

EVIDENCE RELATED TO THE IMPACT ON TOBACCO USERS AND NON-USERS

EVALUATION OF STUDIES RELATED TO PROPOSED LABELS, LABELING, AND ADVERTISING (LLA)

*Presented by
Alexander Persoskie, PhD
Social Scientist
Office of Science
Center for Tobacco Products
U.S. Food and Drug Administration*

Disclaimer: This is not a formal dissemination of information by FDA and does not represent Agency position or policy.



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- Description of labels, labeling, and advertising (LLA) materials and modified risk claims
- Overview and key findings of LLA and claim assessment studies

- LLA materials provided in the applications:
 - IQOS brochure
 - *HeatStick* pack
 - Direct mail communication
- The applicant stated that it may also market IQOS using:
 - Print and digital ads
 - Age-restricted digital and social media channels
 - Package inserts and onserts on combusted cigarette packs
- Outside the U.S., the applicant has also used:
 - IQOS smartphone apps
 - IQOS stores where consumers can learn about the product

LLA materials provided in the applications contain:

1. Description of the product
2. Three modified risk claims
3. Surgeon General (SG) Warnings or “PMI Important Warnings”

1. DESCRIPTION OF THE PRODUCT ON LLA

- Heats but does not burn
- Has attributes similar to combusted cigarettes: real tobacco, paper, filter, similar draw and number of puffs, smooth tobacco flavor
- Has benefits over combusted cigarettes – e.g., less odor and mess
- Intended users:

Who is iQOS for?

✓ It is for smokers who want to continue using tobacco.

Who is iQOS not for?

✗ It is not for smokers who want to quit.

✗ It is not for ex-smokers.

✗ It is not for non-smokers.

2. MODIFIED RISK CLAIMS 1-3

- All begin with the text “AVAILABLE EVIDENCE TO DATE”
- Followed by unique text:

1	2	3
<ul style="list-style-type: none">• The <i>iQOS</i> system heats tobacco but does not burn it.• This significantly reduces the production of harmful and potentially harmful chemicals.• Scientific studies have shown that switching completely from conventional cigarettes to the <i>iQOS</i> system can reduce the risks of tobacco-related diseases.	<p>Switching completely to <i>iQOS</i> presents less risk of harm than continuing to smoke cigarettes.</p>	<ul style="list-style-type: none">• The <i>iQOS</i> system heats tobacco but does not burn it.• This significantly reduces the production of harmful and potentially harmful chemicals.• Scientific studies have shown that switching completely from conventional cigarettes to the <i>iQOS</i> system significantly reduces your body’s exposure to harmful and potentially harmful chemicals.

MODIFIED RISK CLAIM EXAMPLE—BROCHURE EXCERPT



AVAILABLE EVIDENCE TO DATE

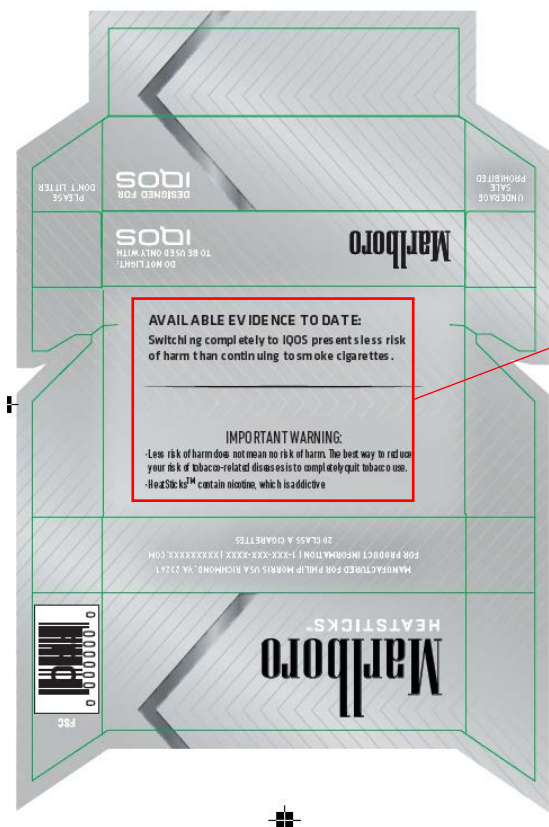
- The iQOS system heats tobacco but does not burn it.
- This significantly reduces the production of harmful and potentially harmful chemicals.
- Scientific studies have shown that switching completely from conventional cigarettes to the iQOS system can reduce the risks of tobacco-related diseases.



SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.

REAL TOBACCO.
NO FIRE.

MODIFIED RISK CLAIM EXAMPLE—HEATSTICK PACK



AVAILABLE EVIDENCE TO DATE:
Switching completely to iQOS presents less risk of harm than continuing to smoke cigarettes.

IMPORTANT WARNING:

- Less risk of harm does not mean no risk of harm. The best way to reduce your risk of tobacco-related diseases is to completely quit tobacco use.
- HeatSticks™ contain nicotine, which is addictive.

