

## **Study Summary**

### **Study THS-PBA-04-US**

**Study Title:** Qualitative Study to Develop THS 2.2 Potential Label, Labeling and Marketing Material

**Sponsor:** Philip Morris International Management S.A.  
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## Study Summary

Philip Morris International Management S.A. conducted this study in the United States in December 2014. 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-04-US

This study summary contains key results.  
The full results for the study are contained in the study report ([PMI 2015](#)).

**Study Title:**

Qualitative Study to Develop THS 2.2 Potential Label, Labeling and Marketing Material

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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behavior that responds to the United States Food and Drug Administration's (US FDA's) recommendations outlined in the Draft Guidance for Modified Risk Tobacco Product ([FDA 2012](#)). Per the Draft Guidance, FDA recognizes that there can be "challenges to constructing appropriate claim language that conveys the potential benefits of the product to tobacco users..."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 three components: A - Scale Development, B - Development and Assessment of Label, Labeling, and Marketing Material (LLM), and C - Use Behavior. The goals of Component B are to develop LLM 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 LLM generate low intent to use among those for whom THS 2.2 is not intended. The studies of Component B are designed to gather data to confirm that the THS 2.2 proposed LLM enable the public to fully understand the information concerning modified risk and effectively communicate the risk associated with the product.

As the first element of Component B, a qualitative study, THS-PBA-02-US, examined consumers' reactions to nine potential product messages for THS 2.2 through a combination of varying types and levels of specificity of product claims pertaining to the modified risk information (e.g., reduced exposure, reduced risk). Based on the findings from this study, a quantitative study, THS-PBA-03-US, assessed consumers' responses to five selected potential messages for THS 2.2 to assess their effect on intent to use, comprehension of messages, risk perception, and intention to quit conventional cigarettes (CC). This current study, the third element of Component B, THS-PBA-04-US, is a qualitative study focused on examining consumers' reaction to five potential LLM and three potential product claims for THS 2.2 in terms of comprehension and intent to use. Per the Draft MRTP Guidance, this study gathered qualitative data primarily addressing "the effect of the tobacco product's marketing on consumer understanding and perceptions" (lines 632 and 633) (FDA 2012). This study was conducted in a manner 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).

In this study, THS 2.2 was referred to as "iQOS" and THS 2.2 Tobacco Stick was referred to as "HeatSticks", their likely respective commercial names, iQOS and HeatSticks together were referred to as the "iQOS system". The names iQOS and HeatSticks are used in this report as materials presented to participants used this nomenclature.

### **Objectives:**

The main objective of this qualitative study was to contribute to the development of the iQOS system's potential LLM by:

- Understanding study participants' response to different potential LLM elements in terms of comprehension and intent to use:
  - How each LLM element contributes to the *comprehension* of communicated claims
  - How each LLM element contributes to *intent to use*
- Identifying potential LLM that generate:
  - high intent to use among adult current smokers of CC and
  - low intent to use among "special relevance populations" (adult never smokers and adult former smokers).
- Assessing *risk perception* for the iQOS system, CC, nicotine replacement therapies (NRTs), e-cigarettes, and cessation, as well as comparing risk perception for these categories among study participants.

### **Methodology:**

#### ***Study Design***

This was a qualitative study conducted at research facilities in two US cities (Chicago, IL and Phoenix, AZ) in December 2014. The study consisted of 30 individual interviews (IDIs): 2 pilot IDIs and 28 main study IDIs, designed to capture participants' comments and responses when exposed to specific LLM.

#### ***Study Methods***

Participants were recruited via telephone by local market research agencies using recruitment lists and databases. Those who met eligibility criteria were categorized based on:

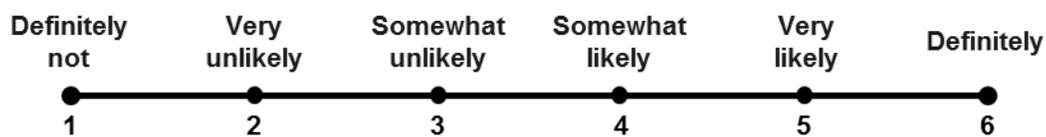
- Smoking status, based on self-report and defined in accordance with guidelines established by the World Health Organization (WHO 1998):

- adult smokers<sup>1</sup>
- adult former smokers
- adult never smokers
- Gender

**Methodology Continued:**

- Age (18–25; 26–35; 36–50 and 51+ years old)
- CC taste most often consumed (full flavor taste [FF]; lighter taste [LTN]) – for adult smokers only
- Type of CC most often consumed (menthol [mCC] or non-menthol [regular CC]) – for adult smokers only

Experienced moderators ( $\geq 5$  years) were utilized to conduct the IDIs. A discussion guide was employed in each IDI to elicit participant feedback in a consistent manner. Visual aids were used as the basis for the discussion of risk perception and intent to use (example shown in [Figure 1](#) for intent to use).



