.	**What is the available evidence to date?** ***Text varied, depending on product message*** **Important Warning** ***Text varied, depending on product message***

Figure 3. THS 2.2 Potential Product Message Example

Nine product messages were assessed in Phase 1 and seven in Phase 2 as a result of refinement and revisions to the product messages tested in Phase 1. A summary of the THS 2.2 potential product messages of reduced exposure and reduced risk assessed, based on the claims that PMI believes will be substantiated by nonclinical and clinical study results, are shown in Table 1 for Phase 1 and Phase 2.

Table 1. THS 2.2 Potential Product Messages in Phase 1 and Phase 2

	Phase 1	
	Specific Potential Claims	**General Potential Claims**
Reduced Exposure	**A**. With THS 2.2, the production of carbon monoxide is reduced by more than 95%	**C**. Switching to THS 2.2 significantly reduces your body's exposure to many harmful chemicals found in cigarette smoke which are identified as likely causes of smoking-related diseases
	B. THS 2.2 produces at least 90% less second-hand smoke than CCs	**D**. THS 2.2 significantly reduces the production of harmful chemicals found in cigarette smoke
Reduced Risk	**E**. Switching to THS 2.2 can lower your cardiovascular disease risks	**H**. Switching to THS 2.2 can lower several risk factors that could lead to smoking-related diseases
	F. Switching to THS 2.2 improves several biomarkers, which are seen as early indicators of emphysema	**J**. Switching to THS 2.2 can reduce risks of smoking-related diseases
	G. Switching to THS 2.2 can improve the level of good cholesterol and can reduce the risk of clogging of arteries due to smoking	
	Phase 2	
	Specific Potential Claims	**General Potential Claims**
Reduced Exposure	**B**. THS 2.2 produces at least 90% less second-hand smoke than CCs	**C**. Switching to THS 2.2 significantly reduces your body's exposure to many harmful chemicals found in cigarette smoke which are identified as likely causes of tobacco-related diseases
	L. THS 2.2 significantly reduces the production of harmful chemicals, such as carbon monoxide which is reduced by 95%, found in cigarette smoke	
Reduced Risk	**E**. Switching to THS 2.2 can lower your cardiovascular disease risks	**H**. Switching to THS 2.2 can lower several risk factors that could lead to tobacco-related diseases
	K. Switching to THS 2.2 can improve lung function	**J**. Switching to THS 2.2 can reduce risks of tobacco-related diseases

Number of Participants:

123 participants were enrolled in Phase 1 and 38 participants were enrolled in Phase 2. The full analysis population (FAP) consisted of 117 participants in Phase 1 and 37 participants in Phase 2. The total number of participants enrolled in the study is shown in Table 2.

Table 2. Total Participants in Study

	Phase 1 - FGDs (n)	***Phase 2 – IDIs (n)***
Planned:	**126**	**39**
Enrolled:	**123[a]**	**38[d]**
Pilot[b]:	**6 males**	**1 male**
Full Analysis Population (FAP)[c]:	**117 (60 males; 57 females)**	**37 (19 males; 18 females)**
Boston, MA	29 (12 males; 17 females)[a]	9 (7 males; 2 females)
Charlotte, NC	30 (18 males; 12 females)	9 (5 males; 4 females)
Chicago, IL	28 (12 males; 16 females)[a]	10 (3 males; 7 females)
Phoenix, AZ	30 (18 males; 12 females)	9 (4 males; 5 females)

[a] Two participants scheduled in one FGD in Chicago and one participant in one FDG in Boston failed to show up. In both cases, this was due to bad weather and poor traffic conditions, which prevented the scheduled participants from reaching the study center.
[b] Pilots conducted in Chicago.

[c] Participants in the pilot FGD and IDI were considered enrolled in the study but were not included in the full analysis population.
[d] Four IDIs with low literacy adult smokers should have taken place as per the protocol. However, one participant did not qualify as a "low literacy" adult smoker based on her responses on the Rapid Estimate of Adult Literacy in Medicine (REALM) test.
Abbreviations: AZ = Arizona; FGD = focus group discussion; IDI = individual interview; IL = Illinois; MA = Massachusetts; NC = North Carolina; n = number of participants.