3. SG WARNINGS OR “PMI IMPORTANT WARNINGS”

SG	One, rotating:		
	<ul style="list-style-type: none"> • SURGEON GENERAL’S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy. • SURGEON GENERAL’S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health. • SURGEON GENERAL’S WARNING: Cigarette Smoke Contains Carbon Monoxide. • SURGEON GENERAL’S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight. 		
or			
“PMI Important Warnings”	For Claim 1	For Claim 2	For Claim 3
	<p>IMPORTANT WARNING:</p> <ul style="list-style-type: none"> • Reduced risk does not mean no risk. The best way to reduce your risk of tobacco-related diseases is to completely quit tobacco use. • HeatSticks™ contain nicotine, which is addictive. • Using the <i>iQOS</i> system can harm your health. 	<p>IMPORTANT WARNING:</p> <ul style="list-style-type: none"> • Less risk of harm does not mean no risk of harm. The best way to reduce your risk of tobacco-related diseases is to completely quit tobacco use. • HeatSticks™ contain nicotine, which is addictive. 	<p>IMPORTANT WARNING:</p> <ul style="list-style-type: none"> • It has not been demonstrated that switching to the <i>iQOS</i> system reduces the risk of developing tobacco-related diseases compared to smoking conventional cigarettes. • HeatSticks™ contain nicotine, which is addictive. • Using the <i>iQOS</i> system can harm your health.

- The applicant submitted four LLA and Claim Assessment studies.
- With few exceptions, all four studies shared:
 - Design
 - Participant recruitment strategy
 - Procedures
 - Measures
 - Key outcomes
- Studies differed by:
 - Participant recruitment cities
 - Claim presence on LLA materials

4 Studies

- None of the Three Claims (NOC)
- Reduced Risk Claim 1 (RRC)
- Reduced Risk Claim 2 (RRC2)
- Reduced Exposure Claim (REC)

5 Conditions*

- Brochure, SG Warning
- Brochure, "PMI Warning"
- HeatSticks* pack, SG Warning
- HeatSticks* pack, "PMI Warning"
- Direct mailer, "PMI Warning"

*(for all but NOC)

5 Smoker Groups

- Current smokers intending to quit
- Current smokers not intending to quit
- Former smokers
- Never smokers
- Young adult never smokers

4 Key Outcomes

- Health and addiction risk perceptions
- Comprehension
- Intent to use *IQOS*
- Intention to quit smoking

CLAIMS TESTED IN FOUR LLA & CLAIM ASSESSMENT STUDIES



Study NOC: No claim	Study RRC: Reduced Risk Claim 1	Study RRC2: Reduced Risk Claim 2	Study REC: Reduced Exposure Claim
	Claim 1	Claim 2	Claim 3
None of the three claims were present on the LLA materials.	<p>AVAILABLE EVIDENCE TO DATE</p> <ul style="list-style-type: none"> •The <i>iQOS</i> system heats tobacco but does not burn it. •This significantly reduces the production of harmful and potentially harmful chemicals. •Scientific studies have shown that switching completely from conventional cigarettes to the <i>iQOS</i> system can reduce the risks of tobacco-related diseases. 	<p>AVAILABLE EVIDENCE TO DATE</p> <p>Switching completely to <i>iQOS</i> presents less risk of harm than continuing to smoke cigarettes.</p>	<p>AVAILABLE EVIDENCE TO DATE</p> <ul style="list-style-type: none"> •The <i>iQOS</i> system heats tobacco but does not burn it. •This significantly reduces the production of harmful and potentially harmful chemicals. •Scientific studies have shown that switching completely from conventional cigarettes to the <i>iQOS</i> system significantly reduces your body’s exposure to harmful and potentially harmful chemicals.

OVERVIEW OF FOUR LLA & CLAIM ASSESSMENT STUDIES



- Design:
 - Random assignment to 5 conditions, varying by:
 - Type of LLA material
 - Surgeon General or PMI Warnings
 - In NOC study, conditions were slightly different (described later in the presentation)
- Key outcomes:
 - Health and addiction risk perceptions for *IQOS* and other products
 - Comprehension of claims
 - Intent to use *IQOS*
 - Intention to quit smoking

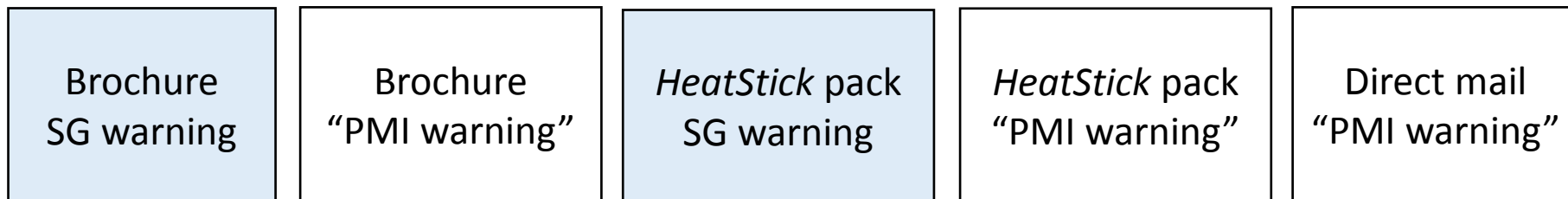
- Adults recruited from research panels in 4 census regions
- Roughly equal numbers of 5 key smoker groups:
 - Current smokers intending to quit
 - Current smokers not intending to quit
 - Former smokers
 - Never smokers
 - Young adult never smokers