**Figure 1. Visual Aid for Intent to Use**

The discussion flow consisted of:

1. Introduction
2. General assessment of participants' awareness of nicotine-containing product(s)
  - a. Discussion to assess participants' awareness of nicotine-containing product(s), as well as the sources of nicotine-containing product information to which they have been exposed
3. Introduction to potential LLM (brochure, direct mail, advertising concept, point of sales advertisement, coupon) and potential reduced exposure or reduced risk claims ([Table 1](#))
  - a. Discussion aimed at assessing participants' spontaneous reactions;
  - b. Discussion focused on *comprehension* of communicated claims and intended users;
    - i. Discussion about potential LLM in terms of wording, amount of information, tone of voice, and look and feel;
  - c. Discussion focused on intent to use; assessment of participants' positions of each potential LLM (visual aid for *intent to use* [Figure 1](#)); and
  - d. Discussion focused on perception of risks; assessment of participants' positions of each potential LLM (visual aid for *risk perception*)
4. Debriefing of participants

Participants were interviewed for ~90 minutes and were compensated US\$125 for their participation. All IDIs were audio-recorded and transcribed to ensure accurate records of the discussions as well as to permit qualitative assessment of verbal material.

<sup>1</sup> In addition to the WHO guidelines, adult smokers were divided into those with no intention to quit and those with an intention to quit, in accordance to Prochaska and DiClemente's Stages of Change model ([Prochaska 1982](#)).

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Three potential claims relating to reduced risk and reduced exposure were assessed. The actual text is outlined in [Table 1](#) below.

**Table 1. Reduced exposure and reduced risk claims assessed**

Reduced Exposure A	Reduced Exposure B	Reduced Risk
<p>Available evidence to date</p> <ul style="list-style-type: none"> <li>When tobacco is burned, it produces many harmful or potentially harmful chemicals.</li> <li>The iQOS system heats tobacco but does not burn it.</li> <li>With the exception of nicotine, with the iQOS system there is a significant reduction in the production of harmful or potentially harmful chemicals.</li> </ul>	<p>Available evidence to date</p> <ul style="list-style-type: none"> <li>The iQOS system heats tobacco but does not burn it.</li> <li>This significantly reduces the production of harmful or potentially harmful chemicals.</li> <li>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.</li> </ul>	<p>Available evidence to date</p> <ul style="list-style-type: none"> <li>The iQOS system heats tobacco but does not burn it.</li> <li>This significantly reduces the production of harmful or potentially harmful chemicals.</li> <li>Scientific studies have shown that switching completely from cigarettes to the iQOS system can reduce the risks of tobacco-related diseases.</li> </ul>
<p><b>Important Warning</b></p> <ul style="list-style-type: none"> <li>It <b>has not been demonstrated</b> that switching to the iQOS system reduces the risk of developing tobacco-related diseases compared to smoking cigarettes.</li> <li>HeatSticks™ contain nicotine which is addictive.</li> <li>Using the iQOS system can harm your health.</li> </ul>	<p><b>Important Warning</b></p> <ul style="list-style-type: none"> <li>A significant reduction in your body's exposure to harmful chemicals, compared to cigarettes, <b>does not mean a reduction in the risk of developing tobacco-related diseases.</b></li> <li>HeatSticks™ contain nicotine which is addictive.</li> </ul>	<p><b>Important Warning</b></p> <ul style="list-style-type: none"> <li>Reduced risk <b>does not mean no risk.</b> The best way to reduce your risk of tobacco-related diseases is to completely quit tobacco-use.</li> <li>HeatSticks™ contain nicotine which is addictive.</li> <li>Using the iQOS system can harm your health.</li> </ul>

This appendix to the Philip Morris Products S.A. Technical & Scientific Dossier For the Electrically Heated Tobacco Product (EHTP) as part of the Tobacco Heating System (THS), Version 2.0, dated 27 May 2016, has been reformatted for publication on pmiscience.com. Data and information in this document that constitute trade secrets or confidential commercial information have been redacted.

- Using the iQOS system can harm your health.

### **Number of Study Participants:**

31 participants were enrolled in the study. Of these, 2 were pilot subjects and 1 was withdrawn from the study upon confirmation that he did not meet study eligibility criteria (Table 2). The remaining 28 individuals defined the full analysis population (FAP), as they were identified as eligible to participate in this study.