Inclusion and Exclusion Criteria:

Inclusion Criteria:

Male or female, aged 21 years or older, able to understand written study information provided, and signed the informed consent form (ICF)

Exclusion Criteria:

- Individuals who were unwilling to participate in a study that involved the reading of materials or who could not read or speak English, as evaluated by the research agency when asked to fill out the ICF;
- Individuals who had no proof of age; individuals who were employed in the fields of market research, marketing, advertising, media or journalism, law, the tobacco industry; or the health sector;
- Individuals who took part in a consumer study within the 6 months prior to recruitment for the current study;
- Individuals who did not fall into 1 of 4 smoking status outlined in the methodology section (i.e., adult smoker with no intention to quit; adult smoker motivated to quit; adult former smoker; and adult never smoker [Phase 2 only]).

Criteria for Evaluation:

The study was qualitative. No formal hypothesis testing was planned nor conducted.

Sample Size:

Phase 1 included 123 participants (66 males; 57 females) from 21 FGDs (five FGDs per city and one pilot FGD conducted in Chicago, IL) with 6 planned participants per FGD:

- 13 FGDs with adult smokers with no intention to quit[2] (including 1 pilot FGD)
  - 9 FGDs with adult smokers of regular CCs
  - 4 FGDs with adult smokers of mCCs
- 8 FGDs with special relevance populations
  - 4 FGDs with adult former smokers
  - 4 FGDs with adult smokers motivated to quit

[2] One FGD in Chicago had four participants and one FGD in Boston had five participants. Both groups met the predefined protocol criterion of a minimum of four participants to be considered valid and thus were included in the analyses.

Sample Size Continued:

Phase 2 included 38 participants (20 males; 18 females) from 9 IDIs each conducted in Boston, Charlotte, and Phoenix; 10 IDIs in Chicago, and one pilot IDI conducted in Chicago:

- 20 IDIs with adult smokers with no intention to quit (including 1 pilot IDI)
  - 13 IDIs with adult smokers of regular CCs
  - 4 IDIs with adult smokers of mCCs
  - 3 IDIs with low literacy adult smokers[3]
- 18 IDIs with special relevance populations
  - 6 IDIs with adult never smokers
  - 6 IDIs with adult former smokers
  - 6 IDIs with adult smokers motivated to quit

Analysis:

The verbal data utilized in the analyses were obtained from all FAP participants in both FGDs (with a minimum of 4 participants) and IDIs who completed the entire interview. Verbal data from participants in the pilot FGD and IDI were not included in the analyses.

Analyses of verbal data were conducted:

- To assess the extent to which a potential product message
  - Had generated intent to use THS 2.2 (intent to use study objective)
  - Had been understood (comprehension study objective)
- To assess and compare the risk perception of THS 2.2, CCs, NRTs, e-cigarettes, and smoking cessation (risk perception study objective)

Verbal data were examined for each potential product message in general and by smoking status.

Summary of Results:

Demography and Baseline Characteristics of Study Participants

Demographics and baseline characteristics are shown in Table 3. The number of participants was comparable across the four cities in both study phases. Overall, participants represented a broad range of demographics (e.g., gender, age, race, education level, and tobacco consumption for adult smokers).

[3] Originally there were four IDIs in the low literacy group; however, one participant did not qualify as belonging to the low literacy group because his/her REALM test score was above the 60, the minimum threshold for low literacy (Davis 1993).

Table 3. Summary of Demographics and Other Baseline Characteristics

Characteristic		Statistic	Phase 1 FAP (N = 117)[a]	Phase 2 FAP (N = 37)[a]
Gender	Male	n (%)	60 (51.3%)	19 (51.4%)
	Female	n (%)	57 (48.7%)	18 (48.6%)
Age (years)		*Mean (SD)*	39.8 (12.39)	42.2 (12.96)
		(min-max)	(21-73)	(23-63)
	21 – 35	n (%)	59 (50.4%)	13 (35.1%)
	36 – 50	n (%)	29 (24.8%)	12 (32.4%)
	51+	n (%)	29 (24.8%)	12 (32.4%)
Race (FDA 2005)	White	n (%)	63 (53.9%)	26 (70.3%)
	Black	n (%)	33 (28.2%)	9 (24.3%)
	Other	n (%)	21 (17.9%)	2 (5.4%)
Education Level	High school and below	n (%)	20 (17.1%)	8 (21.6%)
	Some college and beyond	n (%)	97 (82.9%)	29 (78.4%)
Literacy	REALM score < 61	n (%)	NA	3 (8.1%)
Smoking Status	Adult smoker with no intention to quit	n (%)	69 (59.0%)	19 (51.4%)
	Adult smoker motivated to quit	n (%)	24 (20.5%)	6 (16.2%)
	Adult former smoker	n (%)	24 (20.5%)	6 (16.2%)
	Adult never smoker	n (%)	NA	6 (16.2%)
Taste Category	FF	n (%)	52 (44.4%)	14 (37.8%)
	LTN/SLTN	n (%)	41 (35.0%)	11 (29.7%)
	N/A (adult former smoker or adult never smoker)	n (%)	24 (20.5%)	12 (32.4%)
Cigarette Flavor	Menthol	n (%)	24 (20.5%)	4 (10.8%)