- Participants completed the study in-person, using computer-assisted self-interview
- After answering some initial questions, participants were given hard copies of LLA materials (multi-page brochure, pack, or direct mail) and could view the material throughout the rest of the study
- There was no manipulation check of whether participants noticed the proposed modified risk claims on the LLA materials

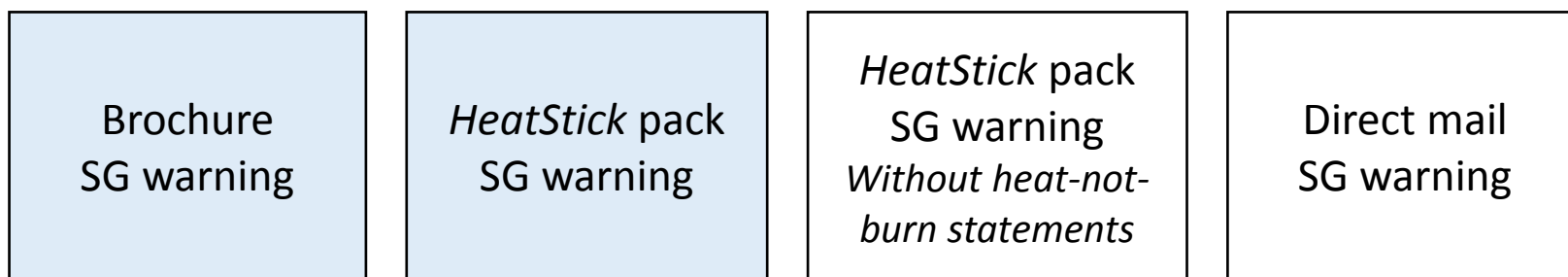
LLA & CLAIM ASSESSMENT STUDIES: CONDITIONS



- RRC, RRC2, REC studies



- NOC study



- Blue conditions match between NOC and the other studies

LLA & CLAIM ASSESSMENT STUDIES: KEY OUTCOMES



Outcome	Measure	Validity information
Health & addiction risk perceptions of: <ul style="list-style-type: none"> -IQOS -Combusted cigarettes -E-cigarettes -NRT -Cessation 	Perceived Risk Instrument (PRI) <ul style="list-style-type: none"> -Perceived Health Risk subscale (18 items/product) -Perceived Addiction Risk subscale (6 or 4 items/product) 	PMI conducted several qualitative and quantitative studies to develop and validate the instrument.
Claim comprehension	Multiple-choice questions about the risks of IQOS.	No validity information submitted. Key items were not administered in the NOC study.
Intent to use IQOS	Intent to Use Questionnaire (ITUQ): Single items assessing intentions to <u>try</u> (2 items) and <u>use</u> (2 items)	Similar to measures used in peer-reviewed literature.
Change in intention to quit smoking*	Intention to quit in next 30 days and next 6 months (2 items). *Measured pre-stimuli viewing, and also post-viewing for smokers intending to quit.	Measures taken from peer-reviewed literature.

- Primary analyses of each study:
 - Descriptive statistics and confidence intervals
 - Described outcomes:
 - Within each smoker group
 - For each condition
- Follow-up analyses of each study:
 - Compared key outcomes in the RRC, RRC2, and REC studies to matching conditions (brochure and pack) in the NOC study
 - Provided information about the potential effects of the studied claims

4 Studies

- None of the Three Claims (NOC)
- Reduced Risk Claim 1 (RRC)
- Reduced Risk Claim 2 (RRC2)
- Reduced Exposure Claim (REC)

5 Conditions*

- Brochure, SG Warning
- Brochure, "PMI Warning"
- HeatSticks* pack, SG Warning
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- Direct mailer, "PMI Warning"

*(for all but NOC)