**Table 2. Total Participants in Study**

	N
<b>Planned:</b>	<b>30</b>
<b>Enrolled:</b>	<b>31</b>
<b>Withdrawn from study:</b>	<b>1<sup>a</sup></b>
<b>Pilot<sup>b</sup></b>	<b>2 (1 male; 1 female)</b>
<b>Full analysis population (FAP):</b>	<b>28 (14 males; 14 females)</b>
Chicago, IL	14 (7 males; 7 females)
Phoenix, AZ	14 (7 males; 7 females)

<sup>a</sup>One participant was mistakenly recruited and enrolled in the study but was withdrawn upon confirming that his tobacco consumption did not meet the study eligibility criteria.

<sup>b</sup>Pilot IDIs were conducted in Chicago, IL and participants were one male adult never smoker and one female adult current smoker. Abbreviations: AZ = Arizona; IL = Illinois.

### **Inclusion and Exclusion Criteria:**

#### ***Inclusion Criteria:***

Male or female, aged 18 years or older, able to understand written study information provided, and signed the informed consent form (ICF)

#### ***Exclusion Criteria:***

- Individuals who had no proof of age;
- Individuals who were unwilling to participate in a study that involved the reading of materials;
- Individuals 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 any of the three smoking status groups outlined in the methodology section (i.e., adult current smokers; adult former smokers; and adult never smokers).

### **Criteria for Evaluation:**

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

### **Sample Size:**

The study included 30 participants (15 males; 15 females). 16 IDIs were conducted in Chicago, IL (including 2 pilot IDIs) and 14 IDIs were conducted in Phoenix, AZ. There were 21 IDIs with adult current smokers (including one pilot IDI):

- 14 IDIs with adult current smokers of regular CC
- 7 IDIs with adult current smokers of menthol CC (mCC)

There were 4 IDIs with adult former smokers and 5 IDIs with adult never smokers (including one pilot IDI).

### **Analysis:**

All IDI participants in the FAP completed the entire discussion process. Data from participants in the pilot IDIs were not included in the analyses.

Verbal data capturing participants' responses to potential LLM were conducted and assessed in terms of:

- *Comprehension of iQOS* communicated claims and intended users.
- *Intent to use the iQOS* system.
- *iQOS* system *risk perception* compared to the perception of risk of CC, NRTs, e-cigarettes, and cessation.

These verbal data were examined for each potential LLM in general and by smoking status.

### **Summary of Results:**

#### ***Demography***

The overall demographics and baseline characteristics are shown in [Table 3](#). The number of participants was comparable across the two cities. Overall, participants represented a broad range of demographics (e.g., gender, age, race, and tobacco consumption for adult smokers).

**Table 3. Summary of Demographics and Other Baseline Characteristics**

Characteristics		Statistic	FAP (N = 28)
<b>Gender</b>	Male	n (%)	14 (50.0)
	Female	n (%)	14 (50.0)
<b>Age</b>		Mean (SD)	36.5 (14.2)
		(min–max)	(19–71)
	18–25	n (%)	7 (25.0)
	26–35	n (%)	8 (28.6)
	36–50	n (%)	8 (28.6)
	51+	n (%)	5 (17.8)
<b>Race (FDA 2005)</b>	White	n (%)	14 (50.0) <sup>a</sup>
	Black	n (%)	11 (39.3)
	Other	n (%)	3 (10.7)
<b>Education Level</b>	High school and below	n (%)	4 (14.3)
	Some College and beyond	n (%)	24 (85.7)
<b>Smoking Status</b>	Adult current smokers	n (%)	20 (71.4)
	Adult former smokers	n (%)	4 (14.3)
	Adult never smoker	n (%)	4 (14.3)
<b>Taste Category (Adult current smokers only)</b>	FF	n (%)	10 (50.0)
	LTN	n (%)	10 (50.0)
<b>Cigarette Flavor (Adult current smokers only)</b>	Menthol	n (%)	8 (40.0)

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<sup>a</sup> Two participants identified themselves as White and another race, other than Black, and were thus characterized as White. Abbreviations: FAP = Full analysis population; FF = Full flavor tasting taste category cigarette; LTN = Lighter tasting taste category cigarette; SD = Standard Deviation; N = Sample size; n = Number of participants.

### ***Sources of Information for Nicotine-containing Products***

By far, the most common source of information about products containing nicotine, according to discussion statements, is word of mouth from friends and family. Point of Sales advertisements and television were also regularly mentioned as sources of information. Overall, participants' comments reflected knowledge of various types of nicotine-containing products such as and their being available in different forms (CC, NRTs, e-cigarettes, pipes, and cigars).