Abbreviations: FAP = full analysis population; FF = full flavor; LTN = low tar and nicotine/light tasting cigarette; SLTN = super low tar and nicotine/super light tasting cigarette; N/A = not applicable; REALM = Rapid Estimate of Adult Literacy in Medicine; SD = Standard Deviation; N = Sample size; n = Number of participants.

Reactions to Tobacco-Related Product Categories

Understanding the Risk Associated with Tobacco Products

In general, participants stated that there is a risk associated with the use of tobacco products to both users and non-users of tobacco products. Additionally, most participants stated that there is a relationship between the risk of exposure to harmful compounds found in tobacco products and/or smoke and the risk of developing tobacco-related diseases, with the risk of diseases described as being more serious than the risk of exposure to harmful compounds.

There was near unanimity among participants in describing conventional cigarettes as having the highest risk of exposure to harmful compounds, followed by e-cigarettes and NRTs. Participants described smoking cessation as having the least risk, but not being entirely risk free due to the risk still existing from second-hand smoke. A similar rank order was observed for the risk of developing tobacco-related diseases.

Understanding of THS 2.2 Product Description

As shown in Table 4, there was a wide variety of reactions to THS 2.2 product description. Overall, participants described THS 2.2 as an e-cigarette with tobacco. Adult smokers with no intention to quit as well as some adult smokers motivated to quit described the concept of an e-cigarette with tobacco as appealing due to potentially improved hygiene and harm reduction benefits, but with continued tobacco taste and satisfaction. Other adult smokers motivated to quit also see THS 2.2 as a potentially robust tool on the path to cessation, offering them potential harm reduction benefits and allowing to wean themselves from tobacco use. Participants asked questions regarding the ease of use, portability and convenience, and cost and most participants' comments indicated a negative reaction to the heavy, bulky appearance of the holder.

Based solely on the THS 2.2 product description, current adult smokers expressed an openness to try THS 2.2 while adult former smokers and adult never smokers clearly stated they were definitely not interested in trying the product. These two latter groups strongly rejected THS 2.2 because it contained tobacco.

Table 4. Response to Common Elements of Potential Product Message - THS 2.2 Product Description

THS 2.2 Description Common Element[a]	Element(s) of Accurate Understanding	Element(s) of Poor Understanding	Key Elements Driving Intent to Use For Adult Smokers	Key Elements Driving Low Intent to Use for Adult Former Smokers/Adult Never Smokers
What is THS 2.2?	• Contained tobacco • Still get flavor and taste satisfaction expected from smoking • Lasted approximately as long as a regular cigarette	• Unclear how tobacco stick lasted as long as a regular cigarette since it was so much smaller than a conventional cigarette	• Innovative implied a coolness factor • Enhanced taste and satisfaction from tobacco • Ability to use in public areas • Less impact on others	• Tobacco in the product
How Does THS 2.2 Work?	• Innovative nature of the product. However, THS 2.2 also triggered some questions (complexity of usage) and concerns (issues with battery, potential costs)	• Specially blended tobacco • Precisely controlled temperature • Emission (smoke or vapor)	• Harm reduction benefits	• Tobacco in the product
Who is THS 2.2 For?	• Very clear product is intended only for smokers who want to continue using tobacco		• Transparency of the intended audience	• Intended audience "it is not for ex-smokers,"; "it is not for nonsmokers"

[a] Element of THS 2.2 product messages that were standard and did not change from product message to product message or from Phase 1 to Phase 2.

Understanding of THS 2.2 Product Description Continued

All participants expressed accurately the intended audience for THS 2.2. The 2 groups of adult smokers described THS 2.2 as a product intended for their use while the adult former smokers and adult never smokers described the product as one not intended for them.