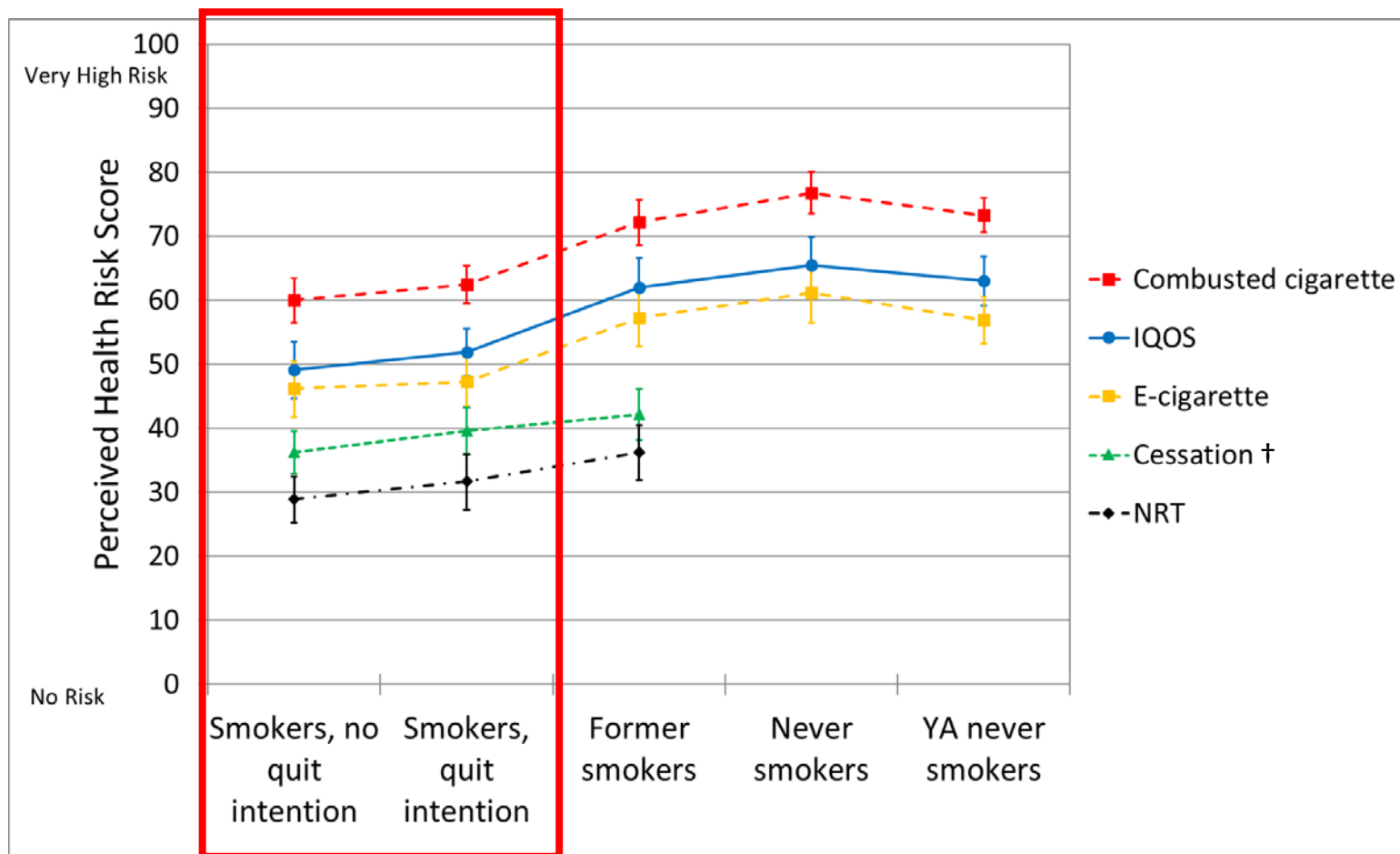
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- Current smokers intending to quit
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- Former smokers
- Never smokers
- Young adult never smokers

4 Key Outcomes

- Health and addiction risk perceptions
- Comprehension
- Intent to use *IQOS*
- Intention to quit smoking

KEY FINDINGS: CURRENT SMOKERS' PERCEIVED HEALTH RISK OF PRODUCTS



Source: Brochure condition in NOC study (THS-PMTA-05-NOC-US Study Report, p. 51). Bars represent 95% CIs.
 † Refers to the risks that remain because you smoked cigarettes.

KEY FINDINGS: CURRENT SMOKERS' PERCEIVED HEALTH RISK OF PRODUCTS



Perceived Health Risk of *IQOS*

Quit Intentions	Adjusted Mean Score		Mean Difference (and 95% CI) Claim Studies – No Claim Study
	Claims Studies	No Claim Study	
Not Intending to Quit	41.5	45.9	-4.4 (-7.5, -1.4)*
Intending to Quit	46.2	48.1	-1.9 (-5.1, 1.3)

Difference between Perceived Combusted Cigarette Health Risk and Perceived *IQOS* Health Risk

Quit Intentions	Adjusted Mean Score		Mean Difference (and 95% CI) Claim Studies – No Claim Study
	Claims Studies	No Claim Study	
Not Intending to Quit	18.6	12.1	6.5 (3.5, 9.4)*
Intending to Quit	19.8	16.1	3.7 (0.6, 6.8)*

*Confidence intervals do not include zero, i.e. providing evidence of an effect.

Note: “Adjusted mean score” refers to scores on the health risk subscale of the applicant’s Perceived Risk Instrument. Analyses adjusted for age, sex, race, education, employment status, and type of LLA material viewed. The Claim Studies included Studies RRC, RRC2, and REC. The No Claim Study was Study NOC.

In Claims Studies, smokers tended to rate *IQOS* as lower in health risk than did smokers in No Claim Study

Source: Modified from September 13, 2017 amendment, p. 103.