### ***Comprehension of iQOS System***

Upon exposure to each of the LLM, all participants described the *iQOS* system as a tobacco product. In turn, based on this view of the *iQOS* system as a tobacco product, participants further stated that there is a health risk associated with using the *iQOS* system.

Most adult smokers' comments reflected the idea that the risks associated with using the *iQOS* system are potentially reduced compared to using CC, as the tobacco is heated and not burned.

According to participants' comments, each LLM clearly communicated that the *iQOS* system is intended for adult current smokers who want to continue smoking. Some participants from the adult current smokers group questioned why this product would not also be for smokers who want to quit using tobacco, given that the *iQOS* system appeared to replicate the act of smoking in a way that could lower risk and might therefore serve as a step-down tool on the path to cessation.

### **Understanding Copylines:**

The 'tobacco heating system' copyline was seen as a suggestion of an alternative to CC amongst adult current smokers. As reflected in participants' statements, adult current smokers also perceived this copyline to mean that the *iQOS* system will produce no ash and less odor, which has social and hygiene benefits.

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The statements of many adult current smokers included the view that eliminating burning can potentially decrease the health risk compared to CC. Nevertheless, the fact that these copylines contained the word 'tobacco' did suggest that there is a health risk with using the *iQOS* system.

### ***Intent to Use the iQOS System***

Intent to use the *iQOS* System was expressed in response to different elements of the LLM, i.e., product message, brand image, and look and feel of the LLM. Reactions to specific LLM and intent to use based on these reactions are shown in [Table 4](#) for adult current smokers, adult former smokers and adult never smokers.

### **Product message:**

Many adult current smokers expressed their intent to use the *iQOS* system on a regular, on-going basis. Their expressed intent to use the *iQOS* system was generally consistent across LLM. Reasons adult current smokers gave for their interest in using the *iQOS* system were:

- As an alternative with a potentially lower health risk compared to CC

- The fact that tobacco is heated not burned, thereby producing significantly lower levels of harmful or potentially harmful chemicals
- A cleaner tobacco experience than CC: less odor, no ash, less mess
- The real tobacco taste satisfaction of a CC that is not currently provided by an e-cigarette

As shown in Table 4, comments made by adult former smokers and adult never smokers reflected no intent to use the *iQOS* system. Among these two subgroups, none of the potential LLM resulted in any statements of intent to use the *iQOS* system. Besides no interest in using tobacco products, these groups cited health and addiction concerns as reasons for no intent to use the *iQOS* system.

#### Perception of LLM look and feel:

Participants' comments of LLM expressed that the execution of the materials and copylines was favorable. Among adult current smokers, the execution appeals for its look, which was viewed by participants as "stylish, simple, clean, cool and classy".

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This generated some intent to use this product on a regular, ongoing basis by this group of adult current smokers. Adult former smokers and adult never smokers described the LLM as interesting from a design point of view; however this did not generate an intent to use the *iQOS* system.

#### Branding:

Participants noted that the *iQOS* system is a good fit with the *Marlboro* brand, given that innovation from a brand like *Marlboro* is credible. In this context, participants stated that since *Marlboro* is a well-known brand, it would be expected that the quality of the tobacco product would be high and that it would consequently impact adult current smokers' intent to use the *iQOS* system

**Table 4. Intent to Use the *iQOS* System**

Potential label, labeling and marketing material	Adult current smokers	Adult former smokers	Adult never smokers
Brochure	HIGH	NO	NO
Direct Mail	SOME	NO	NO
Advertising Concept	SOME	NO	NO
Point of Sales Advertisement	SOME	NO	NO
Coupon	SOME	NO	NO

Notes: HIGH = High intent to use *iQOS* system based on material; SOME = Some intent to use *iQOS* system based on material; NO = No intent to use *iQOS* system based on material.

#### ***Risk Perception with the Potential LLM***

Discussion statements made by participants in each group described the *iQOS* system as having a moderate to high health risk. Participants further described the *iQOS* system as having a lower health risk than CC, a similar or higher health risk than e-cigarettes (since all participants describe the *iQOS* system

as an e-cigarette but with actual tobacco), and a higher health risk than NRTs or smoking cessation. This perception was held across all LLM assessed in the study.

***Comprehension of the Risk Associated with Reduced Risk and Reduced Exposure Claims***

All participants' statements reflected a similar understanding of each of the three claims.

Reduced Risk:

Most adult current smokers, adult former smokers, and adult never smokers expressed that the Reduced Risk claim is easy to understand. Their statements indicated that they appreciated the clear and direct message 'reduced risk does not mean no risk'. After reading the Reduced Risk claim, participants' commented that there is a health risk associated with using the *iQOS* system; however, that risk was described as being reduced compared to CC.