Comprehension of THS 2.2 Product Messages Related to the Claim (i.e., What is the Available Evidence to Date) and Warning (i.e., Important Warning)

Nine product messages were assessed in Phase 1. Refinement and revision of these nine product messages resulted in seven product messages being evaluated in Phase 2. Based on the Phase 1 findings, two product messages (F and G) were deleted due to lack of relevance, use of vague and unfamiliar terms (e.g., biomarker), and lower intent to use among adult current smokers; two were combined into one for clarity (A + D = L); five were carried over with minor wording but not content changes (B, C, E, H, J); and one new product message was added (K) to use more familiar language (lung function instead of biomarkers as early indicators of emphysema) for greater understanding.

Table 5 shows the specific audiences, the THS 2.2 potential product messages, and reasons for resonance with or rejection by the different participant groups.

Table 5. THS 2.2 Potential Product Messages and Participants' Reactions - By Smoking Status

Smoking Status	THS 2.2 Message(s)	Resonated/ Rejected	Reasons/Characteristics
Adult smokers	B, C, J, L	Resonated	• Relevance of benefit • Honest and forthright • Logically, simply worded; easy to understand without contradiction between potential claim and "important warning" • Term "significantly reduces" had impact • Use of "aerosol" was confusing but did into detract from message of claim (Message B) • References to scientific data and graphs lent to credibility (Messages C and L) • References to FDA lent credibility, authority, and value (Message L) • THS 2.2 potentially less harmful than conventional cigarettes • *"Step down" product toward quitting (specific to adult smokers motivated to quit only)*
	E, F, G, H, K	Rejected	• Vague, unspecific, or unclear benefit • Limited benefit • Conditional language causing confusion and perception of contradiction • Unfamiliar terminology • Lack of relevancy, credibility, believability due to unclear logic in product message construction

Adult former smokers/Adult never smokers	All	Rejected	• Did not see themselves as intended audience • Reject THS 2.2 because it is a tobacco product that can be "addictive and can harm your health.

Overall, participants' discussions reflected that the potential product messages resonated with the intended audience, adult smokers with no intention to quit. Based on participants' comments, the best understood messages shared these characteristics:

- references to well-known risks related to tobacco use, clear and compelling statements supported by statistics or authoritative backing
- simple wording and short, straightforward language that is easily understandable
- suggestions that the product was designed to meet the sensory-related needs of adult smokers with no intention to quit

Intent to Use THS 2.2

In general, participants' comments indicated that the THS 2.2 product messages generated an intent to use in their main intended audience (adult smokers with no intention to quit) and not in the non-intended audience (adult former smokers and adult never smokers). Product messages also generated intent to use among adult smokers motivated to quit. This audience viewed THS 2.2 as a potentially lower risk alternative that could be used as a 'step down' product, as a means to help them on their way to quitting smoking. For them, THS 2.2 is understood not to be a substitute to cessation. Reactions to and intent to use resulting from specific product messages are shown in Table 6.

Table 6. THS 2.2 Product Messages and Intent to Use

		Product Message	Adult smokers with no intention to quit	Adult smokers with intention to quit	Adult former smokers/ adult never smokers
Reduced Exposure	General	C. Switching to THS 2.2 significantly reduces your body's exposure to many harmful chemicals found in cigarette smoke which are identified as likely causes of tobacco-related diseases	SOME	LOW	NO
	Specific	L. THS 2.2 significantly reduces the production of harmful chemicals, such as carbon monoxide which is reduced by 95%, found in cigarette smoke	SOME	LOW	NO
		B. THS 2.2 produces at least 90% less second-hand smoke than CCs	SOME	LOW	NO
Reduced Risk	General	H. Switching to THS 2.2 can lower several risk factors that could lead to tobacco-related diseases	LOW	NO	NO
		J. Switching to THS 2.2 can reduce risks of tobacco-related diseases	SOME	LOW	NO
	Specific	E. Switching to THS 2.2 can lower your cardiovascular disease risks	LOW	NO	NO
		F. Switching to THS 2.2 improves several biomarkers, which are seen as early indicators of emphysema	NO	NO	NO
		G. Switching to THS 2.2 can improve the level of good cholesterol and can reduce the risk of clogging of arteries due to smoking	NO	NO	NO
		K. Switching to THS 2.2 can improve lung function	NO	NO	NO

Notes: SOME = Some intention to use THS 2.2 based on product message; LOW = Low intention to use THS 2.2 based on product message; NO = no intention to use THS 2.2 based on product message

Perception of Risk of THS 2.2

The product messages elicited some common conclusions in terms of their risk perception of THS 2.2 across the different audiences. Participants' comments indicated that THS 2.2 was perceived to:

- have a lower risk of exposure to harmful compounds than conventional cigarettes but a higher risk than e-cigarettes, NRTs, and cessation;
- have a lower risk of developing tobacco-related diseases than conventional cigarettes but a higher risk than e-cigarettes, NRTs, and cessation; and
- have a lower risk than conventional cigarettes because the tobacco is heated and not burned, thereby reducing production of harmful chemicals (e.g., carbon monoxide) and providing a possible chance of reducing the risk of tobacco-related diseases.