KEY FINDINGS, ALL PARTICIPANTS: COMPREHENSION OF REDUCED RISK CLAIMS



From **RRC**: “Next, thinking about all of the information on the iQOS material, completely switching from conventional cigarettes to iQOS:”

Response Options	SG Warnings Brochure (n=376)	“PMI Warning” Brochure (n=379)
Can increase the risk of tobacco-related diseases	1%	1%
Can reduce the risk of tobacco-related diseases	63%	69%
Has the same risk of tobacco-related diseases	23%	23%
Can eliminate the risk of tobacco related diseases	6%	2%
Don’t know	7%	5%

Note: We cannot compare to responses in NOC Study, as the item was not given in NOC Study.

Source: RRC study (THS-PBA-05-RRC-US Study Report, p. 54 and Table 15.2.2.2.3).

KEY FINDINGS, ALL PARTICIPANTS: COMPREHENSION OF REDUCED EXPOSURE CLAIM



From **REC**: “Next, thinking about all of the information on the iQOS material, switching completely from conventional cigarettes to iQOS:”

Response Options	SG Warnings Brochure (n=383)	“PMI Warning” Brochure (n=381) [†]
Has a greater risk of tobacco-related diseases	1%	1%
Reduces the risk of tobacco-related diseases	44%	26%
Has not been demonstrated to reduce the risk of tobacco-related diseases	41%	70%
Eliminates the risk of tobacco related diseases	2%	1%
Don’t know	12%	3%

Note: We cannot compare to responses in NOC Study, as the item was not given in NOC Study.

[†] Percentages do not sum to 100% because of rounding.

Source: REC study (THS-PBA-05-REC-US Study Report, p. 53 and Table 15.2.2.2.3).

KEY FINDINGS: CURRENT SMOKERS' INTENT TO USE IQOS IN NOC STUDY



Intentions to <u>try IQOS</u>	“Very likely” or “Definitely”†	“Somewhat likely”†
Smokers not intending to quit	40-44%	31-39%
Smokers intending to quit	38-43%	38-43%

Intentions to <u>use IQOS regularly, if one tries it and likes it</u>	“Very likely” or “Definitely”†	“Somewhat likely”†
Smokers not intending to quit	26-32%	26-44%
Smokers intending to quit	30-33%	29-41%

† Indicates the range across LLA materials in select conditions.

KEY FINDINGS: CURRENT SMOKERS' INTENT TO USE IQOS



Object	Quit Intentions	Adjusted %		Absolute Difference (95% CI) Claim Studies – No Claim Study
		Claims Studies	No Claim Study	
Positive Intention to Try <i>iQOS</i>	Not Intending to Quit	40.0	41.9	-2.0 (-12.5, 8.6)
	Intending to Quit	42.0	40.2	1.7 (-8.7, 12.2)
Positive Intention to Use <i>iQOS</i> Regularly	Not Intending to Quit	33.3	32.0	1.3 (-7.7, 10.3)
	Intending to Quit	30.4	32.6	-2.1 (-11.3, 7.0)

Note: Adjusted % refers to the percentage of participants responding that they “definitely” or “very likely” will try or use *iQOS*. Analyses adjusted for age, sex, race, education, employment status, and type of LLA material viewed. The Claim Studies included Studies RRC, RRC2, and REC. The No Claim Study was Study NOC.

In the Claims Studies vs. No Claim Study, no consistent differences in smokers' likelihood of responding that they would “definitely” or “very likely” use *iQOS*