Reduced Exposure:

Participants described Reduced Exposure (A and B) claims as clearly written and understandable.

- Verbal responses to Reduced Exposure A claim included the expectation that, with the exception of nicotine, the *iQOS* system significantly reduces the production of harmful or potentially harmful chemicals.
- Verbal responses to Reduced Exposure B claim captured the view that switching completely from CC to the *iQOS* system significantly reduces your body's exposure to harmful or potentially harmful chemicals (claim B is viewed as credible as it is supported by citing scientific study results).
- Some participants suggested there was ambiguity in both claims A and B, citing the available evidence to date and important warning elements of the claims to be contradictory. According to participants' comments, the first part of the text (i.e., the available evidence to date) leads to the expectation that switching to the *iQOS* system may potentially reduce the health risk when compared to CC. However, participants' comments indicated that the second part of the text (i.e., important warning) suggests that there is no link between the reduction in the production of, or exposure to, harmful or potentially harmful chemicals and the reduction of the risk of developing tobacco-associated diseases. Most study participants found this difficult to believe. Therefore, after participants read the Reduced Exposure (A and B) claims, their comments reflected the view that the health risk associated with using *iQOS* is very close, yet lower, to the health risk of smoking CC.

**Conclusions:**

The study met its main objective, which was to contribute to the development of potential LLM for the *iQOS* system (1) that generate intent to use among adult current smokers (2) while generating no intent to use the *iQOS* system among adult former smokers, and adult never smokers.

The research demonstrated that the *iQOS* system is viewed as an innovative tobacco product because it heats, rather than burns, tobacco using electronic technology. The *iQOS* system was therefore described as able to combine the tobacco taste satisfaction of CC's with hygiene benefits (less odor, no ash, less mess) and the potential to reduce the health risk compared to smoking CC.

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These copylines clearly conveyed to all participant smoking groups that there is still a health risk associated with using the *iQOS* system.

Comprehension of the *iQOS* system was high among all participants and resulted in an understanding that the *iQOS* system is for adult current smokers who want to continue using tobacco.

Adult current smokers had a favorable overall response to the potential LLM, which resulted in some intent to use *iQOS* on a regular, ongoing basis. Furthermore, association of the *Marlboro* brand with the *iQOS* system was found to be important because the *iQOS* system gained credibility and trust from the *Marlboro* brand reputation. In contrast, adult former smokers and adult never smokers have no interest in using tobacco products in general, including the *iQOS* system, regardless of LLM. These groups, besides being simply uninterested in tobacco products, are also concerned with health and addiction risks.

In this study, participants understood that the *iQOS* system carries health risks with use, although this may be reduced compared to the health risks with CC use. Participants voiced the sense of contradiction between statements on the available evidence to date (which leads to the expectation that switching to the *iQOS* system may potentially reduce the health risk compared to smoking CC) and the Important Warning statement (which suggests that there is no link between the reduction in the production or the exposure to harmful or potentially harmful chemicals and the reduction of the risk of developing tobacco-associated diseases).

Taken together, the findings of the present study are consistent with the results found in the THS-PBA-02-US study, where the tested product messages generated intent to use among current adult smokers, while generating no intent to use the *iQOS* system among adult former smokers and adult never smokers. This provides preliminary evidence that the incorporation of product message in various LLM does not interfere with comprehension of the information on modified risks and intended audience. In fact, the visual aspects of the LLM were found to be favorable and strengthened the communication of the product.

Future research should quantitatively assess the potential LLM including the Reduced Risk and Reduced Exposure claims in terms of comprehension, intent to use, and risk perception. In contrast to this study, where all participants were exposed to all LLM, it is advisable that future research is designed to expose study participants to only one element of the potential LLM to prevent carry-over effect.

**List of abbreviations and definitions of terms:**

AS	adult current smoker
CC	conventional cigarette
FAP	Full Analysis Population
FDA	Food and Drug Administration
FF	full flavor tasting taste category cigarettes
FS	adult former smoker
ICF	informed consent form
IDI	individual interview
IRB	Institutional Review Board
LLM	label, labeling and marketing material
LTN	lighter tasting taste category cigarettes
mCC	menthol-flavored cigarette
MRTTP	Modified Risk Tobacco Product
NRT	nicotine replacement therapies
NS	adult never smoker

PBA	Perception and Behaviour Assessment
PMI	Philip Morris International
SD	standard deviation
THS 2.2	Tobacco Heating System 2.2
US	United States
WHO	World Health Organization

**Reference list:**

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