Participants' comments indicated that the "Important Warning" language stated clearly the relative risk associated with THS 2.2 for both users and non-users of tobacco, in particular that there is no certainty that THS 2.2 would reduce the risk of tobacco-related diseases. Additionally, the statement "Using THS 2.2 is addictive and can harm your health" intensified this risk perception, as captured by participants' comments. The perception of a lower level of risk associated with THS 2.2 was also due to the absence of smoke or second-hand smoke. Finally, participants noted the simple and clear language in Message J, especially the phrase "reduced risk does not mean no risk". Their statements reflected the understanding that using THS 2.2 may still cause harm to their health and that the best way to reduce their risk was to completely quit tobacco use.

Conclusions:

The study met its main objective to contribute to the development of potential product messages for THS 2.2 that generate intent to use among current adult smokers with no intention to quit, i.e., the intended audience, while generating low or no intent to use THS 2.2 among adult smokers motivated to quit, adult former smokers and adult never smokers. The intended audience viewed THS 2.2 as having the flavor and satisfaction of a conventional cigarette while heating the tobacco instead of burning it, which results in a significantly reduced production of harmful chemicals in cigarette smoke. The adult smokers motivated to quit viewed THS 2.2 as a potentially lower risk alternative compared to CC that could be used as a "step down" product to assist with their efforts to quit smoking.

Comprehension of the product messages was high for both users and non-users of tobacco products. There was clarity of understanding regarding the intended audience for THS 2.2 and high comprehension of each specific claim. Product messages that were clear, broadly relevant, easy to understand, honest, straight-forward, and credible (e.g., reference to scientific data and authoritative bodies) resonated the most with the intended audience. Product messages that were rejected tended to use vague or unfamiliar terms (e.g., biomarkers).

As far as risk perception, conventional cigarettes were viewed as having the highest risk because they contained tobacco and generated smoke. E-cigarettes, NRTs, and cessation followed in decreasing level of risk. THS 2.2 was perceived as more risky than e-cigarettes and NRTs (because THS 2.2 contained tobacco) but lower in risk than conventional cigarettes (because the tobacco in THS 2.2 was heated and not burned).

Conclusions Continued:

Participants were more interested in messages related to risk of developing diseases than in the risk of exposure to harmful compounds because the former was recognized as the only concrete evidence where THS 2.2 could be proven to be less harmful than conventional cigarettes. Product Messages B, C, J, and L resonated with adult smokers with no intention to quit. References to flavor and taste satisfaction helped position THS 2.2 as an attractive alternative to adult smokers with no intention to quit and allay concerns about usage experience. Adult former smokers and adult never smokers rejected use of THS 2.2, due to the presence of the statements "using of THS 2.2 is addictive and can harm your health", "it is not for ex-smokers" and/or "it is not for non-smokers" and due to the fact this product contains tobacco. All these factors are important in formulating future THS 2.2 label, labeling, and marketing materials.

List of Abbreviations and Definitions of Terms:

CC	conventional cigarette
FAP	Full Analysis Population
FDA	Food and Drug Administration
FF	full flavour tasting cigarette
FGD	focus group discussion
ICF	informed consent form
IDI	individual interview
IOM	Institute of Medicine
IRB	Institutional Review Board
mCC	menthol-flavored cigarette
LTN	low tar and nicotine/light tasting cigarette
MRTP	Modified Risk Tobacco Product
NRT	nicotine replacement therapy
PBA	Perception and Behaviour Assessment
PMI	Philip Morris International
REALM	Rapid Estimate of Adult Literacy in Medicine
SLTN	super low tar and nicotine/super light tasting cigarette
SD	Standard Deviation
THS 2.2	Tobacco Heating System 2.2
US	United States
WHO	World Health Organization

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Confidentiality Statement

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