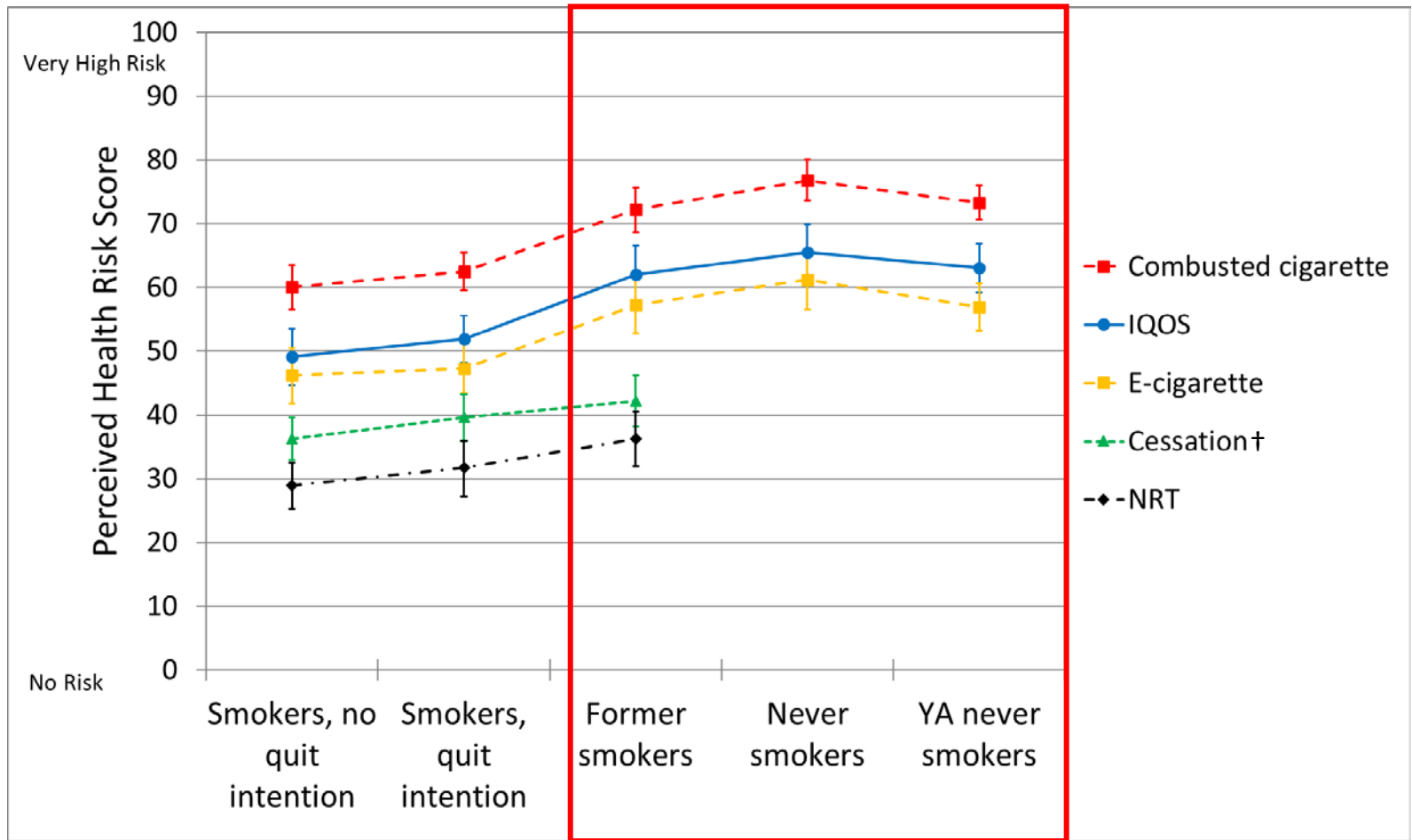
Source: Modified from September 13, 2017 amendment, pp. 104-105.

KEY FINDINGS: CURRENT SMOKERS' QUIT INTENTIONS



- In NOC:
 - Of smokers who initially reported they intended to quit, 1-14% no longer reported intending to quit after viewing LLA materials
- In the claims studies (RRC, RRC2, REC):
 - Of the smokers who initially reported they intended to quit, 1-12% no longer reported intending to quit after viewing LLA materials
- Limitations:
 - Changes in quit intentions may be because of low item reliability or testing effects
 - The applicant did not reassess quit intentions among smokers who initially reported not intending to quit smoking

KEY FINDINGS: NON-SMOKERS' PERCEIVED HEALTH RISK OF PRODUCTS



Source: Brochure condition in NOC study (THS-PMTA-05-NOC-US Study Report, p. 51). Bars represent 95% CIs.
† Refers to the risks that remain because you smoked cigarettes.

KEY FINDINGS: NON-SMOKERS' PERCEIVED HEALTH RISK OF PRODUCTS



Perceived Health Risk of IQOS

Smoking Status	Adjusted Mean Score		Mean Difference (and 95% CI) Claim studies – No Claim study
	Claims Studies	No Claim Study	
Former Smokers	51.8	57.5	-5.7 (-9.3, -2.2)*
Never Smokers	55.2	62.6	-7.3 (-10.8, -3.8)*
Young Adult Never Smokers	56.6	59.4	-2.7 (-5.9, 0.4)

Difference between Perceived Combusted Cigarette Health Risk and Perceived IQOS Health Risk

Smoking Status	Adjusted Mean Score		Mean Difference (and 95% CI) Claim studies – No Claim study
	Claims Studies	No Claim Study	
Former Smokers	17.1	12.4	4.7 (1.8, 7.6)*
Never Smokers	17.8	12.9	4.9 (2.0, 7.9)*
Young Adult Never Smokers	15.8	12.9	2.8 (0.2, 5.5)*

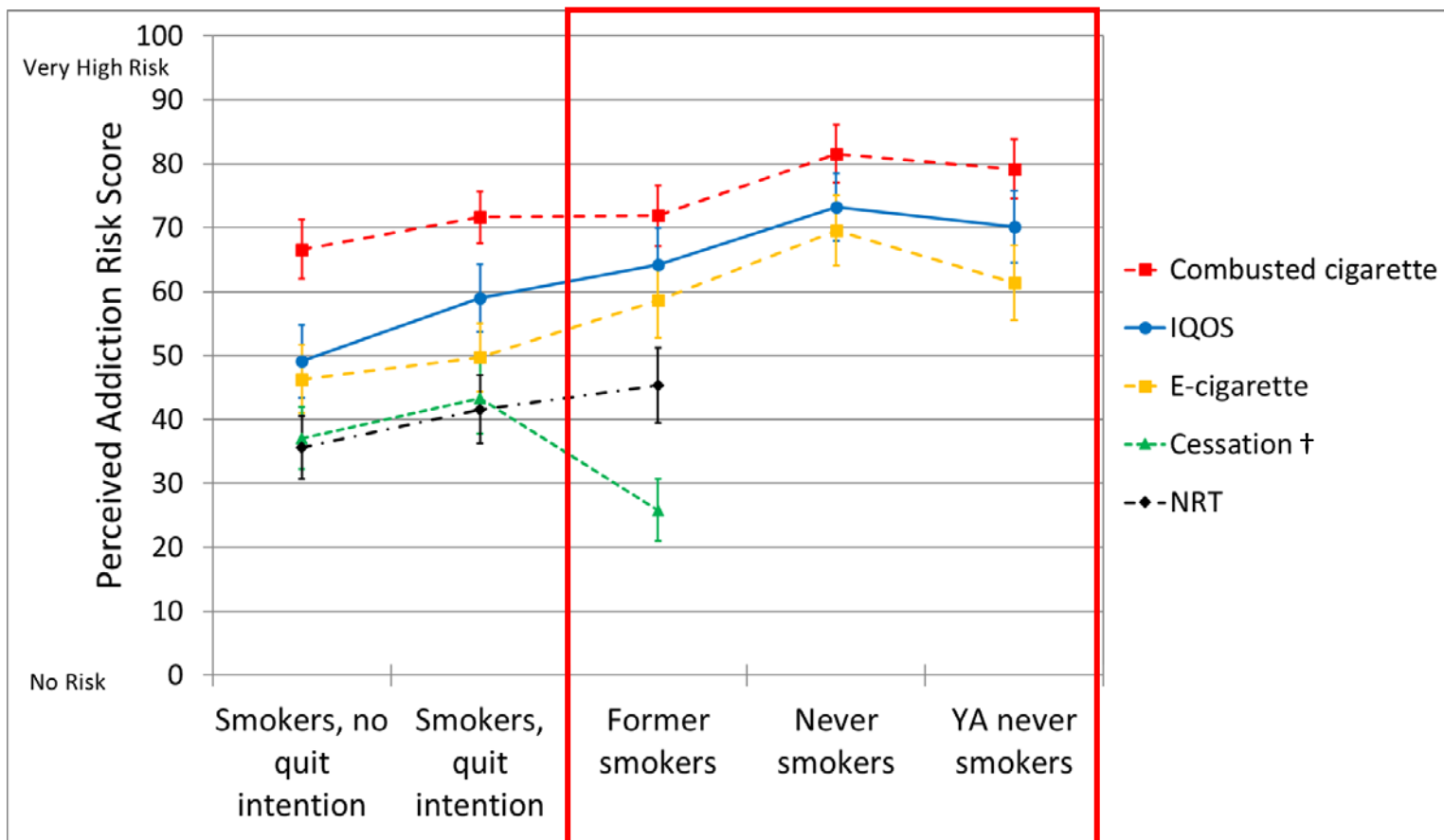
*Confidence intervals do not include zero, i.e. providing evidence of an effect.

Note: “Adjusted mean score” refers to scores on the health risk subscale of the applicant’s Perceived Risk Instrument. Analyses adjusted for age, sex, race, education, employment status, and type of LLA material viewed. The Claim Studies included Studies RRC, RRC2, and REC. The No Claim Study was Study NOC.

In Claims Studies, non-smokers tended to rate IQOS as lower in health risk than did non-smokers in No Claim Study

Source: Modified from September 13, 2017 amendment, p. 103.

KEY FINDINGS: NON-SMOKERS' PERCEIVED ADDICTION RISK OF PRODUCTS



Source: Brochure condition in NOC study (THS-PMTA-05-NOC-US Study Report, p. 53). Bars represent 95% CIs.
 † Refers to the risk of feeling addicted to cigarettes if one quits (current smokers) or stays quit (former smokers).

KEY FINDINGS, ALL PARTICIPANTS: COMPREHENSION OF REDUCED RISK CLAIM



- From RRC: “Based on the information on the iQOS material, what can be the effect of using iQOS on your health?”

Response Options	% Across LLA Materials
None – it is totally safe	2-3%
It is completely unknown	5-7%
It is more harmful than conventional cigarettes	<1%
It can harm your health	85-86%
Don't know	4-7%

- Among non-smokers, 89-96% responded “It can harm your health.”

Note: This item was only assessed for LLA materials with “PMI Warnings,” not SG Warnings. We cannot compare to the NOC Study because the item was not given in NOC Study. Source: RRC Study (THS-PBA-05-RRC-US Study Report Table 15.2.2.2.3).

KEY FINDINGS: NON-SMOKERS' INTENT TO USE IQOS IN NOC STUDY



Intentions to <u>try IQOS</u>	“Very likely” or “Definitely”†	“Somewhat likely”†
Former Smokers	5-7%	11-20%
Never Smokers	0-1%	4-7%
Young Adult Never Smokers	0-1%	7-10%

Intentions to <u>use IQOS regularly, if one tries it and likes it</u>	“Very likely” or “Definitely”†	“Somewhat likely”†
Former Smokers	1-2%	5-13%
Never Smokers	0-2%	0-3%
Young Adult Never Smokers	2%	0-4%

† Indicates the range across LLA materials in select conditions.

KEY FINDINGS: NON-SMOKERS' INTENT TO USE IQOS



Object	Smoking Status	Adjusted %		Absolute Difference (95% CI) Claim Studies – No Claim Study
		Claims Studies	No Claim Study	
Positive Intention to Try <i>iQOS</i>	Former Smokers [†]	6.7	6.4	0.3 (-3.9, 4.5)
	Never Smokers [†]	0.5	0.5	0.0 (-1.2, 1.2)
	Young Adult Never Smokers [†]	0.9	1.1	-0.2 (-1.9, 1.5)
Positive Intention to Use <i>iQOS</i> Regularly	Former Smokers [†]	4.4	1.6	2.8 (0.3, 5.3)
	Never Smokers	0.0	1.6	-1.6 (-3.3, 0.2) ‡
	Young Adult Never Smokers	0.0	2.1	-2.1 (-4.5, -0.1) ‡*

*Confidence intervals do not include zero, i.e., providing evidence of an effect.

† Final model fit with the covariate claim status only as the full model with all covariates did not converge.

‡ Wald confidence intervals (all others are Poisson confidence intervals).

Note: Adjusted% refers to the percentage of participants responding that they “definitely” or “very likely” will try or use *iQOS*.

Analyses adjusted for age, sex, race, education, employment status, and type of LLA material viewed. The Claim Studies included Studies RRC, RRC2, and REC. The No Claim Study was Study NOC.

In the Claims Studies vs. No Claim Study, no consistent differences in non-smokers' likelihood of responding that they would “definitely” or “very likely” use *iQOS*

Source: Modified from September 13, 2017 amendment, pp. 104-105.

KEY FINDINGS: NON-SMOKERS' INTENT TO USE IQOS



- Former smokers' intentions to use IQOS appeared similar to or lower than their intentions to use e-cigarettes
- Never smokers' intentions to try IQOS appeared similar to their intentions to try e-cigarettes
- Limitation: The applicant provided no statistical tests of these differences

SUMMARY: LLA MATERIALS AND CLAIMS



- According to the LLA materials, *IQOS*:
 - is a tobacco product for smokers who don't want to quit using tobacco
 - has attributes similar to combusted cigarettes
 - has benefits compared to combusted cigarettes, such as less odor and mess
- *IQOS* has other features that may affect product uptake:
 - Potentially high start-up price (study materials included a hypothetical device price of \$79.99)
 - Lack of characterizing flavors aside from menthol and tobacco
 - All *HeatSticks* contain nicotine, unlike some e-cigarette products
- The three modified risk claims:
 - Provide information about the health effects of complete switching
 - Provide no information about the health effects of partial switching

- Smokers and non-smokers perceived the health risks of *IQOS* as:
 - Lower than the health risks of combusted cigarettes
 - Similar to or higher than the health risks of e-cigarettes
 - Note: These findings were from average ratings of absolute risks, not direct comparisons of products. Only about a quarter to a third of US adults perceive e-cigarettes as less harmful than combusted cigarettes in direct comparisons.¹
- Smokers and non-smokers perceived *IQOS* as lower in addiction risk than combusted cigarettes.
- Smokers and non-smokers who viewed modified risk claims perceived *IQOS* as lower in health risks (vs. combusted cigarettes) than those who did not view the claims.

¹Majeed et al. (2017). *Am J Prev Med*, 52(3):331-338.

Persoskie et al. (2017). *Addict Behav*, 67:100-105.

- Applicant did not submit evidence for the validity of the comprehension measures
- Comprehension of reduced risk claims:
 - Most participants (roughly 60-80%) answered that completely switching to *IQOS* reduces smokers' health risk
 - Most participants (roughly 90%) answered that using *IQOS* can harm one's health
 - Note: Studies did not assess whether participants believe partial switching would reduce smokers' risk
- Comprehension of reduced exposure claim:
 - Most participants (roughly 60-70%) who viewed the reduced exposure claim with the "PMI Warning" answered that switching to *IQOS* has not been demonstrated to reduce smokers' risk, compared to roughly 30-40% who viewed the SG Warnings
 - A quarter of participants who viewed the reduced exposure claim with the "PMI Warning" answered that switching to *IQOS* reduces a smoker's health risk

SUMMARY: INTENT TO USE PRODUCTS



- Smokers' intent to use *IQOS*:
 - Was much higher than non-smokers' intent to use *IQOS*
 - Was similar regardless of whether they initially intended to quit smoking
- Smokers' intentions to quit smoking:
 - Remained high after viewing LLA materials with or without the modified risk claims
 - Note: Studies did not reassess intention to quit among smokers who first reported no intention to quit
- There was some evidence of former and never smoker intent to use *IQOS*
- Studies provided no evidence that the three modified risk claims increased smokers' or non-smokers' intent to use *IQOS*

CLARIFYING QUESTIONS?

